

sites to elicit interest by community members in serving on the Community/Tribal Subcommittee. From responses to these efforts and to this **Federal Register** notice, a pool of applicants will be obtained from which the Planning Committee will recommend a slate of candidates. The BSC will then select the nine community representatives of the Community/Tribal Subcommittee from the pool, with special consideration given to the recommended slate. Accordingly, any person who lives in a community affected by an NPL or other hazardous waste site, or is a representative of a group that works at local, regional, or national locations with these communities, who wishes to be considered for serving on this Subcommittee should write to Triangle Associates, Inc. at the address above to express their interest and obtain additional information.

Dated: September 25, 1997.

Georgi Jones,

*Director, Office of Policy and External Affairs,
Agency for Toxic Substances and Disease
Registry.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 62 FR 46751, dated September 4, 1997) is amended to reflect the reorganization of the Epidemiology Program Office (EPO) as follows: revise the functional statement for the EPO to more accurately reflect the mission of the office; establish the Office of Program Management and Operations; revise the functional statement for the Scientific Information and Communications Program and retitle as the Office of Scientific and Health Communications; revise the functional statement for the Division of Surveillance and Epidemiology and retitle as Division of Public Health Surveillance and Informatics; revise the functional statement for the Division of Training and retitle as the Division of

Applied Public Health Training; establish the Division of Prevention Research and Analytic Methods; establish the Division of International Health; abolish the Division of Field Epidemiology.

Section C-B, *Organization and Functions*, is hereby amended as follows:

Delete the functional statement for the Epidemiology Program Office (EPO) (CB) and insert the following:

(1) Plans, directs, and manages CDC-wide training and service programs, including the Epidemic Intelligence Service (EIS), the Preventive Medicine Residency (PMR), and the Public Health Program Specialist (PHPS) programs, as well as various internship and fellowship programs; (2) plans, develops, edits, publishes and disseminates the Morbidity and Mortality Weekly Report (MMWR), related publications, and various scientific and health communication documents and special reports; (3) serves as a focal point for the development of innovative methods for the collection, analysis, and communication of public health surveillance information (e.g. National Electronic Telecommunications System for Surveillance, 122 Cities Mortality Reporting System, and CDC WONDER); (4) in collaboration with other Centers, Institutes, and Offices (CIOs) and state health departments, coordinates, develops, implements, and supports various public health information systems for agency application; (5) provides consultation, technical assistance, and training on epidemiology, public health surveillance and informatics, health information systems, prevention effectiveness, scientific communications, behavioral science, statics, and development of community health practice guidelines to CDC/ATSDR, states, other agencies, other countries, and domestic and international organizations; (6) provides policy and staff support for CDC's Health Information and Surveillance Systems Board; (7) provides epidemiologic assistance and epidemic aid through the field assignment of epidemiologists; (8) provides liaison with governmental agencies, international organizations, the Council of State and Territorial Epidemiologists, and other outside groups; (9) plans conducts, and evaluates research activities in various aspects of disease and injury control for global programs; (10) promotes the development of international field epidemiologic training programs; (11) develops, promotes, and implements programs for

international and domestic data policy formation for decision makers to identify information needs and to use information for improved decision making; (12) in carrying out the above functions, collaborates, as appropriate, with the CDC Office of the Director, other CDC CIOs, domestic and international agencies and organizations.

Delete the functional statement for the *Office of the Director (CB1)* and insert the following:

(1) Manages, directs, coordinates, and evaluates the activities of EPO; (2) develops goals and objectives and provides leadership, policy formation, scientific oversight, and guidance in program planning and development; (3) coordinates EPO program activities with other CDC components, other PHS agencies, other federal agencies, other international organizations, state and local health departments, community-based organizations, business, and industry; (4) consults and coordinates activities with medical, scientific and other professional organizations interested in epidemiology, public health surveillance and informatics, health information systems, behavioral science, statistics, scientific communications, community health practice guidelines, prevention effectiveness, and training activities; (5) ensures quality of scientific products of EPO staff and adherence to ethical principles and guidelines as specified in Department of Health and Human Services (DHHS) policy statements; (6) coordinates technical assistance to states, other nations and international organizations; (7) advises the Director, CDC, on policy matters concerning EPO activities.

