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

STATUS: Closed.

MATTERS TO BE CONSIDERED:

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

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

Date: January 15, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88–1159 Filed 1–15–88; 3:56 pm]

BILLING CODE 6210–01–M

MERIT SYSTEMS PROTECTION BOARD

TIME AND DATE: 10:00 a.m., Monday, January 25, 1988.

PLACE: Eighth Floor, 1120 Vermont Avenue, NW., Washington, DC.

STATUS: Closed.

MATTER TO BE CONSIDERED: Adjudication of Chapter 43 cases which raise questions about the weight to be given to an employee's performance during the Performance Improvement Plan period.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

Date: January 15, 1988.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 88–1157 Filed 1–15–88; 3:38 pm]

BILLING CODE 7400–01–M

Corrections

Federal Register
Vol. 53, No. 12
Wednesday, January 20, 1988

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

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Implementation of 1988 Import Controls and Visa Arrangements Based on the Harmonized System

Correction

In notice document 87-29627 beginning on page 48859 in the issue of Monday, December 28, 1987, make the following correction:

On page 48859, in the third column, in paragraph 1, in the fifth line, "0.8312736 sm" should read "0.83612736 sm".

BILLING CODE 1505-01-D

GENERAL SERVICES ADMINISTRATION

48 CFR Part 501

[APD 2800.12 CHGE 51]

Acquisition Regulation; Miscellaneous Changes

Correction

In rule document 88-14 beginning on page 130 in the issue of Tuesday, January 5, 1988, make the following correction:

501.170-4 [Corrected]

On page 131, in the first column, in section 501.170-4(a), in the ninth line, "GSA" should read "GSAR".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-940-08-4212-13; A-13138]

Arizona; Conveyance of Public Land; Order Providing for Opening of Land

Correction

In notice document 87-28304 beginning on page 46847 in the issue of Thursday, December 10, 1987, make the following corrections:

1. On page 46847, in the third column, under T. 20 N., R. 21 W., Sec. 20 should read as follows:
NE¼, NW¼SW¼NE¼NW¼, S½,S½ NE¼NW¼,
NW¼NE¼NW¼NW¼, S½NE¼ NW¼NW¼,
NW¼NW¼NW¼, N½SW¼NW¼NW¼, SE¼NW¼NW¼, E½NE¼SW¼NW¼, S½SW¼NW¼, SE¼NW¼;

2. In the same column, under T. 19 N., R. 15 W., in Sec. 31, "EW½W½" should read "E½W½".

3. On page 46848, in the first column, under T. 20 N., R. 15 W., in the fifth line, "S½" should read "W½" and "NW¼SE½" should read "NW¼SE¼". In the sixth line, "S½W½" should read "W½W½".

4. On the same page, in the third column, in the 11th line, "19 minutes" should read "00 minutes".

5. In the same column, under T. 20 N., R. 15 W., (cont.), in the first line, "W½NW¼" should read "W½NE¼".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-940-08-4212; A-21081]

Arizona; Opening Order

Correction

In notice document 87-28303 beginning on page 46846 in the issue of Thursday, December 10, 1987, make the following correction:

On page 46846, in the second column, under T. 10 S., R. 27 E., in the first line, "S½NW¼" should read "S½NE¼".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-940-08-4212-12; A-20347 (B)]

Reconveyed Land Opened to Entry; Pinal County, AZ

Correction

In notice document 87-28930 appearing on page 47978 in the issue of Thursday, December 17, 1987, make the following correction:

In the second column, under **Gila and Salt River Meridian, Arizona**, the first line should read "T. 7 S., R. 18 E.,".

BILLING CODE 1505-01-D

federal register

Wednesday
January 20, 1988

Part II

Office of Management and Budget

Guidelines for Federal Statistical Activities; Notice

OFFICE OF MANAGEMENT AND BUDGET

Guidelines for Federal Statistical Activities

AGENCY: Office of Management and Budget.

ACTION: Notice of a draft circular establishing guidelines for Federal statistical activities.

SUMMARY: The Office of Management and Budget (OMB) is soliciting public comment on a draft OMB Circular that would revise government-wide guidance for planning and conducting statistical surveys, publishing statistical data, documenting statistical methods and procedures, and using standard statistical classifications, definitions, and data sources. The guidance, which applies to all Federal agencies subject to the Paperwork Reduction Act of 1980, is intended to assure that the results of statistical surveys and studies sponsored by the Federal government are as reliable and useful as possible and that statistical activities are conducted as efficiently as possible.

DATE: Comments must be received on or before April 19, 1988.

ADDRESS: Comments are invited on any aspect of the Circular. They should be made in writing and sent to Dorothy M. Tella, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503. The comments will be available for public examination at this address.

FOR FURTHER INFORMATION CONTACT: Dorothy M. Tella, (202) 395–3093.

SUPPLEMENTARY INFORMATION: Statistics collected and published by the Federal government constitute a large part of the available information about the United States economy, population, natural resources, environment, and public and private institutions. These data are used by the Federal government and others as the basis for actions that affect people's lives and well-being. It is essential that they be collected, processed, and published in a manner that guarantees and inspires confidence in their reliability. The statistical programs of the Federal government are decentralized among seventy or more agencies or separate departmental units. It is therefore also essential that, to the extent permitted by law, there be sufficient government-wide uniformity in statistical methods and practices to ensure the maximum usefulness of the statistics produced.

The Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3504), gives the Director of OMB broad responsibility for improving the usefulness of information collected, maintained, and disseminated by the Federal government and for reducing the Federal government's reporting burden on the public. Among the Director's functions under the Act are statistical policy and coordination functions, which include the development and implementation of policies, principles, standards, and guidelines concerning statistical collection procedures and methods, statistical data classification, statistical information presentation and dissemination, and such statistical data sources as may be required for the administration of Federal programs.

This Circular provides revised guidance for designing, conducting, and publishing statistical surveys and studies sponsored by Federal agencies. The guidelines are intended to ensure that such surveys and studies are designed to produce reliable data as efficiently as possible and that methods are documented and results presented in a manner that makes the data as accessible and useful as possible. The Circular would also establish guidelines for the use of standard classifications, definitions, and data sources. The Circular would rescind and replace guidance on the conduct of Federal statistical activities currently contained in 19 statistical policy directives. (Section 2 of the Circular lists the rescinded directives.) The Circular would, however, leave in place Directive No. 19, "Reports of the Department of Commerce on International Transactions" (43 FR 19272, May 4, 1978).

The Circular would for the first time establish guidelines for documenting all methods, procedures, and models used to produce statistical estimates and would revise and strengthen existing guidance on planning of statistical surveys, treatment of respondents, publication of statistical data, and use of standard statistical classifications, definitions, and data sources. The Circular would discontinue certain classifications and definitions as government-wide statistical standards, as indicated below.

The attachments to the Circular address the following subjects:

Planning Statistical Surveys. The OMB paperwork regulation (5 CFR Part 1320) requires that when agencies seek OMB approval to collect information, they demonstrate that they have taken reasonable steps to ensure that the information is useful and that the cost and burden of collecting it have been minimized. Attachment A of the Circular specifies the documentation that the sponsoring agency shall include in its request for OMB approval of a statistical survey to demonstrate that the survey is designed efficiently and will produce reliable, useful results.

Treatment of Respondents. The guidelines in Attachment B are intended to reassure respondents to statistical surveys that the Federal government is dealing with them honestly and forthrightly and that their interests are being protected. For this purpose, agencies that sponsor statistical surveys should provide certain information to potential respondents about the purpose of each survey and the planned use of the survey data, including any matching or combination of individual respondent data with data from administrative sources. Any such match or combination should meet the conditions specified in section 3.c. of the attachment. Matches for statistical purposes, to which the guidance in Attachment B applies, are not covered by the OMB Guidelines for conducting computerized matching programs (47 FR 21656, May 19, 1982). Agencies should take the specific steps outlined in Attachment B to ensure the protection from public disclosure of information collected under a pledge of confidentiality. Attachment B would also establish certain design guidelines for statistical surveys conducted under mandatory reporting authority, in order to minimize the burden of such surveys on individual respondents.

Statistical Publications. Attachment C contains guidelines for the presentation and documentation of the results of statistical surveys and studies. To ensure that other agencies and the public have an opportunity to verify and use the results of all Federally-sponsored statistical surveys and studies, the sponsoring agency should either publish the results or maintain them in an accessible data base such that requests for summary data or tabulations can be met within 90 days. This guidance is based on the presumption that data collected for statistical purposes have practical utility, as defined in 5 CFR Part 1320, only to the extent that they are accessible to potential users within and outside the Federal government. In deciding whether to publish the results or else to maintain them in an accessible data base, agencies will be expected to conform to the policies on the dissemination of government information products and services established in section 8.a.(9) of OMB Circular A–130, Management of Federal Information Resources (50 FR 52730, December 24, 1985).

Documentation of Methods and Procedures. Attachment D contains

guidelines under which agencies would maintain publicly available documentation of all statistical methods, procedures, and models used to produce statistical data and estimates, thereby enabling users to make informed, independent judgments about the quality of data and estimates and to verify that they have been produced by sound, replicable methods.

Compilation, Release, and Evaluation of Principal Federal Economic Indicators. Attachment E contains guidelines for the compilation, release, and evaluation of data series that have been designated as principal economic indicators by the Director of OMB. The provisions in this attachment are the same as those in Statistical Policy Directive No. 3 (50 FR 38932, September 25, 1985), except for the addition, in Section 8, of the provision that agencies inform the public of the uncertainty or probable range of error in preliminary estimates of economic indicators.

Use of Standard Classifications, Data Sources, and Definitions. Attachment F establishes, and prescribes the uses of, certain standard statistical classifications, data sources, and definitions, which have all been previously established in OMB Statistical Policy Directives. Five classifications or definitions would be discontinued as government-wide statistical standards either because the current standards have not proven useful for the statistical purposes intended (standard Federal administrative regions, the standard industrial classification of enterprises, and the standard reference base period for Federal government general-purpose index numbers) or because they are used by only one or two agencies to collect and publish statistics (the standard classification of fields of science and engineering and the standard gas pressure base). In the latter case, OMB believes it is more practical for the principal user agencies to maintain the standards. The Circular makes it clear that the definitions of Metropolitan Statistical Areas (MSAs), the Standard Industrial Classification (SIC), and the Standard Occupational Classification (SOC) are established and maintained by OMB solely for statistical purposes and that agencies that use these statistical standards in nonstatistical programs bear the responsibility for assuring that the standard definitions or classifications are appropriate for those uses.

Provision of Statistical Data to International Organizations. Attachment G provides guidance on the implementation of Executive Order 10033.

In several cases, statistical activities covered by this Circular are also covered by other OMB Circulars. In such cases, this Circular supplements or clarifies the guidance in the other Circulars as it relates to statistical collections and publications. The specific instances of each are noted in the appropriate portions of the Circular.

Wendy L. Gramm,

Administrator for Information and Regulatory Affairs.

OMB Circular No. A-____

To the Heads of Executive Departments and Establishments.

Subject: Guidelines for Federal Statistical Activities.

1. *Purpose.* This Circular revises government-wide guidance for planning and conducting statistical surveys, publishing statistical data, and documenting statistical methods and procedures. These guidelines are intended to assure that all statistical surveys and studies sponsored by the Federal government produce as accurate and useful information as possible, serve their purposes as efficiently as possible, and impose no unnecessary burden on respondents. The Circular also prescribes four standards—a standard data source for population estimates, a standard data source for labor force and unemployment estimates, standard categories for reporting race and ethnic background, and a standard definition of poverty—to be used in the administration of Federal programs, consistent with statutory requirements. It also clarifies the responsibilities of agencies that use the Standard Industrial Classification (SIC), the Standard Occupational Classification (SOC), and the standard definitions of Metropolitan Statistical Areas (MSAs) for nonstatistical purposes.

2. *Rescissions.* This Circular rescinds and replaces Statistical Policy Directives Nos. 1–2 and 5–18 (43 FR 19260, May 4, 1978); Statistical Policy Directive No. 3 (46 FR 3253, January 14, 1981), as revised (50 FR 38932, September 25, 1985); and the directive entitled "Comparability of Statistics on Business Size" (47 FR 21362, May 18, 1982).

3. *Authority.* The Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3504); the Budget and Accounting Procedures Act of 1950, as amended (31 U.S.C. 1104); Executive Order 10253 of June 11, 1951, as amended (see 31 USCA 1104); and Executive Order 10033 of February 8, 1949, as amended (see 22 USCA 286f).

4. *Background.* The Paperwork Reduction Act grants the Director of the Office of Management and Budget (OMB) broad authority to develop and implement government-wide policies, principles, standards, and guidelines concerning statistical collection procedures and methods, statistical data classifications, statistical information presentation and dissemination, and statistical data sources required for the administration of Federal programs. The Act also reassigns to the Director the authority in the Budget and Accounting Procedures Act to develop programs and issue regulations and orders for the improved gathering, compiling, analyzing, publishing, and disseminating of statistical information for any purpose by the various agencies of the executive branch of the Federal government. Since the Paperwork Reduction Act took effect in 1981, OMB has provided government-wide guidance on collecting and publishing statistical data in 19 statistical policy directives: Directives Nos. 1–2 and 5–19 (43 FR 19260, May 4, 1978); Directive No. 3 (46 FR 3253, January 14, 1981), as revised (50 FR 38932, September 25, 1985); and a directive establishing standard business size categories for statistical purposes, "Comparability of Statistics on Business Size" (47 FR 21362, May 18, 1982). This Circular rescinds and replaces all of these directives except Directive No. 19, "Reports of the Department of Commerce on International Transactions" (43 FR 19272, May 4, 1978).

OMB information collection reviews and other evaluations of statistical activities and publications have pointed to a need for more explicit guidance to agencies on (1) planning statistical surveys so that they meet the requirements set forth in 5 CFR Part 1320 for OMB approval under the Paperwork Reduction Act; (2) treating respondents to statistical surveys in a manner that ensures the public's continued willingness to provide accurate, timely information to the Federal government for statistical purposes; and (3) documenting statistical surveys and studies in such a way as to make their results as useful as possible, minimize the risk that statistics may be misinterpreted, and ensure the public that estimates have been produced by sound, replicable methods. The Circular establishes guidelines on these aspects of statistical work, as well as on the use of standard classifications, data sources, and definitions for statistical and administrative purposes; on the

compilation, release, and evaluation of principal Federal economic indicators; and on the provision of statistical data to international organizations, consistent with the requirements of Executive Order 10033.

5. *Coverage.* The provisions of the Circular apply to all Federal agencies subject to the Paperwork Reduction Act of 1980 (see 5 CFR 1320.7(a)), to all statistical surveys and studies sponsored by those agencies, and to all publications resulting from such surveys and studies.

6. *Agency Implementation.* This Circular provides policy guidance on statistical issues. This guidance should be applied to the extent permitted by the laws governing the agency's actions.

