SUBCHAPTER A—GENERAL

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

Subpart A—Introduction

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Subpart A—Introduction

§ 1.1 Creation and authority.

Reorganization Plan 3 of 1970, established the U.S. Environmental Protection Agency (EPA) in the Executive branch as an independent Agency, effective December 2, 1970.

§ 1.3 Purpose and functions.

The U.S. Environmental Protection Agency permits coordinated and effective governmental action to assure the protection of the environment by abating and controlling pollution on a systematic basis. Reorganization Plan 3 of 1970 transferred to EPA a variety of research, monitoring, standard setting, and enforcement activities related to pollution abatement and control to provide for the treatment of the environment as a single interrelated system. Complementary to these activities are the Agency's coordination and support of research and antipollution activities carried out by State and local governments, private and public groups, individuals, and educational institutions. EPA reinforces efforts among other Federal agencies with respect to the impact of their operations on the environment.

§ 1.5 Organization and general information.

(a) The U.S. Environmental Protection Agency's basic organization consists of Headquarters and 10 Regional Offices. EPA Headquarters in Washington, DC maintains overall planning, coordination and control of EPA programs. Regional Administrators head the Regional Offices and are responsible directly to the Administrator for the execution of the Agency's programs within the boundaries of their Regions.

(b) EPA's Directives System contains definitive statements of EPA's organization, policies, procedures, assignments of responsibility, and delegations of authority. Copies are available for public inspection and copying at the Management and Organization Division, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Information can be obtained from the Office of Public Affairs at all Regional Offices.

(c) EPA conducts procurement pursuant to the Federal Property and Administrative Services Act, the Federal Procurement Regulations, and implementing EPA regulations.

§ 1.7 Location of principal offices.

(a) The EPA Headquarters is in Washington, DC. The mailing address is 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(b) The address of (and States served by) the EPA Regional Offices (see § 1.61) are:

(1) Region I, U.S. Environmental Protection Agency, 5 Post Office Square—Suite 100, Boston, MA 02109–3912. (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.)

(2) Region II, U.S. Environmental Protection Agency, Room 900, 26 Federal Plaza, New York, NY 10278. (New Jersey, New York, Puerto Rico, and the Virgin Islands.)

(3) Region III, U.S. Environmental Protection Agency, 841 Chestnut Street, Philadelphia, PA 19107. (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and the District of Columbia.)

(4) Region IV, U.S. Environmental Protection Agency, 345 Courtland Street NE., Atlanta, GA 30365. (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.)

(5) Region V, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, IL 60604. (Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin.)

(6) Region VI, U.S. Environmental Protection Agency, 1201 Elm Street, Dallas, TX 75270. (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.)

(7) Region 7, U.S. Environmental Protection Agency, 11201 Renner Boulevard, Lenexa, Kansas 66219. (Iowa, Kansas, Missouri, and Nebraska.)

(8) Region VIII, U.S. Environmental Protection Agency, 999 18th street, One Denver Place, Denver, CO 80202. (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.)

(9) Region IX, U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, California 94105. (Arizona, California, Hawaii, Nevada; the territories of American Samoa and Guam; the Commonwealth of the Northern Mariana Islands; the territories of Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Atoll, Palmyra Atoll, and Wake Islands; and certain U.S. Government activities in the freely associated states of the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.)

(10) Region X, U.S. Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101. (Alaska, Idaho, Oregon, and Washington.)

[50 FR 26721, June 28, 1985, as amended at 62 FR 1833, Jan. 14, 1997; 75 FR 69349, Nov. 12, 2010; 76 FR 49670, Aug. 11, 2011; 78 FR 37975, June 25, 2013]

Subpart B—Headquarters

§ 1.21 General.

EPA Headquarters is comprised of:

(a) The Office of the Administrator;

(b) Two Associate Administrators and four staff offices which advise the Administrator on cross-cutting Agency headquarters and regional issues and conduct programs with respect to EPA's interface with other national and international governmental organizations;

(c) The Office of Inspector General;

(d) The Office of General Counsel; and

(e) Nine operational offices, each headed by an Assistant Administrator, responsible for carrying out EPA's major environmental and administrative programs.

§ 1.23 Office of the Administrator.

The Environmental Protection Agency is headed by an Administrator who is appointed by the President, by and with the consent of the Senate. The Administrator is responsible to the President for providing overall supervision to the Agency, and is assisted by a Deputy Administrator also appointed by the President, by and with the consent of the Senate. The Deputy Administrator assists the Administrator in the discharge of Agency duties and responsibilities and serves as Acting Administrator in the absence of the Administrator.

§ 1.25 Staff offices.

(a) *Office of Administrative Law Judges.* The Office of Administrative Law Judges, under the supervision of the Chief Administrative Law Judge, is responsible for presiding over and conducting formal hearings, and issuance of initial decisions, if appropriate, in such proceedings. The Office provides supervision of the Administrative Law Judges, who operate as a component of the Office of Administrative Law

Judges, in certain Agency Regional Offices. The Office provides the Agency Hearing Clerk.

(b) *Office of Civil Rights.* The Office of Civil Rights, under the supervision of a Director, serves as the principal adviser to the Administrator with respect to EPA's civil rights programs. The Office develops policies, procedures, and regulations to implement the Agency's civil rights responsibilities, and provides direction to Regional and field activities in the Office's area of responsibilities. The Office implements and monitors the Agency's equal employment opportunity program; provides advice and guidance to EPA program officials and Regional Administrators on EEO matters; serves as advocate for furthering career opportunities for minorities and women; and processes complaints of discrimination for Agency disposition. The office assures:

(1) Maximum participation of minority business enterprises under EPA contracts and grants;

(2) Equal employment opportunity under Agency service contracts, construction contracts, and grants;

(3) Compliance with the Davis-Bacon Act and related acts;

(4) Compliance with the provisions of laws affecting Agency programs requiring nondiscrimination on account of age and physical handicap and;

(5) Services or benefits are dispensed under any program or activity receiving Agency financial assistance on a nondiscrimination basis.

(c) *Science Advisory Board.* The Science Advisory Board, under the direction of a Director, provides expert and independent advice to the Administrator on the scientific and technical issues facing the Agency. The Office advises on broad, scientific, technical and policy matters; assesses the results of specific research efforts; assists in identifying emerging environmental problems; and advises the Administrator on the cohesiveness and currency of the Agency's scientific programs.

(d) *Office of Small and Disadvantaged Business Utilization.* The Office of Small and Disadvantaged Business Utilization, under the supervision of a Director, is responsible for developing policy and procedures implementing the Agency's small and disadvantaged business utilization responsibilities. The Office provides information and assistance to components of the Agency's field offices responsible for carrying out related activities. The Office develops and implements a program to provide the maximum utilization of women-owned business enterprises in all aspects of EPA contract work; in collaboration with the Procurement and Contracts Management Division, develops programs to stimulate and improve involvement of small and minority business enterprises; and recommends the assignment of technical advisers to assist designated Procurement Center Representatives of the Small Business Administration in their duties. The Office represents EPA at hearings, interagency meetings, conferences and other appropriate forums on matters related to the advancement of these cited business enterprises in EPA's Federal Contracting Program.

(e)(1) *Environmental Appeals Board.* The Environmental Appeals Board is a permanent body with continuing functions composed of no more than four Board Members designated by the Administrator. The Board shall decide each matter before it in accordance with applicable statutes and regulations. The Board typically shall sit on matters before it in three-Member panels, and shall decide each matter by a majority vote. In the event that absence or recusal prevents a three-Member panel, the Board shall sit on a matter as a panel of two Members, and two Members shall constitute a quorum under such circumstances. The Board in its sole discretion shall establish panels to consider matters before it. The Board's decisions regarding panel size and composition shall not be reviewable. In the case of a tie vote, the matter shall be referred to the Administrator to break the tie.

(2) *Functions.* The Environmental Appeals Board shall exercise any authority expressly delegated to it in this title. With respect to any matter for which authority has not been expressly delegated to the Environmental Appeals Board, the Environmental Appeals Board shall, at the Administrator's request, provide advice and consultation, make findings of fact and

conclusions of law, prepare a recommended decision, or serve as the final decisionmaker, as the Administrator deems appropriate. In performing its functions, the Environmental Appeals Board may consult with any EPA employee concerning any matter governed by the rules set forth in this title, provided such consultation does not violate applicable *ex parte* rules in this title.

(3) *Qualifications.* Each member of the Environmental Appeals Board shall be a graduate of an accredited law school and a member in good standing of a recognized bar association of any State or the District of Columbia. Board Members shall not be employed by the Office of Enforcement, the Office of the General Counsel, a Regional Office, or any other office directly associated with matters that could come before the Environmental Appeals Board. A Board Member shall recuse himself or herself from deciding a particular case if that Board Member in previous employment performed prosecutorial or investigative functions with respect to the case, participated in the preparation or presentation of evidence in the case, or was otherwise personally involved in the case.

[50 FR 26721, June 28, 1985, as amended at 57 FR 5323, Feb. 13, 1992; 63 FR 67780, Dec. 9, 1998]

§ 1.27 Offices of the Associate Administrators.

(a) *Office of International Activities.* The Office of International Activities, under the supervision of an Associate Administrator, provides direction to and supervision of the activities, programs, and staff assigned to the Office of International Activities. All of the functions and responsibilities of the Associate Administrator are Agency-wide, and apply to all international activities of the Agency. The Office develops policies and procedures for the direction of the Agency's international programs and activities, subject to U.S. foreign policy, and assures that adequate program, scientific, and legal inputs are provided. It conducts continuing evaluations of the Agency's international activities and makes appropriate recommendations to the Administrator. The Office advises the Administrator and principal Agency officials on the progress and effect of foreign and international programs and issues. The Office serves as the Administrator's representative in contacts with the Department of State and other Federal agencies concerned with international affairs. It negotiates arrangements or understandings relating to international cooperation with foreign organizations. The Office coordinates Agency international contacts and commitments; serves as the focal point for responding to requests for information relating to EPA international activities; and provides an initial point of contact for all foreign visitors. The Office maintains liaison with all relevant international organizations and provides representation where appropriate. It establishes Agency policy, and approves annual plans and modifications for travel abroad and attendance at international conferences and events. It provides administrative support for the general activities of the Executive Secretary of the U.S. side of the US-USSR/PRC agreements on environmental protection and of the U.S. Coordinator for the NATO Committee on the Challenges of Modern Society. The Office supervises these programs with respect to activities which are completely within the purview of EPA.

(b) *Office of Regional Operations.* The Office of Regional Operations, under the supervision of an Associate Administrator, reports directly to the Administrator and Deputy Administrator. The Office serves as the primary communications link between the Administrator/Deputy Administrator and the Regional Administrators. It provides a Headquarters focus for ensuring the involvement of Regions, or consideration of Regional views and needs, in all aspects of the Agency's work. The Office is responsible for assuring Regional participation in Agency decision-making processes, assessing the impact of Headquarters actions on Regional operations, and acting as ombudsman to resolve Regional problems on behalf of the Administrator. The Associate Administrator coordinates Regional issues, organizes Regional Administrator meetings and work groups; and

coordinates Regional responses to specific issues. In addition, the Office is responsible for working with the Regional Offices to further the consistent application of national program policies by reinforcing existing administrative, procedural, and program policy mechanisms as well as through initiation of reviews of significant Regional issues of interest to the Administrator. It continually monitors responsiveness and compliance with established policies and technical needs through formal and informal contact and free dialogue. The Office initiates and conducts on-site field visits to study, analyze, and resolve problems of Regional, sectional, and national scale.

§ 1.29 Office of Inspector General.

The Office of Inspector General assumes overall responsibility for audits and investigations relating to EPA programs and operations. The Office provides leadership and coordination and recommends policies for other Agency activities designed to promote economy and efficiency and to prevent and detect fraud and abuse is such programs and operations. The Office of the Inspector General informs the Administrator, Deputy Administrator, and Congress of serious problems, abuses and deficiencies relating to EPA programs and operations, and of the necessity for and progress of corrective action; and reviews existing and proposed legislation and regulations to assess the impact on the administration of EPA's programs and operations. The Office recommends policies for, and conducts or coordinates relationships between, the Agency and other Federal, State and local government agencies, and nongovernmental entities on all matters relating to the promotion of economy and efficiency in the administration of, or the prevention and detection of fraud and abuse in, programs and operations administered by the Agency.

§ 1.31 Office of General Counsel.

The Office of General Counsel is under the supervision of the General Counsel who serves as the primary legal adviser to the Administrator. The office provides legal services to all organizational elements of the Agency with respect to all Agency programs and activities and also provides legal opinions, legal counsel, and litigation support; and assists in the formulation and administration of the Agency's policies and programs as legal adviser.

§ 1.33 Office of Administration and Resources Management.

The Office of Administration and Resources Management is under the supervision of the Assistance Administrator for Administration and Resources Management who provides services to all of the programs and activities of the Agency, except as may be specifically noted. In addition, the Assistant Administrator has primary responsibility Agencywide for policy and procedures governing the functional areas outlined below. The major functions of the Office include resources management and systems (including budget and financial management), personnel services, occupational health and safety, administrative services, organization and management analysis and systems development, information management and services, automated data processing systems, procurement through contracts and grants, and human resources management. This Office is the primary point of contact and manages Agencywide internal controls, audit resolution and follow up, and government-wide management improvement initiatives. In the performance of the above functions and responsibilities, the Assistant Administrator for Administration and Resources Management represents the Administrator in communications with the Office of Management and Budget, Office of Personnel Management, General Accounting Office, General Services Administration, Department of the Treasury, and other Federal agencies prescribing requirements for the conduct of Government budget, fiscal management and administrative activities.

(a) *Office of Administration and Resources Management, Research Triangle Park, North Carolina, (RTP).* The Office of Administration and Resources Management (OARM), RTP, under the supervision of a Director, provides services to all of the programs and activities at RTP and certain financial and automated data processing services

Agencywide. The major functions of the Office include personnel services, financial management, procurement through contracts, library and other information services, general services (including safety and security, property and supply, printing, distribution, facilities and other administrative services) and providing both local RTP and Agencywide automated data processing systems services. The Director, OARM, RTP, supervises the Office of Administration, Financial Management and Data Processing, RTP.

(b) *Office of Administration, Cincinnati, Ohio.* The Office of Administration at Cincinnati, Ohio, under the supervision of a Director, provides and administers personnel, procurement, safety and security, property and supply, printing, distribution, facilities, and other administrative service programs at Cincinnati and other specified geographic locations.

(c) *Office of the Comptroller.* The Office of the Comptroller, under the supervision of the Comptroller, is responsible for Agencywide budget, resources management and financial management functions, including program analysis and planning; budget formulation, preparation and execution; funding allotments and allocations; and developing and maintaining accounting systems, fiscal controls, and systems for payroll and disbursements. The Assistant Administrator's resource systems responsibilities are administered by this Office.

(d) *Office of Administration.* The Office of Administration, under the supervision of a Director, is responsible for the development and conduct of programs for personnel policies, procedures and operations; organization and management systems, control, and services; facilities, property and space management; personnel and property security; policies, procedures, and operations related to procurement through grants, contracts, and interagency agreements; and occupational health and safety.

(e) *Office of Information Resources Management.* The Office of Information Resources Management (OIRM), under the supervision of a Director, provides for an information resource management program (IRM) consistent with the provisions of Public Law 96–511. The Office establishes policy, goals and objectives for implementation of IRM; develops annual and long-range plans and budgets for IRM functions and activities; and promotes IRM concepts throughout the Agency. The Office coordinates IRM activities; plans, develops and operates information systems and services in support of the Agency's management and administrative functions, and other Agency programs and functions as required. The Office oversees the performance of these activities when carried out by other Agency components. The Office performs liaison for interagency sharing of information and coordinates IRM activities with OMB and GSA. The Office ensures compliance with requirements of Public Law 96–511 and other Federal laws, regulations, and guidelines relative to IRM; and chairs the Agency's IRM Steering Committee. The Office develops Agency policies and standards; and administers or oversees Agency programs for library systems and services, internal records management, and the automated collection, processing, storage, retrieval and transmission of data by or for Agency components and programs. The Office provides national program policy and technical guidance for: The acquisition of all information technology, systems and services by or for Agency components and programs, inculding those systems and services acquired by grantees and contractors using Agency funds; the operation of all Agency computers and telecommunications hardware and facilities; and the establishment and/or application of telecommunications and Federal information processing standards. The Office reviews and evaluates information systems and services, including office automation, which are operated by other Agency components; and sets standards for and approves the selection of Agency personnel who are responsible for the technical management of these activities. The Office coordinates its performance of these functions and activities with the Agency's information collection policies and budgets managed by the Office of Policy, Planning and Evaluation.

(f) *The Office of Human Resources Management*. The Office of Human Resources Management (OHRM), under the supervision of a Director, designs strategies, plans, and policies aimedat developing and training all employees, revitalizing EPA organizations, and matching the right people with the right jobs. The Office is responsible for developing and assuring implementation of policies and practices necessary for EPA to meet its present and future workforce needs. This includes consideration of the interrelationships between the environmental protection workforce needs of EPA and State governments. For Senior Executive Service (SES) personnel, SES candidates, Presidential Executive Interchange Participants, and Management Interns, OHRM establishes policies; assesses and projects Agency executive needs and workforce capabilities; creates, establishes, and implements training and development strategies and programs; provides the full range of personnel functions; supports the Performance Review Board (PRB) and the Executive Resources Board (ERB); and reassigns SES personnel with the concurrence of the ERB. For the areas of workforce management and employee and organizational development, OHRM develops strategies, plans, and policies; coordinates Agencywide implementation of those strategies, plans, and policies; and provides technical assistance to operating personnel offices and States. OHRM, in cooperation with the Office of the Comptroller, evaluates problems with previous workyear use, monitors current workyear utilization, and projects future workyear needs in coordination with the Agency's budget process. The Office is the lead office for coordination of human resources management with the Agency's Strategic Planning and Management System. The Office develops methodologies and procedures for evaluations of Agency human resources management activities; conducts evaluations of human resources management activities Agencywide; and carries out human resources management projects of special interest to Agency management. The Office coordinates its efforts with the Office of Administration (specifically the Personnel Management Division and the Management and Organization Division), the Office of the Comptroller, the Office of Information Resources Management, and the Office of Policy, Planning and Evaluation.

§ 1.35 Office of Enforcement and Compliance Monitoring.

The Office of Enforcement and Compliance Monitoring, under the supervision of the Assistant Administrator for Enforcement and Compliance Monitoring, serves as the principal adviser to the Administrator in matters concerning enforcement and compliance; and provides the principal direction and review of civil enforcement activities for air, water, waste, pesticides, toxics, and radiation. The Assistant Administrator reviews the efforts of each Assistant and Regional Administrator to assure that EPA develops and conducts a strong and consistent enforcement and compliance monitoring program. The Office manages the national criminal enforcement program; ensures coordination of media office administrative compliance programs, and civil and criminal enforcement activities; and provides technical expertise for enforcement activities.

§ 1.37 Office of External Affairs.

(a) *Office of Federal Activities*. The Office of Federal Activities is headed by a Director who reports to the Assistant Administrator for External Affairs and supervises all the functions of the Office. The Director acts as national program manager for five major programs that include:

(1) The review of other agency environmental impact statements and other major actions under the authority of Section 309 of the Clean Air Act;

(2) EPA compliance with the National Environmental Policy Act (NEPA) and related laws, directives, and Executive policies concerning special environmental areas and cultural resources;

(3) Compliance with Executive policy on American Indian affairs and the development of programs for environmental protection on Indian lands; and

(4) The development and oversight of national programs and internal policies, strategies, and procedures for implementing Executive Order 12088 and

other administrative or statutory provisions concerning compliance with environmental requirements by Federal facilities. The Director chairs the Standing Committee on Implementation of Executive Order 12088. The Office serves as the Environmental Protection Agency's (EPA) principal point of contact and liaison with other Federal agencies and provides consultation and technical assistance to those agencies relating to EPA's areas of expertise and responsibility. The Office administers the filing and information system for all Federal Environmental Impact Statements under agreement with the Council on Environmental Quality (CEQ) and provides liaison with CEQ on this function and related matters of NEPA program administration. The Office provides a central point of information for EPA and the public on environmental impact assessment techniques and methodologies.

(b) *Office of Public Affairs.* The Office of Public Affairs is under the supervision of a Director who serves as chief spokesperson for the Agency and as a principal adviser, along with the Assistant Administrator for External Affairs, to the Adminstrator, Deputy Administrator, and Senior Management Officials, on public affairs aspects of the Agency's activities and programs. The Office of Public Affairs provides to the media adequate and timely information as well as responses to queries from the media on all EPA program activities. It assures that the policy of openness in all information matters, as enunciated by the Administrator, is honored in all respects. Develops publications to inform the general public of major EPA programs and activities; it also develops informational materials for internal EPA use in Headquarters and at the Regions, Labs and Field Offices. It maintains clearance systems and procedures for periodicals and nontechnical information developed by EPA for public distribution, and reviews all publications for public affairs interests. The Office of Public Affairs provides policy direction for, and coordination and oversight of EPA's community relations program. It provides a system for ensuring that EPA educates citizens and responds to their concerns about all environmental issues and assures that there are opportunities for public involvement in the resolution of problems. The Office supervises the production of audio-visual materials, including graphics, radio and video materials, for the general public and for internal audiences, in support of EPA policies and programs. The Office provides program direction and professional review of the performance of public affairs functions in the Regional Offices of EPA, as well as at laboratories and other field offices. The Office of Public Affairs is responsible for reviewing interagency agreements and Headquarters purchase request requisitions expected to result in contracts in the area of public information and community relations. It develops proposals and reviews Headquarters grant applications under consideration when public affairs goals are involved.

(c) *Office of Legislative Analysis.* The Office of Legislative Analysis, under the supervision of a Director who serves in the capacity of Legislative Counsel, is responsible for legislative drafting and liaison activities relating to the Agency's programs. It exercises responsibility for legislative drafting; reports to the Office of Management and Budget and congressional committees on proposed legislation and pending and enrolled bills, as required by OMB Circular No. A–19 and Bulletin No. 72–6; provides testimony on legislation and other matters before congressional committees; and reviews transcripts of legislative hearings. It maintains liaison with the Office of Congressional Liaison on all Agency activities of interest to the Congress. The Office works closely with the staffs of various Assistant Administrators, Associate Administrators, Regional Administrators, and Staff Office Directors in accordance with established Agency procedures, in the development of the Agency's legislative program. The Office assists the Assistant Administrator for External Affairs and the Agency's senior policy officials in guiding legislative initiatives through the legislative process. It advises the Assistant Administrator for Administration and Resources Management in matters pertaining to appropriations legislation. It works closely with the Office of Federal Activities to assure

compliance with Agency procedures for the preparation of environmental impact statements, in relation to proposed legislation and reports on legislation. The Office coordinates with the Office of Management and Budget, other agencies, and congressional staff members on matters within its area of responsibility; and develops suggested State and local environmental legislative proposals, using inputs provided by other Agency components. The Legislative Reference Library provides legislative research services for the Agency. The Library secures and furnishes congressional materials to all EPA employees and, if available, to other Government agencies and private organizations; and it also provides the service of securing, upon request, EPA reports and materials for the Congress.

(d) *Office of Congressional Liaison.* The Office of Congressional Liaison is under the supervision of a Director who serves as the principal adviser to the Administrator with respect to congressional activities. All of the functions and responsibilities of the Director are Agencywide and apply to the provision of services with respect to all of the programs and activities of the Agency. The Office serves as the principal point of congressional contact with the Agency and maintains an effective liaison with the Congress on Agency activities of interest to the Congress and, as necessary, maintains liaison with Agency Regional and field officials, other Government agencies, and public and private groups having an interest in legislative matters affecting the Agency. It assures the provision of prompt response to the Congress on all inquiries relating to activities of the Agency; and monitors and coordinates the continuing operating contacts between the staff of the Office of the Comptroller and staff of the Appropriations Subcommittees of Congress.

(e) *Office of Community and Intergovernmental Relations.* The Office of Community and Intergovernmental Relations is under the supervision of a Director who serves as the principal point of contact with public interest groups representing general purpose State and local governments, and is the principal source of advice and information for the Administrator and the Assistant Administrator for External Affairs on intergovernmental relations. The Office maintains liaison on intergovernmental issues with the White House and Office of Management and Budget (OMB); identifies and seeks solutions to emerging intergovernmental issues; recommends and coordinates personal involvement by the Administrator and Deputy Administrator in relations with State, county, and local government officials; coordinates and assists Headquarters components in their handling of broad-gauged and issue-oriented intergovernmental problems. It works with the Regional Administrators and the Office of Regional Operations to encourage the adoption of improved methods for dealing effectively with State and local governments on specific EPA program initiatives; works with the Immediate Office of the Administrator, Office of Congressional Liaison, Office of Public Affairs, and the Regional Offices to develop and carry out a comprehensive liaison program; and tracks legislative initiatives which affect the Agency's intergovernmental relations. It advises and supports the Office Director in implementing the President's Environmental Youth Awards program.

[50 FR 26721, June 28, 1985, as amended at 52 FR 30359, Aug. 14, 1987]

§ 1.39 Office of Policy, Planning and Evaluation.

The Assistant Administrator for Policy, Planning and Evaluation services as principal adviser to the Administrator on Agency policy and planning issues and as such is responsible for supervision and management of the following: Policy analysis; standards and regulations; and management strategy and evaluation. The Assistant Administrator represents the Administrator with Congress and the Office of Management and Budget, and other Federal agencies prescribing requirements for conduct for Government management activities.

(a) *Office of Policy Analysis.* The Office of Policy Analysis is under the supervision of a Director who performs the following functions on an Agencywide basis: economic analysis of Agency programs, policies, standards, and regulations, including the estimation

of abatement costs; research into developing new benefits models; benefit-cost analyses; impact assessments; intermediate and long-range strategic studies; consultation and analytical assistance in the areas described above to senior policy and program officials and other offices in the Agency; development and coordination proposals for major new Agency initiatives; liaison with other agencies; universities, and interest groups on major policy issues and development of a coordinated Agency position; and development of integrated pollution control strategies for selected industrial and geographical areas.

(b) *Office of Standards and Regulations.* The Office of Standards and Regulations is under the supervision of a Director who is responsible for: involving the Office of Policy, Planning and Evaluation (OPPE) in regulatory review; conducting technical and statistical analyses of proposed standards, regulations and guidelines; serving as the Agency focal point for identifying, developing and implementing alternatives to conventional ''command and control'' regulations; conducting analyses of Agency activities related to chemical substances and providing mechanisms for establishing regulatory priorities and resolving scientific issues affecting rulemaking; ensuring Agency compliance with the Paperwork Reduction Act; evaluating and reviewing all Agency information collection requests and activities, and, in cooperation with the Office of Administration and Resources Management and the Office of Management Systems and Evaluation, evaluating Agency management and uses of data for decision-making.

(c) *Office of Management Systems and Evaluation.* The Office of Management Systems and Evaluation is under the supervision of a Director who directs and coordinates the development, implementation and administration of Agencywide systems for planning, tracking, and evaluating the accomplishments of Agency programs. In consultation with other offices, the Office develops a long-range policy framework for Agency goals, and objectives, identifies strategies for achieving goals, establishes timetables for objectives, and ensures that programs are evaluated against their accomplishments of goals.

§ 1.41 Office of Air and Radiation.

The Office of Air and Radiation is under supervision of the Assistant Administrator for Air and Radiation who serves as principal adviser to the Administrator in matters pertaining to air and radiation programs, and is responsible for the management of these EPA programs: Program policy development and evaluation; environmental and pollution sources' standards development; enforcement of standards; program policy guidance and overview, technical support or conduct of compliance activities and evaluation of Regional air and radiation program activities; development of programs for technical assistance and technology transfer; and selected demonstration programs.

(a) *Office of Mobile Sources.* The Office of Mobile Sources, under the supervision of a Director, is responsible for the mobile source air pollution control functions of the Office of Air and Radiation. The Office is responsible for: Characterizing emissions from mobile sources and related fuels; developing programs for their control, including assessment of the status of control technology and in-use vehicle emissions; for carrying out, in coordination with the Office of Enforcement and Compliance Monitoring as appropriate, a regulatory compliance program to ensure adherence of mobile sources to standards; and for fostering the development of State motor vehicles emission inspection and maintenance programs.

(b) *Office of Air Quality Planning and Standards.* The Office of Air Quality Planning and Standards, under the supervision of a Director, is responsible for the air quality planning and standards functions of the Office of Air and Radiation. The Director for Air Quality Planning and Standards is responsible for emission standards for new stationary sources, and emission standards for hazardous pollutants; for developing national programs, technical policies, regulations, guidelines, and criteria for air pollution control; for assessing the national air pollution

control program and the success in achieving air quality goals; for providing assistance to the States, industry and other organizations through personnel training activities and technical information; for providing technical direction and support to Regional Offices and other organizations; for evaluating Regional programs with respect to State implementation plans and strategies, technical assistance, and resource requirements and allocations for air related programs; for developing and maintaining a national air programs data system, including air quality, emissions and other technical data; and for providing effective technology transfer through the translation of technological developments into improved control program procedures.

(c) *Office of Radiation Programs.* The Office of Radiation Programs, under the supervision of a Director, is responsible to the Assistant Administrator for Air and Radiation for the radiation activities of the Agency, including development of radiation protection criteria, standards, and policies; measurement and control of radiation exposure; and research requirements for radiation programs. The Office provides technical assistance to States through EPA Regional Offices and other agencies having radiation protection programs; establishes and directs a national surveillance and investigation program for measuring radiation levels in the environment; evaluates and assesses the impact of radiation on the general public and the environment; and maintains liaison with other public and private organizations involved in environmental radiation protection activities. The Office coordinates with and assists the Office of Enforcement and Compliance Monitoring in enforcement activities where EPA has jurisdiction. The Office provides editorial policy and guidance, and assists in preparing publications.

§ 1.43 Office of Chemical Safety and Pollution Prevention.

The Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP), serves as the principal adviser to the Administrator in matters pertaining to assessment and regulation of pesticides and toxic substances and is responsible for managing the Agency's pesticides and toxic substances programs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); the Toxic Substances Control Act (TSCA); the Pollution Prevention Act (PPA); and portions of several other statutes. The Assistant Administrator has responsibility for establishing Agency strategies for implementation and integration of the pesticides and the toxic substances programs under applicable Federal statutes; developing and operating Agency programs and policies for assessment and control of pesticides and toxic substances; developing recommendations for Agency priorities for research, monitoring, regulatory, and information-gathering activities relating to pesticides and toxic substances; developing scientific, technical, economic, and social databases for the conduct of hazard assessments and evaluations in support of toxic substances and pesticides activities; providing toxic substances and pesticides program guidance to EPA Regional Offices and monitoring, evaluating, and assessing pesticides and toxic substances program operations in EPA Headquarters and Regional Offices.

(a) *Office of Pesticide Programs.* The Office of Pesticide Programs (OPP), under the management of a Director and Deputy Director are responsible to the Assistant Administrator for leadership of the overall pesticide activities of the Agency under the authority of FIFRA, FFDCA, and portions of several other statutes. Responsibilities include the development of strategic plans for the control of the national environmental pesticide situation. Such plans are implemented by OPP, other EPA components, other Federal agencies, or by State, local, and private sectors. OPP is also responsible for establishment of tolerance levels for pesticide residues which occur in or on food; registration and reregistration of pesticides; special review of pesticides suspected of posing unreasonable risks to human health or the environment; monitoring of pesticide residue levels in food, humans, and nontarget fish and wildlife; preparation of

pesticide registration guidelines; development of standards for the registration and reregistration of pesticide products; provision of program policy direction to technical and manpower training activities in the pesticides area; development of research needs and monitoring requirements for the pesticide program and related areas; review of impact statements dealing with pesticides; providing operational guidance to EPA Regional Offices; and carrying out of assigned international activities.

(b) *Office of Pollution Prevention and Toxics.* The Office of Pollution Prevention and Toxics (OPPT), under the management of a Director and Deputy Director is responsible to the Assistant Administrator for those activities of the Agency mandated by TSCA, PPA, and portions of several other statutes. The Director is responsible for developing and operating Agency programs and policies for new and existing chemicals. In each of these areas, the Director is responsible for information collection and coordination; data development; health, environmental, and economic assessment; and negotiated or regulatory control actions. The Director provides operational guidance to EPA Regional Offices, reviews and evaluates toxic substances activities at EPA Headquarters and Regional Offices; coordinates TSCA activities with other EPA offices and Federal and State agencies, and conducts the export notification required by TSCA and provides information to importers. The Director is responsible for developing policies and procedures for the coordination and integration of Agency and Federal activities concerning toxic substances. The Director is also responsible for coordinating communication with the industrial community, environmental groups, and other interested parties on matters relating to the implementation of TSCA; providing technical support to international activities managed by the Office of International Activities; and managing the joint planning of toxic research and development under the auspices of the Pesticides/Toxic Substances Research Committee.

(c) *Office of Science Coordination and Policy.* The Office of Science Coordination and Policy (OSCP) provides coordination, leadership, peer review, and synthesis of science and science policy within OCSPP. OSCP provides guidance to assure sound scientific decisions are made regarding safe pesticide and chemical management through the leadership of the Scientific Advisory Panel (SAP). OSCP also coordinates emerging exposure and hazard assessment topics such as endocrine disruptors and biotechnology.

[77 FR 46290, Aug. 3, 2012]

§ 1.45 Office of Research and Development.

The Office of Research and Development is under the supervision of the Assistant Administrator for Research and Development who serves as the principal science adviser to the Administrator, and is responsible for the development, direction, and conduct of a national research, development and demonstration program in: Pollution sources, fate, and health and welfare effects; pollution prevention and control, and waste management and utilization technology; environmental sciences; and monitoring systems. The Office participates in the development of Agency policy, standards, and regulations and provides for dissemination of scientific and technical knowledge, including analytical methods, monitoring techniques, and modeling methodologies. The Office serves as coordinator for the Agency's policies and programs concerning carcinogenesis and related problems and assures appropriate quality control and standardization of analytical measurement and monitoring techniques utilized by the Agency. The Office exercises review and concurrence responsibilities on an Agencywide basis in all budgeting and planning actions involving monitoring which require Heardquarters approval.

(a) *Office of Acid Deposition, Environmental Monitoring and Quality Assurance.* The Office of Acid Deposition, Environmental Monitoring and Quality Assurance (OADEMQA), under the supervision of an Office Director, is responsible for planning, managing and evaluating a comprehensive program for:

(1) Monitoring the cause and effects of acid deposition;

(2) Research and development on the causes, effects and corrective steps for the acid deposition phenomenon;

(3) Research with respect to the transport and fate of pollutants which are released into the atmosphere;

(4) Development and demonstration of techniques and methods to measure exposure and to relate ambient concentrations to exposure by critical receptors;

(5) Research, development and demonstration of new monitoring methods, systems, techniques and equipment for detection, identification and characterization of pollutants at the source and in the ambient environment and for use as reference or standard monitoring methods;

(6) Establishment, direction and coordination of Agencywide Quality Assurance Program; and

(7) Development and provision of quality assurance methods, techniques and material including validation and standardization of analytical methods, sampling techniques, quality control methods, standard reference materials, and techniques for data collection, evaluation and interpretation. The Office identifies specific research, development, demonstration and service needs and priorities; establishes program policies and guidelines; develops program plans including objectives and estimates of resources required to accomplish objectives; administers the approved program and activities; assigns program responsibility and resources to the laboratories assigned by the Assistant Administrator; directs and supervises assigned laboratories in program administration; and conducts reviews of program progress and takes action as necessary to assure timeliness, quality and responsiveness of outputs.

(b) *Office of Environmental Engineering and Technology Demonstration.* The Office of Environmental Engineering and Technology Demonstration (OEETD) under the supervision of a Director, is responsible for planning, managing, and evaluating a comprehensive program of research, development, and demonstration of cost effective methods and technologies to:

(1) Control Environmental impacts associated with the extraction, processing, conversion, and transportation of energy, minerals, and other resources, and with industrial processing and manufacturing facilities;

(2) Control environmental impacts of public sector activities including publicly-owned waste water and solid waste facilities;

(3) Control and manage hazardous waste generation, storage, treatment, and disposal;

(4) Provide innovative technologies for response actions under Superfund and technologies for control of emergency spills of oils and hazardous waste;

(5) Improve drinking water supply and system operations, including improved understanding of water supply technology and water supply criteria;

(6) Characterize, reduce, and mitigate indoor air pollutants including radon; and

(7) Characterize, reduce, and mitigate acid rain precursors from stationary sources. Development of engineering data needed by the Agency in reviewing premanufacturing notices relative to assessing potential release and exposure to chemicals, treatability by waste treatment systems, containment and control of genetically engineered organisms, and development of alternatives to mitigate the likelihood of release and exposure to existing chemicals. In carrying out these responsibilities, the Office develops program plans and manages the resources assigned to it; implements the approved programs and activities; assigns objectives and resources to the OEETD laboratories; conducts appropriate reviews to assure the quality, timeliness, and responsiveness of outputs; and conducts analyses of the relative environmental and socioeconomic impacts of engineering methods and control technologies and strategies. The Office of Environmental Engineering and Technology Demonstration is the focal point within the Office of Research and Development for providing liaison with the rest of the Agency and with the Department of Energy on issues associated with energy development. The Office is also the focal point within the Office of Research and Development for liaison with the rest of the Agency on issues related to engineering reseach

and development and the control of pollution discharges.

(c) *Office of Environmental Processes and Effects Research.* The Office of Environmental Processes and Effects Research, under the supervision of the Director, is responsible for planning, managing, and evaluating a comprehensive research program to develop the scientific and technological methods and data necessary to understand ecological processes, and predict broad ecosystems impacts, and to manage the entry, movement, and fate of pollutants upon nonhuman organisms and ecosystems. The comprehensive program includes:

(1) The development of organism and ecosystem level effect data needed for the establishment of standards, criteria or guidelines for the protection of nonhuman components of the environment and ecosystems integrity and the prevention of harmful human exposure to pollutants;

(2) The development of methods to determine and predict the fate, transport, and environmental levels which may result in human exposure and exposure of nonhuman components of the environment, resulting from the discharge of pollutants, singly or in combination into the environment, including development of source criteria for protection of environmental quality;

(3) The development and demonstration of methods for the control or management of adverse environmental impacts from agriculture and other rural nonprofit sources;

(4) The development and demonstration of integrated pest management strategies for the management of agriculture and urban pests which utilize alternative biological, cultural and chemical controls;

(5) The development of a laboratory and fieldscale screening tests to provide data that can be used to predict the behavior of pollutants in terms of movement in the environmental, accumulation in the food chain, effects on organisms, and broad escosystem impacts;

(6) Coordination of interagency research activities associated with the health and environmental impacts of energy production and use; and

(7) development and demonstration of methods for restoring degraded ecosystem by means other than source control.

(d) *Office of Health Research.* The Office of Health Research under the supervision of a Director, is responsible for the management of planning, implementing, and evaluating a comprehensive, integrated human health research program which documents acute and chronic adverse effects to man from environmental exposure to pollutants and determines those exposures which have a potentially adverse effect on humans. This documentation is utilized by ORD for criteria development and scientific assessments in support of the Agency's regulating and standard-setting activities. To attain this objective, the program develops tests systems and associated methods and protocols, such as predictive models to determine similarities and differences among test organisms and man; develops methodology and conducts laboratory and field research studies; and develops interagency programs which effectively use pollutants. The Office of Health Research is the Agency's focal point within the Office of Research and Development for providing liaison relative to human health effects and related human exposure issues (excluding issues related to the planning and implementation of research on the human health effects of energy pollutants that is conducted under the Interagency Energy/Environment Program). It responds with recognized authority to changing requirements of the Regions, program offices and other offices for priority technical assistance. In close coordination with Agency research and advisory committees, other agencies and offices, and interaction with academic and other independent scientific bodies, the Office develops health science policy for the Agency. Through these relationships and the scientific capabilities of its laboratories and Headquarters staffs, the Office provides a focal point for matters pertaining to the effects of human exposure to environmental pollutants.

(e) *Office of Health and Environmental Assessment (OHEA).* The Office of Health and Environmental Assessment,

under the supervision of a Director, is the principal adviser on matters relating to the development of health criteria, health affects assessment and risk estimation, to the Assistant Administrator for Research and Development. The Director's Office: Develops recommendations on OHEA programs including the identification and development of alternative program goals, priorities, objectives and work plans; develops recommendations on overall office policies and means for their implementation; performs the critical path planning necessary to assure a timely production of OHEA information in response to program office needs; serves as an Agency health assessment advocate for issue resolution and regulatory review in the Agency Steering Committee, Science Advisory Board, and in cooperation with other Federal agencies and the scientific and technical community; and provides administrative support services to the components of OHEA. The Director's Office provides Headquarters coordination for the Environmental Criteria and Assessment Offices.

(f) *Office of Exploratory Research.* The Office of Exploratory Research (OER), under the supervision of a Director, is responsible for overall planning, administering, managing, and evaluating EPA's anticipatory and extramural grant research in response to Agency priorities, as articulated by Agency planning mechanisms and ORD's Research Committees. The Director advises the Assistance Administrator on the direction, scientific quality and effectiveness of ORD's long-term scientific review and evaluation; and research funding assistance efforts. The responsibilities of this office include: Administering ORD's scientific review of extramural requests for research funding assistance; developing research proposal solicitations; managing grant projects; and ensuring project quality and optimum dissemination of results. The OER is responsible for analyzing EPA's long-range environmental research concerns; forecasting emerging and potential environmental problems and manpower needs; identifying Federal workforce training programs to be used by State and local governments; assuring the participation of minority institutions in environmental research and development activities; and conducting special studies in response to high priority national environmental needs and problems. This office serves as an ORD focal point for university relations and other Federal research and development agencies related to EPA's extramural research program.

[50 FR 26721, June 28, 1985, as amended at 52 FR 30360, Aug. 14, 1987]

§ 1.47 Office of Land and Emergency Management.

The Office of Land and Emergency Management (OLEM), also referred to as the Office of Solid Waste, or the Office of Solid Waste and Emergency Response, under the supervision of the Assistant Administrator for Land and Emergency Management, also referred to as the Assistant Administrator of the Office of Solid Waste, provides Agencywide policy, guidance, and direction for the Agency's solid and hazardous wastes and emergency response programs. This Office has primary responsibility for implementing the Resource Conservation and Recovery Act (RCRA); the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA—''Superfund''), as amended by the Superfund Amendments and Reauthorization Act (SARA); the Emergency Planning and Community Right-to-Know Act; the Oil Pollution Act; Clean Water Act section 311; and the Mercury-Containing and Rechargeable Battery Management Act; among other laws. In addition to managing those programs, the Assistant Administrator serves as principal adviser to the Administrator in matters pertaining to them. The Assistant Administrator's responsibilities include: Program policy development and evaluation; development of appropriate hazardous waste standards and regulations; ensuring compliance with applicable laws and regulations; program policy guidance and overview, technical support, and evaluation of Regional solid and hazardous wastes and emergency response activities; development of programs for technical, programmatic, and compliance assistance to States and local governments; development of guidelines and standards for the land disposal of hazardous wastes;

analyses of the recovery of useful energy from solid waste; development and implementation of a program to respond to uncontrolled hazardous waste sites and spills (including oil spills); long-term strategic planning and special studies; economic and long-term environmental analyses; economic impact assessment of regulations under RCRA, CERCLA, and other relevant statutes; analyses of alternative technologies and trends; and cost-benefit analyses and development of OLEM environmental criteria. For purposes of 42 U.S.C. 6911(a), OLEM carries out the functions of the Office of Solid Waste. For purposes of 42 U.S.C. 6911a, the functions and duties of the Assistant Administrator of the Office of Solid Waste are carried out by the Assistant Administrator for the Office of Land and Emergency Management.

[80 FR 77577, Dec. 15, 2015]

§ 1.49 Office of Water.

The Office of Water, under the supervision of the Assistant Administrator for Water who serves as the principal adviser to the Administrator in matters pertaining to water programs, is responsible for management of EPA's water programs. Functions of the Office include program policy development and evaluation; environmental and pollution source standards development; program policy guidance and overview; technical support; and evaluation of Regional water activities; the conduct of compliance and permitting activities as they relate to drinking water and water programs; development of programs for technical assistance and technology transfer; development of selected demonstration programs; economic and long-term environmental analysis; and marine and estuarine protection.

(a) *Office of Water Enforcement and Permits.* The Office of Water Enforcement and Permits, under the supervision of a Director, develops policies, strategies, procedures and guidance for EPA and State compliance monitoring, evaluation, and enforcement programs for the Clean Water Act and the Marine Protection Research and Sanctuaries Act. The Office also provides national program direction to the National Pollutant Discharge Elimination System permit program. The office has overview responsibilities and provides technical assistance to the regional activities in both enforcement and permitting programs.

(b) *Office of Water Regulations and Standards.* The Office of Water Regulations and Standards, under the supervision of a Director, is responsible for the Agency's water regulations and standards functions. The Office is responsible for developing an overall program strategy for the achievement of water pollution abatement in cooperation with other appropriate program offices. The Office assures the coordination of all national water-related activities within this water program strategy, and monitors national progress toward the achievement of water quality goals and is responsible for the development of effluent guidelines and water quality standards, and other pollutant standards, regulations, and guidelines within the program responsibilities of the Office. It exercises overall responsibility for the development of effective State and Regional water quality regulatory control programs. The Office is responsible for the development and maintenance of a centralized water programs data system including compatible water quality, discharger, and program data files utilizing, but not displacing, files developed and maintained by other program offices. It is responsible for developing national accomplishment plans and resource and schedule guidelines for monitoring and evaluating the performance, progress, and fiscal status of the organization in implementing program plans. The Office represents EPA in activities with other Federal agencies concerned with water quality regulations and standards.

(c) *Office of Municipal Pollution Control.* The Office of Municipal Pollution Control, under the supervision of a Director, is responsible for the Agency's water program operations functions. The Office is responsible for developing national strategies, program and policy recommendations, regulations and guidelines for municipal water pollution control; for providing technical direction and support to Regional Offices and other organizations; and for evaluating Regional and State programs

with respect to municipal point source abatement and control, and manpower development for water-related activities. The Office assures that priority Headquarters and regional activities are planned and carried out in a coordinated and integrated fashion, including developing and implementing data submission systems.

(d) *Office of Drinking Water*. The Office of Drinking Water, under the supervision of a Director, is responsible for water supply activities of the Agency, including the development of an implementation strategy which provides the national policy direction and coordination for the program. This Office develops regulations and guidelines to protect drinking water quality and existing and future underground sources of drinking water, develops program policy and guidance for enforcement and compliance activities, and recommends policy for water supply protection activities. The office provides guidance and technical information to State agencies, local utilities, and Federal facilities through the Regional Offices on program planning and phasing; evaluates the national level of compliance with the regulations; plans and develops policy guidance for response to national, Regional, and local emergencies; reviews and evaluates, with Regional Offices, technical data for the designation of sole-source aquifers; designs a national program of public information; provides program policy direction for technical assistance and manpower training activities in the water supply area; identifies research needs and develops monitoring requirements for the national water supply program; develops national accomplishments' plans and resource schedule guidelines for monitoring and evaluating the program plans, and program performance, and fiscal status; develops program plans, and budget and program status reports for the water supply program; coordinates water supply activities with other Federal agencies as necessary; and serves as liaison with the National Drinking Water Advisory Council.