Delete the title and functional statement for the *Scientific Information and Communications Program (CB12)* and insert the following:

Office of Scientific and Health Communications (CB12). (1) Plans, coordinates, edits, and produces the MMWR series and various special reports and publications; (2) provides editorial services and support to EPO; (3) develops, implements, and evaluates innovative methods for the communication of scientific and health information by EPO and its domestic and international constituents; (4) assists EPO and its constituents in identifying and building needed expertise, state-of-the-art technology, logistical support, and other capabilities required to conduct effective scientific and health communication in domestic and international settings; (5) provides expert consultation and training to EPO, other CIOs, and outside domestic and

international constituencies on development of effective messages, materials, and methods to clearly and effectively communicate risks and prevention recommendation, including written, oral, and visual communication; (6) provides leadership, coordination, and collaboration for the planning and management of EPO communications with other CDC programs and outside organizations in scientific and health communication, including serving as the primary EPO liaison with the CDC Office of Communication; (7) works closely with state and federal agencies and EPO domestic and international constituents to develop health information networks and to promote information sharing; (8) in conjunction with the CDC Office of Communication, collaborates with organization in the public and private sectors to market prevention strategies; (9) coordinates EPO's information-sharing activities, including involvement on the Internet.

Delete the functional statement for the *Office of the Director (CB12)* and insert the following:

(1) Provides leadership and overall direction for the Office of Scientific and Health Communications and for all EPO scientific and health communication application; (2) provides leadership, guidance, consultation, and training on policy, planning, management, and operations of scientific and health communications for EPO activities in domestic and international settings; (3) establishes office goals, objectives, and priorities; (4) monitors progress in implementation of projects and achievement of objectives; (5) provides technical information and support in scientific and health communication methods to the epidemiologic, surveillance, and other scientific services and applied research activities in EPO; (6) provides EPO-wide graphics support and coordinates major scientific and health communications efforts; (7) plans, coordinates, and provides support for the electronic dissemination of the MMWR series.

Delete the title and functional statement for the *MMWR Branch (CB122)* and insert the following:

Morbidity and Mortality Weekly Report Activity (CB122). (1) Develops, plans, coordinates, edits, and produces the weekly component of the MMWR series; (2) participates with other office personnel for the delivery of services and training to external organizations, both domestic and international, in the area of scientific and health communications; (3) provides EPO-wide desktop publishing support, including the support of the MMWR series.

Delete the title and functional statement for the *Public Health Publications Branch (CB123)* and insert the following:

Public Health Publications Activity (CB123): (1) Develops, plans, coordinates, edits, and produces other components of the MMWR series, including the MMWR Recommendations and Reports, CDC Surveillance Summaries, and the Annual Summary of Notifiable Diseases; (2) plans, coordinates, edits, and produces other EPO and CDC program publications; (3) provides editorial services for work to be published outside CDC; (4) reviews EPO documents for editorial clearance for all publications; (5) develops and manages an internship program in scientific and health publications management; (6) participates with other office personnel for the delivery of services and training to external organizations, both domestic and international, in scientific and health communications.

Delete in their entirety the title and functional statement for the *Information Resources Management Branch (CB124)* and insert the following:

Office of Program Management and Operations (CB12). (1) Provides leadership, oversight, and guidance in the management and operations of EPO's programs; (2) plans, coordinates, and provides administrative management support, advice, and guidance to EPO; (3) conducts EPO planning and evaluation activities; (4) reviews, prepares, and coordinates legislation, congressional testimony, and briefing documents; (5) coordinates the development of the EPO annual budget submission; (6) coordinates the annual EPO program briefing; (7) conducts management analyses of EPO programs and staff to ensure optimal utilization of resources and accomplishment of program objectives; (8) plans, allocates, and monitors EPO resources; (9) maintains liaison and collaborates with other CDC components and external organizations in support of EPO management and operations; (10) plans, coordinates, and provides information resource management support, advice, and guidance to EPO.