7. *Definitions.* For the purposes of this Circular:

a. "Benchmarking" is the reconciliation of one estimate with another that is thought to be more accurate.

b. "Data" is used interchangeably with "information", as defined in 5 CFR 1320.7(k), when referring to information collected in or resulting from statistical surveys and studies.

c. An "estimate" is a numerical value or relationship that is derived from a survey, model, other statistical or mathematical procedures, or professional judgment.

d. "Imputation" means assigning estimated values to fill in missing data on individual statistical records or to replace data supplied by respondents that an agency believes to be in error. Changes to correct obvious coding or recording errors made by the agency are not imputations. Filling in missing data with data that the same respondent has supplied on another statistical or administrative record is not defined as imputation if the data were supplied in response to the same question for the same time period.

e. "Publication" means any release of statistical data or results of a statistical study for distribution or sale to the public on paper, computer tape, disk, or any other semipermanent medium, or by means of electronic data bases.

f. A Federal agency is the "sponsor" of a statistical survey or study if:

(1) That agency conducts the survey or study using funds appropriated to it or available for discretionary use through other means;

(2) That agency provides funds appropriated to it to another Federal agency, other government organization, or a private contractor to conduct the survey or study; or

(3) The survey or study is conducted under a grant from or cooperative agreement with that agency and:

(A) The grantee or cooperating party is conducting the survey or study at the specific request of the agency for the planning, operation, or evaluation of its programs; or

(B) The terms and conditions of the grant or agreement provide for prior or ongoing agency approval of the collection of information or the procedures to be used in the survey or study.

g. "Statistics are the quantitative results of a survey or study. Statistics include both aggregate estimates and the elements of individual data records.

h. Information collected for "statistical purposes" is information collected for the purpose of reporting population characteristics, developing statistical procedures, or constructing sampling frames. Information collected for any other purpose is for "nonstatistical purposes".

i. "Statistical study" means any study that makes use of a survey, model, or statistical or mathematical procedure or of estimates derived by these means.

j. "Statistical survey" means a collection of data from or about any population or group for the purpose of studying characteristics of the population or group. Both collections of data gathered directly from respondents in a census or sample of the study population and compilations of data from administrative records for statistical purposes are defined as statistical surveys.

8. *Contents.* The guidance provided by this Circular is set forth in the attachments:

Attachment A—Planning of statistical surveys
Attachment B—Treatment of respondents
Attachment C—Statistical publications
Attachment D—Documentation of methods and procedures
Attachment E—Compilation, release, and evaluation of principal Federal economic indicators
Attachment F—Use of standard classifications, data sources, and definitions
Attachment G—Provision of statistical information to international organizations

9. *Submission of Agency Plan.* Within 120 days of the publication of this Circular, the head of each agency shall submit to the Director a plan, including completion dates, for bringing all the agency's programs into compliance with the guidelines in the Circular. Where appropriate, these plans shall be coordinated with the anticipated schedule for paperwork clearance reviews.

10. *Judicial Review.* This Circular is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

11. *Information Contact.* Chief, Statistical Policy Office, Office of Information and Regulatory Affairs. Telephone: (202) 395–3093.

ATTACHMENT A—Circular No. A–___

Planning of Statistical Surveys

1. This attachment outlines the documentation that is to accompany statistical surveys when they are submitted to OMB for approval under the Paperwork Reduction Act, in order to demonstrate that the surveys meet the relevant requirements of the Act and its implementing regulation, 5 CFR Part 1320. It replaces guidance on the planning of statistical surveys previously contained in Statistical Policy Directive No. 1, "Standards for Statistical Surveys," which is rescinded by this Circular.

2. With every request for OMB approval of a statistical survey under the Paperwork Reduction Act, the sponsoring agency shall submit supporting documentation to demonstrate that the survey has a useful purpose and is designed to accomplish that purpose as efficiently as possible. That documentation shall include the following information:

a. *The analytical purpose of the survey.* The documentation shall state specifically the analytical problem or research question the survey is expected to solve or answer and shall explain the role the survey is expected to play in the analysis. If the analysis calls for any individual match or combination of data collected directly from respondents in the survey with data from administrative sources, the documentation shall fully describe the purpose of and plans for the match or combination. Any such match or combination should comply with the provisions in Attachment B, Section 3.c. When requesting OMB approval of a pretest, the sponsoring agency shall specify the aspect of the survey that is to be pretested, the design features of the actual survey that will be determined by the results of the pretest, and the agency's plans and timetable for evaluating the pretest results.

b. *The statistical objectives of the survey.* The documentation shall specify the population to be investigated, the variables for which data are to be gathered, the parameters to be estimated on the basis of survey data,

and the accuracy requirements for these estimates. If the survey is to investigate relationships among variables, differences among populations, or changes over time, the documentation shall indicate the necessary accuracy of the estimates of these relationships, differences, or changes.

c. *The need for a survey.* For any survey that involves a new collection of data from the public, the sponsoring agency shall describe its efforts to obtain suitable data from other sources, including existing surveys, administrative records, and model-based estimates, and explain why such alternatives were rejected.

d. *The feasibility of the survey.* The sponsoring agency shall submit documentation to demonstrate that the desired information exists and that it can be obtained through a survey in a sufficiently timely manner and at a sufficient level of accuracy and detail to serve the analytical purposes of the survey.

e. *Justification of the proposed frequency of the survey.* If the survey is to be recurring, the sponsoring agency shall submit documentation to demonstrate that:

(1) Measurable changes in the phenomena being studied are expected to occur in the proposed interval between data collections and that such changes need to be estimated to fulfill the analytical purpose of the survey;

(2) Without a survey at the proposed frequency, changes during this interval could not be estimated with an acceptable degree of accuracy; and

(3) The sponsoring agency is able and intends to collect, process, and publish data promptly if collection is at the frequency proposed.

f. *The survey design.* The sponsoring agency shall submit documentation to demonstrate that:

(1) The survey will collect all data not available from other sources that are necessary for the analyses the survey is intended to support.

(2) The survey is designed to satisfy the accuracy requirements of the analyses it is intended to support. The documentation shall include estimates of the variance of key parameters, including composites and projections, to demonstrate that they are likely to be within acceptable limits. If the survey is intended to measure relationships among variables, differences among populations, or changes over time, the documentation shall also include calculations to demonstrate that the relationships, differences, or changes of interest can probably be measured with the precision required. If the sample design calls for nonprobability sampling, the documentation shall explain the basis for statements about the accuracy of the estimates.

(3) The survey design is operationally feasible. The sponsoring agency shall demonstrate that it is able to carry out the survey as designed.

(4) Adequate steps have been taken to minimize the impact of nonsampling error on the estimates to be derived from survey data. The documentation shall identify the potential sources of error and give the sponsoring agency's projection of the size of such errors and their impact, individually and in the aggregate, on the estimates. All potential sources of nonsampling error shall be analyzed, including:

(A) Any differences between the target population (the universe of study) and the sampling frame;

(B) Any conceptual differences between the parameters to be estimated on the basis of survey data and the parameters desired for the planned analyses;

(C) In statistical studies that involve control groups, dissimilarities between the study group and the control group; and

(D) The expected extent and impact of overall and item nonresponse. The documentation shall include estimates of response rates based on the sponsoring agency's prior experience (or the experience of the organization conducting the survey) with the same survey or similar surveys. If the agency anticipates significantly different rates of nonresponse for different subgroups of the sampled population or for different questions in the survey, it shall provide separate estimates for all such subgroups and questions. If timeliness of response is important (for example, if the sponsoring agency has specified cut-off dates for publishing or using data), it shall indicate the expected response rates by the relevant cut-off dates.

Under 5 CFR 1320.6(g), statistical surveys must be designed to produce results that can be generalized to the universe of study. Accordingly, the sponsoring agency shall submit documentation to demonstrate either that nonsampling error is sufficiently small that it is unlikely to bias estimates derived from survey data, or that effective methods have been developed to adjust for such error. All benchmarking, imputation, and other adjustment methods shall be described in the documentation.

(5) The proposed design satisfies the survey objectives in a way that minimizes the burden on respondents, consistent with sound administrative practices and reasonable cost to the government. In estimating the burden on respondents, agencies shall take into account the amount of time it will take to provide proper responses and the cost of the time of the particular individuals who will be asked to respond, including any time that will be required by agency follow-up. Before submitting a survey to OMB for approval, the sponsoring agency shall analyze the benefits and costs of a range of possible design options, including alternative sample sizes and data collection techniques. The documentation supporting the request for approval shall summarize the results of this analysis.

(6) The survey meets the conditions set forth in Attachment B, Section 4, whenever response to the survey is mandatory. The documentation for surveys that use mandatory reporting authority shall also provide a justification of the use of such authority in terms of its effectiveness in meeting the survey's objectives. The documentation shall include the sponsoring agency's plans for enforcing the penalties for nonresponse.

g. *Performance and Quality Measures.* The documentation shall specify what measures the sponsoring agency will use to evaluate the performance of the survey and the quality of the data collected. It shall list the performance indicators that will be calculated and available after completion of the survey, such as:

(1) Nonresponse rates;

(2) Rates of edit failure;

(3) Percentage of cases requiring follow-up or reinterview; and

(4) Timeliness measures, such as the number of days required to collect data from respondents and the number of days between the reference date of the survey and the date survey results are published.

The documentation shall also include a description of the information validation techniques and quality control procedures that will be used to verify that data in publications or in final data bases are equivalent to the data actually collected.

h. *Disclosure control techniques.* The documentation shall state what disclosure control techniques are to be used in each kind of release of survey data (e.g., summary tabulations and microdata products). If variables or table cells are to be suppressed, the documentation shall indicate what variables will be suppressed and what cross classifications are likely to be lost. The description of disclosure control techniques shall be general enough so that it cannot be used to breach the protection against disclosure. The documentation shall report the

sponsoring agency's efforts to minimize the impact of its disclosure control techniques on the usefulness of the survey data.

i. *Quality standards for publishing data.* The documentation shall specify what quality standards the sponsoring agency will use to determine whether data from the survey are publishable or should be suppressed.

j. *Processing and reporting of survey data.* The documentation shall describe:

(1) The editing and imputation procedures to be used in processing the survey data;

(2) The procedures to be used in preparing estimates based on survey data, including benchmarking and seasonal adjustment methods and methods for creating composite variables; and

(3) The contents of all planned products of the survey, including tabulations to be published, analytical reports to be prepared by the sponsoring agency, and public use data products, with the dates that the sponsoring agency intends to release these products. If the data to be gathered in the survey are likely to be of substantial interest for research purposes, the sponsoring agency should plan to produce a public-use data file. The data file should be offered on a cost-recovery basis, i.e., with the fees for purchase or use of the file set so as to recover the agency's incremental cost of preparing, maintaining, and distributing the file, as provided in OMB Circular A–25. The agency's documentation shall indicate whether the agency plans to release a public-use data file in conformity with the provisions in Attachment C, Section 2.d. The documentation shall also provide a schedule for such release.

k. *The basis for any pledge of confidentiality.* If the sponsoring agency intends to make a pledge of confidentiality covering information collected in the survey, the documentation shall include the statement required by Attachment B, Section 3.b.(1) of this Circular, and shall indicate whether the agency has complied with all the other provisions of Attachment B., Section 3.a. and 3.b.

ATTACHMENT B—Circular No. A-____

Treatment of Respondents

1. This attachment sets forth guidelines for the treatment of respondents to statistical surveys, and replaces guidance on this subject previously contained in section 8 of Statistical Policy Directive No. 1. The guidelines in this attachment are independent of obligations imposed on agencies by the Privacy Act and apply regardless of whether the record systems supporting an agency's statistical programs are exempt from certain provisions of that Act under 5 U.S.C. 552a(k). Moreover, these guidelines are to be applied in addition to all relevant provisions of 5 CFR Part 1320. The guidelines for matching or combining statistical and administrative information (Sections 2.d.(3) and 3.c.) apply only to matches for statistical purposes and therefore do not overlap the OMB Guidelines for conducting computerized matching programs (47 FR 21656, May 19, 1982), which specifically exclude from their coverage matches for statistical purposes.

2. *Informing respondents.* Agencies that sponsor statistical surveys should ensure that potential respondents are provided the following information at the time they are asked to participate in such surveys:

a. The names of all sponsors of the survey, including organizations other than Federal agencies that are providing funding for the survey;

b. The subjects about which respondents will be asked to supply information, in sufficient detail to alert respondents to any sensitive topics in the survey;

c. For surveys in which information is to be collected periodically from the same respondents, the period during which and the frequency with which the respondent will be asked to supply information;

d. The uses that are intended to be made of information from the survey (e.g., to publish statistics on a stated subject or to carry out a particular study). The sponsoring agency should explicitly state:

(1) Whether it intends to use the information exclusively for statistical purposes. In cases for which that is the intent, the sponsoring agency should explicitly state the measures it has taken and its legal authority to prevent nonstatistical uses;

(2) Whether a pledge of confidentiality, made in accordance with the requirements of Section 3.b. of this attachment, covers the information collected and the fact of the respondent's participation in the survey; and

(3) Whether it plans to match or combine survey data with information about survey respondents from administrative sources. If any individual match or combination of survey data and administrative information is intended, the sponsoring agency should explain its nature and purpose to potential respondents; and

e. If the survey uses mandatory reporting authority, a full quotation of the relevant text of the statute(s) and/or regulation(s) that establish the mandatory reporting authority and the penalties for nonresponse.

3. *Protection of confidentiality and privacy.*

a. A Federal agency that collects information for statistical purposes under a pledge of confidentiality should protect that information from public disclosure to the extent permitted by law. Measures to provide this protection should include at a minimum:

(1) Written policies that proscribe the use of such information for nonstatistical purposes;

(2) Written policies and procedures for ensuring the physical security of the information while in the possession of the agency, its contractors, or its grantees. Where appropriate, these should include policies implementing the provisions of Appendix III of OMB Circular A–130 (50 FR 52730, December 24, 1985), on the Security of Automated Information Systems;

(3) A program to ensure that the agency's employees, contractors, and grantees are fully aware of their responsibilities for the safeguarding of confidential information; and

(4) Such other policies, programs, or agency rules as are available and necessary to protect from public disclosure respondent information that the agency believes qualifies for exemption from disclosure under the Freedom of Information Act (5 U.S.C. 552).

Policies, programs, or rules established for this purpose should eliminate any legal or administrative discretion otherwise retained by the agency to make public disclosures that are not consistent with the provisions of this section. Before submitting to OMB for review any proposed information collection for statistical purposes that is to be covered by a pledge of confidentiality, the sponsoring agency shall have resolved any legal questions affecting its ability to prevent public disclosure of the information.

b. To ensure consistent and accurate public understanding of pledges of statistical confidentiality, no agency should make such a pledge of confidentiality unless:

(1) It has provided a statement to OMB that it believes the information covered by the pledge is exempt from disclosure under the Freedom of Information Act, indicating upon what exemption it relies and, if the exemption is by statute, citing the relevant statute;

(2) It has met the requirements of Section 3.a. of this attachment for protecting confidentiality; and

(3) It includes in the information collection the following uniform pledge of confidentiality:

This information collection conforms to legal and administrative standards established by the Federal government to assure confidential treatment of statistical information. The information you provide will be used only for statistical purposes and will not be published or released in any form that would reveal specific information reported by any individually identifiable respondent. The [name of sponsoring agency or department] has determined that the information you provide, as well as the fact that you have participated in this survey, is exempt from public disclosure under the Freedom of Information Act.

In any case where potential respondents might misinterpret agency statements concerning statistical use or confidential treatment, OMB may require the sponsoring agency to display on information collection forms, or otherwise convey to potential respondents, an explicit statement of noncompliance with the confidentiality provisions of this Circular.

c. If information is collected for statistical purposes, as stated to respondents pursuant to Section 2.d.(1) of this attachment, any individual match or combination of that information with information from administrative records should meet the following conditions:

(1) The match or combination is exclusively for statistical purposes;

(2) The sponsor of each statistical survey involved in the match or combination has informed all respondents as required in Section 2.d.(3) of this attachment; and

(3) Any match or combination involving a statistical survey is conducted as described in the sponsoring agency's request for OMB approval of the survey, submitted in accordance with Attachment A, Section 2.a. of this Circular.