(e) *Office of Ground-Water Protection*. The Office of Ground-Water Protection, under the supervision of a Director, oversees implementation of the Agency's Ground-water Protection Strategy. This Office coordinates support of Headquarters and regional activities to develop stronger State government organizations and programs which foster ground-water protection. The Office directs and coordinates Agency analysis and approaches to unaddressed problems of ground-water contamination; is principally responsible for establishing and implementing a framework for decision-making at EPA on ground-water protection issues; and serves as the focus of internal EPA policy coordination for ground-water.

(f) *Office of Marine and Estuarine Protection*. The Office of Marine and Estuarine Protection, under the supervision of a Director, is responsible for the development of policies and strategies and implementation of a program to protect the marine/estuarine environment, including ocean dumping. The Office provides national direction for the Chesapeake Bay and other estuarine programs, and policy oversight of the Great Lakes Program.

(g) *Office of Wetlands Protection*. The Office of Wetlands Protection, under the supervision of a Director, administers the 404/Wetlands Program and develops policies, procedures, regulations, and strategies addressing the maintenance, enhancement, and protection of the Nations Wetlands. The Office coordinates Agency issues related to wetlands.

[50 FR 26721, June 28, 1985, as amended at 52 FR 30360, Aug. 14, 1987]

Subpart C—Field Installations

§ 1.61 Regional Offices.

Regional Administrators are responsible to the Administrator, within the boundaries of their Regions, for the execution of the Regional Programs of the Agency and such other responsibilities as may be assigned. They serve as the Administrator's prinicipal representatives in their Regions in contacts and relationships with Federal, State, interstate and local agencies, industry, academic institutions, and other public and private groups. Regional Administrators are responsible for:

(a) Accomplishing national program objectives within the Regions as established by the Administrator, Deputy Administrator, Assistant Administrators, Associate Administrators, and Heads of Headquarters Staff Offices;

(b) Developing, proposing, and implementing approved Regional programs for comprehensive and integrated environmental protection activities;

(c) Total resource management in their Regions within guidelines provided by Headquarters;

(d) Conducting effective Regional enforcement and compliance programs;

(e) Translating technical program direction and evaluation provided by the various Assistant Administrators, Associate Administrators and Heads of Headquarters Staff Offices, into effective operating programs at the Regional level, and assuring that such programs are executed efficiently;

(f) Exercising approval authority for proposed State standards and implementation plans; and

(g) Providing for overall and specific evaluations of Regional programs, both internal Agency and State activities.

PART 2—PUBLIC INFORMATION

Subpart A—Procedures for Disclosure of Records Under the Freedom of Information Act

Sec.

Subpart B—Confidentiality of Business Information

Subpart C—Testimony by Employees and Production of Documents in Civil Legal Proceedings Where the United States Is Not a Party

AUTHORITY: 5 U.S.C. 301, 552 (as amended), 553; secs. 114, 205, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. 7414, 7525, 7542, 7601, 7607); secs. 308, 501 and 509(a), Clean Water Act, as amended (33 U.S.C. 1318, 1361, 1369(a)); sec. 13, Noise Control Act of 1972 (42 U.S.C. 4912); secs. 1445 and 1450, Safe Drinking Water Act (42 U.S.C. 300j–4, 300j–9); secs. 2002, 3007, and 9005, Solid Waste Disposal Act, as amended (42 U.S.C. 6912, 6927, 6995); secs. 8(c), 11, and 14, Toxic Substances Control Act (15 U.S.C. 2607(c), 2610, 2613); secs. 10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136h, 136j, 136w); sec. 408(f), Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 346(f)); secs. 104(f) and 108, Marine Protection Research and Sanctuaries Act of 1972 (33 U.S.C. 1414(f), 1418); secs. 104 and 115, Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9604 and 9615); sec. 505, Motor Vehicle Information and Cost Savings Act, as amended (15 U.S.C. 2005).

EFFECTIVE DATE NOTE: At 84 FR 30032, June 26, 2019, the authority citation for Part 2 was revised, effective July 26, 2019. For the convenience of the user, the revised text is set forth as follows:

AUTHORITY: 5 U.S.C. 301, 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

SOURCE: 41 FR 36902, Sept. 1, 1976, unless otherwise noted.

Subpart A—Procedures for Disclosure of Records Under the Freedom of Information Act

SOURCE: 67 FR 67307, Nov. 5, 2002, unless otherwise noted.

§ 2.100 General provisions.

(a) This subpart contains the rules that the Environmental Protection Agency (EPA or Agency) follows in processing requests for records under the Freedom of Information Act (FOIA), 5 U.S.C. 552. The Agency also has rules that it follows in processing Freedom of Information (FOI) requests for records submitted to it as Confidential Business Information (CBI). Such records are covered in subpart B of this part. Requests made by individuals for records about themselves under the Privacy Act of 1974 which are processed under 40 CFR part 16, will also be treated as FOIA requests under this subpart. This ensures that the requestor has access to all responsive records. Information routinely provided to the public as part of a regular EPA activity may be provided to the public without following this subpart.

(b) When documents responsive to a request are maintained for distribution by agencies operating statutory-based fee schedule programs, such as, but not limited to, the Government Printing Office or the National Technical Information Service, EPA will inform the requester of the steps necessary to obtain records from these sources.

§ 2.101 Where requests for records are to be filed.

(a) You may request records by writing to the Records, FOIA, and Privacy Branch, Office of Environmental Information, Environmental Protection Agency, 1200 Pennsylvania Avenue (2822T), NW, Washington, DC 20460; e-mail: *hq.foia@epa.gov*. You may also access EPA Headquarters and Regional Freedom of Information Offices' Web sites at *http://www.epa.gov/foia* and submit a request via an online form. If you believe the records sought may be located in an EPA regional office, you should send your request to the appropriate regional FOI Officer as indicated in the following list:

(1) Region I (CT, ME, MA, NH, RI, VT): US EPA, FOI Officer, 5 Post Office Square—Suite 100, Boston, MA 02109–3912; e-mail: *r1foia@epa.gov*.

(2) Region II (NJ, NY, PR, VI): EPA, FOI Officer, 290 Broadway, 26th Floor, New York, NY 10007–1866; e-mail: *r2foia@epa.gov*.

(3) Region III (DE, DC, MD, PA, VA, WV): EPA, FOI Officer, 1650 Arch Street, Philadelphia, PA 19103–2029; e-mail: *r3foia@epa.gov*.

(4) Region IV (AL, FL, GA, KY, MS, NC, SC, TN): EPA, Freedom of Information Officer, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA 30303–8960; e-mail: *r4foia@epa.gov*.

(5) Region V (IL, IN, MI, MN, OH, WI): EPA. Freedom of Information Officer, 77 West Jackson Boulevard, Chicago, IL 60604–3507; e-mail: *r5foia@epa.gov*.

(6) Region VI (AR, LA, NM, OK, TX): EPA, Freedom of Information Officer, 1445 Ross Avenue, Dallas, TX 75202–2733; e-mail: *r6foia@epa.gov*.

(7) Region VII (IA, KS, MO, NE): EPA, Freedom of Information Officer, 11201 Renner Boulevard, Lenexa, Kansas 66219; email: *r7foia@epa.gov*. *http://www.epa.gov/region07/citizens/foia/index.htm*, *https://foiaonline.regulations.gov/foia/action/public/home*.

(8) Region VIII (CO, MT, ND, SD, UT, WY): EPA, Freedom of Information Officer, 999 18th Street, Suite 500, Denver, CO 80202–2466, e-mail: *r8foia@epa.gov*.

(9) Region IX (AZ, CA, HI, NV, AS, GU): EPA, Freedom of Information Officer, 75 Hawthorne Street, San Francisco, CA 94105; e-mail: *r9foia@epa.gov*.

(10) Region X (AK, ID, OR, WA): EPA, Freedom of Information Officer, 1200 Sixth Avenue, Seattle, WA 98101; e-mail: *r10foia@epa.gov*.

(b) EPA provides access to all records that the FOIA requires an agency to make regularly available for public inspection and copying. Each office is responsible for determining which of the records it generates are required to be made publicly available and for providing access by the public to them. The Agency will also maintain and make available for public inspection and copying a current subject-matter index of such records and provide a copy or a link to the respective Web site for Headquarters or the Regions. Each index will be updated regularly, at least quarterly, with respect to newly-included records.

(c) All records created by EPA on or after November 1, 1996, which the FOIA requires an agency to make regularly available for public inspection and copying, will be made available electronically through EPA's worldwide Web site, located at *http://www.epa.gov*, or, upon request, through other electronic means. EPA will also include on its worldwide Web site the current subject-matter index of all such records.

[67 FR 67307, Nov. 5, 2002, as amended at 76 FR 49671, Aug. 11, 2011; 78 FR 37975, June 25, 2013]

§ 2.102 Procedures for making requests.

(a) *How made and addressed.* You may make a request for EPA records that are not publicly available under § 2.201(a)–(b) by writing directly to the appropriate FOI Officer, as listed in § 2.101(a). Only written requests for records will be accepted for processing under this subpart. For records located at EPA Headquarters, or in those instances when you cannot determine where to send your request, you may send it to the Records, FOIA, and Privacy Branch, Office of Environmental Information, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; e-mail: *hq.foia@epa.gov*. That office will forward your request to the regional FOI Office it believes most likely to have the records that you want. Your request will be considered received as of the date it is received by the correct FOI Office. Misdirected requests will not be considered received by EPA until the appropriate FOI Office receives the request. For proper handling, you should mark both your request letter and its envelope or e-mail subject line ''Freedom of Information Act Request.'' You should also include your name, mailing address, and daytime telephone number in the event we need to contact you.

(b) EPA employees may attempt in good faith to comply with oral requests for inspection or disclosure of EPA records publicly available under § 2.201(a)–(b) , but such requests are not subject to the FOIA or the regulations in this part.

(c) *Description of records sought.* Your request should reasonably describe the records you are seeking in a way that will permit EPA employees to identify and locate them. Whenever possible, your request should include specific information about each record sought, such as the date, title or name, author, recipient, and subject matter. If known, you should include any file designations or descriptions for the

records that you want. The more specific you are about the records or type of records that you want, the more likely EPA will be able to identify and locate records responsive to your request. If EPA determines that your request does not reasonably describe the records, it will tell you either what additional information you need to provide or why your request is otherwise insufficient. EPA will also give you an opportunity to discuss and modify your request to meet the requirements of this section. Should it be necessary for you to provide a revised description of the records you are seeking, the time necessary to do so will be excluded from the statutory 20 working day period (or any authorized extension of time) that EPA has to respond to your request as discussed in § 2.104.

(d) *Agreement to pay fees.* If you make a FOIA request, EPA will consider your request to be an agreement that you will pay all applicable fees charged under § 2.107, up to $25.00, unless you seek a waiver of fees. The EPA office responsible for responding to your request ordinarily will confirm this agreement in writing. When making a request, you may specify a willingness to pay a greater or lesser amount. Should it be necessary for you to provide a written agreement to pay additional fees, the time necessary to do so will be excluded from the statutory 20 working day period (or any authorized extension of time).

§ 2.103 Responsibility for responding to requests.

(a) *In general.* Except as stated in paragraphs (c), (d), (e), and (f) of this section, the EPA office that has possession of that record is the office responsible for responding to you. In determining which records are within the scope of a request, an office will ordinarily include only those records in its possession as of the date the request was received in the Headquarters or Regional FOI Office. If any other date is used, the office will inform you of that date.

(b) *Authority to grant or deny requests.* The head of an office, or that individual's designee, is authorized to grant or deny any request for a record of that office or other Agency records when appropriate.

(c) *Authority to grant or deny fee waivers or requests for expedited treatment.* The head of the Headquarters FOIA Office and Regional FOI Officers, or their designees, are authorized to grant or deny fee waivers or requests for expedited treatment.

(d) *Consultations and referrals.* When a request to EPA seeks records in its possession that originated with another Federal agency, the EPA office receiving the request shall either:

(1) Consult with the Federal agency where the record or portion thereof originated and then respond to your request, or

(2) Direct the FOI Office to refer your request to the Federal agency where the record or portion thereof originated. Whenever all or any part of the responsibility for responding to a request has been referred to another agency, the FOI Office will notify you accordingly.

(e) *Law enforcement information.* Whenever a request is made for a record containing information that relates to an investigation of a possible violation of law and was originated by another agency, the receiving office will either direct the FOI Office to refer the request to that other agency or consult with that other agency prior to making any release determination.

§ 2.104 Responses to requests and appeals.

(a) Unless the Agency and the requester have agreed otherwise, or when unusual circumstances exist as provided in paragraph (e) of this section, EPA offices will respond to requests no later than 20 working days from the date the request is received and logged in by the appropriate FOI Office. EPA will ordinarily respond to requests in the order in which they were received. If EPA fails to respond to your request within the 20 working day period, or any authorized extension of time, you may seek judicial review to obtain the records without first making an administrative appeal.

(b) On receipt of a request, the FOI Office ordinarily will send a written acknowledgment advising you of the date it was received and of the processing

number assigned to the request for future reference.

(c) *Multitrack processing.* The Agency uses three or more processing tracks by distinguishing between simple and complex requests based on the amount of work and/or time needed to process the request, including limits based on the number of pages involved. The Agency will advise you of the processing track in which your request has been placed and of the limits of the different processing tracks. The Agency may place your request in its slower track(s) while providing you the opportunity to limit the scope of your request in order to qualify for faster processing within the specified limits of the faster track(s). If your request is placed in a slower track, the Agency will contact you either by telephone or by letter, whichever is most efficient in each case.

(d) *Unusual circumstances.* When the statutory time limits for processing a request cannot be met because of ''unusual circumstances,'' as defined in the FOIA, and the time limits are extended on that basis, you will be notified in writing, as soon as practicable, of the unusual circumstances and of the date by which processing of the request should be completed. When the extension is for more than 10 working days, the Agency will provide you with an opportunity either to modify the request so that it may be processed within the 10 working day time limit extension or to arrange an alternative time period for processing the original or modified request.

(e) *Expedited processing.* (1) Requests or appeals will be taken out of order and given expedited treatment whenever EPA determines that such requests or appeals involve a compelling need, as follows:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) An urgency to inform the public about an actual or alleged Federal government activity, if the information is requested by a person primarily engaged in disseminating information to the public.

(2) A request for expedited processing must be made at the time of the initial request for records or at the time of appeal.

(3) If you are seeking expedited processing, you must submit a statement, certified to be true and correct to the best of your knowledge and belief, explaining in detail the basis for the request. For example, if you fit within the category described in paragraph (e)(1)(ii) of this section and are not a full-time member of the news media, you must establish that you are a person whose primary professional activity or occupation is information dissemination, although it need not be your sole occupation. If you fit within the category described in paragraph (e)(1)(ii) of this section, you must also establish a particular urgency to inform the public about the government activity involved in the request, beyond the public's right to know about government activity generally.

(4) Within 10 calendar days from the date of your request for expedited processing, the head of the Headquarters FOI Staff or Regional FOI Officer will decide whether to grant your request and will notify you of the decision. If your request for expedited treatment is granted, the request will be given priority and will be processed as soon as practicable. If your request for expedited processing is denied, any appeal of that decision will be acted on expeditiously.

(f) *Grants of requests.* Once an office makes a determination to grant a request in whole or in part, it will release the records or parts of records to you and notify you of any applicable fee charged under § 2.107. Records released in part will be annotated, whenever technically feasible, with the applicable FOIA exemption(s) at that part of the record from which the exempt information was deleted.

(g) *Adverse determinations of requests.* Once the Agency makes an adverse determination of a request, the requestor will be notified of that determination in writing. An adverse determination consists of a determination to withhold any requested record in whole or in part; a determination that a requested record does not exist or cannot be located; a determination that what has

been requested is not a record subject to the FOIA; a determination on any disputed fee matter, including a denial of a request for a fee waiver; or a denial of a request for expedited treatment.

(h) *Initial denials of requests.* The Deputy Administrator, Assistant Administrators, Regional Administrators, the General Counsel, the Inspector General, Associate Administrators, and heads of headquarters staff offices are delegated the authority to issue initial determinations. However, the authority to issue initial denials of requests for existing, located records (other than initial denials based solely on § 2.204(d)(1)) may be redelegated only to persons occupying positions not lower than division director or equivalent. Each letter will include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason(s) for the denial, including an identification of records being withheld (individual, or if a large number of similar records are being denied, by described category), and any FOIA exemption applied by the office in denying the request;

(3) An estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through annotated deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption; and

(4) A statement that the denial may be appealed under, and a description of the requirements of, paragraph (j) of this section.

(i) *Denial of fee waiver.* The letter denying a request for a fee waiver or expedited treatment will be signed by the head of the Headquarters FOI Staff or Regional FOI Officers.

(j) *Appeals of adverse determinations.* If you are dissatisfied with any adverse determination of your request by an office, you may appeal that determination to the Headquarters Freedom of Information Staff, Records, Privacy and FOIA Branch, Office of Information Collection, Office of Environmental Information, Environmental Protection Agency, 1200 Pennsylvania Avenue (2822T), NW., Washington, DC 20460; e-mail: *hq.foia@epa.gov*. The appeal must be made in writing, and it must be submitted to the Headquarters FOI Staff no later than 30 calendar days from the date of the letter denying the request. The Agency will not consider appeals received after the 30-day limit. The appeal letter may include as much or as little related information as you wish, as long as it clearly identifies the determination being appealed (including the assigned FOIA request number, if known). For quickest possible handling, the appeal letter and its envelope should be marked ''Freedom of Information Act Appeal.'' Unless the Administrator directs otherwise, the General Counsel or his/her designee will act on behalf of the Administrator on all appeals under this section, except that:

(1) In the case of an adverse initial determination by the General Counsel or his/her designee, the Administrator or his/her designee will act on the appeal;

(2) The Counsel to the Inspector General will act on any appeal where the Inspector General or his/her designee has made the initial adverse determination; however, if the Counsel to the Inspector General has signed the initial adverse determination, the General Counsel or his/her designee will act on the appeal;

(3) An adverse determination by the Administrator on an initial request will serve as the final action of the Agency; and

(4) If a requester seeks judicial review because the Agency has not responded in a timely manner, any further action on an appeal will take place through the lawsuit.

(k) The decision on your appeal will be made in writing, normally within 20 working days of its receipt by the Headquarters Freedom of Information Staff. A decision affirming an adverse determination in whole or in part will contain a statement of the reason(s) for the decision, including any FOIA exemption(s) applied, and inform you of the FOIA provisions for judicial review of the decision. If the adverse determination is reversed or modified on appeal, you will be notified in a written

decision. This written decision will either have the requested information that has been determined on appeal to be releasable attached to it, or your request will be returned to the appropriate office so that it may be reprocessed in accordance with the appeal decision.

(l) If you wish to seek judicial review of any adverse determination, you must first appeal that adverse determination under this section, except when EPA has not responded to your request within the statutory 20 working day time limit. In such cases, you may seek judicial review without making an administrative appeal.

§ 2.105 Exemption categories.

(a) The FOIA, 5 U.S.C. 552(b), establishes the following nine categories of information which are exempt from the mandatory disclosure requirements of 5 U.S.C. 552(a):

(1)(i) Specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy; and

(ii) Are in fact properly classified pursuant to such Executive order;

(2) Related solely to the internal personnel rules and practices of an agency;

(3) Specifically exempted from disclosure by statute (other than 5 U.S.C. 552(b)), provided that such statute:

(i) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or

(ii) Establishes particular criteria for withholding information or refers to particular types of information to be withheld;

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the affected agency;

(6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety or any individual;

(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) Geological and geophysical information and data, including maps, concerning wells.

(b) [Reserved]

§ 2.106 Preservation of records.

Each FOI Officer shall preserve all correspondence pertaining to the FOIA requests that it receives until disposition or destruction is authorized by title 44 of the United States Code or the National Archives and Records Administration's General Records Schedule 14. Copies of all responsive records should be maintained by the appropriate program office. Records shall not be disposed of while they are the

subject of a pending request, appeal, or lawsuit under the FOIA.

§ 2.107 Fees.

(a) *In general.* The Agency will charge for processing requests under the FOIA in accordance with paragraph (c) of this section, except where fees are limited under paragraph (d) of this section or where a waiver or reduction of fees is granted under paragraph (l) of this section. Requesters will pay fees by check or money order made payable to the U.S. Environmental Protection Agency.

(b) *Definitions.* For purposes of this section:

(1) *Commercial use request* means a request from or on behalf of a person who seeks information for a use or purpose that furthers his/her commercial, trade, or profit interests, which can include furthering those interests through litigation. FOI Officers will determine, whenever reasonably possible, the use to which a requester will put the requested records. When it appears that the requester will put the records to a commercial use, either because of the nature of the request itself or because an office has reasonable cause to doubt a requester's stated use, the FOI Officer will provide the requester a reasonable opportunity to submit further clarification.

(2) *Direct costs* means those expenses that the Agency actually incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records to respond to a FOIA request. Direct costs include, for example, the salary of the employee performing the work and the cost of operating duplication equipment. Not included in direct costs are overhead expenses such as the costs of space and heating or lighting of the facility in which the records are kept.

(3) *Duplication* means the making of a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, microform, audiovisual materials, or electronic records (for example, magnetic tape, disk, or compact disk), among others. The Agency will honor a requester's specified preference of form or format of disclosure if the record is readily reproducible with reasonable efforts in the requested form or format.

(4) *Educational institution* means a preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education, that operates a program of scholarly research. To be in this category, a requester must show that the request is authorized by, and is made under the auspices of, a qualifying institution and that the records are not sought for a commercial use but are sought to further scholarly research.

(5) *Noncommercial scientific institution* means an institution that is not operated on a ''commercial'' basis, as that term is defined in paragraph (b)(1) of this section, and that is operated solely for the purpose of conducting scientific research which is not intended to promote any particular product or industry. To be in this category, a requester must show that the request is authorized by, and is made under the auspices of, a qualifying institution and that the records are not sought for a commercial use but are sought to further scientific research.

(6) *Representative of the news media* or *news media requester* means any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. The term ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media include television or radio stations broadcasting to the public at large and publishers of periodicals (but only in those instances where they can qualify as disseminators of ''news'') who make their products available for purchase or subscription by the general public. For ''freelance'' journalists to be regarded as working for a news organization, they must demonstrate a solid basis for expecting publication through that organization. A publication contract would be the clearest proof, but FOI Officers will also look to the past publication record of a requester in making this determination. To be in this category, a requester must not be seeking

the requested records for a commercial use. A request for records supporting the news-dissemination function of the requester will not be considered to be for a commercial use.

(7) *Review* means the examination of a record located in response to a request in order to determine whether any portion of it is exempt from disclosure. It also includes processing any record for disclosure (for example, doing all that is necessary to redact it and prepare it for disclosure). Review costs are recoverable even if a record ultimately is not disclosed. Review time includes time spent considering any formal objection to disclosure made by a business submitter requesting confidential treatment, but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(8) *Search* means the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. Offices will ensure that searches are done in the most efficient and least expensive manner reasonably possible. For example, offices will not search line-by-line where duplicating an entire document would be quicker and less expensive.

(c) *Fees to be charged.* (1) There are four categories of requests. Fees for each of these categories will be charged as follows:

(i) *Commercial use requests.* A requester seeking access to records for a commercial use will be charged for the time spent searching for the records, reviewing the records for possible disclosure, and for the cost of each page of duplication. The charges for searching for and/or reviewing the records may be charged even if no responsive records are found or if the records are located but are determined to be exempt from disclosure.

(ii) *Educational or non-commercial scientific requests.* Requesters from educational or scientific institutions, whose purpose is scholarly, noncommercial research, will be charged only for the cost of record duplication, except that the first 100 pages of duplication will be furnished at no charge.

(iii) *News media requests.* Requesters who are representatives of the news media, and whose purpose in seeking records is noncommercial, will be charged only for the cost of duplication, except that the first 100 pages of duplication will be furnished at no charge.

(iv) *All other requests.* Requesters not covered by one of the three categories above will be charged for the full cost of search and duplication, except that the first two hours of search time and the first 100 pages of duplication will be furnished without charge. The charges for searching for the records will be assessed even if no responsive records are found or if the records are located but are determined to be exempt from disclosure.

(2) In responding to FOIA requests, the Agency will charge the following fees unless a waiver or reduction of fees has been granted under paragraph (l) of this section:

(i) *Search.* (A) Search fees will be charged for all requests except for those made by educational institutions, noncommercial scientific institutions, or representatives of the news media subject to the limitations of paragraph (d) of this section. Offices will charge for time spent searching even if no responsive records are found or if the records are located but are determined to be exempt from disclosure.

(B) For searches and retrievals of requested records, either manually or electronically, conducted by clerical personnel, the fee will be $4.00 for each quarter hour of time. For searches and retrievals of requested records, either manually or electronically, requiring the use of professional personnel, the fee will be $7.00 for each quarter hour of time. For searches and retrievals of requested records, either manually or electronically, requiring the use of managerial personnel, the fee will be $10.25 for each quarter hour of time.

(C) When searches and retrievals are conducted by contractors, requesters will be charged for the actual charges up to but not exceeding the rate which would have been charged had EPA employees conducted the search. The costs of actual computer resource

usage in connection with such searches will also be charged, to the extent they can be determined.

(ii) *Duplication.* Duplication fees will be charged to all requesters, subject to the limitations of paragraph (d) of this section. For either a photocopy or a computer-generated printout of a record (no more than one copy of which need be supplied), the fee will be fifteen (15) cents per page. For electronic forms of duplication, other than a computer-generated printout, offices will charge the direct costs of that duplication. Such direct costs will include the costs of the requested electronic medium on which the copy is to be made and the actual operator time and computer resource usage required to produce the copy, to the extent they can be determined.

(iii) *Review.* Review fees will be charged only to requesters who make a commercial use request. Review fees will be charged only for the initial record review (that is, the review done when an office is deciding whether an exemption applies to a particular record or portion of a record at the initial request level). No charge will be made for review at the administrative appeal level for an exemption already applied. However, records or portions of records withheld under an exemption that is subsequently determined not to apply may be reviewed again to determine whether any other exemption not previously considered applies; the costs of that review will be charged when it is made necessary by a change of circumstances. Review fees will be charged at the same rates as those charged for a search under paragraph (c)(1)(i) of this section.

(d) *Limitations on charging fees.* (1) No search or review fees will be charged for requests by educational institutions, noncommercial scientific institutions, or representatives of the news media.

(2) No search fee or review fee will be charged for a quarter-hour period unless more than half of that period is required for search or review.

(3) Except for requesters seeking records for a commercial use, offices will provide without charge:

(i) The first 100 pages of duplication, and

(ii) The first two hours of search.

(4) Whenever a total fee calculated under paragraph (c) of this section is $14.00 or less for any request, no fee will be charged.

(5) The provisions of paragraphs (d)(3) and (4) of this section work together. This means that for requesters other than those seeking records for a commercial use, no fee will be charged unless the cost of search in excess of two hours plus the cost of duplication in excess of 100 pages totals more than $14.00.

(e) *Notice of anticipated fees in excess of $25.00.* When the Agency determines or estimates that the fees to be charged under this section will amount to more than $25.00, the Agency will notify the requester of the actual or estimated amount of the fees, unless the requester has indicated a willingness to pay fees as high as those anticipated. The amount of $25.00 is cumulative for multi-office requests. If only a portion of the fee can be estimated readily, the Agency will advise the requester that the estimated fee may be only a portion of the total fee. When a requester has been notified that actual or estimated fees will amount to more than $25.00, EPA will do no further work on the request until the requester agrees to pay the anticipated total fee. This time will be excluded from the twenty (20) working day time limit. EPA will memorialize any such agreement in writing. A notice under this paragraph will offer the requester an opportunity to discuss the matter with Agency personnel in order to reformulate the request to meet the requester's needs at a lower cost.

(f) *Charges for other services.* Apart from the other provisions of this section, when an office chooses as a matter of administrative discretion to provide a special service-such as certifying that records are true copies or sending records by other than ordinary mail-the direct costs of providing the service ordinarily will be charged.

(g) *Charging interest.* EPA may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. Interest charges will be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the

date of the billing until payment is received by the Agency. EPA will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset. No penalty will be assessed against FOIA requesters for exercising their statutory right to ask that a fee be waived or reduced or to dispute a billing. If a fee is in dispute, penalties will be suspended upon notification.

(h) *Delinquent requesters.* If requesters fail to pay all fees within 60 calendar days of the fees assessment, they will be placed on a delinquency list. Subsequent FOIA requests will not be processed until payment of the overdue fees has first been made.

(i) *Aggregating requests.* When the Agency reasonably believes that a requester or a group of requesters acting together is attempting to divide a request into a series of requests for the purpose of avoiding fees, the Agency may aggregate those requests and charge accordingly. The Agency may presume that multiple requests of this type made within a 30-day period have been made in order to avoid fees. When requests are separated by a longer period, the Agency will aggregate them only if there exists a solid basis for determining that aggregation is warranted under all the circumstances involved. Multiple requests involving unrelated matters will not be aggregated.

(j) *Advance payments.* (1) For requests other than those described in paragraphs (j)(2) and (3) of this section, an office will not require the requester to make an advance payment (that is, a payment made before EPA begins or continues work on a request). Payment owed for work already completed (that is, a prepayment before copies are sent to a requester) is not an advance payment.

(2) When the Agency determines or estimates that a total fee to be charged under this section will be more than $250.00, it may require the requester to make an advance payment of an amount up to the amount of the entire anticipated fee before beginning to process the request, except when it receives a satisfactory assurance of full payment from a requester that has a history of prompt payment.

(3) When a requester has previously failed to pay a properly charged FOIA fee to the Agency within 30 calendar days of the date of billing, the Agency may require the requester to pay the full amount due, plus any applicable interest, and to make an advance payment of the full amount of any anticipated fee, before the Agency begins to process a new request or continues to process a pending request from that requester.

(4) When the Agency requires advance payment or payment due under paragraph (j)(3) of this section, the request will not be considered, and EPA will do no further work on the request until the required payment is made.

(k) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any other statute that specifically requires an agency to set and collect fees for particular types of records. When records responsive to requests are maintained for distribution by agencies operating such statutorily based fee schedule programs, EPA will inform requesters of the steps for obtaining records from those sources so that they may do so most economically.

(l) *Waiver or reduction of fees.* (1) Records responsive to a request will be furnished without charge or at a charge reduced below that established under paragraph (c) of this section when a FOI Office determines, based on all available information, that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(2) To determine whether the first fee waiver requirement is met, FOI Offices will consider the following factors:

(i) The subject of the request: Whether the subject of the requested records concerns ''the operations or activities of the government.'' The subject of the requested records must concern identifiable operations or activities of the Federal government, with a connection that is direct and clear, not remote.

(ii) The informative value of the information to be disclosed: Whether the disclosure is ''likely to contribute'' to an understanding of government operations or activities. The disclosable portions of the requested records must be meaningfully informative about government operations or activities in order to be ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either a duplicative or a substantially identical form, would not be as likely to contribute to such understanding when nothing new would be added to the public's understanding.

(iii) The contribution to an understanding of the subject by the public is likely to result from disclosure: Whether disclosure of the requested information will contribute to ''public understanding.'' The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area and ability and intention to effectively convey information to the public will be considered. It will be presumed that a representative of the news media will satisfy this consideration.

(iv) The significance of the contribution to public understanding: Whether the disclosure is likely to contribute ''significantly'' to public understanding of government operations or activities. The public's understanding of the subject in question, as compared to the level of public understanding existing prior to the disclosure, must be enhanced by the disclosure to a significant extent. FOI Offices will not make value judgments about whether information that would contribute significantly to public understanding of the operations or activities of the government is ''important'' enough to be made public.

(3) To determine whether the second fee waiver requirement is met, FOI Offices will consider the following factors:

(i) The existence and magnitude of a commercial interest: Whether the requester has a commercial interest that would be furthered by the requested disclosure. FOI Offices will consider any commercial interest of the requester (with reference to the definition of ''commercial use request'' in paragraph (b)(1) of this section), or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. Requesters will be given an opportunity in the administrative process to provide explanatory information regarding this consideration.

(ii) The primary interest in disclosure: Whether any identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is ''primarily in the commercial interest of the requester.'' A fee waiver or reduction is justified where the public interest standard is satisfied and that public interest is greater in magnitude than that of any identified commercial interest in disclosure. FOI Offices ordinarily will presume that when a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(4) When only some of the requested records satisfy the requirements for a waiver of fees, a waiver will be granted for only those records.

(5) Requests for the waiver or reduction of fees must address the factors listed in paragraphs (k) (l)–(3) of this section, insofar as they apply to each request. FOI Offices will exercise their discretion to consider the cost-effectiveness of their investment of administrative resources in deciding whether to grant waivers or reductions of fees and will consult the appropriate EPA offices as needed. Requests for the waiver or reduction of fees must be submitted along with the request.

(6) When a fee waiver request is denied, EPA will do no further work on the request until it receives an assurance of payment or an appeal of the fee waiver adverse determination is made and a final appeal determination is made pursuant to § 2.104(j).

§ 2.108 Other rights and services.

Nothing in this subpart shall be construed to entitle any person, as a right, to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

EFFECTIVE DATE NOTE: At 84 FR 30032, June 26, 2019, Subpart A of Part 2 was revised, effective July 26, 2019. For the convenience of the user, the revised text is set forth as follows:

Subpart A—Procedures for Disclosure of Records Under the Freedom of Information Act

§ 2.100 General provisions.

(a) This Subpart contains the rules that the Environmental Protection Agency (EPA or Agency) follows in processing requests for records under the Freedom of Information Act (FOIA), 5 U.S.C. 552. The Agency also has rules that it follows in processing FOIA requests for records submitted to it as Confidential Business Information (CBI). Such records are covered in Subpart B of this Part. Requests made by individuals for records about themselves under the Privacy Act of 1974, which are processed under 40 CFR part 16, will also be treated as FOIA requests under this Subpart. This ensures that the requestor has access to all responsive records. Information routinely provided to the public as part of a regular EPA activity may be provided to the public without following this Subpart.

(b) EPA will inform the requester of the steps necessary to obtain records from agencies operating statutory-based fee schedule programs, such as, but not limited to, the Government Printing Office or the National Technical Information Service.

(c) The Chief FOIA Officer designates the office that performs the duties of the National FOIA Office. The National FOIA Office reports to the Chief FOIA Officer.

(d) The Chief FOIA Officer designates the FOIA Public Liaisons. The FOIA Public Liaisons report to the Chief FOIA Officer. A FOIA Public Liaison is an official to whom a requester can raise concerns about the service the requester received from the FOIA Requester Service Center. A FOIA Public Liaison is responsible for assisting in reducing delays, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes. The public can find more information about the FOIA Public Liaisons at EPA's website.

§ 2.101 Where to file requests for records.

(a) Requesters must submit all requests for records from EPA under the FOIA in writing and by one of the following methods:

(1) EPA's FOIA submission website at *https://www.foiaonline.gov;*

(2) An electronic government submission website established pursuant to 5 U.S.C. 552(m), such as FOIA.gov;

(3) U.S. Mail sent to the following address: National FOIA Office, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW (2310A), Washington, DC 20460; or

(4) Overnight delivery service to National FOIA Office, U.S. Environmental Protection Agency, 1200 Pennsylvania NW, Room 5315, Washington, DC 20460. EPA will not treat a request submitted by any other method as a FOIA request, and the Agency will not reroute the request. The requester or requester organization must include the full name of their point of contact and their mailing address for EPA to process the request. For all requests, requesters should provide an email address and daytime telephone number whenever possible. For requests submitted through EPA's FOIA submission website or as provided by an electronic government submission website established pursuant to 5 U.S.C. 552(m), requesters must include an email address. For requests submitted through U.S. Mail, the requester must mark both the request letter and envelope ''Freedom of Information Act Request.'' The requester should not provide social security numbers when making a request for information under the FOIA. Requesters submitting requests electronically must do so before 5:00 p.m. Eastern Time for the Agency to consider the request as received on that date.

(b) EPA provides access to all records that the FOIA requires an agency to make regularly available for public inspection and copying. Each office is responsible for determining which of the records it generates are required to be made publicly available and for providing access by the public to them. The Agency will also maintain and make available for public inspection and copying a current subject matter index of such records and provide a copy or a link to the respective website for Headquarters or the Regions. Each index will be updated regularly, at least quarterly, with respect to newly-included records.

(c) All records created by EPA on or after November 1, 1996, which the FOIA requires an agency to make regularly available for public inspection and copying, will be made available electronically through EPA's website, located at *http://www.epa.gov,* or, upon request, through other electronic means. EPA will also include on its website the current subject matter index of all such records.

§ 2.102 Procedures for making requests.

(a) *General information.* EPA will consider a request received when the Agency receives a request by one of the methods identified in § 2.101(a).

(b) EPA employees may attempt in good faith to comply with oral requests for inspection or disclosure of EPA records publicly available under § 2.201(a) and (b), but such requests are not subject to the FOIA or this Part.

(c) *Description of records sought.* A request should reasonably describe the records the requester seeks in a way that will permit EPA employees to identify and locate them. Whenever possible, a request should include specific information about each record sought, such as the date, title or name, author, recipient, and subject matter. If known, the requester should include any file designations or descriptions for the records that the requester wants. The more specific the requester is about the records or type of records that the requester wants, the more likely EPA will be able to identify and locate records responsive to the request. If EPA determines that the request does not reasonably describe the records, EPA will tell the requester either what additional information the requester needs to provide or why the request is otherwise insufficient. EPA will also give the requester an opportunity to discuss and modify the request to meet the requirements of this Section.

(d) *Agreement to pay fees.* If the requester makes a FOIA request, EPA will consider the request to be an agreement that the requester will pay all applicable fees charged under § 2.107, up to $25.00, unless the requester seeks a waiver of fees. The EPA office responsible for responding to the request ordinarily will confirm this agreement in writing. When making a request, the requester may specify a willingness to pay a greater or lesser amount.

§ 2.103 Responsibility for responding to requests.

(a) *In general.* Upon receipt of a FOIA request under § 2.101(a) of this Subpart, the National FOIA Office will assign the request to an appropriate office within the Agency for processing. To determine which records are within the scope of a request, an office will ordinarily include only those records in the Agency's possession as of the date the request was received by one of the methods described in § 2.101(a). The Agency will inform the requester if any other date is used.

(b) *Authority to issue final determinations.* The Administrator, Deputy Administrators, Assistant Administrators, Deputy Assistant Administrators, Regional Administrators, Deputy Regional Administrators, General Counsel, Deputy General Counsels, Regional Counsels, Deputy Regional Counsels, and Inspector General or those individuals' delegates, are authorized to make determinations required by 5 U.S.C. 552(a)(6)(A), including to issue final determinations whether to release or withhold a record or a portion of a record on the basis of responsiveness or under one or more exemptions under the FOIA, and to issue ''no records'' responses.

(c) *Authority to grant or deny fee waivers or requests for expedited processing.* EPA's Chief FOIA Officer or EPA's Chief FOIA Officer's delegates are authorized to grant or deny requests for fee waivers or requests for expedited processing.

(d) *Consultations and referrals.* When a request to EPA seeks records in its possession that originated with another Federal agency, the EPA office assigned to process the request shall either:

(1) In coordination with the National FOIA Office, consult with the Federal agency where the record or portion thereof originated and then respond to the request, or

(2) With the concurrence of the National FOIA Office, refer the request to the Federal agency where the record or portion thereof originated. The National FOIA Office will notify the requester whenever all or any part of the responsibility for responding to a request has been referred to another agency.

(e) *Law enforcement information.* Whenever a requester makes a request for a record containing information that relates to an investigation of a possible violation of law and the investigation originated with another agency, the assigned office, with the concurrence of the National FOIA Office, will refer the request to that other agency or consult with that other agency prior to making any release determination.

§ 2.104 Responses to requests and appeals.

(a) *Timing of response.* The EPA office assigned to process the FOIA request will initiate the search, collection, and review process, and respond to a request within 20 working days from the date the request was received by one of the methods identified in § 2.101(a), unless unusual or exceptional circumstances exist as provided in paragraph (e) of this section. If EPA fails to respond to the request within the statutory time-period, or any authorized extension of time, the requester may seek judicial review to obtain the records without first making an administrative appeal.

(b) On receipt of a request, the National FOIA Office ordinarily will send a written acknowledgment advising the requester of the date the Agency received the request and of the processing number assigned to the request for future reference.

(c) *Multitrack processing.* The Agency uses three or more processing tracks by distinguishing between simple and complex requests based on the amount of work, time needed to process the request, or both, including limits based on the number of pages involved. The Agency will advise the requester of the processing track in which the Agency placed the request and the limits of the different processing tracks. The Agency may place the request in a slower track

while providing the requester with the opportunity to limit the scope of the request to qualify for faster processing within the specified limits of a faster track. If the Agency places the request in a slower track, the Agency will contact the requester.

(d) *Tolling the request.* Once the request is received, the Agency shall not toll the processing time-period except:

(1) The Agency may toll the processing time-period one time while seeking clarification from the requester; or

(2) The Agency may toll the processing time-period as many times as necessary to resolve fee issues.

(e) *Unusual circumstances.* When the Agency cannot meet statutory time limits for processing a request because of ''unusual circumstances,'' as defined in the FOIA, and the time limits are extended on that basis, the Agency will notify the requester in writing, as soon as practicable, of the unusual circumstances and of the date by which processing of the request should be completed. If the 20 working-day period is extended, EPA will give the requester an opportunity to limit the scope of the request, modify the request, or agree to an alternative time-period for processing, as described by the FOIA. EPA will also provide contact information for its FOIA Public Liaison to assist in the resolution of any disputes between the requester and the Agency, and the Agency will notify the requester of their right to seek dispute resolution services from the Office of Government Information Services within the National Archives and Records Administration.

(f) *Expedited processing.* (1) EPA will take requests or appeals out of order and give expedited treatment whenever EPA determines that such requests or appeals involve a compelling need, as follows:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) An urgency to inform the public about an actual or alleged Federal government activity, if the information is requested by a person primarily engaged in disseminating information to the public.

(2) Requesters must make a request for expedited processing at the time of the initial request for records or at the time of appeal.

(3) If the requester seeks expedited processing, the requester must submit a statement, certified to be true and correct to the best of the requester's knowledge and belief, explaining in detail the basis for the request. For example, if the requester fits within the category described in paragraph (f)(1)(ii) of this section and is not a full-time member of the news media, the requester must establish that they are a person whose primary professional activity or occupation is information dissemination, although it need not be the requester's sole occupation. If the requester fits within the category described in paragraph (f)(1)(ii) of this section, the requester must also establish a particular urgency to inform the public about the government activity involved in the request, beyond the public's right to know about government activity generally.

(4) Within 10 calendar days from the date of the request for expedited processing, the Chief FOIA Officer, or the Chief FOIA Officer's delegates, will decide whether to grant the request and will notify the requester of the decision. If the Agency grants the request for expedited processing, the Agency will give the request priority and will process the request as soon as practicable. If the Agency denies the request for expedited processing, the Agency will act on any appeal of that decision expeditiously.

(g) *Grants of requests.* Once the Agency determines to grant a request in whole or in part, it will release the records or parts of records to the requester and notify the requester of any applicable fee charged under § 2.107. The office will annotate records released in part, whenever technically feasible, with the applicable FOIA exemption or exemptions at that part of the record from which the exempt information was deleted.

(h) *Adverse determinations of requests.* When the Agency makes an adverse determination, the Agency will notify the requester of that determination in writing. Adverse determinations include:

(1) A decision that the requested record is exempt from disclosure, in whole or in part;

(2) A decision that the information requested is not a record subject to the FOIA;

(3) A decision that the requested record does not exist or cannot be located;

(4) A decision that the requested record is not readily reproducible in the form or format sought by the requester;

(5) A determination on any disputed fee matter, including a denial of a request for a fee waiver; or

(6) A denial of a request for expedited processing.

(i) *Content of final determination letter.* The appropriate official will issue the final determination letter in accordance with § 2.103(b) of this subpart and will include:

(1) The name and title or position of the person responsible for the determination;

(2) A brief statement of the reason or reasons for the denial, including an identification of records being withheld (either individually or, if a large number of similar records are being denied, described by category) and any FOIA exemption applied by the office in denying the request;

(3) An estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through

annotated deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption;

(4) A statement that an adverse determination may be appealed under (j) of this section and description of the requirements for submitting an administrative appeal; and

(5) A statement that the requester has the right to seek dispute resolution services from an EPA FOIA Public Liaison or the Office of Government Information Service.

(j) *Appeals of adverse determinations.* If the requester is dissatisfied with any adverse determination of their request, the requester may appeal that determination by letter to the National FOIA Office, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW (2310A), Washington, DC 20460 or *hq.foia@epa.gov*. The requester must make their appeal in writing, and the Agency must receive the requester's appeal no later than 90 calendar days from the date of the letter that denied the request. The Agency will not consider appeals received after the 90-calendar day limit. Requesters submitting appeals electronically must do so before 5:00 p.m. Eastern Time for the Agency to consider the appeal as received on that date. The appeal letter may include as much or as little related information as the requester wishes, as long as it clearly identifies the determination being appealed (including the assigned FOIA request number, if known). For quickest handling, the requester must mark their appeal letter and its envelope with ''Freedom of Information Act Appeal.'' Unless the Administrator directs otherwise, the General Counsel or the General Counsel's delegate will act on behalf of the Administrator on all appeals under this Section, except that:

(1) The Counsel to the Inspector General will act on any appeal where the Inspector General or the Inspector General's delegate has made the final adverse determination; however, if the Counsel to the Inspector General has signed the final adverse determination, the General Counsel or the General Counsel's delegate will act on the appeal;

(2) An adverse determination by the Administrator on an initial request will serve as the final action of the Agency; and

(3) If a requester seeks judicial review because the Agency has not responded in a timely manner, any further action on an appeal will take place through the lawsuit.

(k) EPA will make the decision on the appeal in writing, normally within 20 working days of its receipt by the National FOIA Office. A decision affirming an adverse determination in whole or in part will contain a statement of the reason or reasons for the decision, including any FOIA exemption or exemptions applied, and inform the requester of the FOIA provisions for judicial review of the decision. If the Agency reverses or modifies the adverse determination on appeal, the Agency will notify the requester in a written decision. In the written decision, the Agency will attach the requested information that the Agency determined on appeal to be releasable, or the Agency will return the request to the appropriate office so that the office may reprocess the request in accordance with the appeal decision.

(l) If the requester wishes to seek judicial review of any adverse determination, the requester must first appeal that adverse determination under this Section, except when EPA has not responded to the request within the applicable time-period. In such cases, the requester may seek judicial review without making an administrative appeal.

§ 2.105 [Reserved]

§ 2.106 Preservation of records.

The Agency shall preserve all correspondence pertaining to the FOIA requests that it receives until disposition or destruction is authorized by title 44 of the United States Code or the National Archives and Records Administration's General Records Schedule 14. Copies of all responsive records should be maintained by the appropriate program office. Records shall not be disposed of while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

§ 2.107 Fees.