Office of the Director (CB131). (1) Directs and coordinates the activities of the office; (2) develops long-range plans, sets annual objectives, monitors progress, and evaluates results; (3) sets policies and procedures; (4) provides leadership and oversight of EPO's program management and operations; (5) plans, allocates, and monitors EPO-wide resources; (6) maintains liaison and collaborates with the Director,

Office of Program Support, other CIOs, CDC staff offices, other federal agencies, state and local health agencies, and other external organizations; (7) maintains liaison, on behalf of EPO, with the CDC Foundation and other similar organizations for the coordination of mutually-beneficial collaborative activities; (8) within the policies and guidelines of DHHS and CDC, conducts EPO planning and evaluation activities including tracking program objectives and performing evaluation studies; (9) coordinates the development of the EPO annual budget submission; (10) coordinates the annual EPO program briefing, including preparation of all written and visual materials; (11) reviews, prepares, and coordinates legislation, congressional testimony, and briefing materials; develops proposed legislation; analyzes bills; and provides for other legislative-related activities; (12) plans and prepares EPO promotional and marketing materials; (13) works closely with other federal agencies involved with EPO interagency agreements; (14) coordinates EPO requirements relating to procurement, materiel management, and interagency agreements; (15) provides fiscal management and stewardship of grants, contracts, and cooperative agreements.

Information Resources Management Activity (CB132). (1) Provides technical information support to the communications, epidemiologic, surveillance, training, and prevention research activities of EPO; (2) manages the EPO Local Area Network (LAN); (3) assists users with network applications; (4) provides personal computer support for EPO users; (5) researches and performs appropriate testing and installation of new software for use in EPO; (6) coordinates and authorizes requests for the acquisition of automatic data processing, word processing, telecommunication, and LAN equipment, and the provision of information services; (7) provides interface with CDC and DHHS management systems; (8) assures that all functional groups within EPO have access to suitable and compatible equipment and services; (9) plans, coordinates, and provides EPO-wide Information Resources Management (IRM) support and services; (10) represents EPO on a variety of IRM committees, task forces, and workgroups; (11) coordinates the utilization of data information systems and technologies.

Management Services Activity (CB133). (1) Plans, coordinates, and provides administrative management support, advice, and guidance to EPO

involving the areas of fiscal management, personnel, travel, and other administrative services; (2) prepares annual budget plans and budget justifications; (3) coordinates EPO requirements relating to contracts, grants, cooperative agreements, and reimbursable agreements; (4) develops and implements administrative policies, procedures, and operations, as appropriate for EPO, and prepares special reports and studies, as required, in the administrative management areas; (5) conducts management analyses of EPO programs and resources to ensure optimal utilization of resources and accomplishment of program objectives.

Delete in its entirety the title and functional statements for the *Division of Field Epidemiology (CB3)*.

Delete the title and functional statement for the *Division of Surveillance and Epidemiology (CB5)* and insert the following:

Division of Public Health Surveillance and Informatics (CB5). (1) Collects, performs analyses, and disseminates public health surveillance information; (2) manages and operates the National Electronic Telecommunications System for Surveillance (NETSS), the National Notifiable Diseases Surveillance System (NNDSS), and the 122 Cities Mortality Reporting System and produces statistical tables and graphics for the MMWR and associated publications; (3) in collaboration with other CIOs and state health departments, coordinates, develops, implements, and supports various CDC-wide public health information systems, including informational and communications applications; (4) develops improved surveillance and informatics methods; (5) provides consultation, technical assistance, and training on public health surveillance and health information systems to CDC and to other agencies and domestic and international organizations; (6) coordinates activities of the CDC Surveillance Coordination Group; (7) provides policy and staff support for CDC's Health Information and Surveillance Systems Board; (8) coordinates a CDC-wide initiative aimed at building state and local capacity to perform the core public health function of assessment and use of data for policy development and assurance.