4. *Designing and conducting surveys that use mandatory reporting authority.*

Unless there is a statutory requirement that the survey be designed otherwise, any statistical survey that uses mandatory reporting authority should meet the following conditions:

a. The survey is designed so that all units in the population of study, or within each designated sampling stratum of the population, have an equal probability of being included in the survey;

b. If the survey requires periodic responses by the same respondents, the sample is redrawn at regular intervals not to exceed 3 years; and

c. The information that respondents are required to provide includes only factual information that can be obtained from and verified by respondents' records.

ATTACHMENT C—Circular No. A-____

Statistical Publications

1. This attachment sets forth guidelines for publishing the results of statistical surveys and studies. It replaces guidance previously contained in Statistical Policy Directive No. 2, "Standards for the Publication of Statistics," which is rescinded by this Circular.

2. *Obligation to publish.*

a. Agencies that sponsor statistical surveys and studies should either publish the results or else make them available upon request in a form that does not reveal information about any individually-identifiable respondent. Nonpublished results should be maintained in a data base that is sufficiently accessible that requests by other agencies or the public for tabulations or summaries can be met within 90 days.

b. Except as provided in Attachment E of this Circular for principal Federal economic indicators, no data collected in a statistical survey should be suppressed or withheld from release unless:

(1) Suppression is necessary to protect the confidentiality of information provided by individual respondents, or

(2) The data fail to meet the quality standards for publication that the sponsoring agency has specified in its request for OMB approval of the data collection, as required in Attachment A, Section 2.i. of this Circular. If it is necessary to suppress data because they fail to meet these standards, the sponsoring agency shall report to OMB the data items to be suppressed and the basis for suppression, as soon as the agency has that information, and should:

(A) Notify potential users that the data will not be published or otherwise released; and

(B) Make no use of the suppressed data in any published reports or estimates.

c. Agencies should annually publish, either in the **Federal Register** or in an agency publication, a catalog of the statistical data in their files, indicating the form in which they are available to the public (e.g., hardcopy reports, public use tapes, online, tabulations upon request), the period of time for which they will remain available in each form, and the name, address, and telephone number of the office within the issuing agency to which inquiries may be directed.

d. Agencies should provide for the prompt release of public-use data files that enable analysts outside the sponsoring agency to reproduce and verify the sponsoring agency's results, test alternative hypotheses, and develop alternative interpretations. If survey plans submitted to OMB included the preparation of public-use data files (see Attachment A, Section 2.j.(3)), the sponsoring agency should release these files no later than 90 days after the sponsoring agency's first published reports (except for preliminary summary tabulations) based on survey data. If such files are not available when the first reports are issued, the reports should contain a notice regarding their forthcoming availability.

3. *Use of standard statistical classifications and definitions.* Agencies should use the standard classifications and definitions set forth in Attachment F when publishing statistics for which there are such standards. When reporting statistics for which there are no such standards, the classifications and definitions used should support the broadest possible range of analytical uses of the data. Publications should explain all standard classifications and definitions that are used and provide appropriate references.

4. *Presentation of statistics.* The following guidelines apply to the presentation of statistical data in publications.

a. Data tables, charts, and graphs. Tables, charts, and graphs should be designed and labeled so that their meaning is clear and unambiguous. The publication should include an explanation of all technical terms and the definitions of all categorizations or appropriate references for them. Any term whose usage differs from common usage or might otherwise be misconstrued should be clearly defined. Labels should be properly aligned, groups clearly separated, and all group totals included. Labels for subgroups should be sufficiently indented to ensure that relationships among the categories are clear. If all subcategories are not displayed, there should be an explanation of what has been omitted. If tables contain percentages, the population totals that are needed to reproduce the numbers on which the percentages are based should be reported.

b. Complete presentation.

(1) Any publication that contains data tables based on sample surveys should also report estimates of standard deviations or variances. Variances and standard deviations should be directly measured from the sample whenever possible. If generalized variances or other approximations to the variances

are used in the publication, the publication should clearly inform users that the variance estimates are approximations and statistics that rely on these variances may be inaccurate. The publication should fully describe the methods used to estimate variances.

(2) To enable users to evaluate further the reliability of estimates, the agency issuing the publication should publish, or offer and be prepared to provide upon request, the actual number of observations in each published table cell.

(3) To enable users to discern the extent and impact of imputation, agencies should identify imputed data items with separate codes when they publish unsummarized data (as in public-use data files). When they publish summarized data, agencies should report the percentage of observations that are imputed for each variable included in the summary and should indicate (by code or other means) the percentage of data items that are imputed in each published table cell.

c. Discussion of findings. The evidence to support conclusions and statements about causes and effects should be presented in full in the publication. Inferences about differences and changes should be based upon generally accepted statistical techniques, which should be identified and described in the publication.

d. Preliminary and revised estimates. Any data or reports that are released prior to final editing, compilation, or correction should be clearly labeled as preliminary. The release should explain the limitations of the preliminary estimates, describe the nature of future corrections, and provide the scheduled dates for the publication of revisions. When revised data are published, the quantitative difference between the preliminary and revised data should be shown, the revision process described, and the effects of the revisions on the interpretation of the data explained.

5. *Documentation.* All publications of results of a statistical survey or study should include documentation that describes the purpose of and the procedures for conducting the survey or study and the quality and limitations of the results. For reports that are part of a regular series, the required documentation may be published separately but should be kept completely current and accurate. For one-time surveys or studies and for the first publication in a series, the documentation should be available at the same time as the publication. Public-use data files should provide the documentation both in paper form and as part of the file. The documentation should cover:

a. The purpose of the study.

b. A description of the study design. The documentation should explain the rationale for the study design and how the study was conducted. The description should be sufficiently detailed to serve most needs of the principal users of the publication and to ensure that all users are alerted to aspects of the study design that affect the interpretation of results. It should include a brief account of the outcome of the quality control procedures used. The publication should refer the user to the complete documentation of methods and procedures that the sponsoring agency maintains in accordance with Attachment D of this Circular.

c. The sources of all statistical data used in the study. The documentation should clearly identify data that were collected through different surveys or from different administrative record systems and describe how such data were changed through editing and imputation. The documentation should clearly identify constructed and estimated variables and describe the methods used to construct composite variables and the models or statistical procedures used to develop estimates. If data have been subjected to aggregate adjustments, such as benchmarking or seasonal adjustment, this should be clearly noted and the adjustment methods described.

d. A discussion of the limitations of the survey or study results. Sufficient information should be presented to enable the user to judge the accuracy of the reported results of the study and the extent to which the results can be extrapolated or generalized to other populations or circumstances.

6. *Review of publications.* Before releasing any publication, the agency should review it to ensure that it clearly and correctly presents information and that it complies with the standards in this Circular. Agencies that regularly issue statistical publications should establish a formal review process with written procedures and specific assignments of responsibility. The process should provide for independent review of each publication by at least one competent professional who was not involved in the preparation of the publication or the survey or study on which it is based.

7. *Assistance to users.* All publications should contain the name, address, and telephone number of an office within the agency issuing the publication that may be contacted for further information or assistance. The documentation of public-use files should indicate what user services are available for the file and what period of time such services will remain available.

ATTACHMENT D—Circular No. A-____

Documentation of Methods and Procedures

1. Agencies that regularly publish statistics should maintain complete and current documentation of all methods and procedures used to produce these estimates. This documentation should be publicly available in its entirety and therefore should not contain any information that the agency considers to be exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). The documentation should include, but is not limited to, the areas detailed in this attachment.

2. *Surveys.* Agencies that sponsor statistical surveys should maintain for each survey a file documenting the survey design and the operations used to collect, process, and publish data from the survey. The file should be maintained until the survey is no longer being conducted and demand for the data no longer exists.

The documentation file should include:

a. Descriptions of: the target population; the sampling frame; the correspondence between the target population and the sampling frame; the sample design; collection methods, locations, and dates; follow-up procedures; the methods used to edit and tabulate survey data; any imputation and adjustment procedures applied to survey data; and the procedures used to control the quality of survey operations.

b. Copies of the forms used in the survey, including the survey questionnaire and the instructions to both respondents and interviewers;

c. The performance statistics, such as those presented in Attachment A, Section 2.g. of this Circular, that the sponsoring agency, its contractors, or its grantees have used for management and evaluation of the survey; and

d. The results of any evaluations of survey operations and data, including quality control audits.

3. *All imputation procedures, coding procedures, and procedures used to adjust data acquired through surveys or administrative records.* The documentation of such procedures, including benchmarking, revision, and seasonal adjustment procedures, should be complete enough to enable a competent professional from outside the agency to duplicate the procedures and results.

4. *Models.* The documentation of models used to generate estimates should be complete enough to enable a competent professional from outside the agency to use the model and duplicate the sponsoring agency's results. Model documentation should include the following: a model specification; a summary of the purpose of the model, including its principles, structure, and assumptions; a complete mathematical statement of the model; a description of any data base used with the model; a description of the validation, verification, and audit record associated with the model; and the results of using the model, including both the raw outputs and analysis based on those outputs.

If the documentation is for a computer model, it should also include a user's guide explaining how to run the model.

5. *The procedures used to generate statistical estimates that are required by statute or by this Circular to be used by Federal agencies in making determinations about the benefits, obligations, privileges, or rights of specific individuals or entities.* Complete, current documentation of all procedures, including specific assumptions and decision rules, should be available in published form at the time such estimates are released. All statistical estimates used in making such determinations should themselves be published.

ATTACHMENT E—Circular No. A-____

Compilation, Release, and Evaluation of Principal Federal Economic Indicators

1. This attachment replaces Statistical Policy Directive No. 3, "Compilation, Release and Evaluation of Principal Federal Economic Indicators," which this Circular rescinds.

2. Agencies that publish statistical estimates that have been designated by the Director of OMB as principal Federal economic indicators should follow the procedures prescribed in this attachment for the compilation, release, and evaluation of these estimates.

3. *Designation of Principal Indicators.* The Director of OMB shall determine, after consultation with the affected Federal agencies, the statistics and estimates to be designated as principal Federal economic indicators and covered by this attachment to the Circular. At the beginning of each calendar year, OMB will publish the list of indicators covered and the scheduled dates for release of each indicator during the year.

4. *Prompt Release.* The interval between the end of the period to which the statistics refer and the date when the data or estimates are released to the public should be as short as practicable. Agencies should compile and release series that are issued quarterly or more frequently within 22 working days of the end of the reference period.

5. *Release Schedule.* The releasing agency is responsible for ensuring that the interested public is aware of the release time and date. The last report of each calendar year should contain the time and date of all reports in the upcoming year. In addition, each release should include an announcement of the time and date of the next release. The releasing agency shall provide a schedule of releases for the upcoming calendar year to the Statistical Policy Office, Office of Information and Regulatory Affairs, OMB, by November 30th of each year. Changes in the release schedule may occur only if special, unforeseen circumstances arise. The releasing agency should announce and fully explain any schedule changes as soon as it has determined they are unavoidable.

There should be one office in the agency that can provide the release schedule of all the agency's principal economic indicators. The name, address, and telephone number of this office should be readily available to the public. Agencies should establish and maintain no more than two specific times of day for the release of their principal economic indicators and should only release indicators at such designated times.

6. *Announcement of Changes.* Agencies should announce any planned change in data collection, analysis, or estimation methods that may affect the interpretation of a principal economic indicator as far in advance of the change as possible. The agency should include the announcement in a regular report of the economic indicator. When possible, a period for public comment should be provided between the announcement of an intended change and its implementation. At a minimum, for quarterly and monthly series, the agency should announce the change at least three reports before the first report affected by the change. For weekly and annual series, the announcement should precede the first report affected by the change by at least three months. In the first report affected by the change, the agency should include a complete description of the change and its impact.

Agencies should fully explain unforeseeable changes due to special circumstances as soon as they are known and in the first report affected by the change.

7. *Release Procedure.* The statistical agency that produces each principal economic indicator should issue it in a press release or other printed report. The agency should issue a press release where this will significantly speed up the dissemination of data to the public.

Each statistical agency is responsible for establishing procedures to ensure that there is no premature release of information or data estimates during the time required for preparation of the public report. This includes the protection of public-use data banks, which should not receive any data or estimates until they are officially released. As soon as copies of materials for public release have been prepared, the agency should physically secure them.

Except for the authorized distribution described in this section, agencies should ensure that no information or data estimates are released before the official release time.

The agency shall provide prerelease information to the President, through the Chairman of the Council of Economic Advisers, as soon as it is available. The agency should grant prerelease access to others only under the following conditions:

a. The agency head has established whatever security arrangements, and imposed whatever conditions on the granting of access, that are necessary to prevent unauthorized dissemination or use.

b. The agency head will ensure that any person granted access has been fully informed of, and has agreed to, these conditions.

c. Any prerelease of information under an embargo will not precede the official release time by more than 30 minutes.

d. In all cases, prerelease access will precede the official release time only to the extent necessary for an orderly review of the data.

All employees of the Executive Branch who receive prerelease distribution of information and data estimates as authorized above are responsible for ensuring that no release occurs prior to the official release time. Except for members of the staff of the agency issuing the principal economic indicator who have been designated by the agency head to provide technical explanations of the data, employees of the Executive Branch should not comment publicly on the data until at least one hour after the official release time.

8. *Preliminary Estimates and Revisions.* Deciding when to release a principal economic indicator requires the balancing of accuracy and timeliness. Agencies should not

withhold information needed to evaluate current economic conditions by imposing unnecessarily stringent accuracy requirements on preliminary estimates. They should, however, fully inform the public of the degree of inaccuracy that is accepted to accommodate timely release.

In the case of estimates based on probability samples, agencies should publish measures of uncertainty based on the sampling variance and consideration of nonsampling errors, e.g., a root-mean-square error estimate or its equivalent. In cases where the confidence interval about any single point estimate cannot be estimated, results should be presented only in the form of an interval estimate. Methods used to estimate upper and lower bound values that define the interval estimate should be designed to meet three objectives: (1) Preliminary interval estimates should include the final point estimate with high probability; (2) the width of the interval should be consistent with the error history of the indicator being estimated; and (3) the bound values should be consistent with any confidence intervals that can be estimated for components of the indicator.

For either point or interval estimates, agencies shall apply the following guidelines when issuing and evaluating preliminary data and revisions:

a. Agencies should clearly identify estimates as preliminary or revised;

b. If the difference between preliminary and final aggregate estimates, or the width of a preliminary interval estimate, is large relative to average period-to-period differences, the agency should either take steps to improve the accuracy of preliminary estimates or delay the release of estimates until a reliable estimate can be made;

c. If preliminary estimates show signs of a consistent bias (for example, if revisions are consistently in the same direction), the agency should take steps to eliminate this bias;

d. Revisions occurring for routine reasons, such as benchmarking and updating of seasonality factors, should be consolidated and released simultaneously;

e. Agencies should release routine revisions of a principal economic indicator only as part of the regular reporting schedule; and

f. Revisions occurring for other than routine reasons should be fully explained and should be released as soon as adjustments can be completed.

9. *Granting of Exceptions.* Prior to taking any action that may be contrary to the provisions of Attachment E, the head of a releasing agency shall consult with the Director of OMB. If the Director determines that the action is contrary to the provisions of this attachment, the head of the agency may apply for an exception. Any agency requesting an exception shall demonstrate that the proposed exception is necessary and consistent with the purposes of the Circular.

10. *Performance Evaluation.* Each agency that issues a principal Federal economic indicator shall submit a performance evaluation of that indicator to the Statistical Policy Office, Office of Information and Regulatory Affairs, OMB, every three years. A schedule for the performance evaluation of data series or estimates designated as principal Federal economic indicators will be prepared by the Statistical Policy Office. The evaluation shall address the following issues:

a. The accuracy and reliability of the series, e.g., the magnitude and direction of all revisions, the performance of the series relative to established benchmarks, and the proportion and effect of nonresponses or responses received after the publication of preliminary estimates;

b. The accuracy, completeness, and accessibility of documentation describing the methods used in compiling and revising the indicator;

c. The agency's performance in meeting the designated release schedule and the prompt release objective of this Circular;

d. The agency's ability to avoid disclosure prior to the scheduled release time; and

e. Any additional issues that the Director may specify in writing to the agency at least 6 months in advance of the scheduled submission date.