(a) *In general.* The Agency will charge for processing requests under the FOIA in accordance with paragraph (c) of this section, except where fees are limited under paragraph (d) of this section or where a waiver or reduction of fees is granted under paragraph (l) of this section. Requesters will pay fees by check or money order made payable to the U.S. Environmental Protection Agency.

(b) *Definitions.* For purposes of this section:

(1) Commercial use request means a request from or on behalf of a person who seeks information for a use or purpose that furthers the requester's commercial, trade, or profit interests, which can include furthering those interests through litigation. The Agency will determine, whenever reasonably possible, the use to which a requester will put the requested records. When it appears that the requester will put the records to a commercial use, either because of the nature of the request itself or because the Agency has reasonable cause to doubt a requester's stated use, the Agency will provide the requester a reasonable opportunity to submit further clarification.

(2) Direct costs means those expenses that the Agency actually incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records to respond to a FOIA request. Direct costs include, for example, the salary of the employee performing the work and the cost of

operating duplication equipment. Not included in direct costs are overhead expenses such as the costs of space and heating or lighting of the facility in which the records are kept.

(3) Duplication means the making of a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, microform, audiovisual materials, or electronic records (for example, magnetic tape, disk, or compact disk), among others. The Agency will honor a requester's specified preference of form or format of disclosure if the record is readily reproducible with reasonable efforts in the requested form or format.

(4) Educational institution means a preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education, that operates a program of scholarly research. To be in this category, a requester must show that the request is authorized by, and is made under the auspices of, a qualifying institution and that the records are not sought for a commercial use but are sought to further scholarly research.

(5) Noncommercial scientific institution means an institution not operated on a ''commercial'' basis, as defined in paragraph (b)(1) of this section, and that is operated solely for conducting scientific research that is not intended to promote any particular product or industry. To be in this category, a requester must show that a qualifying institution authorizes the request, that the requester makes the request under the auspices of the qualifying institution, and that the requester does not seek the records for a commercial use but to further scientific research.

(6) Representative of the news media has the meaning provided at 5 U.S.C. 552(a)(4)(A)(ii).

(7) Review means the examination of a record located in response to a request to determine whether any portion of it is exempt from disclosure. It also includes processing any record for disclosure (for example, doing all that is necessary to redact it and prepare it for disclosure). Review costs are recoverable even if a record ultimately is not disclosed. Review time includes time spent considering any formal objection to disclosure made by a business submitter requesting confidential treatment but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(8) Search means the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. Offices will ensure that searches are done in the most efficient and least expensive manner reasonably possible. For example, offices will not search line-by-line where duplicating an entire document would be quicker and less expensive.

(c) *Fees to be charged.* (1) There are four categories of requests. The Agency charges fees for each of these categories as follows:

(i) *Commercial use requests.* The Agency will charge a requester seeking access to records for a commercial use for the time spent searching for the records, reviewing the records for possible disclosure, and for the cost of each page of duplication. The Agency may charge for searching for and/or reviewing the records even if no responsive records are found or if the records are located but are determined to be exempt from disclosure.

(ii) *Educational or non-commercial scientific requests.* The Agency will charge requesters from educational or noncommercial scientific institution, whose purpose is scholarly or scientific research, only for the cost of record duplication, except that the Agency will furnish the first 100 pages of duplication at no charge.

(iii) *News media requests.* The Agency will charge requesters who are representatives of the news media, and whose purpose in seeking records is noncommercial, for the cost of duplication, except that the first 100 pages of duplication will be furnished at no charge.

(iv) *All other requests.* The Agency will charge requesters not covered by one of the three categories above for the full cost of search and duplication, except that the Agency will furnish without charge the first two hours of search time and the first 100 pages of duplication. The Agency will charge for searching for the records even if no responsive records are found or if the records are located but are determined to be exempt from disclosure.

(2) In responding to FOIA requests, the Agency will charge the following fees unless a waiver or reduction of fees has been granted under paragraph (l) of this section:

(i) *Search.* (A) The Agency will charge search fees for all requests except for those made by educational institutions or noncommercial scientific institutions, or representatives of the news media subject to the limitations of paragraph (d) of this section. The Agency will charge for time spent searching even if no responsive records are found or if the records are located but are determined to be exempt from disclosure.

(B) For searches and retrievals of requested records, either manually or electronically, conducted by clerical personnel, the fee will be $4.00 for each quarter hour of

time. For searches and retrievals of requested records, either manually or electronically, requiring the use of professional personnel, the fee will be $7.00 for each quarter hour of time. For searches and retrievals of requested records, either manually or electronically, requiring the use of managerial personnel, the fee will be $10.25 for each quarter hour of time.

(C) When contractors conduct searches and retrievals, the Agency will charge requesters for the actual charges up to but not exceeding the rate that the Agency would have charged the requester had EPA employees conducted the search. The Agency will charge the costs of actual computer resource usage in connection with such searches, to the extent they can be determined.

(ii) *Duplication*. The Agency will charge duplication fees to all requesters, subject to the limitations of paragraph (d) of this section. For either a photocopy or a computer-generated printout of a record (no more than one copy of which need be supplied), the fee will be fifteen (15) cents per page. For electronic forms of duplication, other than a computer-generated printout, offices will charge the direct costs of that duplication. Such direct costs will include the costs of the requested electronic medium on which the copy is to be made and the actual operator time and computer resource usage required to produce the copy, to the extent they can be determined.

(iii) *Review*. The Agency will charge review fees to requesters who make a commercial use request. The Agency will charge review fees only for the initial record review (that is, the review done when an office is deciding whether an exemption applies to a particular record or portion of a record at the initial request level). The Agency will not charge for review at the administrative appeal level for an exemption already applied. However, the Agency may again review records or portions of records withheld under an exemption that the Agency subsequently determines not to apply to determine whether any other exemption not previously considered applies; the Agency will charge costs of that review when a change of circumstances makes it necessary. The Agency will charge review fees at the same rates as those charged for a search under paragraph (c)(1)(i) of this section.

(d) *Limitations on charging fees*. (1) The Agency will charge no search or review fees for requests by educational institutions or noncommercial scientific institutions, or representatives of the news media.

(2) The Agency will charge no search fee or review fee for a quarter-hour period unless more than half of that period is required for search or review.

(3) Except for requesters seeking records for a commercial use, offices will provide without charge:

(i) The first 100 pages of duplication, and

(ii) The first two hours of search.

(4) The Agency will charge no fee when a total fee calculated under paragraph (c) of this section is $14.00 or less for any request.

(5) The provisions of paragraphs (d)(3) and (4) of this section work together. This means that for requesters other than those seeking records for a commercial use, the Agency will charge no fee unless the cost of search in excess of two hours plus the cost of duplication in excess of 100 pages totals more than $14.00.

(6) If EPA fails to comply with the FOIA's time limits for responding to a request, EPA will not charge search fees, or, in the instance of requesters described in paragraphs (b)(4) through (6) of this section, duplication fees, except as follows:

(i) If EPA determined that unusual circumstances as defined by the FOIA apply and the Agency provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional 10 working days;

(ii) If EPA determined that unusual circumstances as defined by the FOIA apply and more than 5,000 pages are necessary to respond to the request, EPA may charge search fees, or, in the case of requesters described in paragraph paragraphs (b)(4) through (6) of this section, may charge duplication fees, if the following steps are taken: EPA must have provided timely written notice of unusual circumstances to the requester in accordance with the FOIA and the EPA must have discussed with the requester by written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii), which includes notification to the requester of the availability of the FOIA Public Liaison and the right to seek dispute resolution services from the Office of Government Information Services. If this exception is satisfied, EPA may charge all applicable fees incurred in the processing of the request; or

(iii) If a court determines that exceptional circumstances exist, as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order.

(e) *Notice of anticipated fees in excess of $25.00*. When the Agency determines or estimates that the fees the Agency will charge under this Section will amount to more than $25.00, the Agency will notify the requester of the actual or estimated amount of the fees, unless the requester has indicated a willingness to pay fees as high as those anticipated. The amount of $25.00 is cumulative for multi-office requests. If the Agency can only readily estimate a portion of the fee, the Agency will advise the requester that the

estimated fee may be only a portion of the total fee. When the Agency notifies a requester that actual or estimated fees will amount to more than $25.00, the Agency will do no further work on the request until the requester agrees to pay the anticipated total fee. The Agency will exclude time from the twenty (20) working day time limit. EPA will memorialize any such agreement in writing. A notice under this paragraph will offer the requester an opportunity to discuss the matter with Agency personnel to reformulate the request to meet the requester's needs at a lower cost.

(f) *Charges for other services.* Apart from the other provisions of this section, when the Agency chooses as a matter of administrative discretion to provide a special service—such as certifying that records are true copies or sending records by other than ordinary mail—the Agency will ordinarily charge the direct costs of providing the service.

(g) *Charging interest.* EPA may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. The Agency will assess interest charges at the rate provided in 31 U.S.C. 3717 and will accrue from the date of the billing until the Agency receives payment. EPA will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset. The Agency will assess no penalty against FOIA requesters for exercising their statutory right to ask the Agency to waive or reduce a fee or to dispute a billing. If a fee is in dispute, the Agency will suspend penalties upon notification.

(h) *Delinquent requesters.* If requesters fail to pay all fees within 60 calendar days of the fees assessment, the Agency will place the requester on a delinquency list. The Agency will not process subsequent FOIA requests until the requester makes payment of the overdue fees.

(i) *Aggregating requests.* When the Agency reasonably believes that a requester or a group of requesters acting together is attempting to divide a request into a series of requests for the purpose of avoiding fees, the Agency may aggregate those requests and charge accordingly. The Agency may presume that multiple requests of this type made within a 30-day period have been made to avoid fees. When requests are separated by a longer period, the Agency will aggregate them only if there exists a solid basis for determining that aggregation is warranted under all the circumstances involved. The Agency will not aggregate multiple requests involving unrelated matters.

(j) *Advance payments.* (1) For requests other than those described in paragraphs (j)(2) and (3) of this section, the Agency will not require the requester to make an advance payment (that is, a payment made before EPA begins or continues work on a request). Payment owed for work already completed (that is, a prepayment before the Agency sends copies to a requester) is not an advance payment.

(2) When the Agency determines or estimates that a total fee to be charged under this section will be more than $250.00, it may require the requester to make an advance payment of an amount up to the amount of the entire anticipated fee before beginning to process the request, except when it receives a satisfactory assurance of full payment from a requester that has a history of prompt payment.

(3) When a requester has previously failed to pay a properly charged FOIA fee to the Agency within 30 calendar days of the date of billing, the Agency may require the requester to pay the full amount due, plus any applicable interest, and to make an advance payment of the full amount of any anticipated fee, before the Agency begins to process a new request or continues to process a pending request from that requester.

(4) When the Agency requires advance payment or payment due under paragraph (j)(3) of this section, the Agency will not consider the request, and EPA will do no further work on the request until the requester makes the required payment.

(k) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any other statute that specifically requires an agency to set and collect fees for particular types of records. When records responsive to requests are maintained for distribution by agencies operating such statutorily based fee schedule programs, EPA will inform requesters of the steps for obtaining records from those sources so that they may do so most economically.

(l) *Waiver or reduction of fees.* (1) Records responsive to a request will be furnished without charge or at a charge reduced below that established under paragraph (c) of this section when the Agency determines, based on all available information, that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(2) To determine whether the request meets the first fee waiver requirement, the Agency will consider the following factors:

(i) *The subject of the request.* Whether the subject of the requested records concerns ''the operations or activities of the government.'' The subject of the requested records must concern identifiable operations or activities of the Federal government, with a connection that is direct and clear, not remote.

(ii) *The informative value of the information to be disclosed.* Whether the disclosure is ''likely to contribute'' to an understanding of government operations or activities. The disclosable portions of the requested records must be meaningfully informative about government operations or activities in order to be ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either a duplicative or a substantially identical form, would not be as likely to contribute to such understanding when nothing new would be added to the public's understanding.

(iii) The contribution to an understanding of the subject by the public is likely to result from the disclosure. Whether disclosure of the requested information will contribute to ''public understanding.'' The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. The Agency will consider a requester's expertise in the subject area and ability and intention to effectively convey information to the public. The Agency presumes that a representative of the news media will satisfy this consideration.

(iv) *The significance of the contribution to public understanding.* Whether the disclosure is likely to contribute ''significantly'' to public understanding of government operations or activities. The public's understanding of the subject in question, as compared to the level of public understanding existing prior to the disclosure, must be enhanced by the disclosure to a significant extent. The Agency will not make value judgments about whether information that would contribute significantly to public understanding of the operations or activities of the government is ''important'' enough to be made public.

(3) To determine whether the request meets the second fee waiver requirement, the Agency will consider the following factors:

(i) *The existence and magnitude of a commercial interest.* Whether the requester has a commercial interest that would be furthered by the requested disclosure. The Agency will consider any commercial interest of the requester (with reference to the definition of ''commercial use request'' in paragraph (b)(1) of this section), or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. The Agency will give the requester an opportunity in the administrative process to provide explanatory information regarding this consideration.

(ii) *The primary interest in disclosure.* Whether any identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is ''primarily in the commercial interest of the requester.'' A fee waiver or reduction is justified where the public interest standard is satisfied and that public interest is greater in magnitude than that of any identified commercial interest in disclosure. The Agency ordinarily will presume that when a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. The Agency will not presume that disclosure to data brokers or others who merely compile and market government information for direct economic return is to primarily serve the public interest.

(4) When only some of the requested records satisfy the requirements for a waiver of fees, the Agency will grant a waiver for only those records.

(5) Requests for the waiver or reduction of fees must address the factors listed in paragraphs (k)(1) through (3) of this section, as far as they apply to each request. Offices will exercise their discretion to consider the cost-effectiveness of their investment of administrative resources in deciding whether to grant waivers or reductions of fees and will consult the appropriate EPA offices as needed. Requesters must submit requests for the waiver or reduction of fees along with the request.

(6) When the EPA denies a fee waiver request, EPA will do no further work on the request until it receives an assurance of payment from the requester, or until the requester appeals the fee waiver adverse determination and the EPA completes its final appeal determination pursuant to § 2.104(j).

§ 2.108 Other rights and services.

Nothing in this Subpart shall be construed to entitle any person, as a right, to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

Subpart B—Confidentiality of Business Information

§ 2.201 Definitions.

For the purposes of this subpart:

(a) *Person* means an individual, partnership, corporation, association, or other public or private organization or legal entity, including Federal, State or local governmental bodies and agencies and their employees.

(b) *Business* means any person engaged in a business, trade, employment, calling or profession, whether or not all or any part of the net earnings derived from such engagement by such person inure (or may lawfully inure) to

the benefit of any private shareholder or individual.

(c) *Business information* (sometimes referred to simply as *information*) means any information which pertains to the interests of any business, which was developed or acquired by that business, and (except where the context otherwise requires) which is possessed by EPA in recorded form.

(d) *Affected business* means, with reference to an item of business information, a business which has asserted (and not waived or withdrawn) a business confidentiality claim covering the information, or a business which could be expected to make such a claim if it were aware that disclosure of the information to the public was proposed.

(e) *Reasons of business confidentiality* include the concept of trade secrecy and other related legal concepts which give (or may give) a business the right to preserve the confidentiality of business information and to limit its use or disclosure by others in order that the business may obtain or retain business advantages it derives from its rights in the information. The definition is meant to encompass any concept which authorizes a Federal agency to withhold business information under 5 U.S.C. 552(b)(4), as well as any concept which requires EPA to withhold information from the public for the benefit of a business under 18 U.S.C. 1905 or any of the various statutes cited in §§ 2.301 through 2.309.

(f) [Reserved]

(g) Information which is *available to the public* is information in EPA's possession which EPA will furnish to any member of the public upon request and which EPA may make public, release or otherwise make available to any person whether or not its disclosure has been requested.

(h) *Business confidentiality claim* (or, simply, *claim*) means a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality, or a request for a determination that such information is entitled to such treatment.

(i) *Voluntarily submitted information* means business information in EPA's possession—

(1) The submission of which EPA had no statutory or contractual authority to require; and

(2) The submission of which was not prescribed by statute or regulation as a condition of obtaining some benefit (or avoiding some disadvantage) under a regulatory program of general applicability, including such regulatory programs as permit, licensing, registration, or certification programs, but excluding programs concerned solely or primarily with the award or administration by EPA of contracts or grants.

(j) *Recorded* means written or otherwise registered in some form for preserving information, including such forms as drawings, photographs, videotape, sound recordings, punched cards, and computer tape or disk.

(k) [Reserved]

(l) *Administrator*, *Regional Administrator*, *General Counsel*, *Regional Counsel*, and *Freedom of Information Officer* mean the EPA officers or employees occupying the positions so titled.

(m) *EPA office* means any organizational element of EPA, at any level or location. (The terms *EPA office* and *EPA legal office* are used in this subpart for the sake of brevity and ease of reference. When this subpart requires that an action be taken by an *EPA office* or by an *EPA legal office*, it is the responsibility of the officer or employee in charge of that office to take the action or ensure that it is taken.)

(n) *EPA legal office* means the EPA General Counsel and any EPA office over which the General Counsel exercises supervisory authority, including the various Offices of Regional Counsel. (See paragraph (m) of this section.)

(o) A *working day* is any day on which Federal Government offices are open for normal business. Saturdays, Sundays, and official Federal holidays are not working days; all other days are.

§ 2.202 Applicability of subpart; priority where provisions conflict; records containing more than one kind of information.

(a) Sections 2.201 through 2.215 establish basic rules governing business confidentiality claims, the handling by EPA of business information which is or may be entitled to confidential treatment, and determinations by EPA

of whether information is entitled to confidential treatment for reasons of business confidentiality.

(b) Various statutes (other than 5 U.S.C. 552) under which EPA operates contain special provisions concerning the entitlement to confidential treatment of information gathered under such statutes. Sections 2.301 through 2.311 prescribe rules for treatment of certain categories of business information obtained under the various statutory provisions. Paragraph (b) of each of those sections should be consulted to determine whether any of those sections applies to the particular information in question.

(c) The basic rules of §§ 2.201 through 2.215 govern except to the extent that they are modified or supplanted by the special rules of §§ 2.301 through 2.311. In the event of a conflict between the provisions of the basic rules and those of a special rule which is applicable to the particular information in question, the provision of the special rule shall govern.

(d) If two or more of the sections containing special rules apply to the particular information in question, and the applicable sections prescribe conflicting special rules for the treatment of the information, the rule which provides greater or wider availability to the public of the information shall govern.

(e) For most purposes, a document or other record may usefully be treated as a single unit of *information*, even though in fact the document or record is comprised of a collection of individual items of information. However, in applying the provisions of this subpart, it will often be necessary to separate the individual items of information into two or more categories, and to afford different treatment to the information in each such category. The need for differentiation of this type may arise, e.g., because a business confidentiality claim covers only a portion of a record, or because only a portion of the record is eligible for confidential treatment. EPA offices taking action under this subpart must be alert to this problem.

(f) In taking actions under this subpart, EPA offices should consider whether it is possible to obtain the affected business's consent to disclosure of useful portions of records while protecting the information which is or may be entitled to confidentiality (e.g., by withholding such portions of a record as would identify a business, or by disclosing data in the form of industry-wide aggregates, multi-year averages or totals, or some similar form).

(g) This subpart does not apply to questions concerning entitlement to confidential treatment or information which concerns an individual solely in his personal, as opposed to business, capacity.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40000, Sept. 8, 1978; 50 FR 51661, Dec. 18, 1985]

§ 2.203 Notice to be included in EPA requests, demands, and forms; method of asserting business confidentiality claim; effect of failure to assert claim at time of submission.

(a) *Notice to be included in certain requests and demands for information, and in certain forms.* Whenever an EPA office makes a written request or demand that a business furnish information which, in the office's opinion, is likely to be regarded by the business as entitled to confidential treatment under this subpart, or whenever an EPA office prescribes a form for use by businesses in furnishing such information, the request, demand, or form shall include or enclose a notice which—

(1) States that the business may, if it desires, assert a business confidentiality claim covering part or all of the information, in the manner described by paragraph (b) of this section, and that information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in this subpart;

(2) States that if no such claim accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to the business; and

(3) Furnishes a citation of the location of this subpart in the Code of Federal Regulations and the FEDERAL REGISTER.

(b) *Method and time of asserting business confidentiality claim.* A business which is submitting information to

EPA may assert a business confidentiality claim covering the information by placing on (or attaching to) the information, at the time it is submitted to EPA, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as *trade secret*, *proprietary*, or *company confidential*. Allegedly confidential portions of otherwise non-confidential documents should be clearly identified by the business, and may be submitted separately to facilitate identification and handling by EPA. If the business desires confidential treatment only until a certain date or until the occurrence of a certain event, the notice should so state.

(c) *Effect of failure to assert claim at time of submission of information.* If information was submitted by a business to EPA on or after October 1, 1976, in response to an EPA request or demand (or on an EPA-prescribed form) which contained the substance of the notice required by paragraph (a) of this section, and if no business confidentiality claim accompanied the information when it was received by EPA, the inquiry to the business normally required by §2.204(c)(2) need not be made. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files (see §2.204(c)(1)). However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

§2.204 Initial action by EPA office.

(a) *Situations requiring action.* This section prescribes procedures to be used by EPA offices in making initial determinations of whether business information is entitled to confidential treatment for reasons of business confidentiality. Action shall be taken under this section whenever an EPA office:

(1) Learns that it is responsible for responding to a request under 5 U.S.C. 552 for the release of business information; in such a case, the office shall issue an initial determination within the period specified in §2.112;

(2) Desires to determine whether business information in its possession is entitled to confidential treatment, even though no request for release of the information has been received; or

(3) Determines that it is likely that EPA eventually will be requested to disclose the information at some future date and thus will have to determine whether the information is entitled to confidential treatment. In such a case this section's procedures should be initiated at the earliest practicable time, in order to increase the time available for preparation and submission of comments and for issuance of determinations, and to make easier the task of meeting response deadlines if a request for release of the information is later received under 5 U.S.C. 552.

(b) *Previous confidentiality determination.* The EPA office shall first ascertain whether there has been a previous determination, issued by a Federal court or by an EPA legal office acting under this subpart, holding that the information in question is entitled to confidential treatment for reasons of business confidentiality.

(1) If such a determination holds that the information is entitled to confidential treatment, the EPA Office shall furnish any person whose request for the information is pending under 5 U.S.C. 552 an initial determination (see §2.111 and §2.113) that the information has previously been determined to be entitled to confidential treatment, and that the request is therefore denied. The office shall furnish such person the appropriate case citation or EPA determination. If the EPA office believes that a previous determination which was issued by an EPA legal office may be improper or no longer valid, the office shall so inform the EPA legal office, which shall consider taking action under §2.205(h).

(2) With respect to all information not known to be covered by such a previous determination, the EPA office shall take action under paragraph (c) of this section.

(c) *Determining existence of business confidentiality claims.* (1) Whenever action under this paragraph is required by paragraph (b)(2) of this section, the

EPA office shall examine the information and the office's records to determine which businesses, if any, are affected businesses (see § 2.201(d)), and to determine which businesses if any, have asserted business confidentiality claims which remain applicable to the information. If any business is found to have asserted an applicable claim, the office shall take action under paragraph (d) of this section with respect to each such claim.

(2)(i) If the examination conducted under paragraph (c)(1) of this section discloses the existence of any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information, the EPA office shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information. However, no such inquiry need be made to any business—

(A) Which failed to assert a claim covering the information when responding to an EPA request or demand, or supplying information on an EPA form, which contained the substance of the statements prescribed by § 2.203(a);

(B) Which otherwise failed to assert a claim covering the information after being informed by EPA that such failure could result in disclosure of the information to the public; or

(C) Which has otherwise waived or withdrawn a claim covering the information.

(ii) If a request for release of the information under 5 U.S.C. 552 is pending at the time inquiry is made under this paragraph (c)(2), the inquiry shall be made by telephone or equally prompt means, and the responsible official contacted shall be informed that any claim the business wishes to assert must be brought to the EPA office's attention no later than the close of business on the third working day after such inquiry.

(iii) A record shall be kept of the results of any inquiry under this paragraph (c)(2). If any business makes a claim covering the information, the EPA office shall take further action under paragraph (d) of this section.

(3) If, after the examination under paragraph (c)(1) of this section, and after any inquiry made under paragraph (c)(2) of this section, the EPA office knows of no claim covering the information and the time for response to any inquiry has passed, the information shall be treated for purposes of this subpart as not entitled to confidential treatment.

(d) *Preliminary determination.* Whenever action under this paragraph is required by paragraph (c)(1) or (2) of this section on any business's claim, the EPA Office shall make a determination with respect to each such claim. Each determination shall be made after consideration of the provisions of § 2.203, the applicable substantive criteria in § 2.208 or elsewhere in this subpart, and any previously-issued determinations under this subpart which are applicable.

(1) If, in connection with any business's claim, the office determines that the information may be entitled to confidential treatment, the office shall—

(i) Furnish the notice of opportunity to submit comments prescribed by paragraph (e) of this section to each business which is known to have asserted an applicable claim and which has not previously been furnished such notice with regard to the information in question;

(ii) Furnish, to any person whose request for release of the information is pending under 5 U.S.C. 552, a determination (in accordance with § 2.113) that the information may be entitled to confidential treatment under this subpart and 5 U.S.C. 552(b)(4), that further inquiry by EPA pursuant to this subpart is required before a final determination on the request can be issued, that the person's request is therefore initially denied, and that after further inquiry a final determination will be issued by an EPA legal office; and

(iii) Refer the matter to the appropriate EPA legal office, furnishing the information required by paragraph (f) of this section after the time has elapsed for receipt of comments from the affected business.

(2) If, in connection with all applicable claims, the office determines that the information clearly is not entitled to confidential treatment, the office shall take the actions required by

§ 2.205(f). However, if a business has previously been furnished notice under § 2.205(f) with respect to the same information, no further notice need be furnished to that business. A copy of each notice furnished to a business under this paragraph (d)(2) and § 2.205(f) shall be forwarded promptly to the appropriate EPA legal office.

(e) *Notice to affected businesses; opportunity to comment.* (1) Whenever required by paragraph (d)(1) of this section, the EPA office shall promptly furnish each business a written notice stating that EPA is determining under this subpart whether the information is entitled to confidential treatment, and affording the business an opportunity to comment. The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact and date of receipt. The notice shall state the address of the office to which the business's comments shall be addressed (the EPA office furnishing the notice, unless the General Counsel has directed otherwise), the time allowed for comments, and the method for requesting a time extension under § 2.205(b)(2). The notice shall further state that EPA will construe a business's failure to furnish timely comments as a waiver of the business's claim.

(2) If action under this section is occasioned by a request for the information under 5 U.S.C. 552, the period for comments shall be 15 working days after the date of the business's receipt of the written notice. In other cases, the EPA office shall establish a reasonable period for comments (not less than 15 working days after the business's receipt of the written notice). The time period for comments shall be considered met if the business's comments are postmarked or hand delivered to the office designated in the notice by the date specified. In all cases, the notice shall call the business's attention to the provisions of § 2.205(b).

(3) At or about the time the written notice is furnished, the EPA office shall orally inform a responsible representative of the business (by telephone or otherwise) that the business should expect to receive the written notice, and shall request the business to contact the EPA office if the written notice has not been received within a few days, so that EPA may furnish a duplicate notice.

(4) The written notice required by paragraph (e)(1) of this section shall invite the business's comments on the following points (subject to paragraph (e)(5) of this section):

(i) The portions of the information which are alleged to be entitled to confidential treatment;

(ii) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently);

(iii) The purpose for which the information was furnished to EPA and the approximate date of submission, if known;

(iv) Whether a business confidentiality claim accompanied the information when it was received by EPA;

(v) Measures taken by the business to guard against undesired disclosure of the information to others;

(vi) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;

(vii) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies, and a copy of any such determination, or reference to it, if available;

(viii) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business' competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects; and

(ix) Whether the business asserts that the information is voluntarily submitted information as defined in § 2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

(5) To the extent that the EPA office already possesses the relevant facts, the notice need not solicit responses to the matters addressed in paragraphs

(e)(4) (i) through (ix) of this section, although the notice shall request confirmation of EPA's understanding of such facts where appropriate.

(6) The notice shall refer to § 2.205(c) and shall include the statement prescribed by § 2.203(a).

(f) *Materials to be furnished to EPA legal office.* When a matter is referred to an EPA legal office under paragraph (d)(1) of this section, the EPA office taking action under this section shall forward promptly to the EPA legal office the following items:

(1) A copy of the information in question, or (where the quantity or form of the information makes forwarding a copy of the information impractical) representative samples, a description of the information, or both;

(2) A description of the circumstances and date of EPA's acquisition of the information;

(3) The name, address, and telephone number of the EPA employee(s) most familiar with the information;

(4) The name, address and telephone number of each business which asserts an applicable business confidentiality claim;

(5) A copy of each applicable claim (or the record of the assertion of the claim), and a description of when and how each claim was asserted;

(6) Comments concerning each business's compliance or noncompliance with applicable requirements of § 2.203;

(7) A copy of any request for release of the information pending under 5 U.S.C. 552;

(8) A copy of the business's comments on whether the information is entitled to confidential treatment;

(9) The office's comments concerning the appropriate substantive criteria under this subpart, and information the office possesses concerning the information's entitlement to confidential treatment; and

(10) Copies of other correspondence or memoranda which pertain to the matter.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40000, Sept. 8, 1978; 50 FR 51661, Dec. 18, 1985]

§ 2.205 Final confidentiality determination by EPA legal office.

(a) *Role of EPA legal office.* (1) The appropriate EPA legal office (see paragraph (i) of this section) is responsible for making the final administrative determination of whether or not business information covered by a business confidentiality claim is entitled to confidential treatment under this subpart.

(2) When a request for release of the information under 5 U.S.C. 552 is pending, the EPA legal office's determination shall serve as the final determination on appeal from an initial denial of the request.

(i) If the initial denial was issued under § 2.204(b)(1), a final determination by the EPA legal office is necessary only if the requestor has actually filed an appeal.

(ii) If the initial denial was issued under § 2.204(d)(1), however, the EPA legal office shall issue a final determination in every case, unless the request has been withdrawn. (Initial denials under § 2.204(d)(1) are of a procedural nature, to allow further inquiry into the merits of the matter, and a requestor is entitled to a decision on the merits.) If an appeal from such a denial has not been received by the EPA Freedom of Information Officer on the tenth working day after issuance of the denial, the matter shall be handled as if an appeal had been received on that day, for purposes of establishing a schedule for issuance of an appeal decision under § 2.117 of this part.

(b) *Comment period; extensions; untimeliness as waiver of claim.* (1) Each business which has been furnished the notice and opportunity to comment prescribed by § 2.204(d)(1) and § 2.204(e) shall furnish its comments to the office specified in the notice in time to be postmarked or hand delivered to that office not later than the date specified in the notice (or the date established in lieu thereof under this section).

(2) The period for submission of comments may be extended if, before the comments are due, a request for an extension of the comment period is made by the business and approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person

whose request for release of the information under 5 U.S.C. 552 is pending.

(3) The period for submission of comments by a business may be shortened in the manner described in paragraph (g) of this section.

(4) If a business's comments have not been received by the specified EPA office by the date they are due (including any approved extension), that office shall promptly inquire whether the business has complied with paragraph (b)(1) of this section. If the business has complied with paragraph (b)(1) but the comments have been lost in transmission, duplicate comments shall be requested.

(c) *Confidential treatment of comments from business.* If information submitted to EPA by a business as part of its comments under this section pertains to the business's claim, is not otherwise possessed by EPA, and is marked when received in accordance with § 2.203(b), it will be regarded by EPA as entitled to confidential treatment and will not be disclosed by EPA without the business's consent, unless its disclosure is duly ordered by a Federal court, notwithstanding other provisions of this subpart to the contrary.

(d) *Types of final determinations; matters to be considered.* (1) If the EPA legal office finds that a business has failed to furnish comments under paragraph (b) of this section by the specified due date, it shall determine that the business has waived its claim. If, after application of the preceding sentence, no claim applies to the information, the office shall determine that the information is not entitled to confidential treatment under this subpart and, subject to § 2.210, is available to the public.

(2) In all other cases, the EPA legal office shall consider each business's claim and comments, the various provisions of this subpart, any previously-issued determinations under this subpart which are pertinent, the materials furnished it under § 2.204(f), and such other materials as it finds appropriate. With respect to each claim, the office shall determine whether or not the information is entitled to confidential treatment for the benefit of the business that asserted the claim, and the period of any such entitlement (e.g., until a certain date, until the occurrence of a specified event, or permanently), and shall take further action under paragraph (e) or (f) of this section, as appropriate.

(3) Whenever the claims of two or more businesses apply to the same information, the EPA legal office shall take action appropriate under the particular circumstances to protect the interests of all persons concerned (including any person whose request for the information is pending under 5 U.S.C. 552).

(e) *Determination that information is entitled to confidential treatment.* If the EPA legal office determines that the information is entitled to confidential treatment for the full period requested by the business which made the claim, EPA shall maintain the information in confidence for such period, subject to paragraph (h) of this section, § 2.209, and the other provisions of this subpart which authorize disclosure in specified circumstances, and the office shall so inform the business. If any person's request for the release of the information is then pending under 5 U.S.C. 552, the EPA legal office shall issue a final determination denying that request.

(f) *Determination that information is not entitled to confidential treatment; notice; waiting period; release of information.* (1) Notice of denial (or partial denial) of a business confidentiality claim, in the form prescribed by paragraph (f)(2) of this section, shall be furnished—

(i) By the EPA office taking action under § 2.204, to each business on behalf of which a claim has been made, whenever § 2.204(d)(2) requires such notice; and

(ii) By the EPA legal office taking action under this section, to each business which has asserted a claim applicable to the information and which has furnished timely comments under paragraph (b) of this section, whenever the EPA legal office determines that the information is not entitled to confidential treatment under this subpart for the benefit of the business, or determines that the period of any entitlement to confidential treatment is shorter than that requested by the business.

(2) The notice prescribed by paragraph (f)(1) of this section shall be

written, and shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact of receipt and the date of receipt. The notice shall state the basis for the determination, that it constitutes final agency action concerning the business confidentiality claim, and that such final agency action may be subject to judicial review under Chapter 7 of Title 5, United States Code. With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the tenth working day after the date of the business's receipt of the written notice (or on such later date as is established in lieu thereof by the EPA legal office under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination, and to obtain preliminary injunctive relief against disclosure. The notice shall further state that if such an action is timely commenced, EPA may nonetheless make the information available to the public (in the absence of an order by the court to the contrary), once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or whenever it appears to the EPA legal office, after reasonable notice to the business, that the business is not taking appropriate measures to obtain a speedy resolution of the action. If the information has been found to be temporarily entitled to confidential treatment, the notice shall further state that the information will not be disclosed prior to the end of the period of such temporary entitlement to confidential treatment.

(3) The period established in a notice under paragraph (f)(2) of this section for commencement of an action to obtain judicial review may be extended if, before the expiration of such period, a request for an extension is made by the business and approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person whose request for release of the information under 5 U.S.C. 552 is pending.

(4) After the expiration of any period of temporary entitlement to confidential treatment, a determination under this paragraph (f) shall be implemented by the EPA legal office by making the information available to the public (in the absence of a court order prohibiting disclosure) whenever—

(i) The period provided for commencement by a business of an action to obtain judicial review of the determination has expired without notice to the EPA legal office of commencement of such an action;

(ii) The court, in a timely-commenced action, has denied the business' motion for a preliminary injunction, or has otherwise upheld the EPA determination; or

(iii) The EPA legal office, after reasonable notice has been provided to the business, finds that the business is not taking appropriate measures to obtain a speedy resolution of the timely-commenced action.

(5) Any person whose request for release of the information under 5 U.S.C. 552 is pending at the time notice is given under paragraph (f)(2) of this section shall be furnished a determination under 5 U.S.C. 552 stating the circumstances under which the information will be released.

(g) *Emergency situations.* If the General Counsel finds that disclosure of information covered by a claim would be helpful in alleviating a situation posing an imminent and substantial danger to public health or safety, he may prescribe and make known to interested persons such shorter comment period (paragraph (b) of this section), post-determination waiting period (paragraph (f) of this section), or both, as he finds necessary under the circumstances.

(h) *Modification of prior determinations.* A determination that information is entitled to confidential treatment for the benefit of a business, made under this subpart by an EPA legal office, shall continue in effect in accordance with its terms until an EPA legal office taking action under this section, or under § 2.206 or § 2.207, issues a final determination stating that the earlier determination no

longer describes correctly the information's entitlement to confidential treatment because of change in the applicable law, newly-discovered or changed facts, or because the earlier determination was clearly erroneous. If an EPA legal office tentatively concludes that such an earlier determination is of questionable validity, it shall so inform the business, and shall afford the business an opportunity to furnish comments on pertinent issues in the manner described by § 2.204(e) and paragraph (b) of this section. If, after consideration of any timely comments submitted by the business, the EPA legal office makes a revised final determination that the information is not entitled to confidential treatment, or that the period of entitlement to such treatment will end sooner than it would have ended under the earlier determination, the office will follow the procedure described in paragraph (f) of this section. Determinations under this section may be made only by, or with the concurrence of, the General Counsel.

(i) *Delegation and redelegation of authority.* Unless the General Counsel otherwise directs, or this subpart otherwise specifically provides, determinations and actions required by this subpart to be made or taken by an EPA legal office shall be made or taken by the appropriate Regional counsel whenever the EPA office taking action under § 2.204 or § 2.206(b) is under the supervision of a Regional Administrator, and by the General Counsel in all other cases. The General Counsel may redelegate any or all of his authority under this subpart to any attorney employed by EPA on a full-time basis under the General Counsel's supervision. A Regional Counsel may redelegate any or all of his authority under this subpart to any attorney employed by EPA on a full-time basis under the Regional counsel's supervision.

[41 FR 36902, Sept. 1, 1976, as amended at 50 FR 51661, Dec. 18, 1985]

§ 2.206 Advance confidentiality determinations.

(a) An advance determination under this section may be issued by an EPA legal office if—

(1) EPA has requested or demanded that a business furnish business information to EPA;

(2) The business asserts that the information, if submitted, would constitute voluntarily submitted information under § 2.201(i);

(3) The business will voluntarily submit the information for use by EPA only if EPA first determines that the information is entitled to confidential treatment under this subpart; and

(4) The EPA office which desires submission of the information has requested that the EPA legal office issue a determination under this section.

(b) The EPA office requesting an advance determination under this section shall—

(1) Arrange to have the business furnish directly to the EPA legal office a copy of the information (or, where feasible, a description of the nature of the information sufficient to allow a determination to be made), as well as the business's comments concerning the matters addressed in § 2.204(e)(4), excluding, however, matters addressed in § 2.204 (e)(4)(iii) and (e)(4)(iv); and

(2) Furnish to the EPA legal office the materials referred to in § 2.204(f) (3), (7), (8), and (9).

(c) In making a determination under this section, the EPA legal office shall first determine whether or not the information would constitute voluntarily submitted information under § 2.201(i). If the information would constitute voluntarily submitted information, the legal office shall further determine whether the information is entitled to confidential treatment.

(d) If the EPA legal office determines that the information would not constitute voluntarily submitted information, or determines that it would constitute voluntarily submitted information but would not be entitled to confidential treatment, it shall so inform the business and the EPA office which requested the determination, stating the basis of the determination, and shall return to the business all copies of the information which it may have received from the business (except that if a request under 5 U.S.C. 552 for release of the information is received while the EPA legal office is in possession of the information, the legal office

shall retain a copy of the information, but shall not disclose it unless ordered by a Federal court to do so). The legal office shall not disclose the information to any other EPA office or employee and shall not use the information for any purpose except the determination under this section, unless otherwise directed by a Federal court.

(e) If the EPA legal office determines that the information would constitute voluntarily submitted information and that it is entitled to confidential treatment, it shall so inform the EPA office which requested the determination and the business which submitted it, and shall forward the information to the EPA office which requested the determination.

§ 2.207 Class determinations.

(a) The General Counsel may make and issue a class determination under this section if he finds that—

(1) EPA possesses, or is obtaining, related items of business information;

(2) One or more characteristics common to all such items of information will necessarily result in identical treatment for each such item under one or more of the provisions in this subpart, and that it is therefore proper to treat all such items as a class for one or more purposes under this subpart; and

(3) A class determination would serve a useful purpose.

(b) A class determination shall clearly identify the class of information to which it pertains.

(c) A class determination may state that all of the information in the class—

(1) Is, or is not, voluntarily submitted information under § 2.201(i);

(2) Is, or is not, governed by a particular section of this subpart, or by a particular set of substantive criteria under this subpart;

(3) Fails to satisfy one or more of the applicable substantive criteria, and is therefore ineligible for confidential treatment;

(4) Satisfies one or more of the applicable substantive criteria; or

(5) Satisfies one or more of the applicable substantive criteria during a certain period, but will be ineligible for confidential treatment thereafter.

(d) The purpose of a class determination is simply to make known the Agency's position regarding the manner in which information within the class will be treated under one or more of the provisions of this subpart. Accordingly, the notice of opportunity to submit comments referred to in § 2.204(d)(1)(ii) and § 2.205(b), and the list of materials required to be furnished to the EPA legal office under § 2.204(d)(1)(iii), may be modified to reflect the fact that the class determination has made unnecessary the submission of materials pertinent to one or more issues. Moreover, in appropriate cases, action based on the class determination may be taken under § 2.204(b)(1), § 2.204(d), § 2.205(d), or § 2.206. However, the existence of a class determination shall not, of itself, affect any right a business may have to receive any notice under § 2.204(d)(2) or § 2.205(f).

§ 2.208 Substantive criteria for use in confidentiality determinations.

Determinations issued under §§ 2.204 through 2.207 shall hold that business information is entitled to confidential treatment for the benefit of a particular business if—

(a) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;

(b) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;

(c) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);

(d) No statute specifically requires disclosure of the information; and

(e) Either—

(1) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position; or

(2) The information is voluntarily submitted information (see § 2.201(i)),

and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future.

§ 2.209 Disclosure in special circumstances.

(a) *General.* Information which, under this subpart, is not available to the public may nonetheless be disclosed to the persons, and in the circumstances, described by paragraphs (b) through (g) of this section. (This section shall not be construed to restrict the disclosure of information which has been determined to be available to the public. However, business information for which a claim of confidentiality has been asserted shall be treated as being entitled to confidential treatment until there has been a determination in accordance with the procedures of this subpart that the information is not entitled to confidential treatment.)

(b) *Disclosure to Congress or the Comptroller General.* (1) Upon receipt of a written request by the Speaker of the House, President of the Senate, chairman of a committee or subcommittee, or the Comptroller General, as appropriate, EPA will disclose business information to either House of Congress, to a committee or subcommittee of Congress, or to the Comptroller General, unless a statute forbids such disclosure.

(2) If the request is for business information claimed as confidential or determined to be confidential, the EPA office processing the request shall provide notice to each affected business of the type of information disclosed and to whom it is disclosed. Notice shall be given at least ten days prior to disclosure, except where it is not possible to provide notice ten days in advance of any date established by the requesting body for responding to the request. Where ten days advance notice cannot be given, as much advance notice as possible shall be provided. Where notice cannot be given before the date established by the requesting body for responding to the request, notice shall be given as promptly after disclosure as possible. Such notice may be given by notice published in the FEDERAL REGISTER or by letter sent by certified mail, return receipt requested, or telegram. However, if the requesting body asks in writing that no notice under this subsection be given, EPA will give no notice.

(3) At the time EPA discloses the business information, EPA will inform the requesting body of any unresolved business confidentiality claim known to cover the information and of any determination under this subpart that the information is entitled to confidential treatment.

(c) *Disclosure to other Federal agencies.* EPA may disclose business information to another Federal agency if—

(1) EPA receives a written request for disclosures of the information from a duly authorized officer or employee of the other agency or on the initiative of EPA when such disclosure is necessary to enable the other agency to carry out a function on behalf of EPA;

(2) The request, if any, sets forth the official purpose for which the information is needed;

(3) When the information has been claimed as confidential or has been determined to be confidential, the responsible EPA office provides notice to each affected business of the type of information to be disclosed and to whom it is to be disclosed. At the discretion of the office, such notice may be given by notice published in the FEDERAL REGISTER at least 10 days prior to disclosure, or by letter sent by certified mail return receipt requested or telegram either of which must be received by the affected business at least 10 days prior to disclosure. However, no notice shall be required when EPA furnishes business information to another Federal agency to perform a function on behalf of EPA, including but not limited to—

(i) Disclosure to the Department of Justice for purposes of investigation or prosecution of civil or criminal violations of Federal law related to EPA activities;

(ii) Disclosure to the Department of Justice for purposes of representing EPA in any matter; or

(iii) Disclosure to any Federal agency for purposes of performing an EPA statutory function under an interagency agreement.

(4) EPA notifies the other agency of any unresolved business confidentiality

claim covering the information and of any determination under this subpart that the information is entitled to confidential treatment, and that further disclosure of the information may be a violation of 18 U.S.C. 1905; and

(5) The other agency agrees in writing not to disclose further any information designated as confidential unless—

(i) The other agency has statutory authority both to compel production of the information and to make the proposed disclosure, and the other agency has, prior to disclosure of the information to anyone other than its officers and employees, furnished to each affected business at least the same notice to which the affected business would be entitled under this subpart;

(ii) The other agency has obtained the consent of each affected business to the proposed disclosure; or

(iii) The other agency has obtained a written statement from the EPA General Counsel or an EPA Regional Counsel that disclosure of the information would be proper under this subpart.

(d) *Court-ordered disclosure.* EPA may disclose any business information in any manner and to the extent ordered by a Federal court. Where possible, and when not in violation of a specific directive from the court, the EPA office disclosing information claimed as confidential or determined to be confidential shall provide as much advance notice as possible to each affected business of the type of information to be disclosed and to whom it is to be disclosed, unless the affected business has actual notice of the court order. At the discretion of the office, subject to any restrictions by the court, such notice may be given by notice in the FEDERAL REGISTER, letter sent by certified mail return receipt requested, or telegram.

(e) *Disclosure within EPA.* An EPA office, officer, or employee may disclose any business information to another EPA office, officer, or employee with an official need for the information.

(f) *Disclosure with consent of business.* EPA may disclose any business information to any person if EPA has obtained the prior consent of each affected business to such disclosure.

(g) *Record of disclosures to be maintained.* Each EPA office which discloses information to Congress, a committee or subcommittee of Congress, the Comptroller General, or another Federal agency under the authority of paragraph (b) or (c) of this section, shall maintain a record of the fact of such disclosure for a period of not less than 36 months after such disclosure. Such a record, which may be in the form of a log, shall show the name of the affected businesses, the date of disclosure, the person or body to whom disclosure was made, and a description of the information disclosed.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40000, Sept. 8, 1978; 50 FR 51661, Dec. 18, 1985]

§ 2.210 Nondisclosure for reasons other than business confidentiality or where disclosure is prohibited by other statute.