Delete the functional statement for the *Office of the Director (CB51)* and insert the following:

(1) Provides leadership and overall direction for the division; (2) provides leadership and guidance on policy, program planning, program management, and operations; (3) establishes division goals, objectives, and priorities; (4) monitors progress in

implementation of projects and achievements of objectives; (5) provides management, administrative, and support services, and coordinates with appropriate EPO offices on program and administrative matters; (6) provides liaison with other CDC organizations, other governmental agencies, international organizations, the Council of State and Territorial Epidemiologists, and other constituent groups and partners; (7) plans, allocates, and monitors resources; (8) provides scientific leadership and guidance to the division to assure highest scientific quality and ethical standards; (9) plans and coordinates the activities of the CDC Surveillance Coordination Group; (10) provides guidance and supervision to EIS officers and Preventive Medicine Residents assigned to the division; (11) coordinates and serves as a focal point for a CDC-wide initiative aimed at building state and local capacity to perform the core health function of assessment and use of data for public health policy development and assurance.

Delete in their entirety the title and functional statement for the *Statistics and Epidemiology Branch (CB52)* and insert the following:

Public Health Information Systems Branch (CB53). (1) In collaboration with the Information Resources Management Office (IRMO) and other CDC organizations with subject matter expertise and responsibility, coordinates, designs, develops, implements, and supports CDC-wide public health, epidemiologic, scientific, and laboratory information systems, including database, informational, and communications applications (e.g., CDC WONDER); (2) collaborates with CDC organizations to jointly develop, test, and implement CDC-wide public health information systems; (3) participates in the development or implementation of CDC plans for public health information systems; (4) researches and develops new innovative approaches to public health applications development and database design; (5) determines appropriate technology architecture and methodology for branch-developed systems; (6) maintains inventories and data dictionaries of CDC's public health data; (7) develops and recommends approaches for public health systems and interfaces between various information technologies for sharing data and performing cooperative applications processing; (8) in consultation with CDC organizations and the CDC Information Systems Security Officer, determines appropriate security measures for branch-developed databases and applications, in

accordance with sensitivity and criticality of the data or system; (9) evaluates and recommends CDC-wide equipment and software acquisition for public health database and communications systems; (10) coordinates the provision of technical support and training in the use of CDC-wide public health information systems purchased or developed by the branch; (11) coordinates public health information resource management user groups.

Delete in their entirety the title and functional statement for the *Systems Development and Support Branch (CB58)*.

Delete the functional statement for the *Systems Operation and Information Branch (CB59)* and insert the following:

(1) Operates and maintains the NETSS, the NNDSS, and the 122 Cities Mortality Reporting System; (2) provides service and support to other CDC programs and state and local health departments to enable program-specific surveillance information to be collected and disseminated through the NETSS; (3) provides support, technical assistance, consultation, and training on surveillance system development, maintenance, and operation for CDC, states, and international organizations; (4) provides leadership and direction in the development of mainframe systems for use in surveillance and epidemiology; (5) plans, coordinates, and produces tables, graphs, maps, and figures for the Annual MMWR Summary of Notifiable Diseases, U.S.; (6) produces MMWR tables from NNDSS; (7) plans, coordinates and develops training and educational materials for all surveillance systems operated by the branch; (8) provides guidance in the development, implementation, and analysis of electronic public health data to international, state, and local groups; (9) creates, disseminates, and archives historical public health data in an electronic form; (10) provides support, technical assistance, and training for new, developmental systems and software for use in surveillance and epidemiology; (11) provides support, technical assistance, consultation, and training on computerized surveillance system development, maintenance, and operation for CDC, states, and international organizations; (12) provides service and support in the expansion of the NETSS; (13) plans and coordinates state-supported activities related to the NETSS; (14) analyzes needs and designs computer systems for use by public health professionals in the effective practice of public health surveillance and epidemiology; (15) provides technical consultation for

activities of the CDC Surveillance Coordination Group.