The Director will review the evaluation to determine whether the indicator is prepared and published in conformity with all OMB statistical policies, standards, and guidelines. OMB will include a summary of the year's evaluations and their reviews in the annual report to Congress required by 44 U.S.C. 3514.

ATTACHMENT F—Circular No. A-____

Use of Standard Classifications, Data Sources, and Definitions

1. This attachment replaces guidance on the use of standard classifications, data sources, and definitions previously contained in Statistical Policy Directives 5–17 and in the directive on "Comparability of Statistics on Business Size" (47 FR 21362, May 18, 1982), all of which this Circular rescinds. Nine of the standards established in these directives are retained in the Circular. Five others have been discontinued as government-wide statistical standards, either because they have not proven useful for the statistical purposes intended or because they are used by only one or two agencies in collecting and publishing statistics and can effectively be maintained by these agencies. The discontinued standards are a standard reference base period for Federal government general-purpose index numbers; standard Federal administrative regions; the standard industrial classification of enterprises; the standard classification of fields of science and engineering; and the standard gas pressure base.

2. Agencies should use standard statistical classifications, data sources, and definitions for the purposes and in the manner specified in this section.

a. *Metropolitan Statistical Areas*

All agencies that conduct statistical programs to collect and publish data for Metropolitan Statistical Areas (MSAs) should use the most recent definitions of Metropolitan Statistical Areas established by the Office of Management and Budget.

OMB establishes and maintains the definitions of Metropolitan Statistical Areas solely for statistical purposes. In periodically reviewing and revising the MSA definitions, OMB does not take into account or attempt to anticipate any nonstatistical uses that may be made of the definitions, nor will OMB modify the definitions to meet the requirements of any nonstatistical program.

Therefore, if an agency uses the MSA definitions in a nonstatistical program, it is that agency's responsibility to ensure that the definitions are appropriate for such use. In cases where an agency is publishing for comment a proposed regulation that would use the MSA definitions for a nonstatistical purpose, the agency should seek public comment on the proposed use of the MSA definitions. Agencies that use the MSA definitions in a nonstatistical program may modify the MSA definitions, exclusively for the purposes of that program. However, in order to avoid confusion with the standard statistical definitions, all such modifications should be clearly identified as deviations from the OMB standard definitions of Metropolitan Statistical Areas.

b. *Standard Industrial Classification*

All agencies that conduct statistical programs to collect and publish establishment data by industry type should use the Standard Industrial Classification (SIC), as published in the

most recent edition of the *Standard Industrial Classification Manual.*

OMB establishes and maintains the Standard Industrial Classification solely for statistical purposes. In periodically reviewing and revising the SIC, OMB does not take into account or attempt to anticipate any nonstatistical uses that may be made of the classification, nor will OMB modify the classification to meet the requirements of any nonstatistical program.

Therefore, if an agency uses the SIC in a nonstatistical program, it is that agency's responsibility to ensure that the classification is appropriate for such use. In cases where an agency is publishing for comment a proposed regulation that would use the SIC for a nonstatistical purpose, the agency should seek public comment on the proposed use of the SIC. Agencies that use the SIC in a nonstatistical program may modify the SIC, exclusively for the purposes of that program. However, in order to avoid confusion with the standard statistical classification, all such modifications should be clearly identified as deviations from the Standard Industrial Classification.

Any agency requesting or requiring an establishment to provide its SIC code as part of an information collection shall clearly identify within the information collection instrument or its directions the name, address, and telephone number of a unit within that agency that will assist respondents in determining their appropriate SIC code. When submitting any such information collection request to OMB for clearance, the agency shall disclose any modifications it has made in the SIC for the purposes of any nonstatistical program of which the information collection is a part and shall demonstrate that it has sufficient and appropriately-trained personnel to assist its respondents in determining their SIC codes.

c. *Standard Occupational Classification*

All agencies that conduct statistical programs to collect and publish data by occupation should use the Standard Occupational Classification (SOC), as published in the most recent edition of the *Standard Occupational Classification Manual.*

OMB establishes and maintains the Standard Occupational Classification solely for statistical purposes. In periodically reviewing and revising the SOC, OMB does not take into account or attempt to anticipate any nonstatistical uses that may be made of the classification, nor will OMB modify the classification to meet the requirements of any nonstatistical program.

Therefore, if an agency uses the SOC in a nonstatistical program, it is that agency's responsibility to ensure that the classification is appropriate for such use. In cases where an agency is publishing for comment a proposed regulation that would use the SOC for a nonstatistical purpose, the agency should seek public comment on the proposed use of the SOC. Agencies that use the SOC in a nonstatistical program may modify the SOC, exclusively for the purposes of that program. However, in order to avoid confusion with the standard statistical classification, all such modifications should be clearly identified as deviations from the Standard Occupational Classification.

Any agency requesting or requiring respondents to provide SOC codes as part of an information collection shall clearly identify within the information collection instrument or its directions the name, address, and telephone number of a unit within that agency that will assist respondents in determining their appropriate SOC codes. When submitting any such information collection request to OMB for clearance, the agency shall disclose any modifications it has made in the SOC for the purposes of any nonstatistical program of which the information collection is a part and shall demonstrate that it has sufficient and appropriately-trained personnel to assist its respondents in determining their SOC codes.

d. *Standard Business Size Categories*

When publishing statistics, agencies should use the size categories in the table below to classify reporting businesses by number of employees, revenues, or assets. Tabulations based on these categories should be accompanied by precise definitions of the variables used to measure size and of the type of reporting unit tabulated.

BUSINESS SIZE CATEGORIES

[Revenues or assets (dollars)]

	under	$25,000.
$25,000	under	$50,000.
$50,000	under	$100,000.
$100,000	under	$250,000.
$250,000	under	$500,000.
$500,000	under	$1 million.
$1 million	under	$2.5 million.
$2.5 million	under	$5 million.
$5 million	under	$10 million.
$10 million	under	$25 million.
$25 million	under	$50 million.
$50 million	under	$100 million.
$100 million	under	$250 million.
$250 million	under	$500 million.
$500 million	under	$1 billion.
$1 billion	under	$2.5 billion.
$2.5 billion	under	$5 billion.
$5 billion	or more	

BUSINESS SIZE CATEGORIES

[Employment (number of employees)]

0	(none)	
1	under	5
5	under	10
10	under	20
20	under	50
50	under	100
100	under	250
250	under	500
500	under	1,000
1,000	under	2,500
2,500	under	10,000
10,000	or more	

Agencies may combine adjacent size categories or truncate the size scale, if the limited scope of the data, the need to ensure the confidentiality of individual responses, or very large sampling variability makes it undesirable to publish data at the recommended level of detail. The reasons for such actions should be noted in the affected publication. Unless the categories are combined to ensure confidentiality of individual responses, agencies should, when they publish data that combine size categories, maintain unpublished estimates or internal documentation sufficient to allow reasonable retrospective estimates of the unpublished detail. Agencies may define additional partitions within the standard categories to meet particular analytical needs, but these should be in addition to, not in lieu of, the standard categories.

e. *Standard Payroll Reporting Period*

Agency requests to employers for data from their payroll records to be used for statistical purposes should refer to the payroll period that includes the twelfth day of the month.

f. *Source of Population Data for Use in the Administration of Federal Programs*

Agencies that are required by law to allocate Federal funds or determine eligibility for participation in a Federal program on the basis of the total population of State, county, or local units of government should use—to the extent permitted by law—the most current population estimates of the Bureau of the Census that have been published for all units of the relevant levels of government. If total population is used with other variables in a ratio or formula that is the basis of allocating Federal funds or determining eligibility for participation in a Federal program, unless otherwise required by law all the variables shall refer to the same year, which shall be the most recent year for which all data are available.

g. *Standard Source of Labor Force and Unemployment Estimates for Use in the Administration of Federal Programs*

Agencies that are required by law to allocate Federal funds or determine eligibility for participation in a Federal program on the basis of the employment, unemployment, or labor force participation levels or rates in the population or any subgroups of the population of State, county, or local units of government, should use—to the extent permitted by law—the most current estimates published by the Bureau of Labor Statistics that are available for all units of the relevant levels of government.

h. *Definition of Poverty*

Agencies that are required by law to use the definition of poverty established by the Office of Management and Budget, and agencies that publish statistical estimates of the number of persons, families, or households in poverty, should continue to use as the definition of poverty the annual income thresholds that for 1986 and prior years have been published by the Bureau of the Census in its Current Population Reports, P–60 series. For 1987 and subsequent years, the definition of poverty shall be the 1986 thresholds adjusted annually by the year-over-year change in the Consumer Price Index for all urban consumers.

i. *Racial and Ethnic Categories*

To the extent permitted by law, agencies should use the following categories for all purposes that require classifying people by racial and/or ethnic background. A person's racial and/or ethnic background is determined by the way in which the person chooses to be identified in his/her community.

Racial Categories:

American Indian or Alaska Native

Asian or Pacific Islander

Black

White

In establishing reporting systems and collecting data, agencies should permit individuals to identify themselves as "other" if they believe they do not fall into any of the categories listed above.

Ethnic Categories:

Hispanic

Not of Hispanic origin

Agencies may use other, more detailed categories as long as such categories can be aggregated into the basic categories listed in this section.

ATTACHMENT G—Circular No. A-___

Provision of Statistical Information to International Organizations

1. This attachment replaces Statistical Policy Directive No. 18, "Providing of Statistical Information to International Organizations," which this Circular rescinds.

2. In accordance with Section 1 of Executive Order 10033 of February 8, 1949, as amended (see 22 USCA 286f), the Director of OMB will determine, with the concurrence of the Secretary of State, what statistical information shall be provided in response to official requests received by the United States Government from any international organization of which the United States is a member, and will determine which agency or agencies shall prepare the statistical information to be provided. Agencies that have not been previously designated by the Director to prepare such information shall notify the Director and receive his concurrence before compiling or providing any statistical information for publication or use by any international organization of which the United States is a member.

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federal register

Wednesday
January 20, 1988

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 884 and 892

Radiology Devices; General Provisions and Classifications of 59 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 884 and 892

[Docket No. 78N-2742]

Radiology Devices; General Provisions and Classifications of 59 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 59 generic types of radiology devices. The preamble to this rule responds to comments received on the proposed regulations classifying these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: February 19, 1988.

FOR FURTHER INFORMATION CONTACT: Harvey Rudolph, Center for Devices and Radiological Health (HFZ-83), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION:

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A. Background

In the **Federal Register** of January 29, 1982 (47 FR 4406), FDA published a proposed rule containing general provisions applicable to the classification of radiology devices and individual proposed regulations to classify 73 devices. FDA has withdrawn the proposals to classify 2 of the 73 proposed devices (September 17, 1982; 47 FR 41139) because FDA's Center for Drug Evaluation and Research regulates the radionuclide generator as a radiopharmaceutical drug, and the automatic contrast medium injector is essentially the same as, or is included in, the angiographic injector and syringe that has been classified into class II as a cardiovascular device (21 CFR 890.1650).

As to the remaining 71 proposed regulations, in this final rule FDA is classifying 59 devices, as follows: 13 devices into class I, 44 devices into class II, 1 device into class III, and, depending upon its intended use, 1 device into class I or class III. FDA is postponing classifications of certain versions or all versions of 14 devices, as described below under "D. Devices Not Being Classified at this Time."

FDA provided a period of 60 days, later extended to 90 days (March 19, 1982; 47 FR 11879), for interested persons to submit written comments on the proposed regulations. The comments received and FDA's responses are discussed below.

Classification of medical devices in commercial distribution is required by section 513 of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c). 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 that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before July 31, 1990, or within 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to proposed regulations described the development of the general provisions and the proposed regulations classifying radiology devices and the activities of the Radiology Devices Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of radiology devices.

In April 1985, H.R. 2177 (99th Cong., 1st Sess.) was introduced in the U.S. House of Representatives. The bill was a legislative proposal of the Department of Health and Human Services. Among other things, the bill would have (1) amended the act to eliminate the statutory category of class II, (2) and the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamlined the procedure for establishing standards set out in section 514 of the act. If legislation comparable to this bill becomes law, there will be two categories of devices, class I (general controls) and class II (premarket approval, currently class III). Class II devices would be redesignated as class I devices. Because this legislation included transitional provisions that translate classifications under the current law to classifications under the proposed law, FDA is continuing its issuance of classification rules under the current law.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. At this time, however, FDA does not have the resources to establish performance standards for all of the devices already classified (or being classified) in class II. Under the amendments, FDA is using the regulatory controls of class I to regulate a device classified into class II until a performance standard is established under section 514 of the act (21 U.S.C. 360d) for the class II device.

In that notice, FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices.

A. The seriousness of questions concerning the safety and effectiveness of the device; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device.

b. The recommendations of FDA's advisory committees.

c. The impact of an FDA guidelines or recommendation.

d. The effect of a Federal standard or other regulatory controls under an authority other than the act.

e. The impact of voluntary standards.

f. The impact of activities authorized under the general controls provisions of the act.

g. The effect of dissemination of information and education efforts.

h. The sufficiency of voluntary corrective actions.

i. Valid scientific evidence developed since classification.

j. The existence of a petition for reclassification.

k. The impact of any other factors that affect a device's safety or effectiveness.

C. Changes in the Name of the Radiology Device Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Radiologic Devices Panel (the Panel) (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to radiology devices as did its predecessors, the Radiologic Devices Panel (1982–1984), the Obstetrics-Gynecology and Radiologic Devices Panel (1978–1982), and the Radiological Devices Classification Panel (1976–1978). Also, the charter for the new panel has been amended to include the functions of the Medical Radiation Advisory Committee.

D. Devices Not Being Classified at This Time

FDA is postponing classification of certain versions or all versions of the 14 AC-powered radiology devices listed below, to give the agency time to review additional data on the safety of electrically powered devices. Although FDA proposed to classify these devices into class II, it now is considering placing them in class I. When FDA does classify the devices not being classified at this time, it plans to use the same docket numbers.

Note that, as a result of postponing classifications of certain versions of two proposed thermographic devices and classifying other versions of these two devices in this final rule, each of these devices is counted twice—once as a device with classification postponed and also as a device now being classified.

FDA proposed to classify the AC-powered telethermographic system (§ 892.1450) into class II for certain intended uses and into class III for other intended uses. The agency is postponing the classification of this device intended for adjunctive diagnostic use and, in this final rule, is classifying the device intended for use as a sole diagnostic screening tool.

FDA proposed to classify the AC-powered versions of the liquid crystal thermographic system into class II or class III, depending upon the intended use of the device. FDA is postponing the classification of the AC-powered versions of the device intended for adjunctive diagnostic use. In this final rule, FDA is classifying all non-AC-powered versions of the device and is classifying the AC-powered versions of the device intended for use as a sole diagnostic screening tool.

Further, in this final rule, FDA is codifying classifications of the telethermographic system and the liquid crystal thermographic system in 21 CFR Part 884—Obstetrical and Gynecological Devices, because FDA believes this part to be a more appropriate place to publish these classifications in the Code of Federal Regulations.

The 14 devices whose classifications are being postponed are listed below.