(a) Information which is not entitled to confidential treatment under this subpart shall be made available to the public (using the procedures set forth in §§ 2.204 and 2.205) if its release is requested under 5 U.S.C. 552, unless EPA determines (under subpart A of this part) that, for reasons other than reasons of business confidentiality, the information is exempt from mandatory disclosure and cannot or should not be made available to the public. Any such determination under subpart A shall be coordinated with actions taken under this subpart for the purpose of avoiding delay in responding to requests under 5 U.S.C. 552.

(b) Notwithstanding any other provision of this subpart, if any statute not cited in this subpart appears to require EPA to give confidential treatment to any business information for reasons of business confidentiality, the matter shall be referred promptly to an EPA legal office for resolution. Pending resolution, such information shall be treated as if it were entitled to confidential treatment.

§ 2.211 Safeguarding of business information; penalty for wrongful disclosure.

(a) No EPA officer or employee may disclose, or use for his or her private gain or advantage, any business information which came into his or her possession, or to which he or she gained

access, by virtue of his or her official position or employment, except as authorized by this subpart.

(b) Each EPA officer or employee who has custody or possession of business information shall take appropriate measures to properly safeguard such information and to protect against its improper disclosure.

(c) Violation of paragraph (a) or (b) of this section shall constitute grounds for dismissal, suspension, fine, or other adverse personnel action. Willful violation of paragraph (a) of this section may result in criminal prosecution under 18 U.S.C. 1905 or other applicable statute.

(d) Each contractor or subcontractor with the United States Government, and each employee of such contractor or subcontractor, who is furnished business information by EPA under §2.301(h), §2.302(h), §2.304(h), §2.305(h), §2.306(j), §2.307(h), §2.308(i), or §2.310(h) shall use or disclose that information only as permitted by the contract or subcontract under which the information was furnished. Contractors or subcontractors shall take steps to properly safeguard business information including following any security procedures for handling and safeguarding business information which are contained in any manuals, procedures, regulations, or guidelines provided by EPA. Any violation of this paragraph shall constitute grounds for suspension or debarment of the contractor or subcontractor in question. A willful violation of this paragraph may result in criminal prosecution.

[41 FR 36902, Sept. 1, 1976, as amended at 50 FR 51662, Dec. 18, 1985; 58 FR 461, Jan. 5, 1993]

§ 2.212 Establishment of control offices for categories of business information.

(a) The Administrator, by order, may establish one or more mutually exclusive categories of business information, and may designate for each such category an EPA office (hereinafter referred to as a *control office*) which shall have responsibility for taking actions (other than actions required to be taken by an EPA legal office) with respect to all information within such category.

(b) If a control office has been assigned responsibility for a category of business information, no other EPA office, officer, or employee may make available to the public (or otherwise disclose to persons other than EPA officers and employees) any information in that category without first obtaining the concurrence of the control office. Requests under 5 U.S.C. 552 for release of such information shall be referred to the control office.

(c) A control office shall take the actions and make the determinations required by §2.204 with respect to all information in any category for which the control office has been assigned responsibility.

(d) A control office shall maintain a record of the following, with respect to items of business information in categories for which it has been assigned responsibility:

(1) Business confidentiality claims;

(2) Comments submitted in support of claims;

(3) Waivers and withdrawals of claims;

(4) Actions and determinations by EPA under this subpart;

(5) Actions by Federal courts; and

(6) Related information concerning business confidentiality.

§ 2.213 Designation by business of addressee for notices and inquiries.

(a) A business which wishes to designate a person or office as the proper addressee of communications from EPA to the business under this subpart may do so by furnishing in writing to the Headquarters Freedom of Information Operations (1105), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, the following information: The name and address of the business making the designation; the name, address, and telephone number of the designated person or office; and a request that EPA inquiries and communications (oral and written) under this subpart, including inquiries and notices which require reply within deadlines if the business is to avoid waiver of its rights under this subpart, be furnished to the designee pursuant to this section. Only one person or office may serve at any one time

as a business's designee under this subpart.

(b) If a business has named a designee under this section, the following EPA inquiries and notices to the business shall be addressed to the designee:

(1) Inquiries concerning a business's desire to assert a business confidentiality claim, under § 2.204(c)(2)(i)(A);

(2) Notices affording opportunity to substantiate confidentiality claims, under § 2.204(d)(1) and § 2.204(e);

(3) Inquires concerning comments, under § 2.205(b)(4);

(4) Notices of denial of confidential treatment and proposed disclosure of information, under § 2.205(f);

(5) Notices concerning shortened comment and/or waiting periods under § 2.205(g);

(6) Notices concerning modifications or overrulings of prior determinations, under § 2.205(h);

(7) Notices to affected businesses under §§ 2.301(g) and 2.301(h) and analogous provisions in §§ 2.302, 2.303, 2.304, 2.305, 2.306, 2.307, and 2.308; and

(8) Notices to affected businesses under § 2.209.

(c) The Freedom of Information Officer shall, as quickly as possible, notify all EPA offices that may possess information submitted by the business to EPA, the Regional Freedom of Information Offices, the Office of General Counsel, and the offices of Regional Counsel of any designation received under this section. Businesses making designations under this section should bear in mind that several working days may be required for dissemination of this information within EPA and that some EPA offices may not receive notice of such designations.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40001, Sept. 8, 1978]

§ 2.214 Defense of Freedom of Information Act suits; participation by affected business.

(a) In making final confidentiality determinations under this subpart, the EPA legal office relies to a large extent upon the information furnished by the affected business to substantiate its claim of confidentiality. The EPA legal office may be unable to verify the accuracy of much of the information submitted by the affected business.

(b) If the EPA legal office makes a final confidentiality determination under this subpart that certain business information is entitled to confidential treatment, and EPA is sued by a requester under the Freedom of Information Act for disclosure of that information, EPA will:

(1) Notify each affected business of the suit within 10 days after service of the complaint upon EPA;

(2) Where necessary to preparation of EPA's defense, call upon each affected business to furnish assistance; and

(3) Not oppose a motion by any affected business to intervene as a party to the suit under rule 24(b) of the Federal Rules of Civil Procedure.

(c) EPA will defend its final confidentiality determination, but EPA expects the affected business to cooperate to the fullest extent possible in this defense.

[43 FR 40001, Sept. 8, 1978]

§ 2.215 Confidentiality agreements.

(a) No EPA officer, employee, contractor, or subcontractor shall enter into any agreement with any affected business to keep business information confidential unless such agreement is consistent with this subpart. No EPA officer, employee, contractor, or subcontractor shall promise any affected business that business information will be kept confidential unless the promise is consistent with this subpart.

(b) If an EPA office has requested information from a State, local, or Federal agency and the agency refuses to furnish the information to EPA because the information is or may constitute confidential business information, the EPA office may enter into an agreement with the agency to keep the information confidential, notwithstanding the provisions of this subpart. However, no such agreement shall be made unless the General Counsel determines that the agreement is necessary and proper.

(c) To determine that an agreement proposed under paragraph (b) of this section is necessary, the General Counsel must find:

(1) The EPA office requesting the information needs the information to perform its functions;

(2) The agency will not furnish the information to EPA without an agreement by EPA to keep the information confidential; and

(3) Either:

(i) EPA has no statutory power to compel submission of the information directly from the affected business, or

(ii) While EPA has statutory power to compel submission of the information directly from the affected business, compelling submission of the information directly from the business would—

(A) Require time in excess of that available to the EPA office to perform its necessary work with the information,

(B) Duplicate information already collected by the other agency and overly burden the affected business, or

(C) Overly burden the resources of EPA.

(d) To determine that an agreement proposed under paragraph (b) of this section is proper, the General Counsel must find that the agreement states—

(1) The purpose for which the information is required by EPA;

(2) The conditions under which the agency will furnish the information to EPA;

(3) The information subject to the agreement;

(4) That the agreement does not cover information acquired by EPA from another source;

(5) The manner in which EPA will treat the information; and

(6) That EPA will treat the information in accordance with the agreement subject to an order of a Federal court to disclose the information.

(e) EPA will treat any information acquired pursuant to an agreement under paragraph (b) of this section in accordance with the procedures of this subpart except where the agreement specifies otherwise.

[43 FR 40001, Sept. 8, 1978]

§§ 2.216–2.300 [Reserved]

§ 2.301 Special rules governing certain information obtained under the Clean Air Act.

(a) *Definitions.* For the purpose of this section:

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

(2)(i) *Emission data* means, with reference to any source of emission of any substance into the air—

(A) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

(ii) Notwithstanding paragraph (a)(2)(i) of this section, the following information shall be considered to be *emission data* only to the extent necessary to allow EPA to disclose publicly that a source is (or is not) in compliance with an applicable standard or limitation, or to allow EPA to demonstrate the feasibility, practicability, or attainability (or lack thereof) of an existing or proposed standard or limitation:

(A) Information concerning research, or the results of research, on any project, method, device or installation (or any component thereof) which was produced, developed, installed, and used only for research purposes; and

(B) Information concerning any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.

(3) *Standard or limitation* means any emission standard or limitation established or publicly proposed pursuant to

the Act or pursuant to any regulation under the Act.

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(5) *Manufacturer* has the meaning given it in section 216(1) of the Act, 42 U.S.C. 7550(1).

(b) *Applicability.* (1) This section applies to business information which was—

(i) Provided or obtained under section 114 of the Act, 42 U.S.C. 7414, by the owner or operator of any stationary source, for the purpose (A) of developing or assisting in the development of any implementation plan under section 110 or 111(d) of the Act, 42 U.S.C. 7410, 7411(d), any standard of performance under section 111 of the Act, 42 U.S.C. 7411, or any emission standard under section 112 of the Act, 42 U.S.C. 7412, (B) of determining whether any person is in violation of any such standard or any requirement of such a plan, or (C) of carrying out any provision of the Act (except a provision of Part II of the Act with respect to a manufacturer of new motor vehicles or new motor vehicle engines);

(ii) Provided or obtained under section 208 of the Act, 42 U.S.C. 7542, for the purpose of enabling the Administrator to determine whether a manufacturer has acted or is acting in compliance with the Act and regulations under the Act, or provided or obtained under section 206(c) of the Act, 42 U.S.C. 7525(c); or

(iii) Provided in response to a subpoena for the production of papers, books, or documents issued under the authority of section 307(a) of the Act, 42 U.S.C. 7607(a).

(2) Information will be considered to have been provided or obtained under section 114 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 114, or if its submission could have been required under section 114, regardless of whether section 114 was cited as the authority for any request for the information, whether an order to provide the information was issued under section 113(a) of the Act, 42 U.S.C. 7413(a), whether an action was brought under section 113(b) of the Act, 42 U.S.C. 7413(b), or whether the information was provided directly to EPA or through some third person.

(3) Information will be considered to have been provided or obtained under section 208 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 208, or if its submission could have been required under section 208, regardless of whether section 208 was cited as the authority for any request for the information, whether an action was brought under section 204 of the Act, 42 U.S.C. 7523, or whether the information was provided directly to EPA or through some third person.

(4) Information will be considered to have been provided or obtained under section 206(c) of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 206(c), or if its submission could have been required under section 206(c) regardless of whether section 206(c) was cited as authority for any request for the information, whether an action was brought under section 204 of the Act, 42 U.S.C. 7523, or whether the information was provided directly to EPA or through some third person.

(5) Information will be considered to have been provided or obtained under section 307(a) of the Act if it was provided in response to a subpoena issued under section 307(a), or if its production could have been required by subpoena under section 307(a), regardless of whether section 307(a) was cited as the authority for any request for the information, whether a subpoena was issued by EPA, whether a court issued an order under section 307(a), or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules that apply without change.* Except as otherwise provided in paragraph (d) of this section, §§ 2.201 through 2.207, § 2.209, and §§ 2.211 through 2.215 apply without change to information to which this section applies.

(d) *Data submitted under 40 CFR part 98.* (1) Sections 2.201 through 2.215 do not apply to data submitted under 40 CFR part 98 that EPA has determined, pursuant to sections 114(c) and 307(d) of

the Clean Air Act, to be either of the following:

(i) Emission data.

(ii) Data not otherwise entitled to confidential treatment pursuant to section 114(c) of the Clean Air Act.

(2) Except as otherwise provided in paragraphs (d)(2) and (d)(4) of this section, §§ 2.201 through 2.215 do not apply to data submitted under 40 CFR part 98 data that EPA has determined, pursuant to sections 114(c) and 307(d) of the Clean Air Act, to be entitled to confidential treatment. EPA shall treat that information as confidential in accordance with the provisions of § 2.211, subject to paragraph (d)(4) of this section and § 2.209.

(3) Upon receiving a request under 5 U.S.C. 552 for data submitted under 40 CFR part 98 that EPA has determined, pursuant to sections 114(c) and 307(d) of the Clean Air Act, to be entitled to confidential treatment, the EPA office shall furnish the requestor a notice that the information has been determined to be entitled to confidential treatment and that the request is therefore denied. The notice shall include or cite to the appropriate EPA determination.

(4) Modification of prior confidentiality determination. A determination made pursuant to sections 114(c) and 307(d) of the Clean Air Act that information submitted under 40 CFR part 98 is entitled to confidential treatment shall continue in effect unless, subsequent to the confidentiality determination, EPA takes one of the following actions:

(i) EPA determines, pursuant to sections 114(c) and 307(d) of the Clean Air Act, that the information is emission data or data not otherwise entitled to confidential treatment under section 114(c) of the Clean Air Act.

(ii) The Office of General Counsel issues a final determination, based on the criteria in § 2.208, stating that the information is no longer entitled to confidential treatment because of change in the applicable law or newly-discovered or changed facts. Prior to making such final determination, EPA shall afford the business an opportunity to submit comments on pertinent issues in the manner described by §§ 2.204(e) and 2.205(b). If, after consideration of any timely comments submitted by the business, the Office of General Counsel makes a revised final determination that the information is not entitled to confidential treatment under section 114(c) of the Clean Air Act, EPA will notify the business in accordance with the procedures described in § 2.205(f)(2).

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that information which is emission data, a standard or limitation, or is collected pursuant to section 211(b)(2)(A) of the Act is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) *Availability of information not entitled to confidential treatment.* Section 2.210 does not apply to information to which this section applies. Emission data, standards or limitations, and any other information provided under section 114 or 208 of the Act which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public notwithstanding any other provision of this part. Emission data and standards or limitations provided in response to a subpoena issued under section 307(a) of the Act shall be available to the public notwithstanding any other provision of this part. Information (other than emission data and standards or limitations) provided in response to a subpoena issued under section 307(a) of the Act, which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public, unless EPA determines that the information is exempt from mandatory disclosure under 5 U.S.C. 552(b) for reasons other than reasons of business confidentiality and cannot or should not be made available to the public.

(g) *Disclosure of information relevant to a proceeding.* (1) Under sections 114, 208 and 307 of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this

subpart. Release of information because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) In connection with any proceeding other than a proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies which may be entitled to confidential treatment may be made available to the public under this paragraph (g)(2). No information shall be made available to the public under this paragraph (g)(2) until any affected business has been informed that EPA is considering making the information available to the public under this paragraph (g)(2) in connection with an identified proceeding, and has afforded the business a reasonable period for comment (such notice and opportunity to comment may be afforded in connection with the notice prescribed by § 2.204(d)(1) and § 2.204(e)). Information may be made available to the public under this paragraph (g)(2) only if, after consideration of any timely comments submitted by the business, the General Counsel determines that the information is relevant to the subject of the proceeding and the EPA office conducting the proceeding determines that the public interest would be served by making the information available to the public. Any affected business shall be given at least 5 days' notice by the General Counsel prior to making the information available to the public.

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3), shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct his request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the business, the presiding officer determines in writing that (i) the party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the

proceeding will be significantly impaired unless the information is disclosed to him, and (ii) any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and to the public interest that would result from the disclosure. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information to confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(h) *Disclosure to authorized representatives.* (1) Under sections 114, 208 and 307(a) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h) (2) or (3) of this section.

(2)(i) A person under contract or subcontract to the United States government to perform work in support of EPA in connection with the Act or regulations which implement the Act may be considered an authorized representative of the United States for purposes of this paragraph (h). For purposes of this section, the term ''contract'' includes grants and cooperative agreements under the Environmental Programs Assistance Act of 1984 (Pub. L. 98–313), and the term ''contractor'' includes grantees and cooperators under the Environmental Programs Assistance Act of 1984. Subject to the limitations in this paragraph (h)(2), information to which this section applies may be disclosed:

(A) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract; or

(B) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract.

(ii) No information shall be disclosed under this paragraph (h)(2), unless this contract or subcontract in question provides:

(A) That the contractor or subcontractor and the contractor's or subcontractor's employees shall use the information only for the purpose of carrying out the work required by the contract or subcontract, shall refrain from disclosing the information to anyone other than EPA without the prior written approval of each affected business or of an EPA legal office and shall return to EPA all copies of the information (and any abstracts or extracts therefrom) upon request by the EPA program office, whenever the information is no longer required by the contractor or subcontractor for the performance of the work required under the contract or subcontract, or upon completion of the contract or subcontract (where the information was provided to the contractor or subcontractor by an agency other than EPA, the contractor may disclose or return the information to that agency);

(B) That the contractor or subcontractor shall obtain a written agreement to honor such terms of the contract or subcontract from each of the contractor's or subcontractor's employees who will have access to the information, before such employee is allowed such access; and

(C) That the contractor or subcontractor acknowledges and agrees that the contract or subcontract provisions concerning the use and disclosure of business information are included for the benefit of, and shall be enforceable by, both the United States government

and any affected business having an interest in information concerning it supplied to the contractor or subcontractor by the United States government under the contract or subcontract.

(iii) No information shall be disclosed under this paragraph (h)(2) until each affected business has been furnished notice of the contemplated disclosure by the EPA program office and has been afforded a period found reasonable by that office (not less than 5 working days) to submit its comments. Such notice shall include a description of the information to be disclosed, the identity of the contractor or subcontractor, the contract or subcontract number, if any, and the purposes to be served by the disclosure.

(iv) The EPA program office shall prepare a record of each disclosure under this paragraph (h)(2), showing the contractor or subcontractor, the contract or subcontract number, the information disclosed, the date(s) of disclosure, and each affected business. The EPA program office shall maintain the record of disclosure and the determination of necessity prepared under paragraph (h)(2)(i) of this section for a period of not less than 36 months after the date of the disclosure.

(3) A State or local governmental agency which has duties or responsibilities under the Act, or under regulations which implement the Act, may be considered an authorized representative of the United States for purposes of this paragraph (h). Information to which this section applies may be furnished to such an agency at the agency's written request, but only if—

(i) The agency has first furnished to the EPA office having custody of the information a written opinion from the agency's chief legal officer or counsel stating that under applicable State or local law the agency has the authority to compel a business which possesses such information to disclose it to the agency, or

(ii) Each affected business is informed of those disclosures under this paragraph (h)(3) which pertain to it, and the agency has shown to the satisfaction of an EPA legal office that the agency's use and disclosure of such information will be governed by State or local law and procedures which will provide adequate protection to the interests of affected businesses.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40002, Sept. 8, 1978; 43 FR 42251, Sept. 20, 1978; 50 FR 51662, Dec. 18, 1985; 58 FR 461, Jan. 5, 1993; 58 FR 5061, Jan. 19, 1993; 58 FR 7189, Feb. 5, 1993; 76 FR 30817, May 26, 2011; 76 FR 64015, Oct. 17, 2011]

§ 2.302 Special rules governing certain information obtained under the Clean Water Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Clean Water Act, as amended, 33 U.S.C. 1251 *et seq.*

(2)(i) *Effluent data* means, with reference to any source of discharge of any pollutant (as that term is defined in section 502(6) of the Act, 33 U.S.C. 1362 (6))—

(A) Information necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of any pollutant which has been discharged by the source (or of any pollutant resulting from any discharge from the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of the pollutants which, under an applicable standard or limitation, the source was authorized to discharge (including, to the extent necessary for such purpose, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

(ii) Notwithstanding paragraph (a)(2)(i) of this section, the following information shall be considered to be *effluent data* only to the extent necessary to allow EPA to disclose publicly that a source is (or is not) in compliance with an applicable standard or limitation, or to allow EPA to demonstrate the feasibility, practicability,

or attainability (or lack thereof) of an existing or proposed standard or limitation:

(A) Information concerning research, or the results of research, on any product, method, device, or installation (or any component thereof) which was produced, developed, installed, and used only for research purposes; and

(B) Information concerning any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.

(3) *Standard or limitation* means any prohibition, any effluent limitation, or any toxic, pre-treatment or new source performance standard established or publicly proposed pursuant to the Act or pursuant to regulations under the Act, including limitations or prohibitions in a permit issued or proposed by EPA or by a State under section 402 of the Act, 33 U.S.C. 1342.

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this part.

(b) *Applicability.* (1) This section applies only to business information—

(i) Provided to or obtained by EPA under section 308 of the Act, 33 U.S.C. 1318, by or from the owner or operator of any point source, for the purpose of carrying out the objective of the Act (including but not limited to developing or assisting in the development of any standard or limitation under the Act, or determining whether any person is in violation of any such standard or limitation); or

(ii) Provided to or obtained by EPA under section 509(a) of the Act, 33 U.S.C. 1369(a).

(2) Information will be considered to have been provided or obtained under section 308 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 308, or if its submission could have been required under section 308, regardless of whether section 308 was cited as the authority for any request for the information, whether an order to provide the information was issued under section 309(a)(3) of the Act, 33 U.S.C. 1319(a)(3), whether a civil action was brought under section 309(b) of the Act, 33 U.S.C. 1319(b), and whether the information was provided directly to EPA or through some third person.

(3) Information will be considered to have been provided or obtained under section 509(a) of the Act if it was provided in response to a subpoena issued under section 509(a), or if its production could have been required by subpoena under section 509(a), regardless of whether section 509(a) was cited as the authority for any request for the information, whether a subpoena was issued by EPA, whether a court issued an order under section 307(a), or whether the information was provided directly to EPA or through some third person.

(4) This section specifically does not apply to information obtained under section 310(d) or 312(g)(3) of the Act, 33 U.S.C. 1320(d), 1322(g)(3).

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207, 2.209, 2.211 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that information which is effluent data or a standard or limitation is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) *Availability of information not entitled to confidential treatment.* Section 2.210 does not apply to information to which this section applies. Effluent data, standards or limitations, and any other information provided or obtained under section 308 of the Act which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public notwithstanding any other provision of this part. Effluent data and standards or limitations provided in response to a subpoena issued under section 509(a) of the Act shall be available to the public notwithstanding any other provision of this part. Information (other than effluent data and standards or limitations) provided in response to a subpoena issued under section 509(a) of the Act, which is determined under this

subpart not to be entitled to confidential treatment, shall be available to the public, unless EPA determines that the information is exempt from mandatory disclosure under 5 U.S.C. 552(b) for reasons other than reasons of business confidentiality and cannot or should not be made available to the public.

(g) *Disclosure of information relevant to a proceeding.* (1) Under sections 308 and 509(a) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2)–(4) The provisions of § 2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively of this section.

(h) *Disclosure to authorized representatives.* (1) Under sections 308 and 509(a) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2)–(3) The provisions of § 2.301(h) (2) and (3) are incorporated by reference as paragraphs (h) (2) and (3), respectively, of this section.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40003, Sept. 8, 1978]

§ 2.303 Special rules governing certain information obtained under the Noise Control Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Noise Control Act of 1972, 42 U.S.C. 4901 *et seq.*

(2) *Manufacturer* has the meaning given it in 42 U.S.C. 4902(6).

(3) *Product* has the meaning given it in 42 U.S.C. 4902(3).

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 13 of the Act, 42 U.S.C. 4912, by or from any manufacturer of any product to which regulations under section 6 or 8 of the Act (42 U.S.C. 4905, 4907) apply. Information will be deemed to have been provided or obtained under section 13 of the Act, if it was provided in response to a request by EPA made for the purpose of enabling EPA to determine whether the manufacturer has acted or is acting in compliance with the Act, or if its submission could have been required under section 13 of the Act, regardless of whether section 13 was cited as authority for the request, whether an order to provide such information was issued under section 11(d) of the Act, 42 U.S.C. 4910(d), and whether the information was provided directly to EPA by the manufacturer or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 13 of the Act, any information to which this section applies may be released by EPA because of its relevance to a matter in controversy in a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2)–(4) The provisions of § 2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively, of this section.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40003, Sept. 8, 1978]

§ 2.304 Special rules governing certain information obtained under the Safe Drinking Water Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*

(2) *Contaminant* means any physical, chemical, biological, or radiological substance or matter in water.

(3) *Proceeding* means any rulemaking, adjudication, or licensing process conducted by EPA under the Act or under regulations which implement the Act, except for any determination under this part.

(b) *Applicability.* (1) This section applies only to information—

(i) Which was provided to or obtained by EPA pursuant to a requirement of a regulation which was issued by EPA under the Act for the purpose of—

(A) Assisting the Administrator in establishing regulations under the Act;

(B) Determining whether the person providing the information has acted or is acting in compliance with the Act; or

(C) Administering any program of financial assistance under the Act; and

(ii) Which was provided by a person—

(A) Who is a supplier of water, as defined in section 1401(5) of the Act, 42 U.S.C. 300f(5);

(B) Who is or may be subject to a primary drinking water regulation under section 1412 of the Act, 42 U.S.C. 300g–1;

(C) Who is or may be subject to an applicable underground injection control program, as defined in section 1422(d) of the Act, 42 U.S.C.300h–1(d);

(D) Who is or may be subject to the permit requirements of section 1424(b) of the Act, 42 U.S.C. 300h–3(b);

(E) Who is or may be subject to an order issued under section 1441(c) of the Act, 42 U.S.C. 300j(c); or

(F) Who is a grantee, as defined in section 1445(e) of the Act, 42 U.S.C. 300j–4(e).

(2) This section applies to any information which is described by paragraph (b)(1) of this section if it was provided in response to a request by EPA or its authorized representative (or by a State agency administering any program under the Act) made for any purpose stated in paragraph (b)(1) of this section, or if its submission could have been required under section 1445 of the Act, 42 U.S.C. 300j–4, regardless of whether such section was cited in any request for the information, or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207, 2.209, and 2.211 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that information which deals with the existence, absence, or level of contaminants in drinking water is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) *Nondisclosure for reasons other than business confidentiality or where disclosure is prohibited by other statute.* Section 2.210 applies to information to which this section applies, except that information which deals with the existence, absence, or level of contaminants in drinking water shall be available to the public notwithstanding any other provision of this part.

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 1445(d) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2)–(4) The provisions of § 2.301(g) (2), (3), (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively, of this section.

(h) *Disclosure to authorized representatives.* (1) Under section 1445(d) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart.

Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2)–(3) The provisions of § 2.301(h) (2) and (3) are incorporated by reference as paragraphs (h) (2) and (3), respectively, of this section.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40003, Sept. 8, 1978]

§ 2.305 Special rules governing certain information obtained under the Solid Waste Disposal Act, as amended.

(a) *Definitions.* For purposes of this section:

(1) *Act* means the Solid Waste Disposal Act, as amended, including amendments made by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6901 *et seq.*

(2) *Person* has the meaning given it in section 1004(15) of the Act, 42 U.S.C. 6903(15).

(3) *Hazardous waste* has the meaning given it in section 1004(5) of the Act, 42 U.S.C. 6903(5).

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act including the issuance of administrative orders and the approval or disapproval of plans (e.g. closure plans) submitted by persons subject to regulation under the Act, but not including determinations under this subpart.

(b) *Applicability.* This section applies to information provided to or obtained by EPA under section 3001(b)(3)(B), 3007, or 9005 of the Act, 42 U.S.C 6921(b)(3)(B), 6927, or 6995. Information will be considered to have been provided or obtained under sections 3001(b)(3)(B), 3007, or 9005 of the Act if it was provided in response to a request from EDA made for any of the purposes stated in the Act or if its submission could have been required under those provisions of the Act regardless of whether a specific section was cited as the authority for any request for the information or whether the information was provide directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g) *Disclosure of information relevant in a proceeding.* (1) Under sections 3007(b) and 9005(b) of the Act (42 U.S.C. 6927(b) and 6995(b)), any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

(2)–(4) The provisions of § 2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively, of this section.

(h) *Disclosure to authorized representatives.* (1) Under sections 3001(b)(3)(B), 3007(b), and 9005(b) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), and 6995(b)), EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2)–(3) The provisions of § 2.301(h) (2) and (3) are incorporated by reference as paragraphs (h) (2) and (3), respectively, of this section.

(4) At the time any information is furnished to a contractor, subcontractor, or State or local government agency under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any

knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 3001(b)(3)(B), 3007(b)(2), or 9005(b)(1) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), or 6995(b)).

[43 FR 40003, Sept. 8, 1978, as amended at 50 FR 51662, Dec. 18, 1985]

§ 2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(2) *Chemical substance* has the meaning given it in section 3(2) of the Act, 15 U.S.C. 2602(2).

(3)(i) *Health and safety data* means the information described in paragraphs (a)(3)(i) (A), (B), and (C) of this section with respect to any chemical substance or mixture offered for commercial distribution (including for test marketing purposes and for use in research and development), any chemical substance included on the inventory of chemical substances under section 8 of the Act (15 U.S.C. 2607), or any chemical substance or mixture for which testing is required under section 4 of the Act (15 U.S.C. 2603) or for which notification is required under section 5 of the Act (15 U.S.C. 2604).

(A) Any study of any effect of a chemical substance or mixture on health, on the environment, or on both, including underlying data and epidemiological studies; studies of occupational exposure to a chemical substance or mixture; and toxicological, clinical, and ecological studies of a chemical substance or mixture;

(B) Any test performed under the Act; and

(C) Any data reported to, or otherwise obtained by, EPA from a study described in paragraph (a)(3)(i)(A) of this section or a test described in paragraph (a)(3)(i)(B) of this section.

(ii) Notwithstanding paragraph (a)(3)(i) of this section, no information shall be considered to be *health and safety data* if disclosure of the information would—

(A) In the case of a chemical substance or mixture, disclose processes used in the manufacturing or processing the chemical substance or mixture or,

(B) In the case of a mixture, disclose the portion of the mixture comprised by any of the chemical substances in the mixture.

(4) [Reserved]

(5) *Mixture* has the meaning given it in section 3(8) of the Act, 15 U.S.C. 2602(8).

(6) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies to all information submitted to EPA for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose and either relied upon to avoid some requirement or condition of the Act or incorporated into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e)(3) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding § 2.205(i), the General Counsel (or his designee), rather than the regional counsel, shall

make the determinations and take the actions required by § 2.205;

(2) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 20(a) of the Act, 15 U.S.C. 2619, the business may commence an action in an appropriate Federal district court to prevent disclosure.

(3) The following sentence is substituted for the third sentence of § 2.205(f)(2): ''With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business' receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure.''; and

(4) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies, except that health and safety data are not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances.* Section 2.209 applies to information to which this section applies, except that the following two additional provisions apply to § 2.209(c):

(1) The official purpose for which the information is needed must be in connection with the agency's duties under any law for protection of health or the environment or for specific law enforcement purposes; and

(2) EPA notifies the other agency that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the officers and employees of the other agency to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(i) *Disclosure of information relevant in a proceeding.* (1) Under section 14(a)(4) of the Act (15 U.S.C. 2613(a)(4)), any information to which this section applies may be disclosed by EPA when the information is relevant in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. However, any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (i).

(2)–(4) The provisions of § 2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (i) (2), (3), and (4), respectively, of this section.

(j) *Disclosure of information to contractors and subcontractors.* (1) Under section 14(a)(2) of the Act (15 U.S.C. 2613(a)(2)), any information to which this section applies may be disclosed by EPA to a contractor or subcontractor of the United States performing work under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Subject to the limitations in this paragraph (j), information to which this section applies may be disclosed:

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

(2)–(4) The provisions of §2.301(h)(2)(ii), (iii), and (iv) are incorporated by reference as paragraphs (j) (2), (3), and (4), respectively, of this section.

(5) At the time any information is furnished to a contractor or subcontractor under this paragraph (j), the EPA office furnishing the information to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(k) *Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury.* (1) Under section 14(a)(3) of the Act (15 U.S.C 2613(a)(3)), any information to which this section applies may be disclosed by EPA when disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (k).

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the General Counsel in writing of the nature of the unreasonable risk of injury, the extent of the disclosure proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the General Counsel, the EPA office shall notify the General Counsel orally.

(3) Upon receipt of notification under paragraph (k)(2) of this section, the General Counsel shall make a determination in writing whether disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The General Counsel shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the General Counsel determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the General Counsel shall furnish notice to each affected business of the contemplated disclosure and of the General Counsel's determination. Such notice shall be made in writing by certified mail, return receipt requested, at least 15 days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the General Counsel determines that the risk of injury is so imminent that it is impracticable to furnish such notice 15 days before the proposed date of disclosure, the General Counsel may provide notice by means that will provide receipt of the notice by the affected business at least 24 hours before the disclosure is to be made. This may be done by telegram, telephone, or other reasonably rapid means.

[43 FR 40003, Sept. 8, 1978, as amended at 44 FR 17674, Mar. 23, 1979; 58 FR 462, Jan. 5, 1993]

§ 2.307 Special rules governing certain information obtained under the Federal Insecticide, Fungicide and Rodenticide Act.

(a) *Definitions.* For the purposes of this section;

(1) *Act* means the Federal Insecticide, Fungicide and Rodenticide Act, as

amended, 7 U.S.C. 136 *et seq.*, and its predecessor, 7 U.S.C. 135 *et seq*.

(2) *Applicant* means any person who has submitted to EPA (or to a predecessor agency with responsibility for administering the Act) a registration statement or application for registration under the Act of a pesticide or of an establishment.

(3) *Registrant* means any person who has obtained registration under the Act of a pesticide or of an establishment.

(b) *Applicability*. This section applies to all information submitted to EPA by an applicant or registrant for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose but incorporated by the applicant or registrant into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. This section does not apply to information supplied to EPA by a petitioner in support of a petition for a tolerance under 21 U.S.C. 346a(d), unless the information is also described by the first sentence of this paragraph.

(c) *Basic rules which apply without change*. Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office*. Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office*. Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding § 2.205(i), the General Counsel (or his designee), rather than the Regional Counsel, shall make the determinations and take the actions required by § 2.205;

(2) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 10(c) of the Act, 7 U.S.C. 136h(c), the business may commence an action in an appropriate Federal district court for a declaratory judgment;

(3) The following sentence is substituted for the third sentence of § 2.205(f)(2): ''With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business's receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of the Act and to obtain preliminary injunctive relief against disclosure.''; and

(4) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations*. Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances*. (1) Section 2.209 applies without change to information to which this section applies. In addition, under section 12(a)(2)(D) of the Act, 7 U.S.C. 136j(a)(2)(D), EPA possesses authority to disclose any information to which this section applies to physicians, pharmacists, and other qualified persons needing such information for the performance of their duties, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority under section 12(a)(2)(D) of the Act may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it might otherwise be entitled to confidential treatment under this subpart) to physicians, pharmacists, hospitals, veterinarians, law enforcement personnel, or governmental agencies with responsibilities for protection of public health, and to employees of any such persons or agencies, or to other qualified persons, when and to the extent that disclosure is necessary in order to treat illness or injury or to prevent imminent harm to persons, property, or the environment, in the opinion of the Administrator or his designee.

(3) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the Act or regulations which implement the Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedure and requirements of §2.301(h)(2) (ii) through (iv).

(4) Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing or in findings of fact issued by the Administrator, to the extent and in the manner authorized by the Administrator or his designee.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

§ 2.308 Special rules governing certain information obtained under the Federal Food, Drug and Cosmetic Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*

(2) *Petition* means a petition for the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, pursuant to section 408(d) of the Act, 21 U.S.C. 346a(d).

(3) *Petitioner* means a person who has submitted a petition to EPA (or to a predecessor agency).

(b) *Applicability.* (1) This section applies only to business information submitted to EPA (or to an advisory committee established under the Act) by a petitioner, solely in support of a petition which has not been acted on by the publication by EPA of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, as provided in section 408(d) (2) or (3) of the Act, 21 U.S.C. 346a(d) (2) or (3).

(2) Section 2.307, rather than this section, applies to information described by the first sentence of §2.307(b) (material incorporated into submissions in order to satisfy the requirements of the Federal Insecticide, Fungicide and Rodenticide Act, as amended), even though such information was originally submitted by a petitioner in support of a petition.

(3) This section does not apply to information gathered by EPA under a proceeding initiated by EPA to establish a tolerance under section 408(e) of the Act, 21 U.S.C. 346a(e).

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Effect of submission of information without claim.* Section 2.203 (a) and (b) apply without change to information to which this section applies. Section 2.203(c), however, does not apply to information to which this section applies. A petitioner's failure to assert a claim when initially submitting a petition shall not constitute a waiver of any claim the petitioner may have.

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that—

(1) Unless the EPA office has on file a written waiver of a petitioner's claim, a petitioner shall be regarded as an affected business, a petition shall be treated as if it were covered by a business confidentiality claim, and an EPA

office acting under §2.204(d) shall determine that the information in the petition is or may be entitled to confidential treatment and shall take action in accordance with §2.204(d)(1);

(2) In addition to other required provisions of any notice furnished to a petitioner under §2.204(e), such notice shall state that—

(i) Section 408(f) of the Act, 21 U.S.C. 346a(f), affords absolute confidentiality to information to which this section applies, but after publication by EPA of a regulation establishing a tolerance (or exempting the pesticide chemical from the necessity of a tolerance) neither the Act nor this section affords any protection to the information;

(ii) Information submitted in support of a petition which is also incorporated into a submission in order to satisfy a requirement or condition of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*, is regarded by EPA as being governed, with respect to business confidentiality, by §2.307 rather than by this section;

(iii) Although it appears that this section may apply to the information at this time, EPA is presently engaged in determining whether for any reason the information is entitled to confidential treatment or will be entitled to such treatment if and when this section no longer applies to the information; and

(iv) Information determined by EPA to be covered by this section will not be disclosed for as long as this section continues to apply, but will be made available to the public thereafter (subject to §2.210) unless the business furnishes timely comments in response to the notice.

(f) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding §2.205(i), the General Counsel or his designee, rather than the Regional counsel, shall in all cases make the determinations and take the actions required by §2.205;

(2) In addition to the circumstances mentioned in §2.205(f)(1), notice in the form prescribed by §2.205(f)(2) shall be furnished to each affected business whenever information is found to be entitled to confidential treatment under section 408(f) of the Act but not otherwise entitled to confidential treatment. With respect to such cases, the following sentences shall be substituted for the third sentence of §2.205(f)(2): ''With respect to EPA's implementation of the determination, the notice shall state that (subject to §2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the business's receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure; provided, that the information will not be made available to the public for so long as it is entitled to confidential treatment under section 408(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(f).''; and

(3) Notwithstanding §2.205(g), the 31 calendar day period prescribed by §2.205(f)(2), as modified by paragraph (f)(2) of this section, shall not be shortened without the consent of the business.

(g) [Reserved]

(h) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Such information shall be determined to be entitled to confidential treatment for so long as this section continues to apply to it.

(i) *Disclosure in special circumstances.* (1) Section 2.209 applies to information to which this section applies. In addition, under Section 408(f) of the Act, 21 U.S.C. 346a(f), EPA is authorized to disclose the information to other persons. Such authority under section 408(f) of the Act may be exercised only in accordance with paragraph (i)(2) or (i)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the

Act, with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, or regulations which implement either such Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedures and requirements of §2.301(h)(2) (ii) through (iv).

(3) Information to which this section applies may be disclosed by EPA to an advisory committee in accordance with section 408(d) of the Act, 21 U.S.C. 346a(d).

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

§ 2.309 Special rules governing certain information obtained under the Marine Protection, Research and Sanctuaries Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Marine Protection, Research and Sanctuaries Act of 1972, 33 U.S.C. 1401 *et seq.*

(2) *Permit* means any permit applied for or granted under the Act.

(3) *Application* means an application for a permit.

(b) *Applicability.* This section applies to all information provided to or obtained by EPA as a part of any application or in connection with any permit.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Pursuant to section 104(f) of the Act, 33 U.S.C. 1414(f), no information to which this section applies is eligible for confidential treatment.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

§ 2.310 Special rules governing certain information obtained under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(a) *Definitions.* For purposes of this section:

(1) *Act* means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, including amendments made by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. 9601, *et seq.*

(2) *Person* has the meaning given it in section 101(21) of the Act, 42 U.S.C. 9601(21).

(3) *Facility* has the meaning given it in section 101(9) of the Act, 42 U.S.C. 9601(9).

(4) *Hazardous substance* has the meaning given it in section 101(14) of the Act, 42 U.S.C. 9601(14).

(5) *Release* has the meaning given it in section 101(22) of the Act, 42 U.S.C. 9601(22).

(6) *Proceeding* means any rulemaking or adjudication conducted by EPA under the Act or under regulations which implement the Act (including the issuance of administrative orders under section 106 of the Act and cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act), any cost recovery litigation under section 107 of the Act, or any administrative determination made under section 104 of the Act, but not including determinations under this subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 104 of the Act, 42 U.S.C. 9604, by or from any person who stores, treats, or disposes of hazardous wastes; or where necessary to ascertain facts not available at the facility where such hazardous substances are located, by or from any person who generates, transports, or otherwise handles or has handled hazardous substances, or by or from any person who performs or supports removal or remedial actions pursuant to section 104(a) of the Act. Information will be considered to have been provided or obtained under section 104 of the Act if it was provided in response

to a request from EPA or a representative of EPA made for any of the purposes stated in section 104, if it was provided pursuant to the terms of a contract, grant or other agreement to perform work pursuant to section 104, or if its submission could have been required under section 104, regardless of whether section 104 was cited as authority for any request for the information or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and §§ 2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g)(1) Under section 104(e)(7)(A) of the Act (42 U.S.C. 9604(e)(7)(A)) any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g)(2) are to be used as paragraph (g)(2) of this section.

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3) shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct his request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the

business, the presiding officer determines in writing that:

(i) The party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the proceeding will be significantly impaired unless the information is disclosed to him; and

(ii) Any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and the public interest that would result from the disclosure.

The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(5) In connection with cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act (42 U.S.C. 9607, 9622), any information to which this section applies that may be entitled to confidential treatment may be made available to potentially responsible parties pursuant to a contractual agreement to protect the information.

(6) In connection with any cost recovery proceeding under section 107 of the Act involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, any information to which this section applies that may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(6). Such disclosure must be made pursuant to a stipulation and protective order signed by all parties to whom disclosure is made and by the presiding officer.

(h) *Disclosure to authorized representatives.* (1) Under section 104(e)(7) of the Act (42 U.S.C. 9604(e)(7)), EPA possesses authority to disclose to any authorized representative of the Untied States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) The provisions of § 2.301(h)(2) are to be used as paragraph (h)(2) of this section.

(3) The provisions of § 2.301(h)(3) are to be used as paragraph (h)(3) of this section.

(4) At the time any information is furnished to a contractor, subcontractor, or State or local government under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 104(e)(7)(B) of the Act (42 U.S.C. 9604(e)(7)(B)).

[50 FR 51663, Dec. 18, 1985, as amended at 58 FR 462, Jan. 5, 1993]

§ 2.311 Special rules governing certain information obtained under the Motor Vehicle Information and Cost Savings Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Motor Vehicle Information and Cost Savings Act, as amended, 15 U.S.C. 1901 *et seq.*

(2) *Average fuel economy* has the meaning given it in section 501(4) of the Act, 15 U.S.C. 2001(4).

(3) *Fuel economy* has the meaning given it in section 501(6) of the Act, 15 U.S.C. 2001(6).

(4) *Fuel economy data* means any measurement or calculation of fuel economy for any model type and average fuel economy of a manufacturer under section 503(d) of the Act, 15 U.S.C. 2003(d).

(5) *Manufacturer* has the meaning given it in section 501(9) of the Act, 15 U.S.C. 2001(9).

(6) *Model type* has the meaning given it in section 501(11) of the Act, 15 U.S.C. 2001(11).

(b) *Applicability*. This section applies only to information provided to or obtained by EPA under Title V, Part A of the Act, 15 U.S.C. 2001 through 2012. Information will be considered to have been provided or obtained under Title V, Part A of the Act if it was provided in response to a request from EPA made for any purpose stated in Title V, Part A, or if its submission could have been required under Title V Part A, regardless of whether Title V Part A was cited as the authority for any request for information or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change*. Sections 2.201 through 2.207 and §§ 2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations*. Section 2.208 applies without change to information to which this section applies, except that information this is fuel economy data is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g) *Disclosure of information relevant to a proceeding*. (1) Under section 505(d)(1) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding under Title V, Part A of the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g)(2) are to be used as paragraph (g)(2) of this section.

(3) The provisions of § 2.301(g)(3) are to be used as paragraph (g)(3) of this section.

(4) The provisions of § 2.301(g)(4) are to be used as paragraph (g)(3) of this section.

[50 FR 51663, Dec. 18, 1985]

Subpart C—Testimony by Employees and Production of Documents in Civil Legal Proceedings Where the United States Is Not a Party

AUTHORITY: 5 U.S.C. 301; Reorganization Plan No. 3 of 1970, 5 U.S.C. App.; 33 U.S.C. 361(a); 42 U.S.C. 300j–9; 42 U.S.C. 6911a, 42 U.S.C. 7601(a).

SOURCE: 50 FR 32387, Aug. 9, 1985, unless otherwise noted.

§ 2.401 Scope and purpose.

This subpart sets forth procedures to be followed when an EPA employee is requested or subpoenaed to provide testimony concerning information acquired in the course of performing official duties or because of the employee's official status. (In such cases, employees must state for the record that their testimony does not necessarily represent the official position of EPA. If they are called to state the official position of EPA, they should ascertain that position before appearing.) These procedures also apply to subpoenas *duces tecum* for any document in the possession of EPA and to requests for certification of copies of documents.

(a) These procedures apply to:

(1) State court proceedings (including grand jury proceedings);

(2) Federal civil proceedings, except where the United States, EPA or another Federal agency is a party; and

(3) State and local legislative and administrative proceedings.

(b) These procedures do not apply:

(1) To matters which are not related to EPA;

(2) To Congressional requests or subpoenas for testimony or documents;

(3) Where employees provide expert witness services as approved outside activities in accordance with 40 CFR part 3, subpart E (in such cases, employees must state for the record that the testimony represents their own views and does not necessarily represent the official position of EPA);

(4) Where employees voluntarily testify as private citizens with respect to environmental matters (in such cases, employees must state for the record that the testimony represents their own views and does not necessarily represent the official position of EPA).

(c) The purpose of this subpart is to ensure that employees' official time is used only for official purposes, to maintain the impartiality of EPA among private litigants, to ensure that public funds are not used for private purposes and to establish procedures for approving testimony or production of documents when clearly in the interests of EPA.

§ 2.402 Policy on presentation of testimony and production of documents.

(a) With the approval of the cognizant Assistant Administrator, Office Director, Staff Office Director or Regional Administrator or his designee, EPA employees (as defined in 40 CFR 3.102 (a) and (b)) may testify at the request of another Federal agency, or, where it is in the interests of EPA, at the request of a State or local government or State legislative committee.

(b) Except as permitted by paragraph (a) of this section, no EPA employee may provide testimony or produce documents in any proceeding to which this subpart applies concerning information acquired in the course of performing official duties or because of the employee's official relationship with EPA, unless authorized by the General Counsel or his designee under §§ 2.403 through 2.406.