Delete the title and functional statement for the *Division of Training (CB6)* and insert the following:

Division of Applied Public Health Training (CB6). Plans, directs, and manages a CDC-wide training and service program for the teaching and training of public health professionals in applied epidemiology and other public health sciences, preventive medicine, and public health program planning, implementation, and evaluation; (2) plans, directs, and manages CDC-wide training and service programs for the EIS, the PMR, and the PHPS Programs; (3) responds to domestic and international request for assistance and consultation; (4) maintains liaison with other governmental agencies, academic institutions and organizations, state and local health agencies, private health organizations, and professional organizations, and other outside groups; (5) assumes an active national and international leadership role in public health training.

Delete the functional statement for the *Office of the Director (CB61)* and insert the following:

(1) Provides leadership, direction, coordination, and management oversight to the activities of the division; (2) develops long-range plans, sets annual objectives, monitors progress, and evaluates results; (3) sets policies and procedures; (4) plans, allocates, and monitors resources; (5) provides administrative guidance and oversight in the areas of personnel, travel, and other administrative services, and coordinates with the EPO Office of Program Management and Operations, Human Resources Management Office, and Financial Management Office; (6) coordinates collaborative activities of the division and maintains liaison with other CIOs, other federal agencies, and other outside groups.

Delete in their entirety the title and functional statement for the *Epidemiology Training Activity (CB62)*.

Delete the title and functional statement for the *Epidemic Intelligence Service Program (CB63)* and insert the following:

Epidemic Intelligence Service Branch (CB63). (1) Establishes overall policies, plans, and procedures, and evaluates the effectiveness of program activities; (2) develops and maintains a strategic plans for recruitment, analyzes data to more effectively target recruitment efforts, and conducts recruitment in accordance with the CDC workforce diversity goals; (3) plans, directs, and

coordinates the application, interview, selection, and assignment processes for new EIS officers (4) plans, directs, coordinates, and conducts training and training activities for EIS officers in applied epidemiology and public health practice; (5) monitors the completion of program requirements by EIS officers; (6) maintains liaison with supervisors of EIS officers, and evaluates EIS assignments within CDC, state and local health agencies, and other sponsoring organizations; (7) approves request, for epidemiologic assistance (EPI-AIDs) and the expenditures of funds; (8) maintains liaison with alumni within and outside CDC to assist with recruitment and promotional activities; (9) plans, directs, and coordinates the Epidemiologic Elective Program for medical and veterinary students.

Delete in their entirety the title and functional statement for the *Preventive Medicine Residency Program (CB64)* and insert the following:

Public Health Prevention Service Branch (CB65). (1) Establishes overall policies, plans, and procedures, and evaluates the effectiveness of program activities; (2) develops and maintains a strategic plan for recruitment, analyzes data to more effectively target recruitment effort, and conducts recruitment in accordance with the CDC workforce diversity goals; (3) plans, directs, and coordinates the application, interview, selection, and assignment processes for new PHPS trainees; (4) plans, directs, coordinates, and conducts training and training activities for PHPS trainees in the development, implementation, and evaluation of prevention programs and interventions; (5) monitors the completion of program requirements by PHPS trainees; (6) maintains liaison with supervisors of PHPS trainees, and evaluates PHPS assignments within CDC, state and local health agencies, and other sponsoring organizations; (7) coordinates and provides staff support to a steering committee/advisory group charged with advising on policy matters concerning the program.