Section No.	Device	Docket No.
1. 892.1100	Scintillation gamma camera.	78N-2743
2. 892.1110	Positron camera.	78N-2744
3. 892.1130	Nuclear whole body counter.	78N-2745
4. 892.1300	Nuclear rectilinear scanner.	78N-2750
5. 892.1320	Nuclear uptake probe.	78N-2752
6. 892.1330	Nuclear whole body scanner.	78N-2753
7. 892.1350	Nuclear scanning bed.	78N-2754
8. 892.1410	Nuclear electrocardiograph synchronizer.	78N-2760
9. 884.2980 (formerly 892.1450).	AC-powered telethermographic system.	78N-2762
10. 884.2982 (formerly 892.1480).	AC-powered liquid crystal thermographic system.	78N-2763
11. 892.1640	Radiographic film marking system.	78N-2773
12. 892.1890	Radiographic film illuminator.	78N-2795
13. 892.1900	Automatic radiographic film processor.	78N-2796
14. 892.1970	Radiographic ECG/respirator synchronizer.	78N-2803

E. Changes in Classifications of Devices

Based on the comments received and upon additional consideration of all information before the agency, FDA has placed each of the six devices listed below in a different class from that proposed. The agency's specific reasons for changing the classifications of these devices are provided in this preamble under "G. Summary of Comments On Classifications and FDA's Responses" in the respective paragraph number noted below after the name of the devices.

Section No.	Device	Proposed class	Final class
892.1370	Nuclear anthropomorphic phantom (see paragraph 3).	II	I
892.1380	Nuclear flood source phantom (see paragraph 3).	II	I
892.1400	Nuclear sealed calibration source (see paragraph 3).	II	I
892.1420	Radionuclide test pattern phantom (see paragraph 3).	II	I
892.5740	Radionuclide teletherapy source (see paragraph 3).	II	I
892.6500	Personnel protective shield (see paragraph 15).	II	I

FDA does not believe that it is necessary to issue new proposed regulations regarding these decisions. The purpose of publishing a proposed regulation and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposed regulation, 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 regulation for radiology devices (see 47 FR 4406; January 29, 1982). Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

F. List of Radiology Devices

The list below shows for each radiology device the section of the Code of Federal Regulations at which classification of that device is being codified, the docket number of the corresponding proposed classification regulation, and the classification of each device in the final rule. The list includes the radiology devices for which final classifications are being postponed. For each of these devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote [1] and no classification is provided. See "D. Devices Not Being Classified At This Time" for a description of FDA's reasons for postponing classifications of these devices. The names of six devices on the list whose final classifications are different from the classifications proposed for these devices are identified by an asterisk (*). If no comments were received on a proposed regulation, FDA is adopting the proposed regulation without a change in classification of the device unless specified otherwise in this rule.

SUBPART B—DIAGNOSTIC DEVICES

Section No.	Device	Docket No.	Classification
(892.1100)	Scintillation (gamma) camera [1]	78N-2743	
(892.1110)	Positron camera [1]	78N-2744	
(892.1130)	Nuclear whole body counter [1]	78N-2745	
892.1170	Bone densitometer	78N-2746	II
892.1200	Emission computed tomography system	78N-2747	II
892.1220	Fluorescent scanner	78N-2748	II
(892.1300)	Nuclear rectilinear scanner [1]	78N-2750	
892.1310	Nuclear tomography system	78N-2751	II
(892.1320)	Nuclear uptake probe [1]	78N-2752	
(892.1330)	Nuclear whole body scanner [1]	78N-2753	
(892.1350)	Nuclear scanning bed [1]	78N-2754	
892.1360	Radionuclide dose calibrator	78N-2755	II
892.1370	Nuclear anthropomorphic phantom*	78N-2756	I
892.1380	Nuclear flood source phantom*	78N-2757	I
892.1390	Radionuclide rebreathing system	78N-2758	II
892.1400	Nuclear sealed calibration source*	78N-2759	I
(892.1410)	Nuclear electrocardiograph synchronizer [1]	78N-2760	
892.1420	Radionuclide test pattern phantom*	78N-2761	I
884.2980	Telethermographic system (proposed as § 892.1450)	78N-2762	III
(884.2980)	Telethermographic system, AC-powered, if intended for adjunctive diagnostic use (proposed as § 892.1450) [1].	78N-2762	
884.2982	Liquid crystal thermographic system (proposed as § 892.1480)	78N-2763	I, III
(884.2982)	Liquid crystal thermographic system, AC-powered, if intended for adjunctive diagnostic use (proposed as § 892.1480) [1].	78N-2763	
892.1540	Nonfetal ultrasonic monitor	78N-2765	II
892.1550	Ultrasonic pulsed doppler imaging system	78N-2766	II
892.1560	Ultrasonic pulsed echo imaging system	78N-2767	II
892.1570	Diagnostic ultrasonic transducer	78N-2768	II
892.1600	Angiographic X-ray system	78N-2769	II
892.1610	Diagnostic X-ray beam-limiting device	78N-2770	II
892.1620	Cine or spot fluorographic X-ray camera	78N-2771	II
892.1630	Electrostatic X-ray imaging system	78N-2772	II
(892.1640)	Radiographic film marking system [1]	78N-2773	
892.1650	Image-intensified fluoroscopic X-ray system	78N-2774	II
892.1660	Non-image-intensified fluoroscopic X-ray system	78N-2775	II
892.1670	Spot-film device	78N-2776	II
892.1680	Stationary X-ray system	78N-2777	II
892.1700	Diagnostic X-ray high voltage generator	78N-2778	II
892.1710	Mammographic X-ray system	78N-2779	II
892.1720	Mobile X-ray system	78N-2780	II
892.1730	Photofluorographic X-ray system	78N-2781	II
892.1740	Tomographic X-ray system	78N-2782	II
892.1750	Computed tomography X-ray system	78N-2783	II
892.1760	Diagnostic X-ray tube housing assembly	78N-2784	II
892.1770	Diagnostic X-ray tube mount	78N-2785	II
892.1820	Pneumoencephalographic chair	78N-2788	II
892.1830	Radiologic patient cradle	78N-2789	II
892.1840	Radiographic film	78N-2790	I
892.1850	Radiographic film cassette	78N-2791	II
892.1860	Radiographic film/cassette changer	78N-2792	II

[1] Classification postponed.

SUBPART B—DIAGNOSTIC DEVICES—Continued

Section No.	Device	Docket No.	Classification
892.1870	Radiographic film/cassette changer programmer	78N-2793	II
892.1880	Wall-mounted radiographic cassette holder	78N-2794	II
(892.1890)	Radiographic film illuminator[1]	78N-2795	
(892.1900)	Automatic radiographic film processor[1]	78N-2796	
892.1910	Radiographic grid	78N-2797	I
892.1920	Radiographic head holder	78N-2798	I
892.1940	Radiologic quality assurance instrument	78N-2800	I
892.1950	Radiographic anthropomorphic phantom	78N-2801	I
892.1960	Radiographic intensifying screen	78N-2802	I
(892.1970)	Radiograpic ECG/respirator synchronizer[1]	78N-2803	
892.1980	Radiologic table	78N-2804	II

[1] Classification postponed.

SUBPARTS C-E—[RESERVED]

SUBPART F.—THERAPEUTIC DEVICES

892.5050	Medical charged-particle radiation therapy system	78N-2806	II
892.5300	Medical neutron radiation therapy system	78N-2810	II
892.5650	Manual radionuclide applicator system	78N-2813	I
892.5700	Remote controlled radionuclide applicator system	78N-2814	II
892.5710	Radiation therapy beamshaping block	78N-2815	II
892.5730	Radionuclide brachytherapy source	78N-2817	II
892.5740	Radionuclide teletherapy source*	78N-2818	I
892.5750	Radionuclide radiation therapy system	78N-2819	II
892.5770	Powered radiation therapy patient support assembly	78N-2820	II
892.5780	Light beam patient position indicator	78N-2821	II
892.5840	Radiation therapy simulation system	78N-2822	II
892.5900	X-ray radiation therapy system	78N-2823	II
892.5930	Therapeutic X-ray tube housing assembly	78N-2826	II
892.6500	Personnel protective shield*	78N-2827	I

[1] Classification postponed.

G. Summary of Comments on Classifications and FDA's Responses

1. In FDA's proposed regulations, FDA proposed to classify most of the radiology devices into class II. Comments argued (arguments 1a through 1h) that FDA should classify into class I many of the radiology devices that it proposed be in class II. FDA's responses to each of these arguments follow:

1a. Some comments said that electrical shock from devices was not a significant risk to health. These comments said that electrically powered radiology devices should be classified into class I instead of class II as proposed.

FDA currently is reviewing additional data on safety of electrically powered devices. The agency is postponing classifications of those AC-powered radiology devices it proposed be in class II, if FDA believes that the general controls of class I alone are sufficient to control all risks to health presented by the AC-powered devices, including the risks of electrical shock. Thus, FDA tentatively agrees that it should consider classifying certain AC-powered devices into class I. However, as to those devices for which FDA believes that the general controls of class I alone are insufficient to control any risks to health presented by an AC-powered radiology device in addition to the risk of electrical shock, FDA believes that they should not be classified into class I. Accordingly, FDA is postponing classifications of the 14 proposed radiology devices listed earlier in this preamble under "D. Devices Not Being Classified At This Time" while the agency reviews additional data on safety of electrically powered devices. Also, in this final rule FDA is classifying certain AC-powered devices into class II or class III to control risks to health other than electrical shock presented by these devices.

1b. Some comments said that voluntary standards exist for many radiology devices. The comments requested that FDA classify devices subject of such voluntary standards into class I, instead of class II as proposed.

FDA disagrees with the comments. FDA classifies devices using statutory criteria in section 513 of the act. These statutory criteria do not include reliance on voluntary standards. In the Federal Register of October 23, 1985 (50 FR 43060), FDA published a final policy statement regarding class II devices. This statement identifies the factors that FDA takes into account in setting priorities for initiating proceedings to establish performance standards under section 514 of the act for class II devices. Among the factors FDA considers is the existence of an adequate adhered-to voluntary standard. FDA's final policy statement does not include a provision for reliance on voluntary standards, nor does it provide for promotion of such standards. See "B. FDA's Priorities for Establishing Performance Standards" at the beginning of this preamble.

1c. A comment said that, when FDA classifies a device into class II, this constitutes a formal determination by FDA that without a performance standard there is not reasonable assurance that a device is safe and effective. The comment said that many devices that FDA proposed be in class II should be classified into class I until a mandatory standard is available. The comment suggested that, when a mandatory standard is available for

such a device, FDA could change the classification of the device to class II.

FDA agrees that classification of a device into class II is a formal determination by FDA that a mandatory performance standard is necessary (in addition to the requirements of general controls) to provide reasonable assurance of the safety and effectiveness of a device. However, FDA disagrees that the agency could classify a device that meets the statutory criteria for class II into class I until a mandatory performance standard is available and then place the device into class II. Such a temporary classification is unnecessary because the act provides that, until a standard for a class II device is established under section 514 of the act, the device may be marketed subject only to the general controls of the act. Thus, the act provides for the same marketing conditions that would apply if FDA temporarily classified a proposed class II device in class I.

1d. Several general comments stated that FDA proposed to classify too many radiology devices in class II and requested that FDA place more devices in class I.

FDA agrees that certain of the devices that it proposed to classify in class II should be in class I. These devices are identified earlier in this preamble under "E. Changes in Classifications of Devices." FDA's reasons for making these changes are provided below in paragraphs 3 and 15. FDA's reasons for classifying other radiology devices into class II as proposed are provided in FDA's responses below to comments on specific devices. In "A. Background" above, this preamble describes the Department of Health and Human Services' legislative proposal to amend the act to eliminate the statutory category of class II.

1e. Some comments argued that FDA proposed to classify too many radiology devices in class II, because FDA failed to weigh probable benefit against probable risk during its preparation of proposed classification regulations for radiology devices. The comments requested that FDA place more devices in class I. These comments said that FDA's proposed regulations unfairly required manufacturers to prove that their devices do not present health risks.

FDA disagrees with the comments' argument that the proposed classifications of certain radiology devices into class II are unfair and unreasonable. FDA also disagrees that it failed to weigh the probable benefits from the use of devices against the probable risks of these devices. FDA believes that the criteria it uses to determine the safety of a device, which criteria are found in section 513(a)(2) of the act and in 21 CFR 860.7, are required by law and are reasonable.

Further, FDA believes that any risk of injury or illness is unreasonable when no evidence is available of probable benefit to the health of those persons for whose use the device is intended. This conclusion is supported by the legislative history of the Medical Device Amendments of 1976 (Pub. L. 94–295). In its report, the House Committee on Interstate and Foreign Commerce explained the meaning of "potential unreasonable risk" as follows:

> The phrase 'presents a potential unreasonable risk of illness or injury' has two significant features. First, the requirement that a risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against benefits from use. Second, the risk need only be a potential one. The risk may be one demonstrated by reported injuries or it may simply be foreseeable. The fact that a device is being marketed without sufficient testing is an adequate basis for the Secretary's conclusion that the device presents a potential unreasonable risk to health.

H. Rept. 94–853, 94th Cong., 2d Sess. 36 (1976).

Further, the following language in 21 CFR 860.7(d)(1) describes the criteria FDA uses to determine the safety of a device:

> There is reasonable assurance that a device is safe when it has been determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

1f. As is clear, Congress contemplated imposition of the burden of proof of safety on the manufacturer. Some comments said that most of the radiology devices that FDA proposed be in class II should be in class I because manufacturers' compliance with the general controls of class I, such as the requirements of the current good manufacturing practice (CGMP) regulations (21 CFR Part 820), would provide reasonable assurance of the safety and effectiveness of the devices. It is unnecessary, the comments argued, to establish performance standards for these devices.

FDA disagrees that manufacturers' compliance with general controls would provide reasonable assurance of the safety and effectivness of many of the radiology devices that FDA proposed be in class II. FDA believes that, for certain devices, performance standards to control biocompatibility, electrical safety, sterility, radiation emission, or other characteristics sometimes are necessary to provide reasonable assurance of the safety and effectiveness of such devices. Also, FDA believes that certain devices should be classified into class III under the relevant statutory criteria.

1g. A number of comments requested that FDA classify more radiology devices into class I, because classifying such devices into class II would slow development of new devices.

FDA disagrees with the comments. Classification regulations have little immediate impact on device development because they apply only to already developed and marketed products. See the discussion under "N. Economic Impact" later in this preamble.

1h. Some comments requested that many devices that FDA proposed be in class II instead be placed in class I because these devices are intended for use by health care professionals, and establishment of mandatory performance standards for these radiology devices is unnecessary.

FDA disagrees with the comments. The agency bases its classifications of devices on characteristics of the devices themselves under criteria established in the statute. FDA's classifications are intended to assure that the radiology devices being used by health care professionals perform as intended, and otherwise provide reasonable assurance of the safety and effectiveness of devices. FDA's criteria and process for classifying devices are described earlier in this paragraph.

2. Some comments argued that several diagnostic X-ray systems or components of diagnostic X-ray systems that are listed below and that FDA proposed to be in class II are adequately regulated by the performance standard for diagnostic X-ray systems and their major components (21 CFR 1020.30 through 1020.32) promulgated under the Radiation Control for Health and Safety Act of 1968 (RCHSA) (Pub. L. 90–602, 42 U.S.C. 263f). The comments noted that all of the risks to health identified in the proposed regulations are addressed by the performance standard for such devices. The comments also argued that additional standards issued under section 514 of the act would be unnecessary, duplicative, and would not improve the safety and effectiveness of such devices. These comments recommended that FDA classify the radiology devices listed below (all of

which are subject to the performance standards in 21 CFR 1020.30 through 1020.32 and 21 CFR 1040.10) in class I rather than class II.