§ 2.403 Procedures when voluntary testimony is requested.

A request for testimony by an EPA employee under § 2.402(b) must be in writing and must state the nature of the requested testimony and the reasons why the testimony would be in the interests of EPA. Such requests are immediately sent to the General Counsel or his designee (or, in the case of employees in the Office of Inspector General, the Inspector General or his designee) with the recommendations of the employee's supervisors. The General Counsel or his designee, in consultation with the appropriate Assistant Administrator, Regional Administrator, or Staff Office Director (or, in the case of employees in the Office of Inspector General, the Inspector General or his designee), determines whether compliance with the request would clearly be in the interests of EPA and responds as soon as practicable.

§ 2.404 Procedures when an employee is subpoenaed.

(a) Copies of subpoenas must immediately be sent to the General Counsel or his designee with the recommendations of the employee's supervisors. The General Counsel or his designee, in consultation with the appropriate Assistant Administrator, Regional Administrator or Staff Office Director, determines whether compliance with the subpoena would clearly be in the interests of EPA and responds as soon as practicable.

(b) If the General Counsel or his designee denies approval to comply with the subpoena, or if he has not acted by the return date, the employee must appear at the stated time and place (unless advised by the General Counsel or his designee that the subpoena was not validly issued or served or that the subpoena has been withdrawn), produce a copy of these regulations and respectfully refuse to provide any testimony or produce any documents. *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951).

(c) Where employees in the Office of Inspector General are subpoenaed, the Inspector General or his designee makes the determination under paragraphs (a) and (b) of this section in consultation with the General Counsel.

(d) The General Counsel will request the assistance of the Department of Justice or a U.S. Attorney where necessary to represent the interests of the Agency and the employee.

§ 2.405 Subpoenas *duces tecum*.

Subpoenas *duces tecum* for documents or other materials are treated the same as subpoenas for testimony. Unless the General Counsel or his designee, in consultation with the appropriate Assistant Administrator, Regional Administrator or Staff Office Director (or, as to employees in the Office of Inspector General, the Inspector General)

determines that compliance with the subpoena is clearly in the interests of EPA, the employee must appear at the stated time and place (unless advised by the General Counsel or his designee that the subpoena was not validly issued or served or that the subpoena has been withdrawn) and respectfully refuse to produce the subpoenaed materials. However, where a subpoena *duces tecum* is essentially a written request for documents, the requested documents will be provided or denied in accordance with subparts A and B of this part where approval to respond to the subpoena has not been granted.

§ 2.406 Requests for authenticated copies of EPA documents.

Requests for authenticated copies of EPA documents for purposes of admissibility under 28 U.S.C. 1733 and Rule 44 of the Federal Rules of Civil Procedure will be granted for documents which would otherwise be released pursuant to subpart A. For purposes of Rule 44 the *person having legal custody of the record* is the cognizant Assistant Administrator, Regional Administrator, Staff Office Director or Office Director or his designee. The advice of the Office of General Counsel should be obtained concerning the proper form of authentication.

PART 3—CROSS-MEDIA ELECTRONIC REPORTING

Subpart A—General Provisions

Sec.

Subpart B—Electronic Reporting to EPA

Subpart C [Reserved]

Subpart D—Electronic Reporting under EPA-Authorized State, Tribe, and Local Programs

AUTHORITY: 7 U.S.C. 136 to 136y; 15 U.S.C. 2601 to 2692; 33 U.S.C. 1251 to 1387; 33 U.S.C. 1401 to 1445; 33 U.S.C. 2701 to 2761; 42 U.S.C. 300f to 300j–26; 42 U.S.C. 4852d; 42 U.S.C. 6901–6992k; 42 U.S.C. 7401 to 7671q; 42 U.S.C. 9601 to 9675; 42 U.S.C. 11001 to 11050; 15 U.S.C. 7001; 44 U.S.C. 3504 to 3506.

SOURCE: 70 FR 59879, Oct. 13, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 3.1 Who does this part apply to?

(a) This part applies to:

(1) Persons who submit reports or other documents to EPA to satisfy requirements under Title 40 of the Code of Federal Regulations (CFR); and

(2) States, tribes, and local governments administering or seeking to administer authorized programs under Title 40 of the CFR.

(b) This part does not apply to:

(1) Documents submitted via facsimile in satisfaction of reporting requirements as permitted under other parts of Title 40 or under authorized programs;

(2) Electronic documents submitted via magnetic or optical media such as diskette, compact disc, digital video disc, or tape in satisfaction of reporting requirements, as permitted under other parts of Title 40 or under authorized programs; or

(3) Documents and information submitted under grants, cooperative agreements, or financial assistant regulations contained in Title 40.

(c) This part does not apply to any data transfers between EPA and states, tribes, or local governments as a part of their authorized programs or as a part of administrative arrangements

between states, tribes, or local governments and EPA to share data.

[70 FR 59879, Oct. 13, 2005, as amended at 74 FR 59106, Nov. 17, 2009]

§ 3.2 How does this part provide for electronic reporting?

(a) *Electronic reporting to EPA.* Except as provided in § 3.1(b), any person who is required under Title 40 to create and submit or otherwise provide a document to EPA may satisfy this requirement with an electronic document, in lieu of a paper document, provided that:

(1) He or she satisfies the requirements of § 3.10; and

(2) EPA has first published a notice in the FEDERAL REGISTER announcing that EPA is prepared to receive, in electronic form, documents required or permitted by the identified part or subpart of Title 40.

(b) *Electronic reporting under an EPA-authorized state, tribe, or local program.* (1) An authorized program may allow any document submission requirement under that program to be satisfied with an electronic document provided that the state, tribe, or local government seeks and obtains revision or modification of that program in accordance with § 3.1000 and also meets the requirements of § 3.2000 for such electronic reporting.

(2) A state, tribe, or local government that is applying for initial delegation, authorization, or approval to administer a federal program or a program in lieu of the federal program, and that will allow document submission requirements under the program to be satisfied with an electronic document, must use the procedures for obtaining delegation, authorization, or approval under the relevant part of Title 40 and may not use the procedures set forth in § 3.1000; but the application must contain the information required by § 3.1000(b)(1) and the state, tribe, or local government must meet the requirements of § 3.2000.

(c) *Limitations.* This part does not require submission of electronic documents in lieu of paper. This part confers no right or privilege to submit data electronically and does not obligate EPA, states, tribes, or local governments to accept electronic documents.

§ 3.3 What definitions are applicable to this part?

The definitions set forth in this section apply when used in this part.

Acknowledgment means a confirmation of electronic document receipt.

Administrator means the Administrator of the EPA.

Agency means the EPA or a state, tribe, or local government that administers or seeks to administer an authorized program.

Agreement collection certification means a signed statement by which a local registration authority certifies that a subscriber agreement has been received from a registrant; the agreement has been stored in a manner that prevents unauthorized access to these agreements by anyone other than the local registration authority; and the local registration authority has no basis to believe that any of the collected agreements have been tampered with or prematurely destroyed.

Authorized program means a Federal program that EPA has delegated, authorized, or approved a state, tribe, or local government to administer, or a program that EPA has delegated, authorized, or approved a state, tribe or local government to administer in lieu of a Federal program, under other provisions of Title 40 and such delegation, authorization, or approval has not been withdrawn or expired.

Central Data Exchange means EPA's centralized electronic document receiving system, or its successors, including associated instructions for submitting electronic documents.

Chief Information Officer means the EPA official assigned the functions described in section 5125 of the Clinger Cohen Act (Pub. L. 104–106).

Copy of record means a true and correct copy of an electronic document received by an electronic document receiving system, which copy can be viewed in a human-readable format that clearly and accurately associates all the information provided in the electronic document with descriptions or labeling of the information. A *copy of record* includes:

(1) All electronic signatures contained in or logically associated with that document;

(2) The date and time of receipt; and

(3) Any other information used to record the meaning of the document or the circumstances of its receipt.

Disinterested individual means an individual who is not connected with the person in whose name the electronic signature device is issued. A *disinterested individual* is not any of the following: The person's employer or employer's corporate parent, subsidiary, or affiliate; the person's contracting agent; member of the person's household; or relative with whom the person has a personal relationship.

Electronic document means any information in digital form that is conveyed to an agency or third-party, where ''information'' may include data, text, sounds, codes, computer programs, software, or databases. ''Data,'' in this context, refers to a delimited set of data elements, each of which consists of a content or value together with an understanding of what the content or value means; where the electronic document includes data, this understanding of what the data element content or value means must be explicitly included in the electronic document itself or else be readily available to the electronic document recipient.

Electronic document receiving system means any set of apparatus, procedures, software, records, or documentation used to receive electronic documents.

Electronic signature means any information in digital form that is included in or logically associated with an electronic document for the purpose of expressing the same meaning and intention as would a handwritten signature if affixed to an equivalent paper document with the same reference to the same content. The electronic document bears or has on it an electronic signature where it includes or has logically associated with it such information.

Electronic signature agreement means an agreement signed by an individual with respect to an electronic signature device that the individual will use to create his or her electronic signatures requiring such individual to protect the electronic signature device from compromise; to promptly report to the agency or agencies relying on the electronic signatures created any evidence discovered that the device has been compromised; and to be held as legally bound, obligated, or responsible by the electronic signatures created as by a handwritten signature.

Electronic signature device means a code or other mechanism that is used to create electronic signatures. Where the *device* is used to create an individual's electronic signature, then the code or mechanism must be unique to that individual at the time the signature is created and he or she must be uniquely entitled to use it. The *device* is compromised if the code or mechanism is available for use by any other person.

EPA means the United States Environmental Protection Agency.

Existing electronic document receiving system means an electronic document receiving system that is being used to receive electronic documents in lieu of paper to satisfy requirements under an authorized program on October 13, 2005 or the system, if not in use, has been substantially developed on or before that date as evidenced by the establishment of system services or specifications by contract or other binding agreement.

Federal program means any program administered by EPA under any other provision of Title 40.

Federal reporting requirement means a requirement to report information directly to EPA under any other provision of Title 40.

Handwritten signature means the scripted name or legal mark of an individual, handwritten by that individual with a marking-or writing-instrument such as a pen or stylus and executed or adopted with the present intention to authenticate a writing in a permanent form, where ''a writing'' means any intentional recording of words in a visual form, whether in the form of handwriting, printing, typewriting, or any other tangible form. The physical instance of the scripted name or mark so created constitutes the handwritten signature. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other media.

Information or objects of independent origin means data or items that originate from a disinterested individual or are forensic evidence of a unique, immutable trait which is (and may at any time be) attributed to the individual in whose name the device is issued.

Local registration authority means an individual who is authorized by a state, tribe, or local government to issue an agreement collection certification, whose identity has been established by notarized affidavit, and who is authorized in writing by a regulated entity to issue agreement collection certifications on its behalf.

Priority reports means the reports listed in Appendix 1 to part 3.

Subscriber agreement means an electronic signature agreement signed by an individual with a handwritten signature. This agreement must be stored until five years after the associated electronic signature device has been deactivated.

Transmit means to successfully and accurately convey an electronic document so that it is received by the intended recipient in a format that can be processed by the electronic document receiving system.

Valid electronic signature means an electronic signature on an electronic document that has been created with an electronic signature device that the identified signatory is uniquely entitled to use for signing that document, where this device has not been compromised, and where the signatory is an individual who is authorized to sign the document by virtue of his or her legal status and/or his or her relationship to the entity on whose behalf the signature is executed.

§ 3.4 How does this part affect enforcement and compliance provisions of Title 40?

(a) A person is subject to any applicable federal civil, criminal, or other penalties and remedies for failure to comply with a federal reporting requirement if the person submits an electronic document to EPA under this part that fails to comply with the provisions of § 3.10.

(b) A person is subject to any applicable federal civil, criminal, or other penalties or remedies for failure to comply with a State, tribe, or local reporting requirement if the person submits an electronic document to a State, tribe, or local government under an authorized program and fails to comply with the applicable provisions for electronic reporting.

(c) Where an electronic document submitted to satisfy a federal or authorized program reporting requirement bears an electronic signature, the electronic signature legally binds, obligates, and makes the signatory responsible, to the same extent as the signatory's handwritten signature would on a paper document submitted to satisfy the same federal or authorized program reporting requirement.

(d) Proof that a particular signature device was used to create an electronic signature will suffice to establish that the individual uniquely entitled to use the device did so with the intent to sign the electronic document and give it effect.

(e) Nothing in this part limits the use of electronic documents or information derived from electronic documents as evidence in enforcement or other proceedings.

Subpart B—Electronic Reporting to EPA

§ 3.10 What are the requirements for electronic reporting to EPA?

(a) A person may use an electronic document to satisfy a federal reporting requirement or otherwise substitute for a paper document or submission permitted or required under other provisions of Title 40 only if:

(1) The person transmits the electronic document to EPA's Central Data Exchange, or to another EPA electronic document receiving system that the Administrator may designate for the receipt of specified submissions, complying with the system's requirements for submission; and

(2) The electronic document bears all valid electronic signatures that are required under paragraph (b) of this section.

(b) An electronic document must bear the valid electronic signature of a signatory if that signatory would be required under Title 40 to sign the paper

document for which the electronic document substitutes, unless EPA announces special provisions to accept a handwritten signature on a separate paper submission and the signatory provides that handwritten signature.

§ 3.20 How will EPA provide notice of changes to the Central Data Exchange?

(a) Except as provided under paragraph (b) of this section, whenever EPA plans to change Central Data Exchange hardware or software in ways that would affect the transmission process, EPA will provide notice as follows:

(1) *Significant changes to CDX:* Where the equipment, software, or services needed to transmit electronic documents to the Central Data Exchange would be changed significantly, EPA will provide public notice and seek comment on the change and the proposed implementation schedule through the FEDERAL REGISTER;

(2) *Other changes to CDX:* EPA will provide notice of other changes to Central Data Exchange users at least sixty (60) days in advance of implementation.

(3) *De minimis or transparent changes to CDX:* For *de minimis* or transparent changes that have minimal or no impact on the transmission process, EPA may provide notice if appropriate on a case-by-case basis.

(b) *Emergency changes to CDX:* Any change which EPA's Chief Information Officer or his or her designee determines is needed to ensure the security and integrity of the Central Data Exchange is exempt from the provisions of paragraph (a) of this section. However, to the extent consistent with ensuring the security and integrity of the system, EPA will provide notice for any change other than *de minimis* or transparent changes to the Central Data Exchange.

Subpart C [Reserved]

Subpart D—Electronic Reporting Under EPA-Authorized State, Tribe, and Local Programs

§ 3.1000 How does a state, tribe, or local government revise or modify its authorized program to allow electronic reporting?

(a) A state, tribe, or local government that receives or plans to begin receiving electronic documents in lieu of paper documents to satisfy requirements under an authorized program must revise or modify such authorized program to ensure that it meets the requirements of this part.

(1) *General procedures for program modification or revision:* To revise or modify an authorized program to meet the requirements of this part, a state, tribe, or local government must submit an application that complies with paragraph (b)(1) of this section and must follow either the applicable procedures for program revision or modification in other parts of Title 40, or, at the applicant's option, the procedures provided in paragraphs (b) through (e) of this section.

(2) *Programs planning to receive electronic documents under an authorized program:* A state, tribe, or local government that does not have an existing electronic document receiving system for an authorized program must receive EPA approval of revisions or modifications to such program in compliance with paragraph (a)(1) of this section before the program may receive electronic documents in lieu of paper documents to satisfy program requirements.

(3) *Programs already receiving electronic documents under an authorized program:* A state, tribe, or local government with an existing electronic document receiving system for an authorized program must submit an application to revise or modify such authorized program in compliance with paragraph (a)(1) of this section no later than January 13, 2010. On a case-by-case basis, this deadline may be extended by the Administrator, upon request of the state, tribe, or local government, where the Administrator determines that the state, tribe, or local government needs additional time to make legislative or regulatory changes

in order to meet the requirements of this part.

(4) *Programs with approved electronic document receiving systems:* An authorized program that has EPA's approval to accept electronic documents in lieu of paper documents must keep EPA apprised of those changes to laws, policies, or the electronic document receiving systems that have the potential to affect program compliance with § 3.2000. Where the Administrator determines that such changes require EPA review and approval, EPA may request that the state, tribe, or local government submit an application for program revision or modification; additionally, a state, tribe, or local government on its own initiative may submit an application for program revision or modification respecting their receipt of electronic documents. Such applications must comply with paragraph (a)(1) of this section.

(5) *Restrictions on the use of procedures in this section:* The procedures provided in paragraphs (b) through (e) of this section may only be used for revising or modifying an authorized program to provide for electronic reporting and for subsequent revisions or modifications to the electronic reporting elements of an authorized program as provided under paragraph (a)(4) of this section.

(b)(1) To obtain EPA approval of program revisions or modifications using procedures provided under this section, a state, tribe, or local government must submit an application to the Administrator that includes the following elements:

(i) A certification that the state, tribe, or local government has sufficient legal authority provided by lawfully enacted or promulgated statutes or regulations that are in full force and effect on the date of the certification to implement the electronic reporting component of its authorized programs covered by the application in conformance with § 3.2000 and to enforce the affected programs using electronic documents collected under these programs, together with copies of the relevant statutes and regulations, signed by the State Attorney General or his or her designee, or, in the case of an authorized tribe or local government program, by the chief executive or administrative official or officer of the governmental entity, or his or her designee;

(ii) A listing of all the state, tribe, or local government electronic document receiving systems to accept the electronic documents being addressed by the program revisions or modifications that are covered by the application, together with a description for each such system that specifies how the system meets the applicable requirements in § 3.2000 with respect to those electronic documents;

(iii) A schedule of upgrades for the electronic document receiving systems listed under paragraph (b)(1)(ii) of this section that have the potential to affect the program's continued conformance with § 3.2000; and

(iv) Other information that the Administrator may request to fully evaluate the application.

(2) A state, tribe, or local government that revises or modifies more than one authorized program for receipt of electronic documents in lieu of paper documents may submit a consolidated application under this section covering more than one authorized program, provided the consolidated application complies with paragraph (b)(1) of this section for each authorized program.

(3)(i) Within 75 calendar days of receiving an application for program revision or modification submitted under paragraph (b)(1) of this section, the Administrator will respond with a letter that either notifies the state, tribe, or local government that the application is complete or identifies deficiencies in the application that render the application incomplete. The state, tribe, or local government receiving a notice of deficiencies may amend the application and resubmit it. Within 30 calendar days of receiving the amended application, the Administrator will respond with a letter that either notifies the applicant that the amended application is complete or identifies remaining deficiencies that render the application incomplete.

(ii) If a state, tribe, or local government receiving notice of deficiencies under paragraph (b)(3)(i) of this section does not remedy the deficiencies and

resubmit the subject application within a reasonable period of time, the Administrator may act on the incomplete application under paragraph (c) of this section.

(c)(1) The Administrator will act on an application by approving or denying the state's, tribe's or local government's request for program revision or modification.

(2) Where a consolidated application submitted under paragraph (b)(2) of this section addresses revisions or modifications to more than one authorized program, the Administrator may approve or deny the request for revision or modification of each authorized program in the application separately; the Administrator need not take the same action with respect to the requested revisions or modifications for each such program.

(3) When an application under paragraph (b) of this section requests revision or modification of an authorized public water system program under part 142 of this title, the Administrator will, in accordance with the procedures in paragraph (f) of this section, provide an opportunity for a public hearing before a final determination pursuant to paragraph (c)(1) of this section with respect to that component of the application.

(4) Except as provided under paragraph (c)(4)(i) and (ii) of this section, if the Administrator does not take any action under paragraph (c)(1) of this section on a specific request for revision or modification of a specific authorized program addressed by an application submitted under paragraph (b) of this section within 180 calendar days of notifying the state, tribe, or local government under paragraph (b)(3) of this section that the application is complete, the specific request for program revision or modification for the specific authorized program is considered automatically approved by EPA at the end of the 180 calendar days unless the review period is extended at the request of the state, tribe, or local government submitting the application.

(i) Where an opportunity for public hearing is required under paragraph (c)(3) of this section, the Administrator's action on the requested revision or modification will be in accordance with paragraph (f) of this section.

(ii) Where a requested revision or modification addressed by an application submitted under paragraph (b) of this section is to an authorized program with an existing electronic document receiving system, and where notification under paragraph (b)(3) of this section that the application is complete is executed after October 13, 2007, if the Administrator does not take any action under paragraph (c)(1) of this section on the specific request for revision or modification within 360 calendar days of such notification, the specific request is considered automatically approved by EPA at the end of the 360 calendar days unless the review period is extended at the request of the state, tribe, or local government submitting the application.

(d) Except where an opportunity for public hearing is required under paragraph (c)(3) of this section, EPA's approval of a program revision or modification under this section will be effective upon publication of a notice of EPA's approval of the program revision or modification in the FEDERAL REGISTER. EPA will publish such a notice promptly after approving a program revision or modification under paragraph (c)(1) of this section or after an EPA approval occurs automatically under paragraph (c)(4) of this section.

(e) If a state, tribe, or local government submits material to amend its application under paragraph (b)(1) of this section after the date that the Administrator sends notification under paragraph (b)(3)(i) of this section that the application is complete, this new submission will constitute withdrawal of the pending application and submission of a new, amended application for program revision or modification under paragraph (b)(1) of this section, and the 180-day time period in paragraph (c)(4) of this section or the 360-day time period in paragraph (c)(4)(ii) of this section will begin again only when the Administrator makes a new determination and notifies the state, tribe, or local government under paragraph (b)(3)(i) of this section that the amended application is complete.

(f) For an application under this section that requests revision or modification of an authorized public water system program under part 142 of this chapter:

(1) The Administrator will publish notice of the Administrator's preliminary determination under paragraph (c)(1) of this section in the FEDERAL REGISTER, stating the reasons for the determination and informing interested persons that they may request a public hearing on the Administrator's determination. Frivolous or insubstantial requests for a hearing may be denied by the Administrator;

(2) Requests for a hearing submitted under this section must be submitted to the Administrator within 30 days after publication of the notice of opportunity for hearing in the FEDERAL REGISTER. The Administrator will give notice in the FEDERAL REGISTER of any hearing to be held pursuant to a request submitted by an interested person or on the Administrator's own motion. Notice of hearing will be given not less than 15 days prior to the time scheduled for the hearing;

(3) The hearing will be conducted by a designated hearing officer in an informal, orderly, and expeditious manner. The hearing officer will have authority to take such action as may be necessary to assure the fair and efficient conduct of the hearing; and

(4) After reviewing the record of the hearing, the Administrator will issue an order either affirming the determination the Administrator made under paragraph (c)(1) of this section or rescinding such determination and will promptly publish a notice of the order in the FEDERAL REGISTER. If the order is to approve the program revision or modification, EPA's approval will be effective upon publication of the notice in the FEDERAL REGISTER. If no timely request for a hearing is received and the Administrator does not determine to hold a hearing on the Administrator's own motion, the Administrator's determination made under paragraph (c)(1) of this section will be effective 30 days after notice is published pursuant to paragraph (f)(1) of this section.

[70 FR 59879, Oct. 13, 2005, as amended at 72 FR 43169, Aug. 3, 2007; 73 FR 78994, Dec. 24, 2008]

§ 3.2000 What are the requirements authorized state, tribe, and local programs' reporting systems must meet?

(a) Authorized programs that receive electronic documents in lieu of paper to satisfy requirements under such programs must:

(1) Use an acceptable electronic document receiving system as specified under paragraphs (b) and (c) of this section; and

(2) Require that any electronic document must bear the valid electronic signature of a signatory if that signatory would be required under the authorized program to sign the paper document for which the electronic document substitutes, unless the program has been approved by EPA to accept a handwritten signature on a separate paper submission. The paper submission must contain references to the electronic document sufficient for legal certainty that the signature was executed with the intention to certify to, attest to, or agree to the content of that electronic document.

(b) An electronic document receiving system that receives electronic documents submitted in lieu of paper documents to satisfy requirements under an authorized program must be able to generate data with respect to any such electronic document, as needed and in a timely manner, including a copy of record for the electronic document, sufficient to prove, in private litigation, civil enforcement proceedings, and criminal proceedings, that:

(1) The electronic document was not altered without detection during transmission or at any time after receipt;

(2) Any alterations to the electronic document during transmission or after receipt are fully documented;

(3) The electronic document was submitted knowingly and not by accident;

(4) Any individual identified in the electronic document submission as a submitter or signatory had the opportunity to review the copy of record in a human-readable format that clearly and accurately associates all the information provided in the electronic document with descriptions or labeling of the information and had the opportunity to repudiate the electronic document based on this review; and

(5) In the case of an electronic document that must bear electronic signatures of individuals as provided under paragraph (a)(2) of this section, that:

(i) Each electronic signature was a valid electronic signature at the time of signing;

(ii) The electronic document cannot be altered without detection at any time after being signed;

(iii) Each signatory had the opportunity to review in a human-readable format the content of the electronic document that he or she was certifying to, attesting to or agreeing to by signing;

(iv) Each signatory had the opportunity, at the time of signing, to review the content or meaning of the required certification statement, including any applicable provisions that false certification carries criminal penalties;

(v) Each signatory has signed either an electronic signature agreement or a subscriber agreement with respect to the electronic signature device used to create his or her electronic signature on the electronic document;

(vi) The electronic document receiving system has automatically responded to the receipt of the electronic document with an acknowledgment that identifies the electronic document received, including the signatory and the date and time of receipt, and is sent to at least one address that does not share the same access controls as the account used to make the electronic submission; and

(vii) For each electronic signature device used to create an electronic signature on the document, the identity of the individual uniquely entitled to use the device and his or her relation to any entity for which he or she will sign electronic documents has been determined with legal certainty by the issuing state, tribe, or local government. In the case of priority reports identified in the table in Appendix 1 of Part 3, this determination has been made before the electronic document is received, by means of:

(A) Identifiers or attributes that are verified (and that may be re-verified at any time) by attestation of disinterested individuals to be uniquely true of (or attributable to) the individual in whose name the application is submitted, based on information or objects of independent origin, at least one item of which is not subject to change without governmental action or authorization; or

(B) A method of determining identity no less stringent than would be permitted under paragraph (b)(5)(vii)(A) of this section; or

(C) Collection of either a subscriber agreement or a certification from a local registration authority that such an agreement has been received and securely stored.

(c) An authorized program that receives electronic documents in lieu of paper documents must ensure that:

(1) A person is subject to any appropriate civil, criminal penalties or other remedies under state, tribe, or local law for failure to comply with a reporting requirement if the person fails to comply with the applicable provisions for electronic reporting.

(2) Where an electronic document submitted to satisfy a state, tribe, or local reporting requirement bears an electronic signature, the electronic signature legally binds or obligates the signatory, or makes the signatory responsible, to the same extent as the signatory's handwritten signature on a paper document submitted to satisfy the same reporting requirement.

(3) Proof that a particular electronic signature device was used to create an electronic signature that is included in or logically associated with an electronic document submitted to satisfy a state, tribe, or local reporting requirement will suffice to establish that the individual uniquely entitled to use the device at the time of signature did so with the intent to sign the electronic document and give it effect.

(4) Nothing in the authorized program limits the use of electronic documents or information derived from electronic documents as evidence in enforcement proceedings.

APPENDIX 1 TO PART 3—PRIORITY REPORTS

Category	Description	40 CFR Citation
Required Reports		
State Implementation Plan	Emissions data reports for mobile sources	51.60(c).
Excess Emissions and Monitoring Performance Report Compliance Notification Report.	Excess emissions and monitoring performance report detailing the magnitude of excess emissions, and provides the date, time, and system status at the time of the excess emission.	60.7(c), 60.7(d).
New Source Performance Standards Reporting Requirements.	Semi-annual reports (quarterly, if report is approved for electronic submission by the permitting authority) on sulfur dioxide, nitrous oxides and particulate matter emission (includes reporting requirements in Subparts A through DDDD).	60.49a(e) & (j) & (v), 60.49b(v).
Semi-annual Operations and Corrective Action Reports.	Semi-annual report provides information on a company's exceedance of its sulfur dioxide emission rate, sulfur content of the fresh feed, and the average percent reduction and average concentration of sulfur dioxide. When emissions data is unavailable, a signed statement is required which documents the changes, if any, made to the emissions control system that would impact the company's compliance with emission limits.	60.107(c), 60.107(d).
National Emission Standards for Hazardous Air Pollutants Reporting Requirements.	Include such reports as: Annual compliance, calculation, initial startup, compliance status, certifications of compliance, waivers from compliance certifications, quarterly inspection certifications, operations, and operations and process change.	61.11, 61.24(a)(3) & (a)(8), 61.70(c)(1) & (c)(2)(v) & (c)(3) & (c)(4)(iv), 61.94(a) & (b)(9), 61.104(a) & (a)(1)(x) & (a)(1)(xi) & (a)(1)(xvi), 61.138(e) & (f), 61.165(d)(2) & (d)(3) & (d)(4) & (f)(1) & (f)(2) &(f)(3), 61.177(a)(2) & (c)(1) & (c)(2) & (c)(3) & (e)(1) & (e)(3), 61.186(b)(1) & (b)(2) & (b)(3) & (c)(1) & (f)(1), 61.247(a)(1) & (a)(4) & (a)(5)(v) & (b)(5) & (d), 61.254(a)(4), 61.275(a) & (b) & (c), 61.305(f) & (i), 61.357(a) & (b) & (c) & (d), 63.9(h).
Hazardous Air Pollutants Compliance Report.	Reports containing results from performance test, opacity tests, and visible emissions tests. Progress reports; periodic and immediate startup, shutdown, and malfunction reports; results from continuous monitoring system performance evaluations; excess emissions and continuous monitoring system performance report; or summary report.	63.10(d), 63.10(e)(1), 63.10(e)(3).
Notifications and Reports	Reports that document a facility's initial compliance status, notification of initial start-up, and periodic reports which includes the startup, shutdown, and malfunction reports discussed in 40 CFR 65.6(c).	65.5(d), 65.5(e).
Continuous Emissions Monitoring.	Quarterly emissions monitoring reports and opacity reports which document a facility's excess emission.	75.64, 75.65.
Notice of Fuel or Fuel Additive Registration and Health Effects Testing.	Registration of new fuels and additives, and the submission and certification of health effect data.	79.10, 79.11, 79.20, 79.21, 79.51.
Manufacture In-Use and Product Line Emissions Testing.	Reports that document the emissions testing results generated from the in-use testing program for new and in-use highway vehicle ignition engines; non-road spark-ignition engines; marine spark-ignition engines; and locomotives and locomotive engines.	86.1845, 86.1846, 86.1847, 90.113, 90.1205, 90.704, 91.805, 91.504, 92.607, 92.508, 92.509.
Industrial and Publicly Owned Treatment Works Reports.	Discharge monitoring reports for all individual permittees—including baseline reports, pretreatment standards report, periodic compliance reports, and reports made by significant industrial users.	122.41(l)(4)(i), 403.12(b) & (d) & (e) & (h).
Event Driven Notices		
State Implementation Plan	Owners report emissions data from stationary sources	51.211.
Report For Initial Performance Test.	Report that provides the initial performance test results, site-specific operating limits, and, if installed, information on the bag leak detection device used by the facility.	60.2200 (initial performance tests).
Emissions Control Report	Report submitted by new sources within 90 days of set-up which describes emission control equipment used, processes which generate asbestos-containing waste material, and disposal information.	61.153(a)(1), 61.153(a)(4)(i), 61.153(a)(5)(ii).

Category	Description	40 CFR Citation
State Operating Permits—Permit Content.	Monitoring and deviation reports under the State Operating Permit.	70.6(a)(3)(iii)(A), 70.6(a)(3)(iii)(B).
Title V Permits—Permit Content.	Monitoring and deviation reports under the Federal Operating Permit.	71.6(a)(3)(iii).
Annual Export Report	Annual report summarizing the amount and type of hazardous waste exported.	262.56(a).
Exceptions Reports	Reports submitted by a generator when the generator has not received confirmation from the Treatment, Storage, and Disposal Facility (TSDF) that it received the generator's waste and when hazardous waste shipment was received by the TSDF. For exports, reports submitted when the generator has not received a copy of the manifest from the transporter with departure date and place of export indicated; and confirmation from the consignee that the hazardous waste was received or when the hazardous waste is returned to the U.S.	262.42, 262.55.
Contingency Plan Implementation Reports.	Follow-up reports made to the Agency for all incidents noted in the operating record which required the implementation of a facility's contingency plan.	264.56(j), 265.56(j).
Significant Manifest Discrepancy Report.	Report filed by Treatment, Storage, and Disposal Facilities (TSDF) within 15 days of receiving wastes, when the TSDF is unable to resolve manifest discrepancies with the generator.	264.72(b), 265.72(b).
Unmanifested Waste Report	Report that documents hazardous waste received by a Treatment, Storage, and Disposal Facility without an accompanying manifest.	264.76, 265.76.
Noncompliance Report	An owner/operator submitted report which documents hazardous waste that was placed in hazardous waste management units in noncompliance with 40 CFR sections 264.1082(c)(1) and (c)(2); 264.1084(b); 264.1035(c)(4); or 264.1033(d).	264.1090.
Notification—Low Level Mixed Waste.	One-time notification concerning transportation and disposal of conditionally exempted waste.	266.345.
Notification—Land Disposal Restrictions.	One-time notification and certification that characteristic waste is no longer hazardous.	268.9(d).
Underground Storage Tank Notification.	Underground Storage Tank system notifications concerning design, construction, and installation. As well as when systems are being placed in operation. (EPA Form 7530–1 or state version.).	280.22.
Free Product Removal Report and Subsequent Investigation Report.	Report written and submitted within 45 days after confirming a free product release, including information on the release and recovery methods used for the free product, and when test indicate presence of free product, response measures.	280.64, 280.65.
Manufacture or Import Premanufacture Notification.	Premanufacture notification of intent to begin manufacturing, importing, or processing chemicals identified in Subpart E for significant new use (forms 7710–56 and 7710–25).	720.102, 721.25.
Permit Applications [1]		
State Implementation Plan	Information describing the source, its construction schedule, and the planned continuous emissions reductions system.	52.21(n).
State Operating Permits	Reports, notices, or other written submissions required by a State Operating Permit.	70.6(c)(1).
Title V Permits—Permit Content.	Reports, notices, or other written submissions required by a Title V Operating Permit.	71.6(c)(1), 71.25(c)(1).
Title V Permits	Specific criteria for permit modifications and or revisions, including a certification statement by a responsible official.	71.7(e(2)(ii)(c).
Reclaimer Certification	Certification made by a reclaimer that the refrigerant was reprocessed according to specifications and that no more than 1.5% of the refrigerant was released during the reclamation.	82.164.
Application for Certification and Statement of Compliance.	Control of Emissions for New and In-Use Highway Vehicles and Engines statement of compliance made by manufacturer, attesting that the engine family complies with standards for new and in-use highway vehicles and engines.	86.007–21 (heavy duty), 1844–01 (light duty).
Application for Certification	Application made by engine manufacturer to obtain certificate of conformity.	89.115, 90.107, 91.107, 92.203, 94.203.
National Pollutant Discharge Elimination System.	National Pollutant Discharge Elimination System (NPDES) Permits and Renewals (includes individual permit applications, NPDES General Form 1, and NPDES Forms 2A–F, and 2S).	122.21.

Category	Description	40 CFR Citation
Resource Conservation and Recovery Act Permit Applications and Modifications.	Signatures for permit applications and reports; submission of permit modifications. (This category excludes Class I permit modifications (40 CFR 270.42, Appendix I) that do not require prior approval).	270.11, 270.42.
Certifications of Compliance/Non-Applicability		
State Implementation Plan Requirements.	State implementation plan certifications for testing, inspection, enforcement, and continuous emissions monitoring.	51.212(c), 51.214(e).
Certification Statement	Chemical Accident Prevention Provisions—Risk Management Plan certification statements.	68.185.
Title V Permits	Federal compliance certifications and permit applications	70.5(c)(9), 70.5(d), 70.6(c)(5).
State Operating Permits	State compliance certifications and permit applications	71.5(c)(9), 71.5(d), 71.24(f).
Annual and Other Compliance Certification Reports.	Annual compliance certification report and is submitted by units subject to acid rain emissions limitations.	72.90.
Annual Compliance Certification Report, Opt-In Report, and Confirmation Report.	Annual compliance certification report which is submitted in lieu of annual compliance certification report listed in Subpart I of Part 72.	74.43.
Quarterly Reports and Compliance Certifications.	Continuous Emission Monitoring certifications, monitoring plans, and quarterly reports for NO_X emissions.	75.73.
Certification Letters Recovery and Recycling Equipment, Motor Vehicle Air Conditioners Recycling Program, Detergent Package.	Protection of Stratospheric Ozone: Recycling & Emissions Reduction. Acquisition of equipment for recovery or recycling made by auto repair service technician and Fuels and Fuel Additives Detergent additive certification.	79.4, 80.161, 82.162, 82.42.
Response Plan Cover Sheet ...	Oil Pollution Prevention certification to the truth and accuracy of information.	112 (Appendix f).
Closure Report	Report which documents that closure was in accordance with closure plan and/or details difference between actual closure and the procedures outlined in the closure plan.	146.71.
Certification of Closure and Post Closure Care, Post-Closure Notices.	Certification that Treatment, Storage, and Disposal Facilities (TSDF) are closed in accordance with approved closure plan or post-closure plan.	264.115, 264.119, 264.119(b)(2), 264.120, 265.115, 265.119(b)(2), 265.120, 265.19.
Certification of Testing Lab Analysis.	Certification that the testing and/or lab analyses required for the treatment demonstration phase of a two-phase permit was conducted.	270.63.
Periodic Certification	Certification that facility is operating its system to provide equivalent treatment as in initial certification.	437.41(b).

[1] Included within each permit application category, though sometimes not listed, are the permits submitted to run/operate/maintain facilities and/or equipment/products under EPA or authorized programs.

PART 4—UNIFORM RELOCATION ASSISTANCE AND REAL PROPERTY ACQUISITION FOR FEDERAL AND FEDERALLY ASSISTED PROGRAMS

AUTHORITY: Section 213, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987, Title IV of Pub. L. 100–17, 101 Stat. 246–256 (42 U.S.C. 4601 note).

§ 4.1 Uniform relocation assistance and real property acquisition.

Effective April 2, 1989, regulations and procedures for complying with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91–646, 84 Stat. 1894, 42 U.S.C. 4601), as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987 (Pub. L. 100–17, 101 Stat. 246–255, 42 U.S.C. 4601 note) are set forth in 49 CFR part 24.

[52 FR 48023, Dec. 17, 1987 and 54 FR 8912, Mar. 2, 1989]

PART 5—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Subpart A—Introduction

Sec.

AUTHORITY: 20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688.

SOURCE: 65 FR 52865, 52890, Aug. 30, 2000, unless otherwise noted.

Subpart A—Introduction

§ 5.100 Purpose and effective date.

The purpose of these Title IX regulations is to effectuate Title IX of the Education Amendments of 1972, as amended (except sections 904 and 906 of those Amendments) (20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688), which is designed to eliminate (with certain exceptions) discrimination on the basis of sex in any education program or activity receiving Federal financial assistance, whether or not such program or activity is offered or sponsored by an educational institution as defined in these Title IX regulations. The effective date of these Title IX regulations shall be September 29, 2000.

§ 5.105 Definitions.

As used in these Title IX regulations, the term:

Administratively separate unit means a school, department, or college of an educational institution (other than a local educational agency) admission to which is independent of admission to any other component of such institution.

Admission means selection for part-time, full-time, special, associate, transfer, exchange, or any other enrollment, membership, or matriculation in or at an education program or activity operated by a recipient.

Applicant means one who submits an application, request, or plan required to be approved by an official of the Federal agency that awards Federal financial assistance, or by a recipient, as a condition to becoming a recipient.

Designated agency official means the Director, Office of Civil Rights.

Educational institution means a local educational agency (LEA) as defined by 20 U.S.C. 8801(18), a preschool, a private elementary or secondary school, or an applicant or recipient that is an institution of graduate higher education, an institution of undergraduate higher

education, an institution of professional education, or an institution of vocational education, as defined in this section.

Federal financial assistance means any of the following, when authorized or extended under a law administered by the Federal agency that awards such assistance:

(1) A grant or loan of Federal financial assistance, including funds made available for:

(i) The acquisition, construction, renovation, restoration, or repair of a building or facility or any portion thereof; and

(ii) Scholarships, loans, grants, wages, or other funds extended to any entity for payment to or on behalf of students admitted to that entity, or extended directly to such students for payment to that entity.

(2) A grant of Federal real or personal property or any interest therein, including surplus property, and the proceeds of the sale or transfer of such property, if the Federal share of the fair market value of the property is not, upon such sale or transfer, properly accounted for to the Federal Government.

(3) Provision of the services of Federal personnel.

(4) Sale or lease of Federal property or any interest therein at nominal consideration, or at consideration reduced for the purpose of assisting the recipient or in recognition of public interest to be served thereby, or permission to use Federal property or any interest therein without consideration.

(5) Any other contract, agreement, or arrangement that has as one of its purposes the provision of assistance to any education program or activity, except a contract of insurance or guaranty.

Institution of graduate higher education means an institution that:

(1) Offers academic study beyond the bachelor of arts or bachelor of science degree, whether or not leading to a certificate of any higher degree in the liberal arts and sciences;

(2) Awards any degree in a professional field beyond the first professional degree (regardless of whether the first professional degree in such field is awarded by an institution of undergraduate higher education or professional education); or

(3) Awards no degree and offers no further academic study, but operates ordinarily for the purpose of facilitating research by persons who have received the highest graduate degree in any field of study.

Institution of professional education means an institution (except any institution of undergraduate higher education) that offers a program of academic study that leads to a first professional degree in a field for which there is a national specialized accrediting agency recognized by the Secretary of Education.

Institution of undergraduate higher education means:

(1) An institution offering at least two but less than four years of college-level study beyond the high school level, leading to a diploma or an associate degree, or wholly or principally creditable toward a baccalaureate degree; or

(2) An institution offering academic study leading to a baccalaureate degree; or

(3) An agency or body that certifies credentials or offers degrees, but that may or may not offer academic study.

Institution of vocational education means a school or institution (except an institution of professional or graduate or undergraduate higher education) that has as its primary purpose preparation of students to pursue a technical, skilled, or semiskilled occupation or trade, or to pursue study in a technical field, whether or not the school or institution offers certificates, diplomas, or degrees and whether or not it offers full-time study.

Recipient means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and that operates an education program or activity that receives such assistance, including any subunit, successor, assignee, or transferee thereof.

Student means a person who has gained admission.

Title IX means Title IX of the Education Amendments of 1972, Public Law 92–318, 86 Stat. 235, 373 (codified as amended at 20 U.S.C. 1681–1688) (except sections 904 and 906 thereof), as amended by section 3 of Public Law 93–568, 88 Stat. 1855, by section 412 of the Education Amendments of 1976, Public Law 94–482, 90 Stat. 2234, and by Section 3 of Public Law 100–259, 102 Stat. 28, 28–29 (20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688).

Title IX regulations means the provisions set forth at §§ 5.100 through 5.605.

Transition plan means a plan subject to the approval of the Secretary of Education pursuant to section 901(a)(2) of the Education Amendments of 1972, 20 U.S.C. 1681(a)(2), under which an educational institution operates in making the transition from being an educational institution that admits only students of one sex to being one that admits students of both sexes without discrimination.

[65 FR 52865, 52890, Aug. 30, 2000]

§ 5.110 Remedial and affirmative action and self-evaluation.

(a) *Remedial action.* If the designated agency official finds that a recipient has discriminated against persons on the basis of sex in an education program or activity, such recipient shall take such remedial action as the designated agency official deems necessary to overcome the effects of such discrimination.

(b) *Affirmative action.* In the absence of a finding of discrimination on the basis of sex in an education program or activity, a recipient may take affirmative action consistent with law to overcome the effects of conditions that resulted in limited participation therein by persons of a particular sex. Nothing in these Title IX regulations shall be interpreted to alter any affirmative action obligations that a recipient may have under Executive Order 11246, 3 CFR, 1964–1965 Comp., p. 339; as amended by Executive Order 11375, 3 CFR, 1966–1970 Comp., p. 684; as amended by Executive Order 11478, 3 CFR, 1966–1970 Comp., p. 803; as amended by Executive Order 12086, 3 CFR, 1978 Comp., p. 230; as amended by Executive Order 12107, 3 CFR, 1978 Comp., p. 264.

(c) *Self-evaluation.* Each recipient education institution shall, within one year of September 29, 2000:

(1) Evaluate, in terms of the requirements of these Title IX regulations, its current policies and practices and the effects thereof concerning admission of students, treatment of students, and employment of both academic and nonacademic personnel working in connection with the recipient's education program or activity;

(2) Modify any of these policies and practices that do not or may not meet the requirements of these Title IX regulations; and

(3) Take appropriate remedial steps to eliminate the effects of any discrimination that resulted or may have resulted from adherence to these policies and practices.

(d) *Availability of self-evaluation and related materials.* Recipients shall maintain on file for at least three years following completion of the evaluation required under paragraph (c) of this section, and shall provide to the designated agency official upon request, a description of any modifications made pursuant to paragraph (c)(2) of this section and of any remedial steps taken pursuant to paragraph (c)(3) of this section.

§ 5.115 Assurance required.

(a) *General.* Either at the application stage or the award stage, Federal agencies must ensure that applications for Federal financial assistance or awards of Federal financial assistance contain, be accompanied by, or be covered by a specifically identified assurance from the applicant or recipient, satisfactory to the designated agency official, that each education program or activity operated by the applicant or recipient and to which these Title IX regulations apply will be operated in compliance with these Title IX regulations. An assurance of compliance with these Title IX regulations shall not be satisfactory to the designated agency official if the applicant or recipient to whom such assurance applies fails to commit itself to take whatever remedial action is necessary in accordance with § 5.110(a) to eliminate existing discrimination on the basis of sex or to eliminate the effects of past discrimination whether

occurring prior to or subsequent to the submission to the designated agency official of such assurance.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended to provide real property or structures thereon, such assurance shall obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used to provide an education program or activity.

(2) In the case of Federal financial assistance extended to provide personal property, such assurance shall obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases such assurance shall obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Form.* (1) The assurances required by paragraph (a) of this section, which may be included as part of a document that addresses other assurances or obligations, shall include that the applicant or recipient will comply with all applicable Federal statutes relating to nondiscrimination. These include but are not limited to: Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681–1683, 1685–1688).

(2) The designated agency official will specify the extent to which such assurances will be required of the applicant's or recipient's subgrantees, contractors, subcontractors, transferees, or successors in interest.

§ 5.120 Transfers of property.

If a recipient sells or otherwise transfers property financed in whole or in part with Federal financial assistance to a transferee that operates any education program or activity, and the Federal share of the fair market value of the property is not upon such sale or transfer properly accounted for to the Federal Government, both the transferor and the transferee shall be deemed to be recipients, subject to the provisions of §§ 5.205 through 5.235(a).

§ 5.125 Effect of other requirements.