State Branch (CB66). (1) Provides guidance and supervision to EIS officers, PMRs, and career epidemiologists assigned to state and local health departments; (2) monitors and evaluates the quality of assignments through site visits and by maintaining liaison with supervisors and other individuals in CIOs and states; (3) monitors the completion of program requirements and evaluates the performance of state-based EIS officers; (4) serves as the focal point for assistance requests from state health departments; (5) coordinates field

training activities (6) participates in recruitment, interviewing, and assignment activities of EIS officers; (7) provides on-site consultation with state and local health departments on the establishment and maintenance of epidemiology programs; (8) provides technical assistance to other components of CDC in the investigation of multi-state disease outbreaks; (9) coordinates liaison activities with state epidemiologists and other public health officials, (10) evaluates the effectiveness of branch activities.

Division of Prevention Research and Analytic Methods (CB7). (1) Provides leadership to CDC and other organizations on the allocation of resources including the integration of prevention research with policy needs, and assists in making recommendations for policy decisions based on effectiveness and cost-effectiveness; (2) promotes CDC's capacity to conduct epidemiologic, prevention effectiveness, statistical, behavioral science, and evaluative studies; (3) develops, adapts, evaluates, and implements innovative prevention effectiveness, epidemiologic, statistical, evaluative, and behavioral research methods; (4) provides consultation, technical assistance and training on analytic methods, data management and collection, including prevention effectiveness, epidemiologic and statistical methods, evaluation, and behavioral studies issues to CDC and to other agencies and domestic and international organizations; (5) develops projects in defined urban populations in which to evaluate the effectiveness of prevention activities; (6) develops CDC capacity and establishes a national scientific network in epidemiologic, behavioral, prevention effectiveness, statistical, and outcome evaluation science; (7) develops recommendations and guidelines based on effectiveness, cost-effectiveness, behavioral, outcome evaluation, and statistical research to enhance health promotion and disease and injury prevention in various settings and populations; (8) acquires, develops, applies, and evaluates statistical methods for use in public health; (9) supports CDC activities related to the Cochrane Collaboration; (10) develops recommendations (guidelines) based on effectiveness, cost-effectiveness, behavioral, outcome evaluation, and statistical research to enhance health promotion and disease and injury prevention in various settings and populations; (11) designs and conducts epidemiologic studies; (12) in carrying out the above the functions, collaborates, as appropriate, with the other CDC CIOs.

Office of the Director (CB71). (1) Manages, directs, and coordinates the activities of the division; (2) provides leadership and guidance on policy, program planning, program management, and operations; (3) establishes division goals, objectives, and priorities; (4) monitors progress in implementation of projects and achievement of objectives; (5) develops and manages internship, fellowship, and visiting scientist programs in prevention effectiveness, evaluation, behavioral science, and statistical methodologies; (6) develops, conducts, and provides support for training in prevention effectiveness, evaluation, behavioral science, epidemiologic and statistical methodologies CDC-wide, as well as at national, state, and local levels; (7) provides management, administrative and support services, and coordinates with appropriate EPO offices on program and administrative matters; (8) provides liaison with other CDC organizations, other governmental agencies, international organizations, and other outside groups; (9) plans, allocates, and monitors resources; (10) manages grants and CDC-wide prevention effectiveness and statistical analysis contracts; (11) provides support for internal scientific advisory groups; (12) provides scientific leadership and guidance to the division to assure highest scientific quality and ethical standards.

Prevention Effectiveness Branch (CB72). (1) Establishes capacity in the public health community to conduct and use prevention effectiveness studies; (2) develops, adapts, evaluates, and applies economic and decision science methods for public health applications; (3) provides economic technical assistance, consultation, direction, review, and information resources to other organizations units within EPO and throughout CDC; (4) collects and analyzes data; (5) integrates prevention research with policy needs; (6) assists in making recommendations for policy decisions on public health policy based on prevention effectiveness assessments of each prevention strategy; (7) provides coordinative support for CDC's Prevention Effectiveness Working Group.