Section No.	Device	Proposed rule: FR page No.
892.1600...	Angiographic X-ray system.	4423
892.1610...	Diagnostic X-ray beam-limiting device.	4424
892.1630...	Electrostatic X-ray imaging system.	4424
892.1650...	Image-intensified fluoroscopic X-ray system.	4425
892.1660...	Non-image-intensified fluoroscopic X-ray system.	4425
892.1670...	Spot-film device	4426
892.1680...	Stationary X-ray system	4426
892.1700...	Diagnostic X-ray high voltage generator.	4427
892.1710...	Mammographic X-ray system.	4427
892.1720...	Mobile X-ray system	4428
892.1730...	Photofluorographic X-ray system.	4428
892.1740...	Tomographic X-ray system.	4428
892.1750...	Computed tomography X-ray system.	4429
892.1760...	Diagnostic X-ray tube housing assembly.	4429
892.1830...	Radiologic patient cradle.	4430
892.1860...	Radiographic film/cassette changer.	4432
892.1870...	Radiographic film/cassette changer programmer.	4433
892.1880...	Wall-mounted radiographic cassette holder.	4433
892.5780...	Light beam patient position indicator.	4441

FDA believes that performance standards under section 514 of the act are necessary (in addition to those under the Radiation Control for Health and Safety Act) to control the risks to health presented by the 19 devices listed above that were identified in the proposed regulations (47 FR 4406 at the page numbers shown above). FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the devices listed above with minor clarifying changes.

3. A number of comments requested that FDA classify the 13 devices listed below in this paragraph into class I instead of class II as proposed, arguing that the risks to health presented by these devices are adequately controlled through the licensing requirements of the Nuclear Regulatory Commission (NRC) and the Agreement States. "Agreement States" are those states which have entered into an effective agreement with the NRC or its predecessor, the Atomic Energy Commission, under section 247b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

FDA agrees in part and disagrees in part with these comments, as shown below in responses 3a and 3c.

Response 3a. FDA agrees with the comments regarding the five devices listed below.

Section No.	Device
892.1370...	Nuclear anthropomorphic phantom.
892.1380...	Nuclear flood source phantom.
892.1400...	Nuclear sealed calibration source.
892.1420...	Readionuclide test pattern phantom.
892.5740...	Radionuclide teletherapy source.

The establishment of performance standards under section 514 of the act for the devices listed above is unnecessary, because the general controls of class I, particularly the controls of the current good manufacturing practices regulations in 21 CFR Part 820, in conjunction with the regulatory controls of NRC and the Agreement States, provide reasonable assurance of the safety and effectiveness of the devices. NRC and agreement states ensure that sources are encapsulated, sealed, and accurately calibrated. Sealing of sources and compliance with CGMP's provide adequate assurance of safety. Accordingly, FDA is adopting the proposed regulations for each of the five devices listed above with changes in classification from class II into class I and minor clarifying changes.

Response 3b. FDA disagrees with the comments regarding the five devices listed below.

Section No.	*Device*
892.1200...	Emission computed tomography system.
892.1220...	Fluorescent scanner.
892.1310...	Nuclear tomography system.
892.1360...	Radionuclide dose calibrator.
892.5710...	Radiation therapy beam shaping block.

Neither NRC nor the governments of the states regulate the five devices listed above. FDA believes that performance standards under section 514 of the act are necessary to control the risks to health presented by these devices that were identified in the proposed regulations. FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the five devices listed above with minor clarifying changes.

Response 3c. FDA disagrees with the comments regarding the three devices listed below.

Section No.	*Device*
892.1170...	Bone densitometer.
892.5700...	Remote controlled radionuclide applicator system.
892.5730...	Radionuclide brachytherapy source.

Although NRC and agreement states do regulate the radionuclides that may be contained in, or used with, these devices, NRC does not control the overall safety or effectiveness of these devices, and there is no uniformity among the states in the degree of regulatory control provided regarding these three devices. In addition, the radionuclide brachytherapy source is intended to be occasionally implanted in the human body. Section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) requires that FDA classify all implants into class III unless the agency determines that, for a particular implant, premarket approval is unnecessary to provide reasonable assurance of its safety and effectiveness. FDA believes that insufficient evidence of safety and effectiveness is now available to classify into class I any radiology device intended to be implanted. Therefore, performance standards under section 514 of the act are necessary for all three devices to control the risks to health identified in the proposed regulations for these devices. FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the three devices listed above with minor clarifying changes.

4. Other comments requested that FDA classify the 11 devices listed below into class I instead of class II as proposed, arguing that the devices could safely be placed in class I, because voluntary standards exist for these devices.

Section No.	Device	Proposed rule; FR page No.
892.1310...	Nuclear tomography system.	4415
892.1540...	Nonfetal ultrasonic monitor.	4421
892.1550...	Ultrasonic pulsed doppler imaging system.	4422
892.1560...	Ultrasonic pulsed echo imaging system.	4422
892.1570...	Diagnostic ultrasonic transducer.	4423
892.5050...	Medical charged particle therapy system.	4438
892.5300...	Medical neutron radiation therapy system.	4438
892.5700...	Remote controlled radionuclide applicator system.	4439
892.5710...	Radiation therapy beam shaping block.	4439
892.5730...	Radionuclide brachytherapy source.	4440
892.5750...	Radionuclide teletherapy system.	4440

FDA disagrees with the comments for the reasons given in paragraph 1b. See also the discussion at the beginning of this preamble under "B. FDA's Priorities For Establishing Performance Standards." FDA believes that performance standards under section 514 of the act are necessary to control the risks to health presented by these 11 devices that were identified in the proposed regulations (47 FR 4406 and at page numbers shown above). FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the 11 devices listed above with minor clarifying changes.

5. Yet more comments requested that FDA classify the 14 devices listed below into class I instead of class II as proposed, arguing that these electrically powered devices do not present a significant risk to health from electrical shock.

Section No.	Device
892.1170...	Bone densitometer.
892.1200...	Emission computed tomography system.
892.1220...	Fluorescent scanner.
892.1310...	Nuclear tomography system.
892.1540...	Nonfetal ultrasonic monitor.
892.1550...	Ultrasonic pulsed doppler imaging system.
892.1560...	Ultrasonic pulsed echo imaging system.
892.1570...	Diagnostic ultrasonic transducer.
892.1620...	Cine or spot fluorographic X-ray camera.
892.1630...	Electrostatic X-ray imaging system.
892.1640...	Radiologic film marking X-ray system.
892.1770...	Diagnostic X-ray tube mount.
892.1820...	Pneumoencephalographic chair.
892.5700...	Remote controlled radionuclide applicator system.

FDA believes that 13 of the devices listed above present risks to health in addition to the risk of electrical shock that require establishment of performance standards. Except for the radiologic film marking X-ray system (§ 892.1640), FDA believes that all of the devices listed above are intended for use during application of radiation to the body for diagnostic or therapeutic purposes. FDA believes that performance standards under section 514 of the act are necessary to control the risks to health presented by these devices. FDA also believes that sufficient information is available to establish such standards.

In the case of the radiologic film marking X-ray system (§ 892.1640), FDA is not aware of any currently marketed system which uses other than a visible light source to place identification information on X-ray film. Thus, the radiation risk to health identified by the panel no longer exists. Accordingly, FDA is postponing classification of the device, as it presents only the risk of electrical shock. The agency will repropose to classify this device as the radiologic film marking system with clarifying changes in its identification. See "D. Devices Not Being Classified at This Time." However, FDA is adopting the proposed regulations for the 13 other devices listed above with minor clarifying changes.

6. Some other comments requested that FDA classify the two devices named below into class I instead of class II as proposed, because, the comments said, classification into class II would inhibit the development of new phantoms by increasing development costs: § 892.1370 *Nuclear anthropomorphic phantom* and § 892.1420 *Radionuclide test pattern phantom.*

As to the comments' request that the two devices be in class I, FDA agrees but not for the reasons given by the comments. (See paragraphs 1g and 3a.)

7. Some comments requested that FDA classify the three devices listed below into class I instead of class II as proposed, arguing that the RCHSA performance standard (21 CFR 1020.30 through 1020.33) and the Occupational Safety and Health Administration's (OSHA) standards regarding safety in the workplace provide adequate regulatory control of the safety of the devices. The comments said that section 514 standards for the three devices would be unnecessary.

Section No.	Device
892.5840...	Radiation therapy simulation system.
892.5900...	X-ray radiation therapy system.
892.5930...	Therapeutic X-ray tube housing assembly.

FDA disagrees with the comments. FDA has recognized the importance of the safety and effectiveness of the radiation therapy simulation system and has amended the diagnostic X-ray equipment performance standard specifically to exclude this device from radiation safety performance requirements that are inappropriate or that would hamper the effectiveness of this device. The accuracy of the simulation, which includes accurate positioning, determines the effectiveness of the subsequent therapy, which was the concern of the Panel. Improper function of this device may result in excessive patient exposure and tissue damage. The comment mistakenly states that the RCHSA standard addresses this risk. The RCHSA performance standard at 21 CFR 1020.30 through 1020.33 does apply to a radiation therapy simulation system, but this standard only addresses radiation safety and does not assure that the radiation therapy simulation system is safe and effective for its intended uses. FDA believes that a performance standard under section 514 of the act is necessary for the radiation therapy simulation system.

The RCHSA performance standard does not apply to the other two devices named above: The X-ray radiation therapy system and the therapeutic X-ray tube housing assembly. Further, the OSHA standards do not control the safety and effectiveness of the three devices regarding application of radiation to patients. For these reasons, FDA believes that a performance standard under section 514 of the act is necessary for each of the three devices

to provide reasonable assurance of the safety and effectiveness of the devices and to control the risk to health of excessive radiation from improper function presented by the devices. FDA believes that sufficient information is available to establish such performance standards. Accordingly, FDA is adopting the proposed regulations for the three devices listed above with minor clarifying changes.

8. A comment said that the radionuclide dose calibrator (§ 892.1360) is not a medical device and should not be classified.

FDA disagrees with the comment. FDA believes that the radionuclide dose calibrator meets the definition of a device in section 201(h) of the act (21 U.S.C. 321(h)), because it is intended for medical purposes. Radionuclide dose calibrators are used to determine the dosage strength of a radionuclide before the radionuclide is administered to a patient. Therefore, a radionuclide dose calibrator is a component, part, or accessory to a medical device and is, thus, itself a device as defined by section 201(h) of the act. Accordingly, FDA is adopting the proposed regulation for the radionuclide dose calibrator with minor clarifying changes.

9. A comment requested that FDA classify the nuclear anthropomorphic phantom into class I instead of class II as proposed, because many different versions of the device are being used, and the device is intended for use with other devices that emit radiation throughout a large range of frequencies.

Unlike the comment, FDA believes that it would be possible to establish a performance standard for the device under section 514 of the act. However, FDA has decided that such a standard would be unnecessary. FDA is classifying the device into class I rather than class II, for the reasons provided in paragraph 3a.

10. Section 892.1480; Liquid crystal thermographic system—non-AC-powered and AC-powered.

If the device is intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses, FDA proposed that the device be classified as follows: If non-AC-powered, class I; if AC-powered, class II. If the device (non-AC-powered or AC-powered) is intended for use alone in diagnostic screening for detection of breast cancer, FDA proposed that the device be classified into class III.

10a. Some comments requested that (1) the non-AC-powered device be classified into class I as proposed if it is used in diagnostic evaluations as an adjunct to other clinically accepted techniques and (2) the non-AC-powered device be classified into class II instead of class III as proposed if it is used alone in diagnostic evaluations. These comments gave no reasons for the suggested change in classification.

FDA agrees that the general controls of class I by themselves would provide reasonable assurance of the safety and effectiveness of the non-AC-powered liquid crystal thermographic system if the device is intended for diagnostic use as an adjunct to other generally accepted diagnostic procedures. Thus, FDA agrees that the device should be placed in class I if it is intended for adjunctive diagnostic use for various conditions or uses, e.g., in the diagnosis of breast cancer if the device is intended as an adjunct to clinical physical examinations including breast palpation and X-ray mammography.

However, FDA disagrees that the non-AC-powered liquid crystal thermographic system should be classified into class II if it is intended as a sole diagnostic tool (including screening tool) for diagnosis of breast cancer and other diseases. If the device is intended to be used as a sole diagnostic tool, FDA believes that the device cannot be classified as a class II device because there is insufficient information for the establishment of performance standards to provide reasonable assurance of the safety and effectiveness of the device.

10b. One comment suggested that FDA not classify the liquid crystal thermographic system in Part 892 with radiology devices because the device does not emit radiation.

FDA agrees that, for the reason given in the comment, the device should not be codified in Part 892. In this final rule, FDA is codifying the classification of certain versions of the device in 21 CFR Part 884—Obstetrical and Gynecological Devices (§ 884.2982). FDA also is postponing classification of the AC-powered version of the liquid crystal thermographic system intended for certain uses. See "D. Devices Not Being Classified At This Time." When FDA classifies the proposed but postponed versions of the device, the agency will codify its classification in Part 884 using the same docket number.

10c. Comments said that the risk to health of electrical shock is not a significant risk for the AC-powered device. These comments said that the AC-powered and non-AC-powered versions of the device should be placed in class I because no meaningful differences in risks to health exist between the non-AC-powered and AC-powered versions of the device.

FDA tentatively agrees that it is unnecessary to establish performance standards under section 514 of the act to control the risk to health of electrical shock presented by the AC-powered version of the liquid crystal thermographic system intended for certain adjunctive uses. Thus, FDA is postponing classification of the AC-powered version of the device if it is intended for certain uses, and the agency is considering classifying the device intended for these uses into class I. See "D. Devices Not Being Classified At this Time." For the reasons provided below, FDA disagrees that the proposed device should be classified into class I for all intended uses.

10d. Several comments stated that the efficacy of thermography in early detection of breast cancer can be significantly influenced by the degree of expertise and experience of the users. These comments said that the device should be in class I because the skill of the users assured safe and effective performance of the device.

FDA disagrees with the comments. Under the statute, FDA classifies devices based on attributes of the devices, including adequacy of labeling for their intended uses. Although user skill may enhance results obtained for use of a device, in determining the safety and effectiveness of a device for purposes of classification, FDA assumes that the users possess average skills.

10e. One comment requested that FDA classify both the non-AC-powered and the AC-powered versions of the liquid crystal thermographic system into class I for all intended uses instead of into class I, class II, or class III as proposed, depending upon certain intended uses of the device. The comment said that classification of the device, if it is intended for use as the only screening tool in the early detection of breast cancer, into class III would essentially eliminate its use.

FDA disagrees with the comment. Classification of a preamendments device into class II or class III under section 513 (c) and (d) of the act (21 U.S.C. 360c (c) and (d)) has no immediate impact on the commercial availability of the device. For each device classified into class II or class III under these sections of the act, FDA must publish an additional proposed and final regulation allowing further public comment before the agency can establish a performance standard (21 U.S.C. 360d) or require premarket approval (21 U.S.C. 360e) for the device. See the discussion later in this preamble entitled "N. Economic Impact." Further, the essential purpose of the classification procedures provided by Congress is to provide reasonable

assurance of the safety and effectiveness of devices. Continued commercial availability of devices is not one of the criteria that FDA may consider when classifying devices.

10f. Some comments recommended that the liquid crystal thermographic system intended for consumer use, whether over-the-counter or prescription, be classified into class III.

FDA agrees with the comment. The agency is unaware that anyone has ever marketed the liquid crystal thermographic system for diagnostic use by consumers. If such a device were considered for marketing for diagnostic use by consumers, it would not be substantially equivalent to the preamendments device subject to the proposed rulemaking. Accordingly, FDA believes that a liquid crystal thermographic system intended for diagnostic use by consumers would be a new, not substantially equivalent device, classified by statute into class III. Further, before testing a liquid crystal thermographic system with such new intended uses on humans for purposes of gathering data to submit to FDA to obtain premarket approval, manufacturers should obtain from FDA an investigational device exemption for the device as specified in 21 CFR Part 812.