(a) *Effect of other Federal provisions.* The obligations imposed by these Title IX regulations are independent of, and do not alter, obligations not to discriminate on the basis of sex imposed by Executive Order 11246, 3 CFR, 1964–1965 Comp., p. 339; as amended by Executive Order 11375, 3 CFR, 1966–1970 Comp., p. 684; as amended by Executive Order 11478, 3 CFR, 1966–1970 Comp., p. 803; as amended by Executive Order 12087, 3 CFR, 1978 Comp., p. 230; as amended by Executive Order 12107, 3 CFR, 1978 Comp., p. 264; sections 704 and 855 of the Public Health Service Act (42 U.S.C. 295m, 298b-2); Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*); the Equal Pay Act of 1963 (29 U.S.C. 206); and any other Act of Congress or Federal regulation.

(b) *Effect of State or local law or other requirements.* The obligation to comply with these Title IX regulations is not obviated or alleviated by any State or local law or other requirement that would render any applicant or student ineligible, or limit the eligibility of any applicant or student, on the basis of sex, to practice any occupation or profession.

(c) *Effect of rules or regulations of private organizations.* The obligation to comply with these Title IX regulations is not obviated or alleviated by any rule or regulation of any organization, club, athletic or other league, or association that would render any applicant or student ineligible to participate or limit the eligibility or participation of any applicant or student, on the basis of sex, in any education program or activity operated by a recipient and that receives Federal financial assistance.

§ 5.130 Effect of employment opportunities.

The obligation to comply with these Title IX regulations is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for members of one sex than for members of the other sex.

§ 5.135 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each recipient shall designate at least one employee to coordinate its efforts

to comply with and carry out its responsibilities under these Title IX regulations, including any investigation of any complaint communicated to such recipient alleging its noncompliance with these Title IX regulations or alleging any actions that would be prohibited by these Title IX regulations. The recipient shall notify all its students and employees of the name, office address, and telephone number of the employee or employees appointed pursuant to this paragraph.

(b) *Complaint procedure of recipient.* A recipient shall adopt and publish grievance procedures providing for prompt and equitable resolution of student and employee complaints alleging any action that would be prohibited by these Title IX regulations.

§ 5.140 Dissemination of policy.

(a) *Notification of policy.* (1) Each recipient shall implement specific and continuing steps to notify applicants for admission and employment, students and parents of elementary and secondary school students, employees, sources of referral of applicants for admission and employment, and all unions or professional organizations holding collective bargaining or professional agreements with the recipient, that it does not discriminate on the basis of sex in the educational programs or activities that it operates, and that it is required by Title IX and these Title IX regulations not to discriminate in such a manner. Such notification shall contain such information, and be made in such manner, as the designated agency official finds necessary to apprise such persons of the protections against discrimination assured them by Title IX and these Title IX regulations, but shall state at least that the requirement not to discriminate in education programs or activities extends to employment therein, and to admission thereto unless §§ 5.300 through 5.310 do not apply to the recipient, and that inquiries concerning the application of Title IX and these Title IX regulations to such recipient may be referred to the employee designated pursuant to § 5.135, or to the designated agency official.

(2) Each recipient shall make the initial notification required by paragraph (a)(1) of this section within 90 days of September 29, 2000 or of the date these Title IX regulations first apply to such recipient, whichever comes later, which notification shall include publication in:

(i) Newspapers and magazines operated by such recipient or by student, alumnae, or alumni groups for or in connection with such recipient; and

(ii) Memoranda or other written communications distributed to every student and employee of such recipient.

(b) *Publications.* (1) Each recipient shall prominently include a statement of the policy described in paragraph (a) of this section in each announcement, bulletin, catalog, or application form that it makes available to any person of a type, described in paragraph (a) of this section, or which is otherwise used in connection with the recruitment of students or employees.

(2) A recipient shall not use or distribute a publication of the type described in paragraph (b)(1) of this section that suggests, by text or illustration, that such recipient treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by these Title IX regulations.

(c) *Distribution.* Each recipient shall distribute without discrimination on the basis of sex each publication described in paragraph (b)(1) of this section, and shall apprise each of its admission and employment recruitment representatives of the policy of nondiscrimination described in paragraph (a) of this section, and shall require such representatives to adhere to such policy.

Subpart B—Coverage

§ 5.200 Application.

Except as provided in §§ 5.205 through 5.235(a), these Title IX regulations apply to every recipient and to each education program or activity operated by such recipient that receives Federal financial assistance.

§ 5.205 Educational institutions and other entities controlled by religious organizations.

(a) *Exemption.* These Title IX regulations do not apply to any operation of

an educational institution or other entity that is controlled by a religious organization to the extent that application of these Title IX regulations would not be consistent with the religious tenets of such organization.

(b) *Exemption claims.* An educational institution or other entity that wishes to claim the exemption set forth in paragraph (a) of this section shall do so by submitting in writing to the designated agency official a statement by the highest-ranking official of the institution, identifying the provisions of these Title IX regulations that conflict with a specific tenet of the religious organization.

§ 5.210 Military and merchant marine educational institutions.

These Title IX regulations do not apply to an educational institution whose primary purpose is the training of individuals for a military service of the United States or for the merchant marine.

§ 5.215 Membership practices of certain organizations.

(a) *Social fraternities and sororities.* These Title IX regulations do not apply to the membership practices of social fraternities and sororities that are exempt from taxation under section 501(a) of the Internal Revenue Code of 1954, 26 U.S.C. 501(a), the active membership of which consists primarily of students in attendance at institutions of higher education.

(b) *YMCA, YWCA, Girl Scouts, Boy Scouts, and Camp Fire Girls.* These Title IX regulations do not apply to the membership practices of the Young Men's Christian Association (YMCA), the Young Women's Christian Association (YWCA), the Girl Scouts, the Boy Scouts, and Camp Fire Girls.

(c) *Voluntary youth service organizations.* These Title IX regulations do not apply to the membership practices of a voluntary youth service organization that is exempt from taxation under section 501(a) of the Internal Revenue Code of 1954, 26 U.S.C. 501(a), and the membership of which has been traditionally limited to members of one sex and principally to persons of less than nineteen years of age.

§ 5.220 Admissions.

(a) Admissions to educational institutions prior to June 24, 1973, are not covered by these Title IX regulations.

(b) *Administratively separate units.* For the purposes only of this section, §§ 5.225 and 5.230, and §§ 5.300 through 5.310, each administratively separate unit shall be deemed to be an educational institution.

(c) *Application of §§ 5.300 through .310.* Except as provided in paragraphs (d) and (e) of this section, §§ 5.300 through 5.310 apply to each recipient. A recipient to which §§ 5.300 through 5.310 apply shall not discriminate on the basis of sex in admission or recruitment in violation of §§ 5.300 through 5.310.

(d) *Educational institutions.* Except as provided in paragraph (e) of this section as to recipients that are educational institutions, §§ 5.300 through 5.310 apply only to institutions of vocational education, professional education, graduate higher education, and public institutions of undergraduate higher education.

(e) *Public institutions of undergraduate higher education.* §§ 5.300 through 5.310 do not apply to any public institution of undergraduate higher education that traditionally and continually from its establishment has had a policy of admitting students of only one sex.

§ 5.225 Educational institutions eligible to submit transition plans.

(a) *Application.* This section applies to each educational institution to which §§ 5.300 through 5.310 apply that:

(1) Admitted students of only one sex as regular students as of June 23, 1972; or

(2) Admitted students of only one sex as regular students as of June 23, 1965, but thereafter admitted, as regular students, students of the sex not admitted prior to June 23, 1965.

(b) *Provision for transition plans.* An educational institution to which this section applies shall not discriminate on the basis of sex in admission or recruitment in violation of §§ 5.300 through 5.310.

§ 5.230 Transition plans.

(a) *Submission of plans.* An institution to which § 5.225 applies and that is composed of more than one administratively separate unit may submit either a single transition plan applicable to all such units, or a separate transition plan applicable to each such unit.

(b) *Content of plans.* In order to be approved by the Secretary of Education, a transition plan shall:

(1) State the name, address, and Federal Interagency Committee on Education Code of the educational institution submitting such plan, the administratively separate units to which the plan is applicable, and the name, address, and telephone number of the person to whom questions concerning the plan may be addressed. The person who submits the plan shall be the chief administrator or president of the institution, or another individual legally authorized to bind the institution to all actions set forth in the plan.

(2) State whether the educational institution or administratively separate unit admits students of both sexes as regular students and, if so, when it began to do so.

(3) Identify and describe with respect to the educational institution or administratively separate unit any obstacles to admitting students without discrimination on the basis of sex.

(4) Describe in detail the steps necessary to eliminate as soon as practicable each obstacle so identified and indicate the schedule for taking these steps and the individual directly responsible for their implementation.

(5) Include estimates of the number of students, by sex, expected to apply for, be admitted to, and enter each class during the period covered by the plan.

(c) *Nondiscrimination.* No policy or practice of a recipient to which § 5.225 applies shall result in treatment of applicants to or students of such recipient in violation of §§ 5.300 through 5.310 unless such treatment is necessitated by an obstacle identified in paragraph (b)(3) of this section and a schedule for eliminating that obstacle has been provided as required by paragraph (b)(4) of this section.

(d) *Effects of past exclusion.* To overcome the effects of past exclusion of students on the basis of sex, each educational institution to which § 5.225 applies shall include in its transition plan, and shall implement, specific steps designed to encourage individuals of the previously excluded sex to apply for admission to such institution. Such steps shall include instituting recruitment programs that emphasize the institution's commitment to enrolling students of the sex previously excluded.

§ 5.235 Statutory amendments.

(a) This section, which applies to all provisions of these Title IX regulations, addresses statutory amendments to Title IX.

(b) These Title IX regulations shall not apply to or preclude:

(1) Any program or activity of the American Legion undertaken in connection with the organization or operation of any Boys State conference, Boys Nation conference, Girls State conference, or Girls Nation conference;

(2) Any program or activity of a secondary school or educational institution specifically for:

(i) The promotion of any Boys State conference, Boys Nation conference, Girls State conference, or Girls Nation conference; or

(ii) The selection of students to attend any such conference;

(3) Father-son or mother-daughter activities at an educational institution or in an education program or activity, but if such activities are provided for students of one sex, opportunities for reasonably comparable activities shall be provided to students of the other sex;

(4) Any scholarship or other financial assistance awarded by an institution of higher education to an individual because such individual has received such award in a single-sex pageant based upon a combination of factors related to the individual's personal appearance, poise, and talent. The pageant, however, must comply with other nondiscrimination provisions of Federal law.

(c) *Program or activity* or *program* means:

(1) All of the operations of any entity described in paragraphs (c)(1)(i) through (iv) of this section, any part of

which is extended Federal financial assistance:

(i)(A) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(B) The entity of such State or local government that distributes such assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(ii)(A) A college, university, or other postsecondary institution, or a public system of higher education; or

(B) A local educational agency (as defined in section 8801 of title 20), system of vocational education, or other school system;

(iii)(A) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(*1*) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(*2*) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(B) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(iv) Any other entity that is established by two or more of the entities described in paragraphs (c)(1)(i), (ii), or (iii) of this section.

(2)(i) *Program or activity* does not include any operation of an entity that is controlled by a religious organization if the application of 20 U.S.C. 1681 to such operation would not be consistent with the religious tenets of such organization.

(ii) For example, all of the operations of a college, university, or other postsecondary institution, including but not limited to traditional educational operations, faculty and student housing, campus shuttle bus service, campus restaurants, the bookstore, and other commercial activities are part of a ''program or activity'' subject to these Title IX regulations if the college, university, or other institution receives Federal financial assistance.

(d)(1) Nothing in these Title IX regulations shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Medical procedures, benefits, services, and the use of facilities, necessary to save the life of a pregnant woman or to address complications related to an abortion are not subject to this section.

(2) Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion. Accordingly, subject to paragraph (d)(1) of this section, no person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, employment, or other educational program or activity operated by a recipient that receives Federal financial assistance because such individual has sought or received, or is seeking, a legal abortion, or any benefit or service related to a legal abortion.

Subpart C—Discrimination on the Basis of Sex in Admission and Recruitment Prohibited

§ 5.300 Admission.

(a) *General.* No person shall, on the basis of sex, be denied admission, or be subjected to discrimination in admission, by any recipient to which §§ 5.300 through §§ 5.310 apply, except as provided in §§ 5.225 and 5.230.

(b) *Specific prohibitions.* (1) In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which §§ 5.300 through 5.310 apply shall not:

(i) Give preference to one person over another on the basis of sex, by ranking applicants separately on such basis, or otherwise;

(ii) Apply numerical limitations upon the number or proportion of persons of either sex who may be admitted; or

(iii) Otherwise treat one individual differently from another on the basis of sex.

(2) A recipient shall not administer or operate any test or other criterion for admission that has a disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown to predict validly success in the education program or activity in question and alternative tests or criteria that do not have such a disproportionately adverse effect are shown to be unavailable.

(c) *Prohibitions relating to marital or parental status.* In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which §§ 5.300 through 5.310 apply:

(1) Shall not apply any rule concerning the actual or potential parental, family, or marital status of a student or applicant that treats persons differently on the basis of sex;

(2) Shall not discriminate against or exclude any person on the basis of pregnancy, childbirth, termination of pregnancy, or recovery therefrom, or establish or follow any rule or practice that so discriminates or excludes;

(3) Subject to § 5.235(d), shall treat disabilities related to pregnancy, childbirth, termination of pregnancy, or recovery therefrom in the same manner and under the same policies as any other temporary disability or physical condition; and

(4) Shall not make pre-admission inquiry as to the marital status of an applicant for admission, including whether such applicant is ''Miss'' or ''Mrs.'' A recipient may make pre-admission inquiry as to the sex of an applicant for admission, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by these Title IX regulations.

§ 5.305 Preference in admission.

A recipient to which §§ 5.300 through 5.310 apply shall not give preference to applicants for admission, on the basis of attendance at any educational institution or other school or entity that admits as students only or predominantly members of one sex, if the giving of such preference has the effect of discriminating on the basis of sex in violation of §§ 5.300 through 5.310.

§ 5.310 Recruitment.

(a) *Nondiscriminatory recruitment.* A recipient to which §§ 5.300 through 5.310 apply shall not discriminate on the basis of sex in the recruitment and admission of students. A recipient may be required to undertake additional recruitment efforts for one sex as remedial action pursuant to § 5.110(a), and may choose to undertake such efforts as affirmative action pursuant to § 5.110(b).

(b) *Recruitment at certain institutions.* A recipient to which §§ 5.300 through 5.310 apply shall not recruit primarily or exclusively at educational institutions, schools, or entities that admit as students only or predominantly members of one sex, if such actions have the effect of discriminating on the basis of sex in violation of §§ 5.300 through 5.310.

Subpart D—Discrimination on the Basis of Sex in Education Programs or Activities Prohibited

§ 5.400 Education programs or activities.

(a) *General.* Except as provided elsewhere in these Title IX regulations, no person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, or other education program or activity operated by a recipient that receives Federal financial assistance. Sections 5.400 through 5.455 do not apply to actions of a recipient in connection with admission of its students to an education program or activity of a recipient to which §§ 5.300 through 5.310 do not apply, or an entity, not a recipient, to which §§ 5.300 through 5.310 would not apply if the entity were a recipient.

(b) *Specific prohibitions.* Except as provided in §§ 5.400 through 5.455, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or

condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-state fees and tuition;

(6) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of sex in providing any aid, benefit, or service to students or employees;

(7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

(c) *Assistance administered by a recipient educational institution to study at a foreign institution.* A recipient educational institution may administer or assist in the administration of scholarships, fellowships, or other awards established by foreign or domestic wills, trusts, or similar legal instruments, or by acts of foreign governments and restricted to members of one sex, that are designed to provide opportunities to study abroad, and that are awarded to students who are already matriculating at or who are graduates of the recipient institution; *Provided,* that a recipient educational institution that administers or assists in the administration of such scholarships, fellowships, or other awards that are restricted to members of one sex provides, or otherwise makes available, reasonable opportunities for similar studies for members of the other sex. Such opportunities may be derived from either domestic or foreign sources.

(d) *Aids, benefits or services not provided by recipient.* (1) This paragraph (d) applies to any recipient that requires participation by any applicant, student, or employee in any education program or activity not operated wholly by such recipient, or that facilitates, permits, or considers such participation as part of or equivalent to an education program or activity operated by such recipient, including participation in educational consortia and cooperative employment and student-teaching assignments.

(2) Such recipient:

(i) Shall develop and implement a procedure designed to assure itself that the operator or sponsor of such other education program or activity takes no action affecting any applicant, student, or employee of such recipient that these Title IX regulations would prohibit such recipient from taking; and

(ii) Shall not facilitate, require, permit, or consider such participation if such action occurs.

§ 5.405 Housing.

(a) *Generally.* A recipient shall not, on the basis of sex, apply different rules or regulations, impose different fees or requirements, or offer different services or benefits related to housing, except as provided in this section (including housing provided only to married students).

(b) *Housing provided by recipient.* (1) A recipient may provide separate housing on the basis of sex.

(2) Housing provided by a recipient to students of one sex, when compared to that provided to students of the other sex, shall be as a whole:

(i) Proportionate in quantity to the number of students of that sex applying for such housing; and

(ii) Comparable in quality and cost to the student.

(c) *Other housing.* (1) A recipient shall not, on the basis of sex, administer different policies or practices concerning occupancy by its students of housing other than that provided by such recipient.

(2)(i) A recipient which, through solicitation, listing, approval of housing, or otherwise, assists any agency, organization, or person in making housing available to any of its students, shall take such reasonable action as may be necessary to assure itself that such housing as is provided to students of one sex, when compared to that provided to students of the other sex, is as a whole:

(A) Proportionate in quantity; and

(B) Comparable in quality and cost to the student.

(ii) A recipient may render such assistance to any agency, organization, or person that provides all or part of such housing to students of only one sex.

§ 5.410 Comparable facilities.

A recipient may provide separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex.

§ 5.415 Access to course offerings.

(a) A recipient shall not provide any course or otherwise carry out any of its education program or activity separately on the basis of sex, or require or refuse participation therein by any of its students on such basis, including health, physical education, industrial, business, vocational, technical, home economics, music, and adult education courses.

(b)(1) With respect to classes and activities in physical education at the elementary school level, the recipient shall comply fully with this section as expeditiously as possible but in no event later than one year from September 29, 2000. With respect to physical education classes and activities at the secondary and post-secondary levels, the recipient shall comply fully with this section as expeditiously as possible but in no event later than three years from September 29, 2000.

(2) This section does not prohibit grouping of students in physical education classes and activities by ability as assessed by objective standards of individual performance developed and applied without regard to sex.

(3) This section does not prohibit separation of students by sex within physical education classes or activities during participation in wrestling, boxing, rugby, ice hockey, football, basketball, and other sports the purpose or major activity of which involves bodily contact.

(4) Where use of a single standard of measuring skill or progress in a physical education class has an adverse effect on members of one sex, the recipient shall use appropriate standards that do not have such effect.

(5) Portions of classes in elementary and secondary schools, or portions of education programs or activities, that deal exclusively with human sexuality may be conducted in separate sessions for boys and girls.

(6) Recipients may make requirements based on vocal range or quality that may result in a chorus or choruses of one or predominantly one sex.

§ 5.420 Access to schools operated by LEAs.

A recipient that is a local educational agency shall not, on the basis of sex, exclude any person from admission to:

(a) Any institution of vocational education operated by such recipient; or

(b) Any other school or educational unit operated by such recipient, unless such recipient otherwise makes available to such person, pursuant to the same policies and criteria of admission, courses, services, and facilities comparable to each course, service, and facility offered in or through such schools.

§ 5.425 Counseling and use of appraisal and counseling materials.

(a) *Counseling.* A recipient shall not discriminate against any person on the basis of sex in the counseling or guidance of students or applicants for admission.

(b) *Use of appraisal and counseling materials.* A recipient that uses testing or other materials for appraising or counseling students shall not use different materials for students on the basis of their sex or use materials that permit or require different treatment of students on such basis unless such different materials cover the same occupations and interest areas and the use of such different materials is shown to be essential to eliminate sex bias. Recipients shall develop and use internal procedures for ensuring that such materials do not discriminate on the basis of sex. Where the use of a counseling test or other instrument results in a substantially disproportionate number of members of one sex in any particular course of study or classification, the recipient shall take such action as is

necessary to assure itself that such disproportion is not the result of discrimination in the instrument or its application.

(c) *Disproportion in classes.* Where a recipient finds that a particular class contains a substantially disproportionate number of individuals of one sex, the recipient shall take such action as is necessary to assure itself that such disproportion is not the result of discrimination on the basis of sex in counseling or appraisal materials or by counselors.

§ 5.430 Financial assistance.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in providing financial assistance to any of its students, a recipient shall not:

(1) On the basis of sex, provide different amounts or types of such assistance, limit eligibility for such assistance that is of any particular type or source, apply different criteria, or otherwise discriminate;

(2) Through solicitation, listing, approval, provision of facilities, or other services, assist any foundation, trust, agency, organization, or person that provides assistance to any of such recipient's students in a manner that discriminates on the basis of sex; or

(3) Apply any rule or assist in application of any rule concerning eligibility for such assistance that treats persons of one sex differently from persons of the other sex with regard to marital or parental status.

(b) *Financial aid established by certain legal instruments.* (1) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established pursuant to domestic or foreign wills, trusts, bequests, or similar legal instruments or by acts of a foreign government that require that awards be made to members of a particular sex specified therein; *Provided,* that the overall effect of the award of such sex-restricted scholarships, fellowships, and other forms of financial assistance does not discriminate on the basis of sex.

(2) To ensure nondiscriminatory awards of assistance as required in paragraph (b)(1) of this section, recipients shall develop and use procedures under which:

(i) Students are selected for award of financial assistance on the basis of nondiscriminatory criteria and not on the basis of availability of funds restricted to members of a particular sex;

(ii) An appropriate sex-restricted scholarship, fellowship, or other form of financial assistance is allocated to each student selected under paragraph (b)(2)(i) of this section; and

(iii) No student is denied the award for which he or she was selected under paragraph (b)(2)(i) of this section because of the absence of a scholarship, fellowship, or other form of financial assistance designated for a member of that student's sex.

(c) *Athletic scholarships.* (1) To the extent that a recipient awards athletic scholarships or grants-in-aid, it must provide reasonable opportunities for such awards for members of each sex in proportion to the number of students of each sex participating in interscholastic or intercollegiate athletics.

(2) A recipient may provide separate athletic scholarships or grants-in-aid for members of each sex as part of separate athletic teams for members of each sex to the extent consistent with this paragraph (c) and § 5.450.

§ 5.435 Employment assistance to students.

(a) *Assistance by recipient in making available outside employment.* A recipient that assists any agency, organization, or person in making employment available to any of its students:

(1) Shall assure itself that such employment is made available without discrimination on the basis of sex; and

(2) Shall not render such services to any agency, organization, or person that discriminates on the basis of sex in its employment practices.

(b) *Employment of students by recipients.* A recipient that employs any of its students shall not do so in a manner that violates §§ 5.500 through 5.550.

§ 5.440 Health and insurance benefits and services.

Subject to § 5.235(d), in providing a medical, hospital, accident, or life insurance benefit, service, policy, or plan to any of its students, a recipient shall

not discriminate on the basis of sex, or provide such benefit, service, policy, or plan in a manner that would violate §§ 5.500 through 5.550 if it were provided to employees of the recipient. This section shall not prohibit a recipient from providing any benefit or service that may be used by a different proportion of students of one sex than of the other, including family planning services. However, any recipient that provides full coverage health service shall provide gynecological care.

§ 5.445 Marital or parental status.

(a) *Status generally.* A recipient shall not apply any rule concerning a student's actual or potential parental, family, or marital status that treats students differently on the basis of sex.

(b) *Pregnancy and related conditions.* (1) A recipient shall not discriminate against any student, or exclude any student from its education program or activity, including any class or extracurricular activity, on the basis of such student's pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom, unless the student requests voluntarily to participate in a separate portion of the program or activity of the recipient.

(2) A recipient may require such a student to obtain the certification of a physician that the student is physically and emotionally able to continue participation as long as such a certification is required of all students for other physical or emotional conditions requiring the attention of a physician.

(3) A recipient that operates a portion of its education program or activity separately for pregnant students, admittance to which is completely voluntary on the part of the student as provided in paragraph (b)(1) of this section, shall ensure that the separate portion is comparable to that offered to non-pregnant students.

(4) Subject to § 5.235(d), a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom in the same manner and under the same policies as any other temporary disability with respect to any medical or hospital benefit, service, plan, or policy that such recipient administers, operates, offers, or participates in with respect to students admitted to the recipient's educational program or activity.

(5) In the case of a recipient that does not maintain a leave policy for its students, or in the case of a student who does not otherwise qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, and recovery therefrom as a justification for a leave of absence for as long a period of time as is deemed medically necessary by the student's physician, at the conclusion of which the student shall be reinstated to the status that she held when the leave began.

§ 5.450 Athletics.

(a) *General.* No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, be treated differently from another person, or otherwise be discriminated against in any interscholastic, intercollegiate, club, or intramural athletics offered by a recipient, and no recipient shall provide any such athletics separately on such basis.

(b) *Separate teams.* Notwithstanding the requirements of paragraph (a) of this section, a recipient may operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport. However, where a recipient operates or sponsors a team in a particular sport for members of one sex but operates or sponsors no such team for members of the other sex, and athletic opportunities for members of that sex have previously been limited, members of the excluded sex must be allowed to try out for the team offered unless the sport involved is a contact sport. For the purposes of these Title IX regulations, contact sports include boxing, wrestling, rugby, ice hockey, football, basketball, and other sports the purpose or major activity of which involves bodily contact.

(c) *Equal opportunity.* (1) A recipient that operates or sponsors interscholastic, intercollegiate, club, or intramural athletics shall provide equal athletic opportunity for members of both sexes. In determining whether equal opportunities are available, the

designated agency official will consider, among other factors:

(i) Whether the selection of sports and levels of competition effectively accommodate the interests and abilities of members of both sexes;

(ii) The provision of equipment and supplies;

(iii) Scheduling of games and practice time;

(iv) Travel and per diem allowance;

(v) Opportunity to receive coaching and academic tutoring;

(vi) Assignment and compensation of coaches and tutors;

(vii) Provision of locker rooms, practice, and competitive facilities;

(viii) Provision of medical and training facilities and services;

(ix) Provision of housing and dining facilities and services;

(x) Publicity.

(2) For purposes of paragraph (c)(1) of this section, unequal aggregate expenditures for members of each sex or unequal expenditures for male and female teams if a recipient operates or sponsors separate teams will not constitute noncompliance with this section, but the designated agency official may consider the failure to provide necessary funds for teams for one sex in assessing equality of opportunity for members of each sex.

(d) *Adjustment period.* A recipient that operates or sponsors interscholastic, intercollegiate, club, or intramural athletics at the elementary school level shall comply fully with this section as expeditiously as possible but in no event later than one year from September 29, 2000. A recipient that operates or sponsors interscholastic, intercollegiate, club, or intramural athletics at the secondary or postsecondary school level shall comply fully with this section as expeditiously as possible but in no event later than three years from September 29, 2000.

§ 5.455 Textbooks and curricular material.

Nothing in these Title IX regulations shall be interpreted as requiring or prohibiting or abridging in any way the use of particular textbooks or curricular materials.

Subpart E—Discrimination on the Basis of Sex in Employment in Education Programs or Activities Prohibited

§ 5.500 Employment.

(a) *General.* (1) No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination in employment, or recruitment, consideration, or selection therefor, whether full-time or part-time, under any education program or activity operated by a recipient that receives Federal financial assistance.

(2) A recipient shall make all employment decisions in any education program or activity operated by such recipient in a nondiscriminatory manner and shall not limit, segregate, or classify applicants or employees in any way that could adversely affect any applicant's or employee's employment opportunities or status because of sex.

(3) A recipient shall not enter into any contractual or other relationship which directly or indirectly has the effect of subjecting employees or students to discrimination prohibited by §§ 5.500 through 5.550, including relationships with employment and referral agencies, with labor unions, and with organizations providing or administering fringe benefits to employees of the recipient.

(4) A recipient shall not grant preferences to applicants for employment on the basis of attendance at any educational institution or entity that admits as students only or predominantly members of one sex, if the giving of such preferences has the effect of discriminating on the basis of sex in violation of these Title IX regulations.

(b) *Application.* The provisions of §§ 5.500 through 5.550 apply to:

(1) Recruitment, advertising, and the process of application for employment;

(2) Hiring, upgrading, promotion, consideration for and award of tenure, demotion, transfer, layoff, termination, application of nepotism policies, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation, and changes in compensation;

(4) Job assignments, classifications, and structure, including position descriptions, lines of progression, and seniority lists;

(5) The terms of any collective bargaining agreement;

(6) Granting and return from leaves of absence, leave for pregnancy, childbirth, false pregnancy, termination of pregnancy, leave for persons of either sex to care for children or dependents, or any other leave;

(7) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(8) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, selection for tuition assistance, selection for sabbaticals and leaves of absence to pursue training;

(9) Employer-sponsored activities, including social or recreational programs; and

(10) Any other term, condition, or privilege of employment.

§ 5.505 Employment criteria.

A recipient shall not administer or operate any test or other criterion for any employment opportunity that has a disproportionately adverse effect on persons on the basis of sex unless:

(a) Use of such test or other criterion is shown to predict validly successful performance in the position in question; and

(b) Alternative tests or criteria for such purpose, which do not have such disproportionately adverse effect, are shown to be unavailable.

§ 5.510 Recruitment.

(a) *Nondiscriminatory recruitment and hiring.* A recipient shall not discriminate on the basis of sex in the recruitment and hiring of employees. Where a recipient has been found to be presently discriminating on the basis of sex in the recruitment or hiring of employees, or has been found to have so discriminated in the past, the recipient shall recruit members of the sex so discriminated against so as to overcome the effects of such past or present discrimination.

(b) *Recruitment patterns.* A recipient shall not recruit primarily or exclusively at entities that furnish as applicants only or predominantly members of one sex if such actions have the effect of discriminating on the basis of sex in violation of §§ 5.500 through 5.550.

§ 5.515 Compensation.

A recipient shall not make or enforce any policy or practice that, on the basis of sex:

(a) Makes distinctions in rates of pay or other compensation;

(b) Results in the payment of wages to employees of one sex at a rate less than that paid to employees of the opposite sex for equal work on jobs the performance of which requires equal skill, effort, and responsibility, and that are performed under similar working conditions.

§ 5.520 Job classification and structure.

A recipient shall not:

(a) Classify a job as being for males or for females;

(b) Maintain or establish separate lines of progression, seniority lists, career ladders, or tenure systems based on sex; or

(c) Maintain or establish separate lines of progression, seniority systems, career ladders, or tenure systems for similar jobs, position descriptions, or job requirements that classify persons on the basis of sex, unless sex is a bona fide occupational qualification for the positions in question as set forth in § 5.550.

§ 5.525 Fringe benefits.

(a) *''Fringe benefits'' defined.* For purposes of these Title IX regulations, *fringe benefits* means: Any medical, hospital, accident, life insurance, or retirement benefit, service, policy or plan, any profit-sharing or bonus plan, leave, and any other benefit or service of employment not subject to the provision of § 5.515.

(b) *Prohibitions.* A recipient shall not:

(1) Discriminate on the basis of sex with regard to making fringe benefits available to employees or make fringe benefits available to spouses, families, or dependents of employees differently upon the basis of the employee's sex;

(2) Administer, operate, offer, or participate in a fringe benefit plan that

does not provide for equal periodic benefits for members of each sex and for equal contributions to the plan by such recipient for members of each sex; or

(3) Administer, operate, offer, or participate in a pension or retirement plan that establishes different optional or compulsory retirement ages based on sex or that otherwise discriminates in benefits on the basis of sex.

§ 5.530 Marital or parental status.

(a) *General.* A recipient shall not apply any policy or take any employment action:

(1) Concerning the potential marital, parental, or family status of an employee or applicant for employment that treats persons differently on the basis of sex; or

(2) Which is based upon whether an employee or applicant for employment is the head of household or principal wage earner in such employee's or applicant's family unit.

(b) *Pregnancy.* A recipient shall not discriminate against or exclude from employment any employee or applicant for employment on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom.

(c) *Pregnancy as a temporary disability.* Subject to § 5.235(d), a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, recovery therefrom, and any temporary disability resulting therefrom as any other temporary disability for all job-related purposes, including commencement, duration, and extensions of leave, payment of disability income, accrual of seniority and any other benefit or service, and reinstatement, and under any fringe benefit offered to employees by virtue of employment.

(d) *Pregnancy leave.* In the case of a recipient that does not maintain a leave policy for its employees, or in the case of an employee with insufficient leave or accrued employment time to qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, and recovery therefrom as a justification for a leave of absence without pay for a reasonable period of time, at the conclusion of which the employee shall be reinstated to the status that she held when the leave began or to a comparable position, without decrease in rate of compensation or loss of promotional opportunities, or any other right or privilege of employment.

§ 5.535 Effect of state or local law or other requirements.

(a) *Prohibitory requirements.* The obligation to comply with §§ 5.500 through 5.550 is not obviated or alleviated by the existence of any State or local law or other requirement that imposes prohibitions or limits upon employment of members of one sex that are not imposed upon members of the other sex.

(b) *Benefits.* A recipient that provides any compensation, service, or benefit to members of one sex pursuant to a State or local law or other requirement shall provide the same compensation, service, or benefit to members of the other sex.

§ 5.540 Advertising.

A recipient shall not in any advertising related to employment indicate preference, limitation, specification, or discrimination based on sex unless sex is a bona fide occupational qualification for the particular job in question.

§ 5.545 Pre-employment inquiries.

(a) *Marital status.* A recipient shall not make pre-employment inquiry as to the marital status of an applicant for employment, including whether such applicant is ''Miss'' or ''Mrs.''

(b) *Sex.* A recipient may make pre-employment inquiry as to the sex of an applicant for employment, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by these Title IX regulations.

§ 5.550 Sex as a bona fide occupational qualification.

A recipient may take action otherwise prohibited by §§ 5.500 through 5.550 provided it is shown that sex is a bona fide occupational qualification for that action, such that consideration of sex with regard to such action is essential to successful operation of the employment function concerned. A recipient shall not take action pursuant to this

section that is based upon alleged comparative employment characteristics or stereotyped characterizations of one or the other sex, or upon preference based on sex of the recipient, employees, students, or other persons, but nothing contained in this section shall prevent a recipient from considering an employee's sex in relation to employment in a locker room or toilet facility used only by members of one sex.

Subpart F—Procedures

§ 5.600 Notice of covered programs.

Within 60 days of September 29, 2000, each Federal agency that awards Federal financial assistance shall publish in the FEDERAL REGISTER a notice of the programs covered by these Title IX regulations. Each such Federal agency shall periodically republish the notice of covered programs to reflect changes in covered programs. Copies of this notice also shall be made available upon request to the Federal agency's office that enforces Title IX.

§ 5.605 Enforcement procedures.

The investigative, compliance, and enforcement procedural provisions of Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) (''Title VI'') are hereby adopted and applied to these Title IX regulations. These procedures may be found at 40 CFR 7.105 through 7.135.

[65 FR 52890, Aug. 30, 2000]

PART 6—PROCEDURES FOR IMPLEMENTING THE NATIONAL ENVIRONMENTAL POLICY ACT AND ASSESSING THE ENVIRONMENTAL EFFECTS ABROAD OF EPA ACTIONS

Subpart A—General Provisions for EPA Actions Subject to NEPA

Sec.

Subpart B—EPA's NEPA Environmental Review Procedures

Subpart C—Requirements for Environmental Information Documents and Third-Party Agreements for EPA Actions Subject to NEPA

Subpart D—Assessing the Environmental Effects Abroad of EPA Actions

AUTHORITY: 42 U.S.C. 4321 *et seq.;* also 40 CFR parts 1500 through 1508, unless otherwise noted.

SOURCE: 72 FR 53662, Sept. 19, 2007, unless otherwise noted.

Subpart A—General Provisions for EPA Actions Subject to NEPA

§ 6.100 Policy and purpose.

(a) The National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, as implemented by the Council on Environmental Quality (CEQ) Regulations (40 CFR Parts 1500 through 1508), requires that Federal agencies include in their decision-making processes appropriate and careful consideration of all environmental effects of proposed actions, analyze potential environmental effects of proposed actions and their alternatives for public understanding and scrutiny, avoid or minimize adverse effects of proposed actions, and restore and enhance environmental quality to the extent practicable. The U.S. Environmental Protection Agency (EPA) shall integrate

these NEPA requirements as early in the Agency planning processes as possible. The environmental review process shall be the focal point to ensure NEPA considerations are taken into account.

(b) Through this part, EPA adopts the CEQ Regulations (40 CFR Parts 1500 through 1508) implementing NEPA; subparts A through C of this part supplement those regulations, for actions proposed by EPA that are subject to NEPA requirements. Subparts A through C supplement, and are to be used in conjunction with, the CEQ Regulations.

§ 6.101 Applicability.

(a) Subparts A through C of this part apply to the proposed actions of EPA that are subject to NEPA. EPA actions subject to NEPA include the award of wastewater treatment construction grants under Title II of the Clean Water Act, EPA's issuance of new source National Pollutant Discharge Elimination System (NPDES) permits under section 402 of the Clean Water Act, certain research and development projects, development and issuance of regulations, EPA actions involving renovations or new construction of facilities, and certain grants awarded for projects authorized by Congress through the Agency's annual Appropriations Act.

(b) Subparts A through C of this part do not apply to EPA actions for which NEPA review is not required. EPA actions under the Clean Water Act, except those identified in §6.101(a), and EPA actions under the Clean Air Act are statutorily exempt from NEPA. Additionally, the courts have determined that certain EPA actions for which analyses that have been conducted under another statute are functionally equivalent with NEPA.

(c) The appropriate Responsible Official will undertake certain EPA actions required by the provisions of subparts A through C of this part.

(d) Certain procedures in subparts A through C of this part apply to the responsibilities of the NEPA Official.

(e) Certain procedures in subparts A through C of this part apply to applicants who are required to provide environmental information to EPA.

(f) When the Responsible Official decides to perform an environmental review under the *Policy for EPA's Voluntary Preparation of National Environmental Policy Act (NEPA) Documents*, the Responsible Official generally will follow the procedures set out in subparts A through C of this part.

§ 6.102 Definitions.

(a) Subparts A through C of this part use the definitions found at 40 CFR part 1508. Additional definitions are listed in this subpart.

(b) *Definitions.* (1) *Administrator* means the Administrator of the United States Environmental Protection Agency.

(2) *Applicant* means any individual, agency, or other entity that has:

(i) Filed an application for federal assistance;

(ii) Applied to EPA for a permit; or

(iii) Requested other EPA approval.

(3) *Assistance agreement* means an award of federal assistance in the form of money or property in lieu of money from EPA to an eligible applicant including grants or cooperative agreements.

(4) *Environmental information document* (EID) means a written analysis prepared by an applicant that provides sufficient information for the Responsible Official to undertake an environmental review and prepare either an EA and FONSI or an EIS and record of decision (ROD) for the proposed action.

(5) *Environmental review or NEPA review* means the process used to comply with section 102(2) of NEPA or the CEQ Regulations including development, supplementation, adoption, and revision of NEPA documents.

(6) *Extraordinary circumstances* means those circumstances listed in section 6.204 of this part that may cause a significant environmental effect such that a proposed action that otherwise meets the requirements of a categorical exclusion may not be categorically excluded.

(7) *NEPA document* is a document prepared pursuant to NEPA.

(8) *NEPA Official* is the Associate Administrator for the Office of Policy, who is responsible for EPA's NEPA compliance.

(9) *Responsible Official* means the EPA official responsible for compliance with NEPA for individual proposed actions.

[72 FR 53662, Sept. 19, 2007, as amended at 74 FR 5993, Feb. 4, 2009; 83 FR 48546, Sept. 26, 2018]

§ 6.103 Responsibilities of the NEPA and Responsible Officials.

(a) The NEPA Official will:

(1) Ensure EPA's compliance with NEPA pursuant to 40 CFR 1507.2(a) and the regulations in subparts A through C of this part.

(2) Act as EPA's liaison with the CEQ and other federal agencies, state and local governments, and federally-recognized Indian tribes on matters of policy and administrative procedures regarding compliance with NEPA.

(3) Approve procedural deviations from subparts A through C of this part.

(4) Monitor the overall timeliness and quality of EPA's compliance with subparts A through C of this part.

(5) Advise the Administrator on NEPA-related actions that involve more than one EPA office, are highly controversial, are nationally significant, or establish new EPA NEPA-related policy.

(6) Support the Administrator by providing policy guidance on NEPA-related issues.

(7) Assist EPA's Responsible Officials with establishing and maintaining adequate administrative procedures to comply with subparts A through C of this part, performing their NEPA duties, and training personnel and applicants involved in the environmental review process.

(8) Consult with Responsible Officials and CEQ regarding proposed changes to subpart A through C of this part, including:

(i) The addition, amendment, or deletion of a categorical exclusion, or

(ii) Changes to the listings of types of actions that normally require the preparation of an EA or EIS.

(9) Determine whether proposed changes are appropriate, and if so, coordinate with CEQ, pursuant to 40 CFR 1507.3, and initiate a process to amend this part.

(b) The Responsible Official will:

(1) Ensure EPA's compliance with the CEQ regulations and subparts A through C of this part for proposed actions.

(2) Ensure that environmental reviews are conducted on proposed actions at the earliest practicable point in EPA's decision-making process and in accordance with the provisions of subparts A through C of this part.

(3) Ensure, to the extent practicable, early and continued involvement of interested federal agencies, state and local governments, federally-recognized Indian tribes, and affected applicants in the environmental review process.

(4) Coordinate with the NEPA Official and other Responsible Officials, as appropriate, on resolving issues involving EPA-wide NEPA policy and procedures (including the addition, amendment, or deletion of a categorical exclusion and changes to the listings of the types of actions that normally requires the preparation of an EA or EIS) and/or unresolved conflicts with other federal agencies, state and local governments, and federally-recognized Indian tribes, and/or advising the Administrator when necessary.

(5) Coordinate with other Responsible Officials, as appropriate, on NEPA-related actions involving their specific interests.

(6) Consistent with national NEPA guidance, provide specific policy guidance, as appropriate, and ensure that the Responsible Official's office establishes and maintains adequate administrative procedures to comply with subparts A through C of this part.

(7) Upon request of an applicant and consistent with 40 CFR 1501.8, set time limits on the NEPA review appropriate to individual proposed actions.

(8) Make decisions relating to the preparation of the appropriate NEPA documents, including preparing an EA or EIS, and signing the decision document.

(9) Monitor the overall timeliness and quality of the Responsible Official's respective office's efforts to comply with subparts A through C of this part.

(c) The NEPA Official and the Responsible Officials may delegate NEPA-related responsibilities to a level no lower than the Branch Chief or equivalent organizational level.

Subpart B—EPA's NEPA Environmental Review Procedures

§ 6.200 General requirements.

(a) The Responsible Official must determine whether the proposed action meets the criteria for categorical exclusion or whether it requires preparation of an EA or an EIS to identify and evaluate its environmental impacts. The Responsible Official may decide to prepare an EIS without first undertaking an EA.

(b) The Responsible Official must determine the scope of the environmental review by considering the type of proposed action, the reasonable alternatives, and the type of environmental impacts. The scope of an EIS will be determined as provided in 40 CFR 1508.25.

(c) During the environmental review process, the Responsible Official must:

(1) Integrate the NEPA process and the procedures of subparts A through C of this part into early planning to ensure appropriate consideration of NEPA's policies and to minimize or eliminate delay;

(2) Emphasize cooperative consultation among federal agencies, state and local governments, and federally-recognized Indian tribes before an EA or EIS is prepared to help ensure compliance with the procedural provisions of subparts A through C of this part and with other environmental review requirements, to address the need for interagency cooperation, to identify the requirements for other agencies' reviews, and to ensure appropriate public participation.

(3) Identify at an early stage any potentially significant environmental issues to be evaluated in detail and insignificant issues to be de-emphasized, focusing the scope of the environmental review accordingly;

(4) Involve other agencies and the public, as appropriate, in the environmental review process for proposed actions that are not categorically excluded to:

(i) Identify the federal, state, local, and federally-recognized Indian tribal entities and the members of the public that may have an interest in the action;

(ii) Request that appropriate federal, state, and local agencies and federally-recognized Indian tribes serve as cooperating agencies consistent with 40 CFR 1501.6 and 1508.5; and

(iii) Integrate, where possible, review of applicable federal laws and executive orders into the environmental review process in conjunction with the development of NEPA documents.

(d) When preparing NEPA documents, the Responsible Official must:

(1) Utilize a systematic, interdisciplinary approach to integrate the natural and social sciences with the environmental design arts in planning and making decisions on proposed actions subject to environmental review under subparts A through C of this part (see 40 CFR 1501.2(a) and 1507.2);

(2) Plan adequate time and funding for the NEPA review and preparation of the NEPA documents. Planning includes consideration of whether an applicant will be required to prepare an EID for the proposed action.

(3) Review relevant planning or decision-making documents, whether prepared by EPA or another federal agency, to determine if the proposed action or any of its alternatives have been considered in a prior federal NEPA document. EPA may adopt the existing document, or will incorporate by reference any pertinent part of it, consistent with 40 CFR 1506.3 and 1502.21.

(4) Review relevant environmental review documents prepared by a state or local government or a federally-recognized Indian tribe to determine if the proposed action or any of its alternatives have been considered in such a document. EPA will incorporate by reference any pertinent part of that document consistent with 40 CFR 1502.21.

(e) During the decision-making process for the proposed action, the Responsible Official must:

(1) Incorporate the NEPA review in decision-making on the action. Processing and review of an applicant's application must proceed concurrently with the NEPA review procedures set out in subparts A through C of this part. EPA must complete its NEPA review before making a decision on the action.

(2) Consider the relevant NEPA documents, public and other agency comments (if any) on those documents, and EPA responses to those comments, as part of consideration of the action (see 40 CFR 1505.1(d)).

(3) Consider the alternatives analyzed in an EA or EIS before rendering a decision on the action; and

(4) Ensure that the decision on the action is to implement an alternative analyzed or is within the range of alternatives analyzed in the EA or EIS (see 40 CFR 1505.1(e)).

(f) To eliminate duplication and to foster efficiency, the Responsible Official should use tiering (see 40 CFR 1502.20 and 1508.28) and incorporate material by reference (see 40 CFR 1502.21) as appropriate.

(g) For applicant-related proposed actions:

(1) The Responsible Official may request that the applicant submit information to support the application of a categorical exclusion to the applicant's pending action.

(2) The Responsible Official may gather the information and prepare the NEPA document without assistance from the applicant, or, pursuant to Subpart C of this part, have the applicant prepare an EID or a draft EA and supporting documents, or enter into a third-party agreement with the applicant.

(3) During the environmental review process, applicants may continue to compile additional information needed for the environmental review and/or information necessary to support an application for a permit or assistance agreement from EPA.