Statistics and Epidemiology Branch (CB73). (1) Provides and maintains leadership in the acquisition, development, application, and evaluation of statistical and epidemiologic methods for use in public health; (2) provides statistical and epidemiologic consultation, training, and analytic assistance to EPO, other components of CDC, and to outside organizations; (3) conducts research in

methods development and evaluation; (4) analyzes public health data; (5) coordinates and supports CDC's Statistical Advisory Group; (6) provides programming and data management consultation and support for major studies; (7) develops scientific methods to address cross-cutting issues of epidemiology, such as disabilities, race and ethnicity, special settings, and gender; (8) designs and conducts epidemiologic studies to determine risk factors and causes of selected diseases and other conditions of public health importance; (9) collaborates on international epidemiologic and statistical science projects by providing technical assistance and consultation; (10) supports the CDC-based Cochrane Collaboration; (11) provides guidance and supervision to EIS officers and PMRs assigned to the division.

Community Preventive Services Guide Section (CB732). (1) Coordinates and develops community health practice guidelines for the assessment of effectiveness of prevention strategies; (2) assists CRC programs on methods for guidelines development processes; (3) coordinates and manages CRC-wide working group on practice guidelines methodology; (4) convenes a task force for development of community health practice guidelines; (5) produces a Guide to Community Health Practice Guidelines based on available scientific evidence; (6) identifies research needs for developing science-based guidelines; (7) updates guidelines on an ongoing basis.

Evaluation and Behavioral Science Methods Section (CB733). (1) Develops a conceptual framework for conducting behavioral and evaluation studies; (2) organizes and establishes populations for research in urban areas; (3) develops within CDC outcome evaluation capacity and systematize method for evaluating health outcomes; (4) develops key combinations of evaluation and behavioral interventions in urban populations; (5) provides information for public policy for urban areas by establishing credibility of the scientific approach; (6) assists in making recommendations for policy decisions; (7) conducts public health surveillance in urban health communities; (8) provides technical assistance; (9) provides coordinative support for CDC's Behavioral and Social Sciences Work Group.

Division of International Health (CB8). (1) Develops, promotes, and conducts international training, consultation, capacity building, and other assistance in applied epidemiology, public health surveillance, and systematic use of

epidemiologic and other data for health policy formulation, allocation of health resources, and direction and evaluation of public health program operations and effectiveness; (2) provides policy direction for all EPO activities associated with international health; (3) collaborates with the other CDC organizations, international agencies, foreign governments, and non-profit organizations in support of EPO's international activities.

Office of the Director (CB81). (1) Provides leadership and overall direction for the division; (2) provides leadership and guidance on policy, program planning, program management, and operations; (3) plans, allocates, and monitors resources; (4) provides leadership and management oversight in assisting national ministries of health, international agencies, and non-profit organizations in the delivery of epidemiologic services and the development of international epidemiologic networks; (5) provides liaison with other CDC organizations, other federal agencies, national ministries of health, and international organizations.

Data for Decision Making and Policy Branch (CB82). (1) Plans, directs, and coordinates data for decision making activities, both foreign and domestic; (2) assists with the development of capacity to design and conduct economic evaluation of health care interventions; (3) collaborates with national ministries of health to facilitate data use for policy formulation, resource allocation, and public health program management; (4) provides leadership and expertise in assisting national ministries of health and domestic entities in utilizing trained epidemiology generalists in developing health policy and implementing and evaluating health programs; (5) collaborates with federal agencies, national ministries of health, international agencies, and non-profit organizations to promote systematic use of data to improve public health.