10g. Other comments indicated that FDA's statements in the proposed regulations about the unacceptably high levels of false-negative and false-positive results from using the liquid crystal thermographic system for diagnosing breast cancer were not accurate. One comment said that the false-negative rate for breast cancer detection using thermography is less than the false-negative rate using X-ray mammography. Another comment said that the high false-positive rate for breast cancer detection using thermography is of greater significance than the false-negative rate.

Some comments stated that the device should be in class I instead of class III when it is intended only for screening and detection of breast cancer. The comments stated that there is adequate evidence to show the safety and effectiveness of the device for this intended use. The comments submitted (or cited) a number of published studies to support their requests that the device be in class I.

FDA acknowledges the importance of both the false-negative and the false-positive rates when evaluating the efficacy of any cancer detection method. FDA is concerned that (1) based upon a false-negative thermogram, a woman may not seek proper medical attention, and (2) a false-positive result may cause a woman to lose faith in medicine and not participate in further routine clinical screening programs for cancer. Therefore, both the false-negative and the false-positive rates are important in evaluating the safety and effectiveness of thermographic devices. FDA has reviewed the data submitted and cited by the comments and other data and available information and has observed no scientific consensus regarding the safety and effectiveness of thermography when used alone in diagnosis of cancer. Based upon available data, FDA believes that thermography in the detection of breast cancer is appropriate only as an adjunct to other clinically accepted independent screening techniques, i.e., a clinical physical examination including palpation and X-ray mammography. Thermography may be useful to detect breast temperature variations which may be indicative of abnormalities. But its effectiveness, when used alone in the specific detection of breast cancer, has not been demonstrated.

To summarize, FDA is adopting the proposed regulation for the nonelectrically powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other diagnostic uses without a change in classification of the device from that proposed. Although FDA tentatively agrees that the AC-powered version of the liquid crystal thermographic system should be placed in class I if it is intended for adjunctive diagnostic use, for the reasons given above in paragraph 10c, FDA is postponing classification of the AC-powered version of the device if it is intended for adjunctive diagnostic use.

FDA believes that there is insufficient information to determine whether or not the general controls of class I by themselves are sufficient to provide reasonable assurance of the safety and effectiveness of the non-AC-powered or AC-powered liquid crystal thermographic system intended for use as the sole diagnostic tool in screening for breast cancer or other conditions and that insufficient information exists for the establishment of performance standards to provide such assurance. FDA believes that this device, when used as the only screening tool for the diagnosis of breast cancer or other conditions, is of substantial importance in preventing impairment of human health. Because of the potential for high levels of false-negative and false-positive test results, the device presents a potential unreasonable risk of illness or injury. Accordingly, FDA is adopting the proposed regulation classifying the nonelectrically powered and the electrically powered liquid crystal thermographic system intended as the only screening tool for the diagnosis of breast cancer or other conditions into class III with clarifying change in the identification of the device.

10h. FDA recognizes that the liquid crystal thermographic system is being commercially distributed for use in a wide range of diagnostic applications where variations in skin temperature may occur, such as (a) peripheral vascular disease, (b) musculoskeletal disorders, (c) extracranial cerebral vascular disease, (d) abnormalities of the thyroid gland, and (e) various neoplastic and inflammatory conditions. FDA believes that the liquid crystal thermographic system (non-AC-powered and AC-powered) intended for adjunctive use in diagnostic screening for breast cancer or other uses is a preamendments device. FDA believes that this preamendments device, if intended for use as the sole screening tool in diagnostic screening for breast cancer or other uses, has been substantially altered and has undergone a major change or modification of its intended use (see 21 CFR 807.85) and is not substantially equivalent to the liquid crystal thermographic system in commercial distribution on the enactment date of the amendments.

Because FDA believes that the liquid crystal thermographic system is being commercially distributed while intended for a new use, i.e., use unaided in diagnostic screening, FDA is codifying the statutory classification of the new device into class III for such new use. See § 884.3(b). Accordingly, the regulation classifying this class III device states that, as of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed.

11. Section 892.1450; Telethermographic System—AC-powered.

If the device is intended for adjunctive use in diagnostic screening for detection of breast cancer, FDA proposed that the device be classified in class II. If the device is intended for use alone in diagnostic screening for detection of breast cancer, FDA proposed that the device be classified in class III.

11a. One comment suggested that FDA not classify the telethermographic system in Part 892 with radiology devices because the device does not emit radiation.

FDA agrees that, for the reason given in the comment, the device should not be codified in Part 892. In this final rule, FDA is codifying the classification of

one version of the proposed device in 21 CFR Part 884—Obstetrical and Gynecological Devices (§ 884.2980). FDA also is postponing classification of the telethermographic system intended for certain uses. See "D. Devices Not Being Classified At This Time." When FDA classifies the proposed but postponed version of the device, the agency will codify its classification in Part 884 using the same docket number.

11b. Some comments on the proposed regulation said that the device should be placed in class I for all intended uses, because the risk to health of electric shock is not a significant risk for this device.

FDA tentatively agrees that it is unnecessary to establish performance standards under section 514 of the act to control the risk to health of electric shock presented by the telethermographic system. Thus, FDA is postponing classification of the telethermographic system, if the device is intended for certain uses, and the agency is considering classifying the device intended for these uses into class I. See "D. Devices Not Being Classified At This Time." For the reasons provided below, FDA disagrees that the proposed device should be classified into class I for all intended uses.

11c. Several comments stated that the efficacy of thermography in early detection of breast cancer can be significantly influenced by the degree of expertise and experience of the users. These comments said that the device should be in class I because the skill of the users assured safe and effective performance of the device.

FDA disagrees with the comments. Under the statute, FDA classifies a device based on attributes of the device, including adequacy of labeling for its intended uses. Although user skill may enhance results obtained from use of a device, in determining the safety and effectiveness of a device for purposes of classification, FDA assumes that users possess average skills.

11d. One comment requested that FDA classify the telethermographic system into class I for all intended uses instead of into class II or class III as proposed, depending upon certain intended uses of the device. The comment said that classification of the device into class III if it is intended for use as the only screening tool in the early detection of breast cancer would essentially eliminate its use.

FDA disagrees with the comment. Classification of a preamendments device into class II or class III under section 513 (c) and (d) of the act has no immediate impact on the commercial availability of the device. For each device classified into class II or class III under this section of the act, FDA must publish and additional proposed and final regulation allowing further public comment before the agency can establish a performance standard (21 U.S.C. 360d) or require premarket approval (21 U.S.C. 360e) for the device. See the discussion later in this preamble entitled "N. Economic Impact." Further, the essential purpose of the classification procedures provided by Congress is to provide reasonable assurance of the safety and effectiveness of the devices. Continued commerical availability of devices is not one of the criteria that FDA may consider when classifying devices.

11e. Some comments recommended that the telethermographic system intended for consumer use, whether over-the-counter or prescription, be classified into class III.

FDA agrees with the comment. The agency believes that the telethermographic system intended for diagnostic use by consumers has never been marketed and that, if the device is intended for diagnostic use by consumers, it would not be substantially equivalent to the preamendments device subject to the proposed rulemaking. Accordingly, FDA believes that a telethermographic system intended for diagnostic use by consumers would be a new significant risk device. Before testing a telethermographic device with such new intended uses on humans for purposes of gathering data to submit to FDA to obtain premarket approval, manufacturers should obtain from FDA an investigational device exemption for the device as specified in 21 CFR Part 812.

11f. Other comments indicated that FDA's statements in the proposed regulations about the unacceptably high levels of false-negative and false-positive results from using the telethermographic system for diagnosing breast cancer were not accurate. One comment said that the false-negative rate for breast cancer detection using thermography is less than the false-negative rate using X-ray mammography. Another comment said that the high false-positive rate for breast cancer detection using thermography is of greater significance than the false-negative rate.

Some comments stated that the device should be in class I instead of class III when it is intended only for screening and detection of breast cancer. The comments stated that adequate evidence exists to show the safety and effectiveness of the device for this intended use. The comments submitted (or cited) a number of published studies to support their requests that the device be in class I.

FDA acknowledges the importance of both the false-negative and the false-positive rates when evaluating the efficacy of any cancer detection method. FDA is concerned that (1) based upon a false-negative thermogram, a woman may not seek proper medical attention, and (2) a false-positive result may cause a woman to lose faith in medicine and not participate in further routine clinical screening programs for cancer. Therefore, both the false-negative and the false-positive rates are important in evaluating the safety and effectiveness of thermographic devices. FDA has reviewed the data submitted and cited by the comments and other data and information available and has observed a lack of scientific consensus regarding the safety and effectiveness of thermography when used along in diagnosis of cancer. Based upon available data, FDA believes that thermography in the detection of breast cancer is appropriate only as an adjunct to other clinically accepted independent screening techniques, i.e., a clinical physical examination including palpation and X-ray mammography. Thermography may be useful to detect breast temperature variations which may be indicative of abnormalities. Thermography's effectiveness, when used alone in the specific detection of breast cancer, has not been demonstrated.

To summarize, although FDA tentatively agrees that the telethermographic system should be placed in class I if it is intended for adjuctive diagnostic use, for the reasons given above in paragraph 11b, FDA is postponing classification of the device if it is intended for adjunctive diagnostic use. Further, FDA believes that there is insufficient information to determine whether or not the general controls of class I by themselves are sufficient to provide reasonable assurance of the safety and effectiveness of the telethermographic system intended for use as the sole diagnostic tool in screening for breast cancer or other conditions and that insufficient information exists for the establishment of performance standards to provide such assurance. FDA believes that this device, when used as the only screening tool for the diagnosis of breast cancer or other conditions, is of substantial importance in preventing impairment of human health. Because of the potential for high levels of false-negative and false-positive test results, the device presents a potential unreasonable risk of illness or injury. Accordingly, FDA is

adopting the proposed regulation classifying the telethermographic system intended as the only screening tool for the diagnosis of breast cancer or other conditions into class III with clarifying changes in the identification of the device.

11g. FDA recognizes that the telethermographic system is being commercially distributed for use in a wide range of diagnostic applications where variations in skin temperature may occur, such as (a) peripheral vascular disease, (b) musculoskeletal disorders, (c) extracranial cerebral vascular disease, (d) abnormalities of the thyroid gland, and (e) various neoplastic and inflammatory conditions. FDA believes that the telethermographic system intended for adjunctive use in diagnostic screening for breast cancer or other uses is a preamendments device. FDA believes that this preamendments device, if intended for use as the sole tool in diagnostic screening for breast cancer or other uses, has been substantially altered and has undergone a major change or modification of its intended use (see 21 CFR 807.85) and is not substantially equivalent to the telethermographic system in commercial distribution on the enactment date of the amendments.

Because FDA believes that the telethermographic system is being commercially distributed while intended for a new use, i.e., used unaided in diagnostic screening, FDA is codifying the statutory classification of the new device into class III for such new use. See § 884.3(b). Accordingly, the regulation classifying this class III device states that, as of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed.

12. Section 892.1820; Pneumoencephalographic chair; proposed class II.

A comment on the proposed regulation requested that FDA classify the device into class I instead of class II, arguing that the adjustment of the tension of the restraint straps to prevent constriction of the patient's blood vessels is under control of the medical staff while the device is in use and that structural or control mechanism failure is not a significant hazard for this device.

FDA believes that, whether or not the comment is correct, the agency must classify the device into class II because the Panel cited additional risks to health, i.e., electromechanical malfunction or difficulties in administering contrast agents, in addition to the risk of vascular constriction. FDA believes that the identified risks would be minimized by establishing a performance standard for the device and that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that sufficient information is available to develop a performance standard for the device. Accordingly, FDA is adopting the proposed regulation classifying the pneumoencephalographic chair with minor clarifying changes.

13. Section 892.1850; Radiographic film cassette; proposed class II.

Some comments on the proposed regulation requested that FDA classify the device into class I instead of class II as proposed, arguing that the risk to health of misdiagnosis from poor contact of the radiographic film with the intensifying screen would be minimized if the user of the device employed readily available quality assurance tests.

FDA disagrees with the comments. Data collected by FDA indicate that significant differences in patient exposure can result from the choice of cassette used in a radiographic examination (Refs. 1 and 3). The aluminum equivalence of cassette front panels range from 0.06 to 1.7 millimeters. These thicknesses result in X-ray transmissions ranging from 98 to 61 percent of the incident beam and a worst-case difference in exposure to the patient of 1 to 1.6. In addition to direct exposure differences, the differences between cassettes can result in degradation of image quality and increased repeat rates. The agency believes that this information provides both a basis for and data to support development of a standard for the device. Accordingly, FDA is adopting the proposed regulation for the radiographic film cassette with a minor clarifying change.

14. Section 892.5770; Powered radiation therapy patient support assembly; proposed class II.

A comment on the proposed regulation requested that FDA classify the device into class I instead of class II, arguing that the risk to patients from failure of the device's structural integrity or control mechanism is not a significant risk.

FDA disagrees with the comment. FDA has received reports of patients being injured due to failures of this device. FDA believes that a performance standard is necessary for the powered radiation therapy patient support assembly to control the risk to patients' health from trauma resulting from failure of the structural or control mechanisms of the device. FDA also believes that sufficient information is available to develop a performance standard for the device. The agency further believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation for the powered radiation therapy patient support assembly with a minor clarifying change.

15. Section 892.6500; Personnel protective shield; proposed class II.

Some comments on the proposed regulation requested that FDA classify the device into class I instead of class II, arguing that performance standards are unnecessary to control the risk to health of excessive radiation exposure of patients from improper function of the device. The comments said that exposure to unnecessary radiation is a potential hazard but that unnecessary radiation exposure is unlikely to result from improper functioning of the device. The comments further stated that manufacturers' adherence to the requirements of the current good manufacturing practice (CGMP) regulations and testing by users before acceptance of the devices would provide a reasonable assurance of the safety and effectiveness of the personnel protective shield. One comment argued that the establishment of performance standards for all of the various kinds of shields encompassed in this generic type of device would not be cost effective.

FDA agrees with the comments. The general controls of class I alone for the personnel protective shield, particularly the requirements of the CGMP regulations in 21 CFR Part 820, would provide reasonable assurance of the safety and effectiveness of the device. The personnel protective shield is intended to protect the patient, the operator of radiation emitting medical devices, or other persons from any unnecessary radiation. The amount of shielding required varies (a) with the levels of radiation emitted, and (b) with the distance between the radiation source and the person being protected. FDA believes that users of radiation-emitting devices are essentially responsible for the amount and placement of shielding needed to prevent unnecessary or excessive radiation exposure from these devices. FDA now believes that the general controls of class I would provide reasonable assurance that the personnel protective shield is constructed properly and that it is unnecessary to establish performance standards for the device under section 514 of the act. Accordingly, FDA is adopting the

proposed regulation for the personnel protective shield with a change in classification from class II to class I and minor clarifying changes.

H. Exemptions For Class I Devices

16. The various panels reviewing radiology devices recommended that FDA exempt the five radiology devices listed below from certain requirements of the act. In the preamble to the proposed regulations, the agency provided its reasons for agreeing or disagreeing with the panels' recommendations regarding exemptions (47 FR 4406 at 4410 and 4436).

In response to the panels' recommendations, FDA proposed that the first four radiology devices listed below be exempt from most requirements of the CGMP regulations (21 CFR Part 820) and the requirement of premarket notification (section 510(k) of the act and Subpart E of 21 CFR Part 807). FDA proposed to classify the radiographic intensifying screen into class I with no exemptions.