(h) For all NEPA determinations (CEs, EA/FONSIs, or EIS/RODs) that are five years old or older, and for which the subject action has not yet been implemented, the Responsible Official must re-evaluate the proposed action, environmental conditions, and public views to determine whether to conduct a supplemental environmental review of the action and complete an appropriate NEPA document or reaffirm EPA's original NEPA determination. If there has been substantial change in the proposed action that is relevant to environmental concerns, or if there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts, the Responsible Official must conduct a supplemental environmental review of the action and complete an appropriate NEPA document.

§ 6.201 Coordination with other environmental review requirements.

Consistent with 40 CFR 1500.5(g) and 1502.25, the Responsible Official must determine the applicability of other environmental laws and executive orders, to the fullest extent possible. The Responsible Official should incorporate applicable requirements as early in the NEPA review process as possible.

§ 6.202 Interagency cooperation.

(a) Consistent with 40 CFR 1501.5, 1501.6, and 1508.5, the Responsible Official will request other appropriate federal and non-federal agencies to be joint lead or cooperating agencies as a means of encouraging early coordination and cooperation with federal agencies, state and local governments, and federally-recognized Indian tribes with jurisdiction by law or special expertise.

(b) For an EPA action related to an action of any other federal agency, the Responsible Official must comply with the requirements of 40 CFR 1501.5 and 1501.6 relating to lead agencies and cooperating agencies, respectively. The Responsible Official will work with the other involved agencies to facilitate coordination and to reduce delay and duplication.

(c) To prepare a single document to fulfill both NEPA and state or local government, or federally-recognized Indian tribe requirements, consistent with 40 CFR 1506.2, the Responsible Official should enter into a written agreement with the involved state or local government, or federally-recognized Indian tribe that sets out the intentions of the parties, including the responsibilities each party intends to assume and procedures the parties intend to follow.

§ 6.203 Public participation.

(a) *General requirements.* (1) The procedures in this section apply to EPA's environmental review processes, including development, supplementation,

adoption, and revision of NEPA documents.

(2) The Responsible Official will make diligent efforts to involve the public, including applicants, in the preparation of EAs or EISs consistent with 40 CFR 1501.4 and 1506.6 and applicable EPA public participation regulations (e.g., 40 CFR Part 25).

(3) EPA NEPA documents will use plain language to the extent possible.

(4) The Responsible Official will, to the greatest extent possible, give notice to any state or local government, or federally-recognized Indian tribe that, in the Official's judgment, may be affected by an action for which EPA plans to prepare an EA or an EIS.

(5) The Responsible Official must use appropriate communication procedures to ensure meaningful public participation throughout the NEPA process. The Responsible Official must make reasonable efforts to involve the potentially affected communities where the proposed action is expected to have environmental impacts or where the proposed action may have human health or environmental effects in any communities, including minority communities, low-income communities, or federally-recognized Indian tribal communities.

(b) *EA and FONSI requirements.* (1) At least thirty (30) calendar days before making the decision on whether, and if so how, to proceed with a proposed action, the Responsible Official must make the EA and preliminary FONSI available for review and comment to the interested federal agencies, state and local governments, federally-recognized Indian tribes and the affected public. The Responsible Official must respond to any substantive comments received and finalize the EA and FONSI before making a decision on the proposed action.

(2) Where circumstances make it necessary to take the action without observing the 30 calendar day comment period, the Responsible Official must notify the NEPA Official before taking such action. If the NEPA Official determines that a reduced comment period would be in the best interest of the Government, the NEPA Official will inform the Responsible Official, as soon as possible, of this approval. The Responsible Official will make the EA and preliminary FONSI available for review and comment for the reduced comment period.

(c) *EIS and ROD requirements.* (1) As soon as practicable after the decision to prepare an EIS and before beginning the scoping process, the Responsible Official must ensure that a notice of intent (NOI) (see 40 CFR 1508.22) is published in the FEDERAL REGISTER. The NOI must briefly describe the proposed action; a preliminary list of environmental issues to be analyzed, and possible alternatives; EPA's proposed scoping process including, if available, whether, when, and where any scoping meeting will be held; and the name and contact information for the person designated by EPA to answer questions about the proposed action and the EIS. The NOI must invite comments and suggestions on the scope of the EIS.

(2) The Responsible Official must disseminate the NOI consistent with 40 CFR 1506.6.

(3) The Responsible Official must conduct the scoping process consistent with 40 CFR 1501.7 and any applicable EPA public participation regulations (e.g., 40 CFR Part 25).

(i) Publication of the NOI in the FEDERAL REGISTER begins the scoping process.

(ii) The Responsible Official must ensure that the scoping process for an EIS allows a minimum of thirty (30) days for the receipt of public comments.

(iii) The Responsible Official may hold one or more public meetings as part of the scoping process for an EPA EIS. The Responsible Official must announce the location, date, and time of public scoping meetings in the NOI or by other appropriate means, such as additional notices in the FEDERAL REGISTER, news releases to the local media, or letters to affected parties. Public scoping meetings should be held at least fifteen (15) days after public notification.

(iv) The Responsible Official must use appropriate means to publicize the availability of draft and final EISs and the time and place for public meetings or hearings on draft EISs. The methods chosen for public participation must focus on reaching persons who may be

interested in the proposed action. Such persons include those in potentially affected communities where the proposed action is known or expected to have environmental impacts including minority communities, low-income communities, or federally-recognized Indian tribal communities.

(v) The Responsible Official must circulate the draft and final EISs consistent with 40 CFR 1502.19 and any applicable EPA public participation regulations and in accordance with the 45-day public review period for draft EISs and the 30-day public review period for final EISs (see § 6.209 of this part). Consistent with section 6.209(b) of this part, the Responsible Official may establish a longer public comment period for a draft or final EIS.

(vi) After preparing a draft EIS and before preparing a final EIS, the Responsible Official must solicit the comments of appropriate federal agencies, state and/or local governments, and/or federally-recognized Indian tribes, and the public (see 40 CFR 1503.1). The Responsible Official must respond in the final EIS to substantive comments received (see 40 CFR 1503.4).

(vii) The Responsible Official may conduct one or more public meetings or hearings on the draft EIS as part of the public involvement process. If meetings or hearings are held, the Responsible Official must make the draft EIS available to the public at least thirty (30) days in advance of any meeting or hearing.

(4) The Responsible Official must make the ROD available to the public upon request.

§ 6.204 Categorical exclusions and extraordinary circumstances.

(a) A proposed action may be categorically excluded if the action fits within a category of action that is eligible for exclusion and the proposed action does not involve any extraordinary circumstances.

(1) Certain actions eligible for categorical exclusion require the Responsible Official to document a determination that a categorical exclusion applies. The documentation must include: A brief description of the proposed action; a statement identifying the categorical exclusion that applies to the action; and a statement explaining why no extraordinary circumstances apply to the proposed action. The Responsible Official must make a copy of the determination document available to the public upon request. The categorical exclusions requiring this documentation are listed in paragraphs (a)(1)(i) through (a)(1)(v) of this section.

(i) Actions at EPA owned or operated facilities involving routine facility maintenance, repair, and groundskeeping; minor rehabilitation, restoration, renovation, or revitalization of existing facilities; functional replacement of equipment; acquisition and installation of equipment; or construction of new minor ancillary facilities adjacent to or on the same property as existing facilities.

(ii) Actions relating to existing infrastructure systems (such as sewer systems; drinking water supply systems; and stormwater systems, including combined sewer overflow systems) that involve minor upgrading, or minor expansion of system capacity or rehabilitation (including functional replacement) of the existing system and system components (such as the sewer collection network and treatment system; the system to collect, treat, store and distribute drinking water; and stormwater systems, including combined sewer overflow systems) or construction of new minor ancillary facilities adjacent to or on the same property as existing facilities. This category does not include actions that: involve new or relocated discharges to surface or ground water; will likely result in the substantial increase in the volume or the loading of pollutant to the receiving water; will provide capacity to serve a population 30% greater than the existing population; are not supported by the state, or other regional growth plan or strategy; or directly or indirectly involve or relate to upgrading or extending infrastructure systems primarily for the purposes of future development.

(iii) Actions in unsewered communities involving the replacement of existing onsite systems, providing the new onsite systems do not result in substantial increases in the volume of discharge or the loadings of pollutants

from existing sources, or relocate existing discharge.

(iv) Actions involving re-issuance of a NPDES permit for a new source providing the conclusions of the original NEPA document are still valid (including the appropriate mitigation), there will be no degradation of the receiving waters, and the permit conditions do not change or are more environmentally protective.

(v) Actions for award of grants authorized by Congress under EPA's annual Appropriations Act that are solely for reimbursement of the costs of a project that was completed prior to the date the appropriation was enacted.

(2) Certain actions eligible for categorical exclusion do not require the Responsible Official to document a determination that a categorical exclusion applies. These categorical exclusions are listed in paragraphs (a)(2)(i) through (a)(2)(x) of this section.

(i) Procedural, ministerial, administrative, financial, personnel, and management actions necessary to support the normal conduct of EPA business.

(ii) Acquisition actions (compliant with applicable procedures for sustainable or ''green'' procurement) and contracting actions necessary to support the normal conduct of EPA business.

(iii) Actions involving information collection, dissemination, or exchange; planning; monitoring and sample collection wherein no significant alteration of existing ambient conditions occurs; educational and training programs; literature searches and studies; computer studies and activities; research and analytical activities; development of compliance assistance tools; and architectural and engineering studies. These actions include those conducted directly by EPA and EPA actions relating to contracts or assistance agreements involving such actions.

(iv) Actions relating to or conducted completely within a permanent, existing contained facility, such as a laboratory, or other enclosed building, provided that reliable and scientifically-sound methods are used to appropriately dispose of wastes and safeguards exist to prevent hazardous, toxic, and radioactive materials in excess of allowable limits from entering the environment. Where such activities are conducted at laboratories, the Lab Director or other appropriate official must certify in writing that the laboratory follows good laboratory practices and adheres to all applicable federal, state, local, and federally-recognized Indian tribal laws and regulations. This category does not include activities related to construction and/or demolition within the facility (see paragraph (a)(1)(i) of this section).

(v) Actions involving emergency preparedness planning and training activities.

(vi) Actions involving the acquisition, transfer, lease, disposition, or closure of existing permanent structures, land, equipment, materials or personal property provided that the property: Is either vacant or has been used solely for office functions; has never been used for laboratory purposes by any party; does not require site remediation; and will be used in essentially the same manner such that the type and magnitude of the impacts will not change substantially. This category does not include activities related to construction and/or demolition of structures on the property (see paragraph (a)(1)(i) of this section).

(vii) Actions involving providing technical advice to federal agencies, state or local governments, federally-recognized Indian tribes, foreign governments, or public or private entities.

(viii) Actions involving approval of EPA participation in international ''umbrella'' agreements for cooperation in environmental-related activities that would not commit the United States to any specific projects or actions.

(ix) Actions involving containment or removal and disposal of asbestos-containing material or lead-based paint from EPA owned or operated facilities when undertaken in accordance with applicable regulations.

(x) Actions involving new source NPDES permit modifications that make only technical corrections to the NPDES permit (such as correcting typographical errors) that do not result in a change in environmental impacts or conditions.

(b) The Responsible Official must review actions eligible for categorical exclusion to determine whether any extraordinary circumstances are involved. Extraordinary circumstances are listed in paragraphs (b)(1) through (b)(10) of this section. (See 40 CFR 1508.4.)

(1) The proposed action is known or expected to have potentially significant environmental impacts on the quality of the human environment either individually or cumulatively over time.

(2) The proposed action is known or expected to have disproportionately high and adverse human health or environmental effects on any community, including minority communities, low-income communities, or federally-recognized Indian tribal communities.

(3) The proposed action is known or expected to significantly affect federally listed threatened or endangered species or their critical habitat.

(4) The proposed action is known or expected to significantly affect national natural landmarks or any property with nationally significant historic, architectural, prehistoric, archeological, or cultural value, including but not limited to, property listed on or eligible for the National Register of Historic Places.

(5) The proposed action is known or expected to significantly affect environmentally important natural resource areas such as wetlands, floodplains, significant agricultural lands, aquifer recharge zones, coastal zones, barrier islands, wild and scenic rivers, and significant fish or wildlife habitat.

(6) The proposed action is known or expected to cause significant adverse air quality effects.

(7) The proposed action is known or expected to have a significant effect on the pattern and type of land use (industrial, commercial, agricultural, recreational, residential) or growth and distribution of population including altering the character of existing residential areas, or may not be consistent with state or local government, or federally-recognized Indian tribe approved land use plans or federal land management plans.

(8) The proposed action is known or expected to cause significant public controversy about a potential environmental impact of the proposed action.

(9) The proposed action is known or expected to be associated with providing financial assistance to a federal agency through an interagency agreement for a project that is known or expected to have potentially significant environmental impacts.

(10) The proposed action is known or expected to conflict with federal, state or local government, or federally-recognized Indian tribe environmental, resource-protection, or land-use laws or regulations.

(c) The Responsible Official may request that an applicant submit sufficient information to enable the Responsible Official to determine whether a categorical exclusion applies to the applicant's proposed action or whether an exceptional circumstance applies. Pursuant to Subpart C of this part, applicants are not required to prepare EIDs for actions that are being considered for categorical exclusion.

(d) The Responsible Official must prepare an EA or EIS when a proposed action involves extraordinary circumstances.

(e) After a determination has been made that a categorical exclusion applies to an action, if new information or changes in the proposed action involve or relate to at least one of the extraordinary circumstances or otherwise indicate that the action may not meet the criteria for categorical exclusion and the Responsible Official determines that an action no longer qualifies for a categorical exclusion, the Responsible Official will prepare an EA or EIS.

(f) The Responsible Official, or other interested parties, may request the addition, amendment, or deletion of a categorical exclusion.

(1) Such requests must be made in writing, be directed to the NEPA Official, and contain adequate information to support and justify the request.

(2) Proposed new categories of actions for exclusion must meet these criteria:

(i) Actions covered by the proposed categorical exclusion generally do not individually or cumulatively have a

significant effect on the human environment and have been found by EPA to have no such effect.

(ii) Actions covered by the proposed categorical exclusion generally do not involve extraordinary circumstances as set out in paragraphs (b)(1) through (b)(10) of this section and generally do not require preparation of an EIS; and

(iii) Information adequate to determine that a proposed action is properly covered by the proposed category will generally be available.

(3) The NEPA Official must determine that the addition, amendment, or deletion of a categorical exclusion is appropriate.

(g) Any addition, amendment, or deletion of a categorical exclusion will be done by rule-making and in coordination with CEQ pursuant to 40 CFR 1507.3 to amend paragraph (a)(1) or paragraph (a)(2) of this section.

[72 FR 53662, Sept. 19, 2007, as amended at 74 FR 5993, Feb. 4, 2009]

§ 6.205 Environmental assessments.

(a) The Responsible Official must prepare an environmental assessment (EA) (see 40 CFR 1508.9) for a proposed action that is expected to result in environmental impacts and the significance of the impacts is not known. An EA is not required if the proposed action is categorically excluded, or if the Responsible Official has decided to prepare an EIS. (See 40 CFR 1501.3.)

(b) Types of actions that normally require the preparation of an EA include:

(1) The award of wastewater treatment construction grants under Title II of the Clean Water Act;

(2) EPA's issuance of new source NPDES permits under section 402 of the Clean Water Act;

(3) EPA actions involving renovations or new construction of facilities;

(4) Certain grants awarded for special projects authorized by Congress through the Agency's annual Appropriations Act; and

(5) Research and development projects, such as initial field demonstration of a new technology, field trials of a new product or new uses of an existing technology, alteration of a local habitat by physical or chemical means, or actions that may result in the release of radioactive, hazardous, or toxic substances, or biota.

(c) The Responsible Official, or other interested parties, may request changes to the list of actions that normally require the preparation of an EA (i.e., the addition, amendment, or deletion of a type of action).

(d) Consistent with 40 CFR 1508.9, an EA must provide sufficient information and analysis for determining whether to prepare an EIS or to issue a FONSI (see 40 CFR 1508.9(a)), and may include analyses needed for other environmental determinations. The EA must focus on resources that might be impacted and any environmental issues that are of public concern.

(e) An EA must include:

(1) A brief discussion of:

(i) The need for the proposed action;

(ii) The alternatives, including the no action alternative (which must be assessed even when the proposed action is specifically required by legislation or a court order);

(iii) The affected environment, including baseline conditions that may be impacted by the proposed action and alternatives;

(iv) The environmental impacts of the proposed action and alternatives, including any unresolved conflicts concerning alternative uses of available resources; and

(v) Other applicable environmental laws and executive orders.

(2) A listing or summary of any coordination or consultation undertaken with any federal agency, state or local government, or federally-recognized Indian tribe regarding compliance with applicable laws and executive orders;

(3) Identification and description of any mitigation measures considered, including any mitigation measures that must be adopted to ensure the action will not have significant impacts; and

(4) Incorporation of documents by reference, if appropriate, including, when available, the EID for the action.

§ 6.206 Findings of no significant impact.

(a) The Responsible Official may issue a finding of no significant impact (FONSI) (see 40 CFR 1508.13) only if the

EA supports the finding that the proposed action will not have a significant effect on the human environment. If the EA does not support a FONSI, the Responsible Official must prepare an EIS and issue a ROD before taking action on the proposed action.

(b) Consistent with 40 CFR 1508.13, a FONSI must include:

(1) The EA, or in lieu of the EA, a summary of the supporting EA that includes a brief description of the proposed action and alternatives considered in the EA, environmental factors considered, and project impacts; and

(2) A brief description of the reasons why there are no significant impacts.

(c) In addition, the FONSI must include:

(1) Any commitments to mitigation that are essential to render the impacts of the proposed action not significant;

(2) The date of issuance; and

(3) The signature of the Responsible Official.

(d) The Responsible Official must ensure that an applicant that has committed to mitigation possesses the authority and ability to fulfill the commitments.

(e) The Responsible Official must make a preliminary FONSI available to the public in accordance with section 6.203(b) of this part before taking action.

(f) The Responsible Official may proceed with the action subject to any mitigation measures described in the FONSI after responding to any substantive comments received on the preliminary FONSI during the 30-day comment period, or 30 days after issuance of the FONSI if no substantive comments are received.

(g) The Responsible Official must ensure that the mitigation measures necessary to the FONSI determination, at a minimum, are enforceable, and conduct appropriate monitoring of the mitigation measures.

(h) The Responsible Official may revise a FONSI at any time provided the revision is supported by an EA. A revised FONSI is subject to all provisions of paragraph (d) of this section.

§ 6.207 Environmental impact statements.

(a) The Responsible Official will prepare an environmental impact statement (EIS) (see 40 CFR 1508.11) for major federal actions significantly affecting the quality of the human environment, including actions for which the EA analysis demonstrates that significant impacts will occur that will not be reduced or eliminated by changes to or mitigation of the proposed action.

(1) EISs are normally prepared for the following actions:

(i) New regional wastewater treatment facilities or water supply systems for a community with a population greater than 100,000.

(ii) Expansions of existing wastewater treatment facilities that will increase existing discharge to an impaired water by greater than 10 million gallons per day (mgd).

(iii) Issuance of new source NPDES permit for a new major industrial discharge.

(iv) Issuance of a new source NPDES permit for a new oil/gas development and production operation on the outer continental shelf.

(v) Issuance of a new source NPDES permit for a deepwater port with a projected discharge in excess of 10 mgd.

(2) The Responsible Official, or other interested party, may request changes to the list of actions that normally require the preparation of an EIS (i.e., the addition, amendment, or deletion of a type of action).

(3) A proposed action normally requires an EIS if it meets any of the following criteria. (See 40 CFR 1507.3(b)(2)).

(i) The proposed action would result in a discharge of treated effluent from a new or modified existing facility into a body of water and the discharge is likely to have a significant effect on the quality of the receiving waters.

(ii) The proposed action is likely to directly, or through induced development, have significant adverse effect upon local ambient air quality or local ambient noise levels.

(iii). The proposed action is likely to have significant adverse effects on surface water reservoirs or navigation projects.

(iv) The proposed action would be inconsistent with state or local government, or federally-recognized Indian tribe approved land use plans or regulations, or federal land management plans.

(v) The proposed action would be inconsistent with state or local government, or federally-recognized Indian tribe environmental, resource-protection, or land-use laws and regulations for protection of the environment.

(vi) The proposed action is likely to significantly affect the environment through the release of radioactive, hazardous or toxic substances, or biota.

(vii) The proposed action involves uncertain environmental effects or highly unique environmental risks that are likely to be significant.

(viii) The proposed action is likely to significantly affect national natural landmarks or any property on or eligible for the National Register of Historic Places.

(ix) The proposed action is likely to significantly affect environmentally important natural resources such as wetlands, significant agricultural lands, aquifer recharge zones, coastal zones, barrier islands, wild and scenic rivers, and significant fish or wildlife habitat.

(x) The proposed action in conjunction with related federal, state or local government, or federally-recognized Indian tribe projects is likely to produce significant cumulative impacts.

(xi) The proposed action is likely to significantly affect the pattern and type of land use (industrial, commercial, recreational, residential) or growth and distribution of population including altering the character of existing residential areas.

(4) An EIS must be prepared consistent with 40 CFR Part 1502.

(b) When appropriate, the Responsible Official will prepare a legislative EIS consistent with 40 CFR 1506.8.

(c) In preparing an EIS, the Responsible Official must determine if an applicant, other federal agencies or state or local governments, or federally-recognized Indian tribes are involved with the project and apply the applicable provisions of § 6.202 and Subpart C of this part.

(d) An EIS must:

(1) Comply with all requirements at 40 CFR parts 1500 through 1508.

(2) Analyze all reasonable alternatives and the no action alternative (which may be the same as denying the action). Assess the no action alternative even when the proposed action is specifically required by legislation or a court order.

(3) Describe the potentially affected environment including, as appropriate, the size and location of new and existing facilities, land requirements, operation and maintenance requirements, auxiliary structures such as pipelines or transmission lines, and construction schedules.

(4) Summarize any coordination or consultation undertaken with any federal agency, state and/or local government, and/or federally-recognized Indian tribe, including copies or summaries of relevant correspondence.

(5) Summarize any public meetings held during the scoping process including the date, time, place, and purpose of the meetings. The final EIS must summarize the public participation process including the date, time, place, and purpose of meetings or hearings held after publication of the draft EIS.

(6) Consider substantive comments received during the public participation process. The draft EIS must consider the substantive comments received during the scoping process. The final EIS must include or summarize all substantive comments received on the draft EIS, respond to any substantive comments on the draft EIS, and explain any changes to the draft EIS and the reason for the changes.

(7) Include the names and qualifications of the persons primarily responsible for preparing the EIS including an EIS prepared under a third-party contract (if applicable), significant background papers, and the EID (if applicable).

(e) The Responsible Official must prepare a supplemental EIS when appropriate, consistent with 40 CFR 1502.9.

§ 6.208 Records of decision.

(a) The Responsible Official may not make any decisions on the action until the time periods in 40 CFR 1506.10 have been met.

(b) A record of decision (ROD) records EPA's decision on the action. Consistent with 40 CFR 1505.2, a ROD must include:

(1) A brief description of the proposed action and alternatives considered in the EIS, environmental factors considered, and project impacts;

(2) Any commitments to mitigation; and

(3) An explanation if the environmentally preferred alternative was not selected.

(c) In addition, the ROD must include:

(1) Responses to any substantive comments on the final EIS;

(2) The date of issuance; and

(3) The signature of the Responsible Official.

(d) The Responsible Official must ensure that an applicant that has committed to mitigation possesses the authority and ability to fulfill the commitment.

(e) The Responsible Official must make a ROD available to the public.

(f) Upon issuance of the ROD, the Responsible Official may proceed with the action subject to any mitigation measures described in the ROD. The Responsible Official must ensure adequate monitoring of mitigation measures identified in the ROD.

(g) If the mitigation identified in the ROD will be included as a condition in the permit or grant, the Responsible Official must ensure that EPA has the authority to impose the conditions. The Responsible Official should ensure that compliance with assistance agreement or permit conditions will be monitored and enforced under EPA's assistance agreement and permit authorities.

(h) The Responsible Official may revise a ROD at any time provided the revision is supported by an EIS. A revised ROD is subject to all provisions of paragraph (d) of this section.

§ 6.209 Filing requirements for EPA EISs.

(a) The Responsible Official must file an EIS with the NEPA Official no earlier than the date the document is transmitted to commenting agencies and made available to the public. The Responsible Official must comply with any guidelines established by the NEPA Official for the filing system process and comply with 40 CFR 1506.9 and 1506.10. The review periods are computed through the filing system process and published in the FEDERAL REGISTER in the Notice of Availability.

(b) The Responsible Official may request that the NEPA Official extend the review periods for an EIS. The NEPA Official will publish notice of an extension of the review period in the FEDERAL REGISTER and notify the CEQ.

§ 6.210 Emergency circumstances.

If emergency circumstances make it necessary to take an action that has a significant environmental impact without observing the provisions of subparts A through C of this part that are required by the CEQ Regulations, the Responsible Official must consult with the NEPA Official at the earliest possible time. Consistent with 40 CFR 1506.11, the Responsible Official and the NEPA Official should consult with CEQ about alternative arrangements at the earliest opportunity. Actions taken without observing the provisions of subparts A through C of this part will be limited to actions necessary to control the immediate impacts of the emergency; other actions remain subject to the environmental review process.

Subpart C—Requirements for Environmental Information Documents and Third-Party Agreements for EPA Actions Subject to NEPA

§ 6.300 Applicability.

(a) This section applies to actions that involve applications to EPA for permits or assistance agreements, or request other EPA approval.

(b) The Responsible Official is responsible for the environmental review process on EPA's action (that is, issuing the permit or awarding the assistance agreement) with the applicant contributing through submission of an EID or a draft EA and supporting documents.

(c) An applicant is not required to prepare an EID when:

(1) The action has been categorically excluded or requires the preparation of an EIS; or

(2) The applicant will prepare and submit a draft EA and supporting documents.

(d) The Responsible Official must notify the applicant if EPA will not require submission of an EID.

[72 FR 53662, Sept. 19, 2007, as amended at 74 FR 5994, Feb. 4, 2009]

§ 6.301 Applicant requirements.

(a) The applicant must prepare an EID in consultation with the Responsible Official, unless the Responsible Official has notified the applicant that an EID is not required. The EID must be of sufficient scope and content to enable the Responsible Official to prepare an EA and FONSI or, if necessary, an EIS and ROD. The applicant must submit the EID to the Responsible Official.

(b) The applicant must consult with the Responsible Official as early as possible in the planning process to obtain guidance with respect to the appropriate level and scope of environmental information required for the EID.

(c) As part of the EID process, the applicant may consult with appropriate federal agencies, state and local governments, federally-recognized Indian tribes, and other potentially affected parties to identify their interests in the project and the environmental issues associated with the project.

(d) The applicant must notify the Responsible Official as early as possible of other federal agency, state or local government, or federally-recognized Indian tribe requirements related to the project. The applicant also must notify the Responsible Official of any private entities and organizations affected by the proposed project. (See 40 CFR 1501.2(d)(2).)

(e) The applicant must notify the Responsible Official if, during EPA's environmental review process, the applicant:

(1) Changes its plans for the project as originally submitted to EPA; and/or

(2) Changes its schedule for the project from that originally submitted to EPA.

(f) In accordance with § 6.204, where appropriate, the applicant may request a categorical exclusion determination by the Responsible Official. If requested by the Responsible Official, the applicant must submit information to the Responsible Official regarding the application of a categorical exclusion to EPA's pending action and the applicant's project.

§ 6.302 Responsible Official requirements.

(a) Consistent with 40 CFR 1501.2(d), the Responsible Official must ensure early involvement of applicants in the environmental review process to identify environmental effects, avoid delays, and resolve conflicts.

(b) The Responsible Official must notify the applicant if a determination has been made that the action has been categorically excluded, or if EPA needs additional information to support the application of a categorical exclusion or if the submitted information does not support the application of a categorical exclusion and that an EA, or an EIS, will be required.

(c) When an EID is required for a project, the Responsible Official must consult with the applicant and provide the applicant with guidance describing the scope and level of environmental information required.

(1) The Responsible Official must provide guidance on a project-by-project basis to any applicant seeking such assistance. For major categories of actions involving a large number of applicants, the Responsible Official may prepare and make available generic guidance describing the recommended level and scope of environmental information that applicants should provide.

(2) The Responsible Official must consider the extent to which the applicant is capable of providing the required information. The Responsible Official may not require the applicant to gather data or perform analyses that unnecessarily duplicate either existing data or the results of existing analyses available to EPA. The Responsible Official must limit the request for environmental information to that necessary for the environmental review.

(d) If, prior to completion of the environmental review for a project, the Responsible Official receives notification, that the applicant is proposing to or taking an action that would result in significant impacts or would limit alternatives, the Responsible Official must notify the applicant promptly that EPA will take appropriate action to ensure that the objectives and procedures of NEPA are achieved (see 40 CFR 1506.1(b)). Such actions may include withholding grant funds or denial of permits.

(e) The Responsible Official must begin the NEPA review as soon as possible after receiving the applicant's EID or draft EA. The Responsible Official must independently evaluate the information submitted and be responsible for its accuracy (see 40 CFR 1506.5).

(f) At the request of an applicant and at the discretion of the Responsible Official, an applicant may prepare an EA or EIS and supporting documents or enter into a third-party contract pursuant to § 6.303.

(g) The Responsible Official must review, and take responsibility for the completed NEPA documents, before rendering a final decision on the proposed action.

§ 6.303 Third-party agreements.

(a) If an EA or EIS is to be prepared for an action subject to subparts A through C of this part, the Responsible Official and the applicant may enter into an agreement whereby the applicant engages and pays for the services of a third-party contractor to prepare an EA or EIS and any associated documents for consideration by EPA. In such cases, the Responsible Official must approve the qualifications of the third-party contractor. The third-party contractor must be selected on the basis of ability and absence of any conflict of interest. Consistent with 40 CFR 1506.5(c), in consultation with the applicant, the Responsible Official shall select the contractor. The Responsible Official must provide guidance to the applicant and contractor regarding the information to be developed, including the project's scope, and guide and participate in the collection, analysis, and presentation of the information. The Responsible Official has sole authority for final approval of and EA or EIS.

(1) The applicant must engage and pay for the services of a contractor to prepare the EA or EIS and any associated documents without using EPA financial assistance (including required match).

(2) The Responsible Official, in consultation with the applicant, must ensure that the contractor is qualified to prepare an EA or EIS, and that the substantive terms of the contract specify the information to be developed, and the procedures for gathering, analyzing and presenting the information.

(3) The Responsible Official must prepare a disclosure statement for the applicant to include in the contract specifying that the contractor has no financial or other interest in the outcome of the project (see 40 CFR 1506.5(c)).

(4) The Responsible Official will ensure that the EA or EIS and any associated documents contain analyses and conclusions that adequately assess the relevant environmental issues.

(b) In order to make a decision on the action, the Responsible Official must independently evaluate the information submitted in the EA or EIS and any associated documents, and issue an EA or draft and final EIS. After review of, and appropriate changes to, the EA or EIS submitted by the applicant, the Responsible Official may accept it as EPA's document. The Responsible Official is responsible for the scope, accuracy, and contents of the EA or EIS and any associated documents (see 40 CFR 1506.5).

(c) A third-party agreement may not be initiated unless both the applicant and the Responsible Official agree to its creation and terms.

(d) The terms of the contract between the applicant and the third-party contractor must ensure that the contractor does not have recourse to EPA for financial or other claims arising under the contract, and that the Responsible Official, or other EPA designee, may give technical advice to the contractor.

Subpart D—Assessing the Environmental Effects Abroad of EPA Actions

AUTHORITY: 42 U.S.C. 4321, note, E.O. 12114, 44 FR 1979, 3 CFR, 1979 Comp., p. 356.

§ 6.400 Purpose and policy.

(a) *Purpose.* On January 4, 1979, the President signed Executive Order 12114 entitled ''Environmental Effects Abroad of Major Federal Actions.'' The purpose of this Executive Order is to enable responsible Federal officials in carrying out or approving major Federal actions which affect foreign nations or the global commons to be informed of pertinent environmental considerations and to consider fully the environmental impacts of the actions undertaken. While based on independent authority, this Order furthers the purpose of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) and the Marine Protection, Research, and Sanctuaries Act (MPRSA) (33 U.S.C. 1401 *et seq.*). It should be noted, however, that in fulfilling its responsibilities under Executive Order 12114, EPA shall be guided by CEQ regulations only to the extent that they are made expressly applicable by this subpart. The procedures set forth below reflect EPA's duties and responsibilities as required under the Executive Order and satisfy the requirement for issuance of procedures under section 2–1 of the Executive Order.

(b) *Policy.* It shall be the policy of this Agency to carry out the purpose and requirements of the Executive Order to the fullest extent possible. EPA, within the realm of its expertise, shall work with the Department of State and the Council on Environmental Quality to provide information to other Federal agencies and foreign nations to heighten awareness of and interest in the environment. EPA shall further cooperate to the extent possible with Federal agencies to lend special expertise and assistance in the preparation of required environmental documents under the Executive Order. EPA shall perform environmental reviews of activities significantly affecting the global commons and foreign nations as required under Executive Order 12114 and as set forth under these procedures.

§ 6.401 Applicability.

(a) Administrative actions requiring environmental review. The environmental review requirements apply to the activities of EPA as follows:

(1) Major research or demonstration projects which affect the global commons or a foreign nation.

(2) Ocean dumping activities carried out under section 102 of the MPRSA which affect the related environment.

(3) Major permitting or licensing by EPA of facilities which affect the global commons or the environment of a foreign nation. This may include such actions as the issuance by EPA of hazardous waste treatment, storage, or disposal facility permits pursuant to section 3005 of the Resource Conservation and Recovery Act (42 U.S.C. 6925), NPDES permits pursuant to section 402 of the Clean Water Act (33 U.S.C. 1342), and prevention of significant deterioration approvals pursuant to Part C of the Clean Air Act (42 U.S.C. 7470 *et seq.*)

(4) Wastewater Treatment Construction Grants Program under section 201 of the Clean Water Act when activities addressed in the facility plan would have environmental effects abroad.

(5) Other EPA activities as determined by OFA and OIA (see § 6.406(c)).

(b) [Reserved]

§ 6.402 Definitions.

As used in this subpart, *environment* means the natural and physical environment and excludes social, economic and other environments; *global commons* is that area (land, air, water) outside the jurisdiction of any nation; and *responsible official* is either the EPA Assistant Administrator or Regional Administrator as appropriate for the particular EPA program. Also, an action *significantly* affects the environment if it does *significant* harm to the environment even though on balance the action may be beneficial to the environment. To the extent applicable, the responsible official shall address the considerations set forth in the CEQ regulations under 40 CFR 1508.27 in determining significant effect.

§ 6.403 Environmental review and assessment requirements.

(a) *Research and demonstration projects.* The appropriate Assistant Administrator is responsible for performing the necessary degree of environmental review on research and demonstration projects undertaken by EPA. If the research or demonstration project affects the environment of the global commons, the applicant shall prepare an environmental analysis. This will assist the responsible official in determining whether an EIS is necessary. If it is determined that the action significantly affects the environment of the global commons, then an EIS shall be prepared. If the undertaking significantly affects a foreign nation EPA shall prepare a unilateral, bilateral or multilateral environmental study. EPA shall afford the affected foreign nation or international body or organization an opportunity to participate in this study. This environmental study shall discuss the need for the action, analyze the environmental impact of the various alternatives considered and list the agencies and other parties consulted.

(b) *Ocean dumping activities.* (1) The Assistant Administrator for Water shall ensure the preparation of appropriate environmental documents relating to ocean dumping activities in the global commons under section 102 of the MPRSA. For ocean dumping site designations prescribed pursuant to section 102(c) of the MPRSA and 40 CFR part 228, and for the establishment or revision of criteria under section 102(a) of the MPRSA, EPA shall prepare appropriate environmental documents consistent with EPA's Notice of Policy and Procedures for Voluntary Preparation of National Environmental Policy Act (NEPA) Documents dated October 29, 1998.

(2) For individual permits issued by EPA under section 102(b) an environmental assessment shall be made by EPA. Pursuant to 40 CFR part 221, the permit applicant shall submit with the application an environmental analysis which includes a discussion of the need for the action, an outline of alternatives, and an analysis of the environmental impact of the proposed action and alternatives consistent with the EPA criteria established under section 102(a) of MPRSA. The information submitted under 40 CFR part 221 shall be sufficient to satisfy the environmental assessment requirement.

(c) *EPA permitting and licensing activities.* The appropriate Regional Administrator is responsible for conducting concise environmental reviews with regard to permits issued under section 3005 of the Resource Conservation and Recovery Act (RCRA permits), section 402 of the Clean Water Act (NPDES permits), and section 165 of the Clean Air Act (PSD permits), for such actions undertaken by EPA which affect the global commons or foreign nations. The information submitted by applicants for such permits or approvals under the applicable consolidated permit regulations (40 CFR parts 122 and 124) and Prevention of Significant Deterioration (PSD) regulations (40 CFR part 52) shall satisfy the environmental document requirement under Section 2–4(b) of Executive Order 12114. Compliance with applicable requirements in part 124 of the consolidated permit regulations (40 CFR part 124) shall be sufficient to satisfy the requirements to conduct a concise environmental review for permits subject to this paragraph.

(d) *Wastewater treatment facility planning.* 40 CFR part 6, subparts A through C, detail the environmental review process for the facilities planning process under the wastewater treatment works construction grants program. For the purpose of these regulations, the facility plan shall also include a concise environmental review of those activities that would have environmental effects abroad. This shall apply only to the Step 1 grants awarded after January 14, 1981, but on or before December 29, 1981, and facilities plans developed after December 29, 1981. Where water quality impacts identified in a facility plan are the subject of water quality agreements with Canada or Mexico, nothing in these regulations shall impose on the facility planning process coordination and consultation requirements in addition to those required by such agreements.

(e) *Review by other Federal agencies and other appropriate officials.* The responsible officials shall consult with

other Federal agencies with relevant expertise during the preparation of the environmental document. As soon as feasible after preparation of the environmental document, the responsible official shall make the document available to the Council on Environmental Quality, Department of State, and other appropriate officials. The responsible official with assistance from OIA shall work with the Department of State to establish procedures for communicating with and making documents available to foreign nations and international organizations.

§ 6.404 Lead or cooperating agency.

(a) *Lead Agency*. Section 3–3 of Executive Order 12114 requires the creation of a lead agency whenever an action involves more than one Federal agency. In implementing section 3–3, EPA shall, to the fullest extent possible, follow the guidance for the selection of a lead agency contained in 40 CFR 1501.5 of the CEQ regulations.

(b) *Cooperating Agency*. Under Section 2–4(d) of the Executive Order, Federal agencies with special expertise are encouraged to provide appropriate resources to the agency preparing environmental documents in order to avoid duplication of resources. In working with a lead agency, EPA shall to the fullest extent possible serve as a cooperating agency in accordance with 40 CFR 1501.6. When other program commitments preclude the degree of involvement requested by the lead agency, the responsible EPA official shall so inform the lead agency in writing.

§ 6.405 Exemptions and considerations.

Under section 2–5 (b) and (c) of the Executive Order, Federal agencies may provide for modifications in the contents, timing and availability of documents or exemptions from certain requirements for the environmental review and assessment. The responsible official, in consultation with the Director, Office of Federal Activities (OFA), and the Assistant Administrator, Office of International Affairs (OIA), may approve modifications for situations described in section 2–5(b). The responsible official, in consultation with the Director, OFA and Assistant Administrator, OIA, shall obtain exemptions from the Administrator for situations described in section 2–5(c). The Department of State and the Council on Environmental Quality shall be consulted as soon as possible on the utilization of such exemptions.

§ 6.406 Implementation.

(a) *Oversight*. OFA is responsible for overseeing the implementation of these procedures and shall consult with OIA wherever appropriate. OIA shall be utilized for making formal contacts with the Department of State. OFA shall assist the responsible officials in carrying out their responsibilities under these procedures.

(b) *Information exchange*. OFA with the aid of OIA, shall assist the Department of State and the Council on Environmental Quality in developing the informational exchange on environmental review activities with foreign nations.

(c) *Unidentified activities*. The responsible official shall consult with OFA and OIA to establish the type of environmental review or document appropriate for any new EPA activities or requirements imposed upon EPA by statute, international agreement or other agreements.

PART 7—NONDISCRIMINATION IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL ASSISTANCE FROM THE ENVIRONMENTAL PROTECTION AGENCY

Subpart A—General

Sec.

Subpart B—Discrimination Prohibited on the Basis of Race, Color, National Origin or Sex

Subpart C—Discrimination Prohibited on the Basis of Handicap

AUTHORITY: 42 U.S.C. 2000d to 2000d–7 and 6101 *et seq.;* 29 U.S.C. 794; 33 U.S.C. 1251nt.

SOURCE: 49 FR 1659, Jan. 12, 1984, unless otherwise noted.

Subpart A—General

§ 7.10 Purpose of this part.

This part implements: Title VI of the Civil Rights Act of 1964, as amended; section 504 of the Rehabilitation Act of 1973, as amended; the Age Discrimination Act of 1975, as amended; and section 13 of the Federal Water Pollution Control Act Amendments of 1972, Public Law 92–500, (collectively, the Acts).

[75 FR 31707, June 4, 2010]

§ 7.15 Applicability.

This part applies to all applicants for, and recipients of, EPA assistance in the operation of programs or activities receiving such assistance beginning February 13, 1984. New construction (§ 7.70) for which design was initiated prior to February 13, 1984, shall comply with the accessibility requirements in the Department of Health, Education and Welfare (now the Department of Health and Human Services) nondiscrimination regulation, 45 CFR 84.23, issued June 3, 1977, or with equivalent standards that ensure the facility is readily accessible to and usable by handicapped persons. Such assistance includes but is not limited to that which is listed in the *Catalogue of Federal Domestic Assistance* under the 66.000 series. It supersedes the provisions of former 40 CFR parts 7 and 12.

§ 7.20 Responsible agency officers.

(a) The EPA Office of Civil Rights (OCR) is responsible for developing and administering EPA's means of ensuring compliance under the Acts.

(b) EPA's Project Officers will, to the extent possible, be available to explain to each recipient its obligations under this part and to provide recipients with technical assistance or guidance upon request.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

§ 7.25 Definitions.

As used in this part:

Action, for purposes of subpart F of this part, means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

Administrator means the Administrator of EPA. It includes any other agency official authorized to act on his or her behalf, unless explicity stated otherwise.

Age, for purposes of subpart F of this part, means how old a person is, or the

number of elapsed years from the date of a person's birth.

Age distinction, for purposes of subpart F of this part, means any action using age or an age-related term.

Age-related term, for purposes of subpart F of this part, means a word or words which necessarily imply a particular age or range of ages (for example; ''children,'' ''adult,'' ''older persons,'' but not ''student'' or ''grade'').

Alcohol abuse means any misuse of alcohol which demonstrably interferes with a person's health, interpersonal relations or working ability.

Applicant means any entity that files an application or unsolicited proposal or otherwise requests EPA assistance (see definition for *EPA assistance*).

Assistant Attorney General is the head of the Civil Rights Division, U.S. Department of Justice.

Award Official means the EPA official with the authority to approve and execute assistance agreements and to take other assistance related actions authorized by this part and by other EPA regulations or delegation of authority.

Drug abuse means:

(a) The use of any drug or substance listed by the Department of Justice in 21 CFR 1308.11, under authority of the Controlled Substances Act, 21 U.S.C. 801, as a controlled substance unavailable for prescription because:

(1) The drug or substance has a high potential for abuse,

(2) The drug or other substance has no currently accepted medical use in treatment in the United States, or

(3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

NOTE: Examples of drugs under paragraph (a)(1) of this section include certain opiates and opiate derivatives (e.g., heroin) and hallucinogenic substances (e.g., marijuana, mescaline, peyote) and depressants (e.g., methaqualone). Examples of (a)(2) include opium, coca leaves, methadone, amphetamines and barbiturates.

(b) The misuse of any drug or substance listed by the Department of Justice in 21 CFR 1308.12–1308.15 under authority of the Controlled Substances Act as a controlled substance available for prescription.

EPA means the United States Environmental Protection Agency.

EPA assistance means any grant or cooperative agreement, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which EPA provides or otherwise makes available assistance in the form of:

(1) Funds;

(2) Services of personnel; or

(3) Real or personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if EPA's share of its fair market value is not returned to EPA.

Facility means all, or any part of, or any interests in structures, equipment, roads, walks, parking lots, or other real or personal property.

Handicapped person:

(a) *Handicapped person* means any person who (1) has a physical or mental impairment which substantially limits one or more major life activities, (2) has a record of such an impairment, or (3) is regarded as having such an impairment. For purposes of employment, the term *handicapped person* does not include any person who is an alcoholic or drug abuser whose current use of alcohol or drugs prevents such individual from performing the duties of the job in question or whose employment, by reason of such current drug or alcohol abuse, would constitute a direct threat to property or the safety of others.

(b) As used in this paragraph, the phrase:

(1) *Physical or mental impairment* means (i) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genito-urinary; hemic and lymphatic; skin; and endocrine; and (ii) any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(2) *Major life activities* means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) *Has a record of such an impairment* means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) *Is regarded as having an impairment* means:

(i) Has a physical or mental impairment that does not substantially limit major life activities but that is treated by a recipient as constituting such a limitation;

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined above but is treated by a recipient as having such an impairment.

Normal operation, for purposes of subpart F of this part, means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

Office of Civil Rights or OCR means the Director of the Office of Civil Rights, EPA Headquarters or his/her designated representative.

Program or activity and *program* mean all of the operations of any entity described in paragraphs (1) through (4) of this definition, any part of which is extended Federal financial assistance:

(1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(ii) The entity of such State or local government that distributes such assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

(ii) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity which is established by two or more of the entities described in paragraph (1), (2), or (3) of this definition.

Project Officer means the EPA official designated in the assistance agreement (as defined in *EPA assistance*) as EPA's contact with the recipient; Project Officers are responsible for monitoring the project.

Qualified handicapped person means:

(a) With respect to employment: A handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question.

(b) With respect to services: A handicapped person who meets the essential eligibility requirements for the receipt of such services.

Racial classifications:[1]

(a) *American Indian or Alaskan native*. A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

(b) *Asian or Pacific Islander*. A person having origins in any of the original

[1] Additional subcategories based on national origin or primary language spoken may be used where appropriate on either a national or a regional basis. Subparagraphs (a) through (e) are in conformity with Directive 15 of the Office of Federal Statistical Policy and Standards, whose function is now in the Office of Information and Regulatory Affairs, Office of Management and Budget. Should that office, or any successor office, change or otherwise amend the categories listed in Directive 15, the categories in this paragraph shall be interpreted to conform with any such changes or amendments.

peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, Japan, Korea, the Philippine Islands, and Samoa.

(c) *Black and not of Hispanic origin.* A person having origins in any of the black racial groups of Africa.

(d) *Hispanic.* A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless or race.

(e) *White, not of Hispanic origin.* A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

Recipient means, for the purposes of this regulation, any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

Section 13 refers to section 13 of the Federal Water Pollution Control Act Amendments of 1972.

Statutory objective, for purposes of subpart F of this part, means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

United States includes the States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, and all other territories and possessions of the United States; the term *State* includes any one of the foregoing.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003; 75 FR 31707, June 4, 2010]

Subpart B—Discrimination Prohibited on the Basis of Race, Color, National Origin or Sex

§ 7.30 General prohibition.