Program Development Branch (CB83). (1) Plans, directs, and coordinates field epidemiology training programs; (2) provides leadership and management oversight in assisting national ministries of health in training epidemiology generalists for future ministry positions and for positions with international organizations; (3) oversees provision of consultation to national ministries of health and international organizations regarding epidemiologic practice, surveillance systems development and operation, and epidemiologic training; (4) assigns professional epidemiologist as long-term consultants to national programs in epidemiologic training and

public health capacity development; (5) provides on-site epidemiologic consultation to national ministries of health and international organizations as required; (6) provides on-site technical assistance, consultation, and training to other countries and international organizations in applied communications, publications management, health information systems development and management, and health economics.

Effective Date: September 19, 1997.

David Satcher,

Director.

[FR Doc. 97-25946 Filed 9-30-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0390]

Guidance for the Submission of 510(k)'s for Solid State X-Ray Imaging Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices." The draft guidance is neither final nor is it in effect at this time. This draft guidance applies to a new category of medical devices, Solid State X-ray Imagers (SSXI), and is currently available for comment. This draft guidance is intended to provide guidance to the significant number of premarket (510(k)) submissions resulting from this new technology. The draft guidance addresses the type of data needed by the Center for Devices and Radiological Health (CDRH) to establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic film/screen system, fluoroscopic image intensified imaging system, or SSXI.

DATES: Written comments by December 30, 1997.

ADDRESSES: Submit written requests for single copies of "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" to the Division of Small Manufacturers Assistance (HFZ-200), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that

office in processing your requests. Submit written comments on "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" to the contact person listed below.

FOR FURTHER INFORMATION CONTACT:

Robert J. Doyle, Center for Devices and Radiological Health (HFZ-476), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-1212.

SUPPLEMENTARY INFORMATION: The final version of this guidance will provide instruction concerning the type of data needed by CDRH to clear a new category of medical devices, SSXI's, for marketing via section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)). This new category of medical devices is intended to replace conventional x-ray film/screen systems and image intensifier based fluoroscopic and image recording systems. As solid state imaging technology continues to progress, FDA anticipates a significant number of premarket (510(k)) submissions to be based on this new technology. By issuing the guidance, FDA hopes to receive a larger percentage of complete premarket submissions upon submittal. This will avoid the need for additional information requests which are time consuming for both FDA and manufacturers.

Under the Medical Device Amendments to the act, a device may be cleared for marketing via a 510(k) premarket notification. To do so, the device must be shown to be substantially equivalent to a legally marketed predicate device. This guidance sets forth nonclinical and clinical data necessary to establish the substantial equivalence of the new device to the identified predicate device(s).

This draft guidance document represents the agency's current thinking on the data necessary to establish the substantial equivalence of SSXI to a previously cleared device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before December 30, 1997, submit to the contact person (address above) written comments regarding this draft guidance. Persons with access to the Internet may obtain the draft guidance via the World Wide Web (WWW) at "http://www.fda.gov/cdrh".

Dated: July 31, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 62 FR 46751, dated September 4, 1997) is amended to reflect the organizational structure for mine safety and health research functions within the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention.

Section C-B, *Organization and Functions*, is hereby amended as follows:

After the functional statement for the *Contracts and Purchases Branch (CA582)*, *Procurement and Grants Office (CA58)*, *Office of Program Support (CA5)*, insert the following:

Contracts Management Branch (Pittsburgh) (CA583). (1) Provides leadership, direction, procurement options and approaches in developing specifications/statements of work and contract awards; (2) Executes research and development contracts for all of NIOSH.

Revise the functional statement for the *Office of Administrative and Management Services (CC11)* to insert the following as item (4) and renumber the remaining items accordingly: (4) provides management information, advice, and guidance to CDC/OPS regarding the conduct and the evaluation of Staff Office procurement activities with respect to their effectiveness in meeting NIOSH's administrative and programmatic needs.

After the functional statement for the *Office of Administrative and Management Services (CC11)*, insert the following:

Administrative Services Branch (Pittsburgh) (CC112). (1) Provides basic facilities operations, maintenance, and