Section No.	Device
892.1840	Radiographic film.
892.1920	Radiographic head holder.
892.1940	Radiologic quality assurance instrument.
892.1950	Radiographic anthropomorphic phantom.
892.1960	Radiographic intensifying screen.

However, as stated in the proposed rule, the agency has determined that exemption of manufacturers of any device from §§ 820.180 and 820.198 of the CGMP regulations 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 in § 820.180 concerning records 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 CGMP regulations, if one has been granted, is still appropriate.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device CGMP regulations. A sterile device must be subject to all of the CGMP regulations to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during manufacturing processes. This reduction is accomplished through adherence to a comprehensive quality assurance program, as is required by the CGMP regulations, including adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

16a. Exemptions from CGMP regulations.

Many general comments on the proposed regulations for radiology devices requested that the agency grant all of the exemptions that the panels had recommended.

FDA agrees that it should grant to the manufacturers of three of the five radiology devices listed in paragraph 16 above an exemption from most requirements of the CGMP regulations, as FDA proposed (§§ 892.1920, 892.1940, and 892.1950).

FDA disagrees that the agency should grant to manufacturers of the radiographic intensifying screen an exemption from the CGMP regulations. FDA believes that, in order to control the risks to health that may result from unnecessary radiation exposure from repreated radiographs or loss of diagnostic information due to the use of a substandard product and thereby to provide reasonable assurance of the safety and effectiveness of the device, this device should be subject to all of the requirements of the CGMP regulations.

FDA now believes that radiographic film should not be exempt from CGMP requirements because of wide variations in the amount of X-rays transmitted to patients and in the image quality produced by various types of film which is affected by the manufacturing process.

Accordingly, FDA is adopting the proposed regulations classifying the radiographic head holder, radiologic quality assurance instrument, and radiographic anthropomorphic phantom into class I with the exemptions from CGMP that were proposed.

16b. Exemptions from premarket notification procedures.

Many comments requested that FDA grant the exemptions from premarket notification procedures in section 510(k) of the act and Subpart E of 21 CFR Part 807 that the panels had recommended.

In this final rule, FDA is granting the exemption from the requirement of premarket notification for manufacturers of each of the four radiology devices that were proposed (§§ 892.1840, 892.1920, 892.1940, and 892.1950). Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant an exemption from the requirement of premarket notification for six additional class I radiology devices. In that proposed rule, FDA explains its recently developed policy on granting such exemptions.

I. Minor Changes or Clarifications

Occasionally, the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. Also, the agency is adding new §§ 884.3 and 892.3 in Subpart A of each part to explain the various effective dates for premarket approval requirements for devices classified into class III. FDA also is adding a new paragraph in the classification regulation for each device classified into class III to declare, where applicable, the effective date of premarket approval requirements for the device.

J. Guidelines For Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Devices

FDA has developed guidelines to assist diagnostic ultrasound manufacturers prepare 510(k) premarket notifications on their devices. A copy of these guidelines, entitled "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Devices," can be obtained upon request from: Lillian L. Yin, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

K. 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 name	Publication date in **Federal Register**
Circulatory Systems Devices Panel	March 9, 1979; 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Clinical Toxicology Devices Panel	February 2, 1982; 47 FR 4802–4929 (proposals); May 1, 1987; 52 FR 16102–16138 (final regulations).
Hematology and Pathology Devices Panel	September 11, 1979; 44 FR 52950–53063 (proposals); September 12, 1980; 45 FR 60576–60651 (final regulations).
General Hospital and Personal Use Devices Panel	August 24, 1979; 44 FR 49844–49954 (proposals); October 21, 1980; 45 FR 69678–69737 (final regulations).

Panel name	Publication date in Federal Register
Gastroenterology-Urology Devices Panel	January 23, 1981; 46 FR 7562-7641 (proposals); November 23, 1983; 48 FR 53012-53029 (final regulations).
Immunology Devices Panel	April 22, 1980; 45 FR 27204-27359 (proposals); November 9, 1982; 47 FR 50814-50840 (final regulations).
Microbiology Devices Panel	April 22, 1980; 45 FR 27204-27359 (proposals); November 9, 1982; 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel	April 3, 1979; 44 FR 19894-19971 (proposals); February 26, 1980; 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel	January 29, 1982; 47 FR 4406-4451 (proposals); January 20, 1988 (final regulations).
Ophthalmic Devices Panel	January 26, 1982; 47 FR 3694-3749 (proposals); September 2, 1987; 52 FR 33346-33363 (final regulations).
Ear, Nose, and Throat Devices Panel	January 22, 1982; 47 FR 3280-3325 (proposals); November 6, 1986; 51 FR 40378-40393 (final regulations).
Dental Devices Panel	December 30, 1980; 45 FR 85962-86168 (proposals); August 12, 1987; 52 FR 30082-30106 (final regulations).
Anesthesiology and Respiratory Therapy Devices Panel	November 2, 1979; 44 FR 63292-63426 (proposals); July 16, 1982; 47 FR 31130-31150 (final regulations).
Neurological Devices Panel	November 23, 1978; 43 FR 54640-55732 (proposals); September 4, 1979; 44 FR 51726-51778 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices)	August 28, 1979; 44 FR 50458-50537 (proposals); November 23, 1983; 48 FR 53032-53054 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices)	July 2, 1982; 47 FR 29052-29140 (proposals); September 4, 1987; 52 FR 33686-33711 (final regulations).
General and Plastic Surgery Devices Panel	January 19, 1982; 47 FR 2810-2853 (proposals).

L. Reference

The following information has been placed on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

Schuping, R. E., et al., "Dose Reduction Potential of Carbon Fiber Material in Diagnostic Radiology," *Proceedings of the Society of Photo-Optical Instrumentation Engineers*, Vol. 233 (1980).

M. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

N. Economic Impact

The agency has carefully analyzed the economic effects of this final rule and has determined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of the Executive Order 12291, the agency has carefully analyzed the impact of this final rule and it has determined that the final rule does not constitute a major rule as defined in section 1(b) of the Exeuctive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is 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 do not have a significant impact on a substantial number of small entities and are not major rules.

List of Subjects

21 CFR Part 884

Medical devices.

21 CFR Part 892

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 884 and Part 892 as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR Part 884 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 552-559, 565-574, 576-577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. By adding new § 884.2980, to read as follows:

§ 884.2980 Telethermographic system.

(a) [Reserved]

(b) *Telethermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A telethermographic system for use as the sole diagnostic screening tool for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

3. By adding new § 884.2982, to read as follows:

§ 884.2982 Liquid crystal thermographic system.

(a) *A nonelectrically powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A nonelectrically powered liquid crystal thermographic system intended for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classification.* Class I.

(b) *A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic

system intended for use as the sole diagnostic screening tool for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include image display and recording equipment, patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

4. By adding new Part 892 to read as follows:

PART 892—RADIOLOGY DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Subparts C–E—[Reserved]

Subpart F—Therapeutic Devices

Subpart G—Miscellaneous Devices

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

Subpart A—General Provisions

§ 892.1 Scope.

(a) This part sets forth the classification of radiology 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 cannot show merely that the device is accurately described by the section title and identification provision 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, a radiology device that has two or more types of uses (e.g., use both as a diagnostic device and a therapeutic device) is listed in one subpart only.

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

§ 892.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without

any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commerically distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

Subpart B—Diagnostic Devices

§ 892.1170 Bone densitometer.

(a) *Identification.* A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by X-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1200 Emission computed tomography system.

(a) *Identification.* An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1220 Fluorescent scanner.

(a) *Identification.* A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain X-rays or low-energy gamma rays. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.

(b) *Classification.* Class II.

§ 892.1310 Nuclear tomography system.

(a) *Identification.* A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of devices may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1360 Radionuclide dose calibrator.

(a) *Identification.* A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients.

(b) *Classification.* Class II.

§ 892.1370 Nuclear anthropomorphic phantom.

(a) *Identification.* A nuclear anthropomorphic phantom is a human tissue facsimile that contains a radioactive source or a cavity in which a radioactive sample can be inserted. It is intended to calibrate nuclear uptake probes or other medical instruments.

(b) *Classification.* Class I.

§ 892.1380 Nuclear flood source phantom.

(a) *Identification.* A nuclear flood source phantom is a device that consists of a radiolucent container filled with a uniformly distributed solution of a desired radionuclide. It is intended to calibrate a medical gamma camera-collimator system for uniformity of response.

(b) *Classification.* Class I.

§ 892.1390 Radionuclide rebreathing system.

(a) *Identification.* A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere). This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1400 Nuclear sealed calibration source.

(a) *Identification.* A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.

(b) *Classification.* Class I.

§ 892.1420 Radionuclide test pattern phantom.

(a) *Identification.* A radionuclide test pattern phantom is a device that consists of an arrangement of radiopaque or radioactive material sealed in a solid pattern intended to serve as a test for a performance characteristic of a nuclear medicine imaging device.

(b) *Classification.* Class I.

§ 892.1540 Nonfetal ultrasonic monitor.

(a) *Identification.* A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1550 Ultrasonic pulsed doppler imaging system.

(a) *Identification.* An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1560 Ultrasonic pulsed echo imaging system.

(a) *Identification.* An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1570 Diagnostic ultrasonic transducer.

(a) *Identification.* A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.

(b) *Classification.* Class II.

§ 892.1600 Angiographic X-ray system.

(a) *Identification.* An angiographic X-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1610 Diagnostic X-ray beam-limiting device.

(a) *Identification.* A diagnostic X-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic X-ray field by limiting the size of the primary X-ray beam.

(b) *Classification.* Class II.

§ 892.1620 Cine or spot fluorographic X-ray camera.

(a) *Identification.* A cine or spot fluorographic X-ray camera is a device intended to photograph diagnostic images produced by X-rays with an image intensifier.

(b) *Classification.* Class II.

§ 892.1630 Electrostatic X-ray imaging system.

(a) *Identification.* An electrostatic X-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of X-radiation into an electrostatic image and, subsequently, into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1650 Image-intensified fluoroscopic X-ray system.

(a) *Identification.* An image-intensified fluroscopic X-ray system is a device intended to visualize anatomical structures by converting a pattern of X-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1660 Non-image-intensified fluroscopic X-ray system.

(a) *Identification.* A non-image-intensified fluoroscopic X-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of X-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1670 Spot-film device.

(a) *Identification.* A spot-film device is an electromechanical component of a fluoroscopic X-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.

(b) *Classification.* Class II.

§ 892.1680 Stationary X-ray system.

(a) *Identification.* A stationary X-ray system is a permanently installed diagnostic system intended to generate and control X-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1700 Diagnostic X-ray high voltage generator.

(a) *Identification.* A diagnostic X-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic X-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the X-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.

(b) *Classification.* Class II.

§ 892.1710 Mammographic X-ray system.

(a) *Identification.* A mammographic X-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1720 Mobile X-ray system.

(a) *Identification.* A mobile X-ray system is a transportable device system intended to be used to generate and control X-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1730 Photofluorographic X-ray system.

(a) *Identification.* A photofluorographic X-ray system is a device that includes a fluoroscopic X-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1740 Tomographic X-ray system.

(a) *Identification.* A tomographic X-ray system is an X-ray device intended to be used to produce radiologic images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1750 Computed tomography X-ray system.

(a) *Identification.* A computed tomography X-ray system is a diagnostic X-ray system intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1760 Diagnostic X-ray tube housing assembly.

(a) *Identification.* A diagnostic X-ray tube housing assembly is an X-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification.* Class II.

§ 892.1770 Diagnostic X-ray tube mount.

(a) *Identification.* A diagnostic X-ray tube mount is a device intended to support and to position the diagnostic X-ray tube housing assembly for a medical radiographic procedure.

(b) *Classification.* Class II.

§ 892.1820 Pneumoencephalographic chair.

(a) *Identification.* A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (X-ray imaging of the brain).

(b) *Classification.* Class II.

§ 892.1830 Radiologic patient cradle.

(a) *Identification.* A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.

(b) *Classification.* Class II.

§ 892.1840 Radiographic film.

(a) *Identification.* Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 892.1850 Radiographic film cassette.

(a) *Identification.* A radiographic film cassette is a device intended for use during diagnostic X-ray procedures to hold a radiographic film in close contact with an X-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.

(b) *Classification.* Class II.

§ 892.1860 Radiographic film/cassette changer.

(a) *Identification.* A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between X-ray exposures and to position it during the exposure.

(b) *Classification.* Class II.

§ 892.1870 Radiographic film/cassette changer programmer.

(a) *Identification.* A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.

(b) *Classification.* Class II.

§ 892.1880 Wall-mounted radiographic cassette holder.

(a) *Identification.* A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use.

(b) *Classification.* Class II.

§ 892.1910 Radiographic grid.

(a) *Identification.* A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor.

(b) *Classification.* Class I.

§ 892.1920 Radiographic head holder.

(a) *Identification.* A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1940 Radiologic quality assurance instrument.

(a) *Identification.* A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1950 Radiographic anthropomorphic phantom.

(a) *Identification.* A radiographic anthropomorphic phantom is a device intended for medical purposes to simulate a human body for positioning radiographic equipment.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1960 Radiographic intensifying screen.

(a) *Identification.* A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident X-ray photons into visible light and intended for medical purposes to expose radiographic film.

(b) *Classification.* Class I.

§ 892.1980 Radiologic table.

(a) *Identification.* A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.

(b) *Classification.* Class II.

Subparts C–E—[Reserved]

Subpart F—Therapeutic Devices

§ 892.5050 Medical charged-particle radiation therapy system.

(a) *Identification.* A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5300 Medical neutron radiation therapy system.

(a) *Identification.* A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment support, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5650 Manual radionuclide applicator system.

(a) *Identification.* A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class I.

§ 892.5700 Remote controlled radionuclide applicator system.

(a) *Identification.* A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class II.

§ 892.5710 Radiation therapy beam-shaping block.

(a) *Identification.* A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to

modify the shape of a beam from a radiation therapy source.

(b) *Classification.* Class II.

§ 892.5730 Radionuclide brachytherapy source.

(a) *Identification.* A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

(b) *Classification.* Class II.

§ 892.5740 Radionuclide teletherapy source.

(a) *Identification.* A radionuclide teletherapy source is a device consisting of a radionuclide enclosed in a sealed container. The device is intended for radiation therapy, with the radiation source located at a distance from the patient's body.

(b) *Classification.* Class I.

§ 892.5750 Radionuclide radiation therapy system.

(a) *Identification.* A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts (including beam-limiting devices), and accessories.

(b) *Classification.* Class II.

§ 892.5770 Powered radiation therapy patient support assembly.

(a) *Identification.* A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy.

(b) *Classification.* Class II.

§ 892.5780 Light beam patient position indicator.

(a) *Identification.* A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. The beam of light is intended to be used during radiologic procedures to ensure proper positioning of the patient and to monitor alignment of the radiation beam with the patient's anatomy.

(b) *Classification.* Class II.

§ 892.5840 Radiation therapy simulation system.

(a) *Identification.* A radiation therapy simulation system is a fluoroscopic or radiographic X-ray system intended for use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5900 X-ray radiation therapy system.

(a) *Identification.* An X-ray radiation therapy system is a device intended to produce and control X-rays used for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5930 Therapeutic X-ray tube housing assembly.

(a) *Identification.* A therapeutic X-ray tube housing assembly is an X-ray generating tube encased in a radiation-shielded housing intended for use in radiation therapy. This generic type of device may include high-voltage and filament transformers or other appropriate components when contained in radiation-shielded housing.

(b) *Classification.* Class II.

Subpart G—Miscellaneous Devices

§ 892.6500 Personnel protective shield.

(a) *Identification.* A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.

(b) *Classification.* Class I.

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Frank E. Young,

Commissioner of Food and Drugs.

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