No person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving EPA assistance on the basis of race, color, national origin, or on the basis of sex in any program or activity receiving EPA assistance under the Federal Water Pollution Control Act, as amended, including the Environmental Financing Act of 1972.

§ 7.35 Specific prohibitions.

(a) As to any program or activity receiving EPA assistance, a recipient shall not directly or through contractual, licensing, or other arrangements on the basis of race, color, national origin or, if applicable, sex:

(1) Deny a person any service, aid or other benefit of the program or activity;

(2) Provide a person any service, aid or other benefit that is different, or is provided differently from that provided to others under the program or activity;

(3) Restrict a person in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, aid, or benefit provided by the program or activity;

(4) Subject a person to segregation in any manner or separate treatment in any way related to receiving services or benefits under the program or activity;

(5) Deny a person or any group of persons the opportunity to participate as members of any planning or advisory body which is an integral part of the program or activity, such as a local sanitation board or sewer authority;

(6) Discriminate in employment on the basis of sex in any program or activity subject to section 13, or on the basis of race, color, or national origin in any program or activity whose purpose is to create employment; or, by means of employment discrimination, deny intended beneficiaries the benefits of EPA assistance, or subject the beneficiaries to prohibited discrimination.

(7) In administering a program or activity receiving Federal financial assistance in which the recipient has previously discriminated on the basis of race, color, sex, or national origin, the recipient shall take affirmative action to provide remedies to those who have been injured by the discrimination.

(b) A recipient shall not use criteria or methods of administering its program or activity which have the effect of subjecting individuals to discrimination because of their race, color, national origin, or sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program or activity with respect to individuals of a particular race, color, national origin, or sex.

(c) A recipient shall not choose a site or location of a facility that has the purpose or effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any program or activity to which this part applies on the grounds of race, color, or national origin or sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of this subpart.

(d) The specific prohibitions of discrimination enumerated above do not limit the general prohibition of § 7.30.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

Subpart C—Discrimination Prohibited on the Basis of Handicap

§ 7.45 General prohibition.

No qualified handicapped person shall solely on the basis of handicap be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity receiving EPA assistance.

§ 7.50 Specific prohibitions against discrimination.

(a) A recipient, in providing any aid, benefit or service under any program or activity receiving EPA assistance shall not, on the basis of handicap, directly or through contractual, licensing, or other arrangement:

(1) Deny a qualified handicapped person any service, aid or other benefit of a federally assisted program or activity;

(2) Provide different or separate aids, benefits, or services to handicapped persons or to any class of handicapped persons than is provided to others unless the action is necessary to provide qualified handicapped persons with aids, benefits, or services that are as effective as those provided to others;

(3) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an entity that discriminates on the basis of handicap in providing aids, benefits, or services to beneficiaries of the recipient's program or activity;

(4) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(5) Limit a qualified handicapped person in any other way in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit or service from the program or activity.

(b) A recipient may not, in determining the site or location of a facility, make selections: (1) That have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives EPA assistance or (2) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity receiving EPA assistance with respect to handicapped persons.

(c) A recipient shall not use criteria or methods of administering any program or activity receiving EPA assistance which have the effect of subjecting individuals to discrimination because of their handicap, or have the effect of defeating or substantially impairing accomplishment of the objectives of such program or activity with respect to handicapped persons.

(d) Recipients shall take appropriate steps to ensure that communications with their applicants, employees, and beneficiaries are available to persons with impaired vision and hearing.

(e) The exclusion of non-handicapped persons or specified classes of handicapped persons from aid, benefits, or services limited by Federal statute or Executive Order to handicapped persons or a different class of handicapped

persons is not prohibited by this subpart.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

§ 7.55 Separate or different aid, benefits, or services.

Recipients shall not deny a qualified handicapped person an opportunity equal to that afforded others to participate in or benefit from the aid, benefit, or service in the program or activity receiving EPA assistance. Recipients shall administer programs or activities in the most integrated setting appropriate to the needs of qualified handicapped persons.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

§ 7.60 Prohibitions and requirements relating to employment.

(a) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity that receives Federal assistance.

(b) A recipient shall make all decisions concerning employment under any program or activity to which this part applies in a manner which ensures that discrimination on the basis of handicap does not occur, and shall not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(c) The prohibition against discrimination in employment applies to the following activities:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer sponsored activities, including those that are social or recreational; or

(9) Any other term, condition, or privilege of employment.

(d) A recipient shall not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this paragraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeships.

(e) A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program or activity.

(f) A recipient shall not use employment tests or criteria that discriminate against handicapped persons and shall ensure that employment tests are adapted for use by persons who have handicaps that impair sensory, manual, or speaking skills.

(g) A recipient shall not conduct a preemployment medical examination or make a preemployment inquiry as to whether an applicant is a handicapped person or as to the nature or severity of a handicap except as permitted by the Department of Justice in 28 CFR 42.513.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

§ 7.65 Accessibility.

(a) *General.* A recipient shall operate each program or activity receiving EPA assistance so that when each part is viewed in its entirety it is readily accessible to and usable by handicapped persons. This paragraph does not:

(1) Necessarily require a recipient to make each of its existing facilities or every part of an existing facility accessible to and usable by handicapped persons.

(2) Require a recipient to take any action that the recipient can demonstrate would result in a fundamental alteration in the nature of its program or activity or in undue financial and administrative burdens. If an action would result in such an alternation or such financial and administrative burdens, the recipient shall be required to take any other action that would not result in such an alteration or financial and administrative burdens but would nevertheless ensure that handicapped persons receive the benefits and services of the program or activity receiving EPA assistance.

(b) *Methods of ensuring compliance in existing facilities.* A recipient may comply with the accessibility requirements of this section by making structural changes, redesigning equipment, reassigning services to accessible buildings, assigning aides to beneficiaries, or any other means that make its program or activity accessible to handicapped persons. In choosing among alternatives, a recipient must give priority to methods that serve handicapped persons in the most integrated setting appropriate.

(c) *Deadlines.* (1) Except where structural changes in facilities are necessary, recipients must adhere to the provisions of this section within 60 days after the effective date of this part.

(2) Recipients having an existing facility which does require alterations in order to comply with paragraph (a) of this section must prepare a transition plan in accordance with § 7.75 within six months from the effective date of this part. The recipient must complete the changes as soon as possible, but not later than three years from date of award.

(d) *Notice of accessibility.* The recipient must make sure that interested persons, including those with impaired vision or hearing, can find out about the existence and location of the services, activities, and facilities that are accessible to and usable by handicapped persons.

(e) *Structural and financial feasibility.* This section does not require structural alterations to existing facilities if making such alterations would not be structurally or financially feasible. An alteration is not structurally feasible when it has little likelihood of being accomplished without removing or altering a load-bearing structural member. Financial feasibility shall take into account the degree to which the alteration work is to be assisted by EPA assistance, the cost limitations of the statute under which such assistance is provided, and the relative cost of accomplishing such alterations in manners consistent and inconsistent with accessibility.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

§ 7.70 New construction.

(a) *General.* New facilities shall be designed and constructed to be readily accessible to and usable by handicapped persons. Alterations to existing facilities shall, to the maximum extent feasible, be designed and constructed to be readily accessible to and usable by handicapped persons.

(b) *Conformance with Uniform Federal Accessibility Standards.* (1) Effective as of January 18, 1991, design, construction, or alteration of buildings in conformance with sections 3-8 of the Uniform Federal Accessibility Standards (USAF) (appendix A to 41 CFR subpart 101–19.6) shall be deemed to comply with the requirements of this section with respect to those buildings. Departures from particular technical and scoping requirements of UFAS by the use of other methods are permitted where substantially equivalent or greater access to and usability of the building is provided.

(2) For purposes of this section, section 4.1.6(1)(g) of UFAS shall be interpreted to exempt from the requirements of UFAS only mechanical rooms and other spaces that, because of their intended use, will not require accessibility to the public or beneficiaries or result in the employment or residence therein of persons with physical handicaps.

(3) This section does not require recipients to make building alterations

that have little likelihood of being accomplished without removing or altering a load-bearing structural member.

[49 FR 1659, Jan. 12, 1984, as amended at 55 FR 52138, 52142, Dec. 19, 1990]

§ 7.75 Transition plan.

If structural changes to facilities are necessary to make the program or activity accessible to handicapped persons, a recipient must prepare a transition plan.

(a) *Requirements.* The transition plan must set forth the steps needed to complete the structural changes required and must be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons. At a minimum, the transition plan must:

(1) Identify the physical obstacles in the recipient's facilities that limit handicapped persons' access to its program or activity,

(2) Describe in detail what the recipient will do to make the facilities accessible,

(3) Specify the schedule for the steps needed to achieve full accessibility under §7.65(a), and include a year-by-year timetable if the process will take more than one year,

(4) Indicate the person responsible for carrying out the plan.

(b) *Availability.* Recipients shall make available a copy of the transition plan to the OCR upon request and to the public for inspection at either the site of the project or at the recipient's main office.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

Subpart D—Requirements for Applicants and Recipients

§ 7.80 Applicants.

(a) *Assurances*—(1) *General.* Applicants for EPA assistance shall submit an assurance with their applications stating that, with respect to their programs or activities that receive EPA assistance, they will comply with the requirements of this part. Applicants must also submit any other information that the OCR determines is necessary for preaward review. The applicant's acceptance of EPA assistance is an acceptance of the obligation of this assurance and this part.

(2) *Duration of assurance*—(i) *Real property.* When EPA awards assistance in the form of real property, or assistance to acquire real property, or structures on the property, the assurance will obligate the recipient, or transferee, during the period the real property or structures are used for the purpose for which EPA assistance is extended, or for another purpose in which similar services or benefits are provided. The transfer instrument shall contain a covenant running with the land which assures nondiscrimination. Where applicable, the covenant shall also retain a right of reverter which will permit EPA to recover the property if the covenant is ever broken.

(ii) *Personal property.* When EPA provides assistance in the form of personal property, the assurance will obligate the recipient for so long as it continues to own or possess the property.

(iii) *Other forms of assistance.* In all other cases, the assurance will obligate the recipient for as long as EPA assistance is extended.

(b) *Wastewater treatment project.* EPA Form 4700–4 shall also be submitted with applications for assistance under Title II of the Federal Water Pollution Control Act.

(c) *Compliance information.* Each applicant for EPA assistance shall submit regarding the program or activity that would receive EPA assistance:

(1) Notice of any lawsuit pending against the applicant alleging discrimination on the basis of race, color, sex, age, handicap, or national origin;

(2) A brief description of any applications pending to other Federal agencies for assistance, and of Federal assistance being provided at the time of the application; and

(3) A statement describing any civil rights compliance reviews regarding the applicant conducted during the two-year period before the application, and information concerning the agency or organization performing the reviews.

(Approved by the Office of Management and Budget under control number 2000–0006)

[49 FR 1659, Jan. 12, 1984, as amended at 75 FR 31707, June 4, 2010]

§ 7.85 Recipients.

(a) *Compliance information.* Each recipient shall collect, maintain, and on request of the OCR, provide the following information to show compliance with this part:

(1) A brief description of any lawsuits pending against the recipient that allege discrimination which this part prohibits;

(2) Racial/ethnic, national origin, age, sex and handicap data, or EPA Form 4700–4 information submitted with its application;

(3) A log of discrimination complaints which identifies the complaint, the date it was filed, the date the recipient's investigation was completed, the disposition, and the date of disposition; and

(4) Reports of any compliance reviews conducted by any other agencies.

(b) *Additional compliance information.* If necessary, the OCR may require recipients to submit data and information specific to certain programs or activities to determine compliance where there is reason to believe that discrimination may exist in a program or activity receiving EPA assistance or to investigate a complaint alleging discrimination in a program or activity receiving EPA assistance. Requests shall be limited to data and information which is relevant to determining compliance and shall be accompanied by a written statement summarizing the complaint or setting forth the basis for the belief that discrimination may exist.

(c) *Self-evaluation.* (1) Each recipient must conduct a self-evaluation of its administrative policies and practices, to consider whether such policies and practices may involve handicap discrimination prohibited by this part. When conducting the self-evaluation, the recipient shall consult with interested and involved persons including handicapped persons or organizations representing handicapped persons. The evaluation shall be completed within 18 months after the effective date of this part.

(2) Each recipient employing the equivalent of 15 or more full time employees may be required to complete a written self-evaluation of its compliance under the Age Discrimination Act as part of a compliance review or complaint investigation. This self-evaluation will pertain to any age distinction imposed in its program or activity receiving Federal assistance from EPA. If required, each recipient's self-evaluation shall identify and justify each age distinction imposed by the recipient and each recipient shall take corrective and remedial action whenever a self-evaluation indicates a violation of the Age Discrimination Act.

(d) Preparing compliance information. In preparing compliance information, a recipient must:

(1) [Reserved]

(2) Use the racial classifications set forth in § 7.25 in determining categories of race, color or national origin.

(e) *Maintaining compliance information.* Recipients must keep records for paragraphs (a) and (b) of this section for three (3) years after completing the project. When any complaint or other action for alleged failure to comply with this part is brought before the three-year period ends, the recipient shall keep records until the complaint is resolved.

(f) Accessibility to compliance information. A recipient shall:

(1) Give the OCR access during normal business hours to its books, records, accounts and other sources of information, including its facilities, as may be pertinent to ascertain compliance with this part;

(2) Make compliance information available to the public upon request; and

(3) Assist in obtaining other required information that is in the possession of other agencies, institutions, or persons not under the recipient's control. If such party refuses to release that information, the recipient shall inform the OCR and explain its efforts to obtain the information.

(g) *Coordination of compliance effort.* If the recipient employs fifteen (15) or more employees, it shall designate at least one person to coordinate its efforts to comply with its obligations under this part.

(Approved by the Office of Management and Budget under control number 2000–0006)

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003; 75 FR 31707, June 4, 2010]

§ 7.90 Grievance procedures.

(a) *Requirements.* Each recipient shall adopt grievance procedures that assure the prompt and fair resolution of complaints which allege violation of this part.

(b) *Exception.* Recipients with fewer than fifteen (15) full-time employees need not comply with this section unless the OCR finds a violation of this part or determines that creating a grievance procedure will not significantly impair the recipient's ability to provide benefits or services.

§ 7.95 Notice of nondiscrimination.

(a) *Requirements.* A recipient shall provide initial and continuing notice that it does not discriminate on the basis of race, color, national origin, age, or handicap in a program or activity receiving EPA assistance or, in programs or activities covered by section 13, on the basis of sex. Methods of notice must accommodate those with impaired vision or hearing. At a minimum, this notice must be posted in a prominent place in the recipient's offices or facilities. Methods of notice may also include publishing in newspapers and magazines, and placing notices in recipient's internal publications or on recipient's printed letterhead. Where appropriate, such notice must be in a language or languages other than English. The notice must identify the responsible employee designated in accordance with § 7.85.

(b) *Deadline.* Recipients of assistance must provide initial notice by thirty (30) calendar days after award and continuing notice for the duration of EPA assistance.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003; 75 FR 31707, June 4, 2010]

§ 7.100 Intimidation and retaliation prohibited.

No applicant, recipient, nor other person shall intimidate, threaten, coerce, or discriminate against any individual or group, either:

(a) For the purpose of interfering with any right or privilege guaranteed by the Acts or this part, or

(b) Because the individual has filed a complaint or has testified, assisted or participated in any way in an investigation, proceeding or hearing under this part, or has opposed any practice made unlawful by this regulation.

Subpart E—Agency Compliance Procedures

§ 7.105 General policy.

EPA's Administrator, Director of the Office of Civil Rights, Project Officers and other responsible officials shall seek the cooperation of applicants and recipients in securing compliance with this part, and are available to provide help.

§ 7.110 Preaward compliance.

(a) *Review of compliance information.* Within EPA's application processing period, the OCR will determine whether the applicant is in compliance with this part and inform the Award Official. This determination will be based on the submissions required by § 7.80 and any other information EPA receives during this time (including complaints) or has on file about the applicant. When the OCR cannot make a determination on the basis of this information, additional information will be requested from the applicant, local government officials, or interested persons or organizations, including aged and handicapped persons or organizations representing such persons. The OCR may also conduct an on-site review only when it has reason to believe discrimination may be occurring in a program or activity which is the subject of the application.

(b) *Voluntary compliance.* If the review indicates noncompliance, an applicant may agree in writing to take the steps the OCR recommends to come into compliance with this part. The OCR must approve the written agreement before any award is made.

(c) *Refusal to comply.* If the applicant refuses to enter into such an agreement, the OCR shall follow the procedure established by paragraph (b) of § 7.130.

[49 FR 1659, Jan. 12, 1984, as amended at 75 FR 31707, June 4, 2010]

§ 7.115 Postaward compliance.

(a) *Periodic review.* The OCR may periodically conduct compliance reviews of any recipient's programs or activities receiving EPA assistance, including the request of data and information, and may conduct on-site reviews when it has reason to believe that discrimination may be occurring in such programs or activities.

(b) *Notice of review.* After selecting a recipient for review or initiating a complaint investigation in accordance with § 7.120, the OCR will inform the recipient of:

(1) The nature of and schedule for review, or investigation; and

(2) Its opportunity, before the determination in paragraph (d) of this section is made, to make a written submission responding to, rebutting, or denying the allegations raised in the review or complaint.

(c) *Postreview notice.* (1) Within 180 calendar days from the start of the compliance review or complaint investigation, the OCR will notify the recipient in writing by certified mail, return receipt requested, of:

(i) Preliminary findings;

(ii) Recommendations, if any, for achieving voluntary compliance; and

(iii) Recipient's right to engage in voluntary compliance negotiations where appropriate.

(2) The OCR will notify the Award Official and the Assistant Attorney General for Civil Rights of the preliminary findings of noncompliance.

(d) *Formal determination of noncompliance.* After receiving the notice of the preliminary finding of noncompliance in paragraph (c) of this section, the recipient may:

(1) Agree to the OCR's recommendations, or

(2) Submit a written response sufficient to demonstrate that the preliminary findings are incorrect, or that compliance may be achieved through steps other than those recommended by OCR.

If the recipient does not take one of these actions within fifty (50) calendar days after receiving this preliminary notice, the OCR shall, within fourteen (14) calendar days, send a formal written determination of noncompliance to the recipient and copies to the Award Official and Assistant Attorney General.

(e) *Voluntary compliance time limits.* The recipient will have ten (10) calendar days from receipt of the formal determination of noncompliance in which to come into voluntary compliance. If the recipient fails to meet this deadline, the OCR must start proceedings under paragraph (b) of § 7.130.

(f) *Form of voluntary compliance agreements.* All agreements to come into voluntary compliance must:

(1) Be in writing;

(2) Set forth the specific steps the recipient has agreed to take, and

(3) Be signed by the Director, OCR or his/her designee and an official with authority to legally bind the recipient.

§ 7.120 Complaint investigations.

The OCR shall promptly investigate all complaints filed under this section unless the complainant and the party complained against agree to a delay pending settlement negotiations.

(a) *Who may file a complaint.* A person who believes that he or she or a specific class of persons has been discriminated against in violation of this part may file a complaint. The complaint may be filed by an authorized representative. A complaint alleging employment discrimination must identify at least one individual aggrieved by such discrimination. Complaints solely alleging employment discrimination against an individual on the basis of race, color, national origin, sex or religion shall be processed under the procedures for complaints of employment discrimination filed against recipients of Federal assistance (see 28 CFR part 42, subpart H and 29 CFR part 1691). Complaints of employment discrimination based on age against an individual by recipients of Federal financial assistance are subject to the Age Discrimination in Employment Act of 1967 and should be filed administratively with the Equal Employment Opportunity Commission (*see* 29 CFR part 1626). Complainants are encouraged but not required to make use of any grievance procedure established under § 7.90 before filing a complaint. Filing a complaint through a grievance procedure does not extend the 180 day calendar

requirement of paragraph (b)(2 of this section.

(b) *Where, when and how to file complaint.* The complainant may file a complaint at any EPA office. The complaint may be referred to the region in which the alleged discriminatory acts occurred.

(1) The complaint must be in writing and it must describe the alleged discriminatory acts which violate this part.

(2) The complaint must be filed within 180 calendar days of the alleged discriminatory acts, unless the OCR waives the time limit for good cause. The filing of a grievance with the recipient does not satisfy the requirement that complaints must be filed within 180 days of the alleged discriminatory acts.

(c) *Notification.* The OCR will notify the complainant and the recipient of the agency's receipt of the complaint within five (5) calendar days.

(d) *Complaint processing procedures.* After acknowledging receipt of a complaint, the OCR will immediately initiate complaint processing procedures.

(1) *Preliminary investigation.* (i) Within twenty (20) calendar days of acknowledgment of the complaint, the OCR will review the complaint for acceptance, rejection, or referral to the appropriate Federal agency.

(ii) If the complaint is accepted, the OCR will notify the complainant and the Award Official. The OCR will also notify the applicant or recipient complained against of the allegations and give the applicant or recipient opportunity to make a written submission responding to, rebutting, or denying the allegations raised in the complaint.

(iii) The party complained against may send the OCR a response to the notice of complaint within thirty (30) calendar days of receiving it.

(iv) Complaints alleging age discrimination under the Age Discrimination Act of 1975 will be referred to a mediation agency in accordance with §7.180.

(2) *Informal resolution.* (i) OCR shall attempt to resolve complaints informally whenever possible. When a complaint cannot be resolved informally, OCR shall follow the procedures established by paragraphs (c) through (e) of §7.115.

(ii) [Reserved]

(e) *Confidentiality.* EPA agrees to keep the complainant's identity confidential except to the extent necessary to carry out the purposes of this part, including the conduct of any investigation, hearing, or judicial proceeding arising thereunder. Ordinarily in complaints of employment discrimination, the name of the complainant will be given to the recipient with the notice of complaint.

(f) [Reserved]

(g) *Dismissal of complaint.* If OCR's investigation reveals no violation of this part, the Director, OCR, will dismiss the complaint and notify the complainant and recipient.

[49 FR 1659, Jan. 12, 1984, as amended at 75 FR 31707, June 4, 2010]

§ 7.125 Coordination with other agencies.

If, in the conduct of a compliance review or an investigation, it becomes evident that another agency has jurisdiction over the subject matter, OCR will cooperate with that agency during the continuation of the review of investigation. EPA will:

(a) Coordinate its efforts with the other agency, and

(b) Ensure that one of the agencies is designated the lead agency for this purpose. When an agency other than EPA serves as the lead agency, any action taken, requirement imposed, or determination made by the lead agency, other than a final determination to terminate funds, shall have the same effect as though such action had been taken by EPA.

§ 7.130 Actions available to EPA to obtain compliance.

(a) *General.* If compliance with this part cannot be assured by informal means, EPA may terminate or refuse to award or to continue assistance. EPA may also use any other means authorized by law to get compliance, including a referral of the matter to the Department of Justice.

(b) *Procedure to deny, annul, suspend or terminate EPA assistance*—(1) *OCR finding.* If OCR determines that an applicant or recipient is not in compliance with this part, and if compliance cannot be achieved voluntarily, OCR

shall make a finding of noncompliance. The OCR will notify the applicant or recipient (by registered mail, return receipt requested) of the finding, the action proposed to be taken, and the opportunity for an evidentiary hearing.

(2) *Hearing.* (i) Within 30 days of receipt of the above notice, the applicant or recipient shall file a written answer, under oath or affirmation, and may request a hearing.

(ii) The answer and request for a hearing shall be sent by registered mail, return receipt requested, to the Chief Administrative Law Judge (ALJ) (A–110), United States Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Upon receipt of a request for a hearing, the ALJ will send the applicant or recipient a copy of the ALJ's procedures. If the recipient does not request a hearing, it shall be deemed to have waived its right to a hearing, and the OCR finding shall be deemed to be the ALJ's determination.

(3) *Final decision and disposition.* (i) The applicant or recipient may, within 30 days of receipt of the ALJ's determination, file with the Administrator its exceptions to that determination. When such exceptions are filed, the Administrator may, within 45 days after the ALJ's determination, serve to the applicant or recipient, a notice that he/she will review the determination. In the absence of either exceptions or notice of review, the ALJ's determination shall constitute the Administrator's final decision.

(ii) If the Administrator reviews the ALJ's determination, all parties shall be given reasonable opportunity to file written statements. A copy of the Administrator's decision will be sent to the applicant or recipient.

(iii) If the Administrator's decision is to deny an application, or annul, suspend or terminate EPA assistance, that decision becomes effective thirty (30) days from the date on which the Administrator submits a full written report of the circumstances and grounds for such action to the Committees of the House and Senate having legislative jurisdiction over the program or activity involved. The decision of the Administrator shall not be subject to further administrative appeal under EPA's General Regulation for Assistance Programs (40 CFR part 30, subpart L).

(4) *Scope of decision.* The denial, annulment, termination or suspension shall be limited to the particular applicant or recipient who was found to have discriminated, and shall be limited in its effect to the particular program or activity or the part of it in which the discrimination was found.

[49 FR 1659, Jan. 12, 1984, as amended at 68 FR 51372, Aug. 26, 2003]

§ 7.135 Procedure for regaining eligibility.

(a) *Requirements.* An applicant or recipient whose assistance has been denied, annulled, terminated, or suspended under this part regains eligibility as soon as it:

(1) Provides reasonable assurance that it is complying and will comply with this part in the future, and

(2) Satisfies the terms and conditions for regaining eligibility that are specified in the denial, annulment, termination or suspension order.

(b) *Procedure.* The applicant or recipient must submit a written request to restore eligibility to the OCR declaring that it has met the requirements set forth in paragraph (a) of this section. Upon determining that these requirements have been met, the OCR must notify the Award Official, and the applicant or recipient that eligibility has been restored.

(c) Rights on denial of restoration of eligibility. If the OCR denies a request to restore eligibility, the applicant or recipient may file a written request for a hearing before the EPA Chief Administrative Law Judge in accordance with paragraph (c) § 7.130, listing the reasons it believes the OCR was in error.

Subpart F—Discrimination Prohibited on the Basis of Age

SOURCE: 75 FR 31707, June 4, 2010, unless otherwise noted.

§ 7.140 General prohibition.

No person in the United States may, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination

under any program or activity receiving EPA assistance.

§ 7.145 Specific prohibitions.

(a) As to any program or activity receiving EPA assistance, a recipient shall not directly or through contractual, licensing, or other arrangements on the basis of age:

(1) Exclude any individuals from, deny them the service, aid or benefits of, or subject them to discrimination under, a program or activity;

(2) Provide a person any service, aid or other benefit that is different, or is provided differently from that provided to others under the program or activity;

(3) Restrict a person in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, aid, or benefit provided by the program or activity;

(4) Subject a person to segregation in any manner or separate treatment in any way related to receiving services or benefits under the program or activity;

(5) Deny a person or any group of persons the opportunity to participate as members of any planning or advisory body which is an integral part of the program or activity, such as a local sanitation board or sewer authority;

(6) In administering a program or activity receiving Federal financial assistance in which the recipient has previously discriminated on the basis of age, the recipient shall take affirmative action to provide remedies to those who have been injured by the discrimination.

(b) A recipient shall not use criteria or methods of administering its program or activity which have the effect of subjecting individuals to discrimination because of their age, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program or activity with respect to individuals of a particular age.

(c) A recipient shall not choose a site or location of a facility that has the purpose or effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any program or activity to which this part applies on the ground of age; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of this subpart.

(d) The specific prohibitions of discrimination enumerated above do not limit the general prohibition of § 7.140.

§ 7.150 Exceptions to the rules against age discrimination—normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by §§ 7.140 and 7.145, if the action reasonably takes into account age as a factor necessary to the normal operation or achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity if:

(a) Age is used as a measure or approximation of one or more other characteristics;

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity;

(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 7.155 Exceptions to the rules against age discrimination—reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by §§ 7.140 and 7.145 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 7.160 Burden of proof.

The burden of proving that an age distinction or other action falls within

the exceptions outlined in §§7.150 and 7.155 is on the recipient of EPA financial assistance.

§ 7.165 Special benefits for children and the elderly.

If a recipient operating a program which serves the elderly or children in addition to persons of other ages, provides special benefits to the elderly or to children the provision of those benefits shall be presumed to be voluntary affirmative action provided that it does not have the effect of excluding otherwise eligible persons from participation in the program.

§ 7.170 Alternative funds disbursal procedures.

(a) When EPA withholds funds from a recipient under Subpart F of these regulations, the Administrator may disburse the withheld funds directly to an alternate recipient: Any public or nonprofit private organization or agency, or State or political subdivision of the State.

(b) The Administrator will require any alternate recipient to demonstrate the ability to achieve the goals of the Federal statute authorizing the funds and these regulations (40 CFR Part 7).

§ 7.175 Exhaustion of administrative remedy.

(a) A complainant may file a civil action following the exhaustion of administrative remedies under the Age Discrimination Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and EPA has made no finding with regard to the complaint; or

(2) EPA issues any finding in favor of the recipient.

(b) If EPA fails to make a finding within 180 days or issues a finding in favor of the recipient, EPA shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right to bring a civil action for injunctive relief; and

(3) Inform the complainant that:

(i) The complainant may bring a civil action only in a United States district court for the district in which the recipient is found or transacts business;

(ii) A complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint;

(iii) Before commencing the action, the complainant shall give 30 days notice by registered mail to the Secretary of the Department of Health and Human Services, the Administrator, the Attorney General of the United States, and the recipient;

(iv) The notice must state: The alleged violation of the Age Discrimination Act; the relief requested; the court in which the complainant is bringing the action; and, whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) The complainant may not bring an action if the same alleged violation of the Age Discrimination Act by the same recipient is the subject of a pending action in any court of the United States.

§ 7.180 Mediation of age discrimination complaints.

(a) The OCR will refer all accepted complaints alleging age discrimination to the Mediation Agency designated by the Secretary of the Department of Health and Human Services.

(b) Both the complainant and the recipient must participate in the mediation process to the extent necessary to reach an agreement or make an informed judgment that an agreement is not possible. The recipient and the complainant must meet with the mediator at least once before the OCR will accept a judgment that an agreement is not possible. The recipient and the complainant, however, need not meet with the mediator at the same time.

(c) If the complainant and the recipient reach an agreement, the mediator must prepare a written statement of the agreement and have the complainant and recipient sign it. The mediator will send a copy of the agreement to the OCR, which will take no further action on the complaint unless the complainant or the recipient fails to comply with the agreement.

(d) The mediator must protect the confidentiality of all information obtained in the course of the mediation

process. No mediator may testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the agency appointing the mediator.

(e) Mediation ends after sixty (60) days from the time EPA received the complaint or if:

(1) An agreement is reached; or

(2) The Mediator determines that an agreement cannot be reached.

(f) The mediator must return unresolved complaints to OCR to be processed in accordance with the procedure in §7.120.

APPENDIX A TO PART 7—TYPES OF EPA ASSISTANCE AS LISTED IN THE ''CATALOG OF FEDERAL DOMESTIC ASSISTANCE''

1. Assistance provided by the Office of Air, Noise and Radiation under the Clean Air Act of 1977, as amended; Pub. L. 95–95, 42 U.S.C. 7401 *et seq*. (ANR 66.001)

2. Assistance provided by the Office of Air, Noise and Radiation under the Clean Air Act of 1977, as amended; Pub. L. 95–95, 42 U.S.C. 7401 *et seq*. (ANR 66.003)

3. Assistance provided by the Office of Water under the Clean Water Act of 1977, as amended; sections 101(e), 109(b), 201–05, 207, 208(d), 210–12, 215–19, 304(d)(3), 313, 501, 502, 511 and 516(b); Pub. L. 97–117; Pub. L. 95–217; Pub. L. 96–483; 33 U.S.C. 1251 *et seq*. (OW 66.418)

4. Assistance provided by the Office of Water under the Clean Water Act of 1977, as amended; section 106; Pub. L. 95–217; 33 U.S.C. 1251 *et seq*. (OW 66.419)

5. Assistance provided by the Office of Water under the Clean Water Act of 1977, as amended; Pub. L. 95–217; 33 U.S.C. 1251 *et seq*. (OW 66.426)

6. Assistance provided by the Office of Water under the Public Health Service Act, as amended by the Safe Drinking Water Act, Pub. L. 93–523; as amended by Pub. L. 93–190; Pub. L. 96–63; and Pub. L. 93–502. (OW 66.432)

7. Assistance provided by the Office of Water under the Safe Drinking Water Act, Pub. L. 93–523, as amended by Pub. L. 96–63, Pub. L. 95–190, and Pub. L. 96–502. (OW 66.433)

8. Assistance provided by the Office of Water under the Clean Water Act of 1977, section 205(g), as amended by Pub. L. 95–217 and the Federal Water Pollution Control Act, as amended; Pub. L. 97–117; 33 U.S.C. 1251 *et seq*. (OW 66.438)

9. Assistance provided by the Office of Water under the Resource Conservation and Recovery Act of 1976; as amended by the Solid Waste Disposal Act; Pub. L. 94–580; section 3011, 42 U.S.C. 6931, 6947, 6948–49. (OW 66.802).

10. Assistance provided by the Office of Research and Development under the Clean Air Act of 1977, as amended; Pub. L. 95–95; 42 U.S.C. *et seq*.; Clean Water Act of 1977, as amended; Pub. L. 95–217; 33 U.S.C. 1251 *et seq*., section 8001 of the Solid Water Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976; Pub. L. 94–580; 42 U.S.C. 6901, Public Health Service Act as amended by the Safe Drinking Water Act as amended by Pub. L. 95–190; Federal Insecticide, Fungicide and Rodenticide Act; Pub. L. 95–516; 7 U.S.C. 136 *et seq*., as amended by Pub. L.'s 94–140 and 95–396; Toxic Substances Control Act; 15 U.S.C. 2609; Pub. L. 94–469. (ORD 66.500)

11. Assistance provided by the Office of Research and Development under the Clean Air Act of 1977, as amended; Pub. L. 95–95; 42 U.S.C. 7401 *et seq*. (ORD 66.501)

12. Assistance provided by the Office of Research and Development under the Federal Insecticide, Fungicide and Rodenticide Act, Pub. L. 95–516, 7 U.S.C. 136 *et seq*., as amended by Pub. L.'s 94–140 and 95–396. (ORD 66.502)

13. Assistance provided by the Office of Research and Development under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976; 42 U.S.C. 6901, Pub. L. 94–580, section 8001. (ORD 66.504)

14. Assistance provided by the Office of Research and Development under the Clean Water Act of 1977, as amended; Pub. L. 95–217; 33 U.S.C. 1251 *et seq*. (ORD 66.505)

15. Assistance provided by the Office of Research and Development under the Public Health Service Act as amended by the Safe Drinking Water Act, as amended by Pub. L. 95–190 (ORD 66.506)

16. Assistance provided by the Office of Research and Development under the Toxic Substances Control Act; Pub. L. 94–469; 15 U.S.C. 2609; section 10. (ORD 66.507)

17. Assistance provided by the Office of Administration, including but not limited to: Clean Air Act of 1977, as amended, Pub. L. 95–95; 42 U.S.C. 7401 *et seq*., Clean Water Act of 1977, as amended; Pub. L. 95–217; 33 U.S.C. 1251 *et seq*.; Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976; 42 U.S.C. 6901; Pub. L. 94–580; Federal Insecticide, Fungicide and Rodenticide Act; Pub. L. 92–516; 7 U.S.C. 136 *et seq*. as amended by Pub. L.'s 94–140 and 95–396; Public Health Service Act, as amended by the Safe Drinking Water Act, as amended by Pub. L. 95–190. (OA 66.600)

18. Assistance provided by the Office of Administration under the Clean Water Act of 1977, as amended; Pub. L. 95–217; section 213; 33 U.S.C. 1251 *et seq*. (OA 66.603)

19. Assistance provided by the Office of Enforcement Counsel under the Federal Insecticide and Rodenticide Act, as amended; Pub. L. 92–516; 7 U.S.C. 136 *et seq.*, as amended by Pub. L. 94–140, section 23(a) and Pub. L. 95–396. (OA 66.700)

20. Assistance provided by the Office of Land and Emergency Management under the Comprehensive Environmental Responses, Compensation and Liability Act of 1980; Pub. L. 96–510, section 3012, 42 U.S.C. 9601, *et seq.* (OLEM—number not to be assigned since Office of Management and Budget does not catalog one-year programs.)

21. Assistance provided by the Office of Water under the Clean Water Act as amended; Pub. L. 97–117, 33 U.S.C. 1313. (OW—66.454)

[49 FR 1659, Jan. 12, 1984, as amended at 80 FR 77577, Dec. 15, 2015]

PART 8—ENVIRONMENTAL IMPACT ASSESSMENT OF NONGOVERNMENTAL ACTIVITIES IN ANTARCTICA

Sec.

AUTHORITY: 16 U.S.C. 2401 *et seq.*, as amended, 16 U.S.C. 2403a.

SOURCE: 66 FR 63468, Dec. 6, 2001, unless otherwise noted.

§ 8.1 Purpose.

(a) This part is issued pursuant to the Antarctic Science, Tourism, and Conservation Act of 1996. As provided in that Act, this part implements the requirements of Article 8 and Annex I to the Protocol on Environmental Protection to the Antarctic Treaty of 1959 and provides for:

(1) The environmental impact assessment of nongovernmental activities, including tourism, for which the United States is required to give advance notice under paragraph 5 of Article VII of the Antarctic Treaty of 1959; and

(2) Coordination of the review of information regarding environmental impact assessment received by the United States from other Parties under the Protocol.

(b) The procedures in this part are designed to: ensure that nongovernmental operators identify and assess the potential impacts of their proposed activities, including tourism, on the Antarctic environment; that operators consider these impacts in deciding whether or how to proceed with proposed activities; and that operators provide environmental documentation pursuant to the Act and Annex I of the Protocol. These procedures are consistent with and implement the environmental impact assessment provisions of Article 8 and Annex I to the Protocol on Environmental Protection to the Antarctic Treaty.

§ 8.2 Applicability and effect.

(a) This part is intended to ensure that potential environmental effects of nongovernmental activities undertaken in Antarctica are appropriately identified and considered by the operator during the planning process and that to the extent practicable, appropriate environmental safeguards which would mitigate or prevent adverse impacts on the Antarctic environment are identified by the operator.

(b) The requirements set forth in this part apply to nongovernmental activities for which the United States is required to give advance notice under paragraph 5 of Article VII of the Antarctic Treaty of 1959: All nongovernmental expeditions to and within Antarctica organized in or proceeding from its territory.

(c) This part does not apply to activities undertaken in the Antarctic Treaty area that are governed by the Convention on the Conservation of Antarctic Marine Living Resources or the Convention for the Conservation of Antarctic Seals. Persons traveling to Antarctica are subject to the requirements of the Marine Mammal Protection Act, 16 U.S.C. 1371 *et seq.*

§ 8.3 Definitions.

As used in this part:

Act means 16 U.S.C. 2401 *et seq.*, Public Law 104–227, the Antarctic Science, Tourism, and Conservation Act of 1996.

Annex I refers to Annex I, Environmental Impact Assessment, of the Protocol.

Antarctic environment means the natural and physical environment of Antarctica and its dependent and associated ecosystems, but excludes social, economic, and other environments.

Antarctic Treaty area means the area south of 60 degrees south latitude.

Antarctic Treaty Consultative Meeting (ATCM) means a meeting of the Parties to the Antarctic Treaty, held pursuant to Article IX(1) of the Treaty.

Antarctica means the Antarctic Treaty area; i.e., the area south of 60 degrees south latitude.

Comprehensive Environmental Evaluation (CEE) means a study of the reasonably foreseeable potential effects of a proposed activity on the Antarctic environment, prepared in accordance with the provisions of this part and includes all comments received thereon. (See: § 8.8.)

Environmental document or environmental documentation (Document) means a preliminary environmental review memorandum, an initial environmental evaluation, or a comprehensive environmental evaluation.

Environmental impact assessment (EIA) means the environmental review process required by the provisions of this part and by Annex I of the Protocol, and includes preparation by the operator and U.S. government review of an environmental document, and public access to and circulation of environmental documents to other Parties and the Committee on Environmental Protection as required by Annex I of the Protocol.

EPA means the Environmental Protection Agency.

Expedition means any activity undertaken by one or more nongovernmental persons organized within or proceeding from the United States to or within the Antarctic Treaty area for which advance notification is required under Paragraph 5 of Article VII of the Treaty.

Impact means impact on the Antarctic environment and dependent and associated ecosystems.

Initial Environmental Evaluation (IEE) means a study of the reasonably foreseeable potential effects of a proposed activity on the Antarctic environment prepared in accordance with § 8.7.

More than a minor or transitory impact has the same meaning as the term ''significantly'' as defined in regulations under the National Environmental Policy Act at 40 CFR 1508.27.

Operator or *operators* means any person or persons organizing a nongovernmental expedition to or within Antarctica.

Person has the meaning given that term in section 1 of title 1, United States code, and includes any person subject to the jurisdiction of the United States except that the term does not include any department, agency, or other instrumentality of the Federal Government.

Preliminary environmental review means the environmental review described under that term in § 8.6.

Preliminary Environmental Review Memorandum (PERM) means the documentation supporting the conclusion of the preliminary environmental review that the impact of a proposed activity will be less than minor or transitory on the Antarctic environment.

Protocol means the Protocol on Environmental Protection to the Antarctic Treaty, done at Madrid October 4, 1991, and all annexes thereto which are in force for the United States.

This part means 40 CFR part 8.

§ 8.4 Preparation of environmental documents, generally.

(a) *Basic information requirements.* In addition to the information required pursuant to other sections of this part, all environmental documents shall contain the following:

(1) The name, mailing address, and phone number of the operator;

(2) The anticipated date(s) of departure of each expedition to Antarctica;

(3) An estimate of the number of persons in each expedition;

(4) The means of conveyance of expedition(s) to and within Antarctica;

(5) Estimated length of stay of each expedition in Antarctica;

(6) Information on proposed landing sites in Antarctica; and

(7) Information concerning training of staff, supervision of expedition members, and what other measures, if any, that will be taken to avoid or minimize possible environmental impacts.

(b) *Preparation of an environmental document.* Unless an operator determines and documents that a proposed activity will have less than a minor or transitory impact on the Antarctic environment, the operator will prepare an IEE or CEE in accordance with this part. In making the determination what level of environmental documentation is appropriate, the operator should consider, as applicable, whether and to what degree the proposed activity:

(1) Has the potential to adversely affect the Antarctic environment;

(2) May adversely affect climate or weather patterns;

(3) May adversely affect air or water quality;

(4) May affect atmospheric, terrestrial (including aquatic), glacial, or marine environments;

(5) May detrimentally affect the distribution, abundance, or productivity of species, or populations of species of fauna and flora;

(6) May further jeopardize endangered or threatened species or populations of such species;

(7) May degrade, or pose substantial risk to, areas of biological, scientific, historic, aesthetic, or wilderness significance;

(8) Has highly uncertain environmental effects, or involves unique or unknown environmental risks; or

(9) Together with other activities, the effects of any one of which is individually insignificant, may have at least minor or transitory cumulative environmental effects.

(c) *Type of environmental document.* The type of environmental document required under this part depends upon the nature and intensity of the environmental impacts that could result from the activity under consideration. A PERM must be prepared by the operator to document the conclusion of the operator's preliminary environmental review that the impact of a proposed activity on the Antarctic environment will be less than minor or transitory. (See §8.6.) An IEE must be prepared by the operator for proposed activities which may have at least (but no more than) a minor or transitory impact on the Antarctic environment. (See §8.7.) A CEE must be prepared by the operator if an IEE indicates, or if it is otherwise determined, that a proposed activity is likely to have more than a minor or transitory impact on the Antarctic environment (See §8.8.)

(d) *Incorporation of information, consolidation of environmental documentation, and multi-year environmental documentation.* (1) An operator may incorporate material into an environmental document by referring to it in the document when the effect will be to reduce paperwork without impeding the review of the environmental document by EPA and other federal agencies. The incorporated material shall be cited and its content briefly described. No material may be incorporated by referring to it in the document unless it is reasonably available to the EPA.

(2) Provided that environmental documentation complies with all applicable provisions of Annex I to the Protocol and this part and is appropriate in light of the specific circumstances of the operator's proposed expedition or expeditions, an operator may include more than one proposed expedition within one environmental document and one environmental document may also be used to address expeditions being carried out by more than one operator provided that the environmental document indicates the names of each operator for which the environmental documentation is being submitted pursuant to obligations under this part.

(e) *Multi-year environmental documentation.* (1) Provided that environmental documentation complies with all applicable provisions of Annex I to the Protocol and this part, an operator may submit environmental documentation for proposed expeditions for a period of up to five consecutive austral summer seasons, provided that the conditions described in the multi-year environmental document, including the assessment of cumulative impacts, are unchanged and meets the provisions of paragraphs (e)(1) (i) through (iii) of this section.

(i) The operator shall identify the environmental documentation submitted for multi-year documentation purposes in the first year it is submitted. If the operator, or operators, fail to make this initial identification to EPA, this provision shall not be in effect although subsequent years' submissions by the operator, or operators, may use this environmental documentation as provided in paragraphs (d) (1) and (2) of this section.

(ii) In subsequent years, up to a total maximum of five years, the operator, or operators, shall reference the multi-year documentation identified initially if it is necessary to update the basic information requirements listed in paragraph (a) of this section.

(iii) An operator, or operators, may supplement a multi-year environmental document for an additional activity or activities by providing information regarding the proposed activity in accordance with the appropriate provisions of this part. The operator, or operators, shall identify this submission as a proposed supplement to the multi-year documentation in effect. Addition of the supplemental information shall not extend the period of the multi-year environmental documentation beyond the time period associated with the documentation as originally submitted.

(2) Multi-year environmental documentation may include more than one proposed expedition within the environmental document and the multi-year environmental document may also be used to address expeditions being carried out by more than one operator provided that the environmental document indicates the names of each operator for which the environmental documentation is being submitted pursuant to obligations under this part.

(3) The schedules for multi-year environmental documentation depend on the level of the environmental document and shall be the same as the schedules for comparable environmental documentation submitted on an annual basis; e.g., a multi-year PERM shall comply with the schedule in § 8.6, a multi-year IEE shall comply with the schedule in § 8.7, and a multi-year CEE shall comply with the schedule in § 8.8. These schedules apply to the operator's submission of the initial multi-year environmental document; the operator's subsequent annual submissions pursuant to paragraphs (e)(1) (ii) and (iii) of this section; EPA's review, in consultation with other interested federal agencies, and comment on the multi-year environmental documentation and subsequent annual submissions; and a finding the EPA may make, with the concurrence of the National Science Foundation, that the environmental documentation submitted does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part.

§ 8.5 Submission of environmental documents.

(a) An operator shall submit environmental documentation to the EPA for review. The EPA, in consultation with other interested federal agencies, will carry out a review to determine if the submitted environmental documentation meets the requirements of Article 8 and Annex I of the Protocol and the provisions of this part. The EPA will provide its comments, if any, on the environmental documentation to the operator and will consult with the operator regarding any suggested revisions. If EPA has no comments, or if the documentation is satisfactorily revised in response to EPA's comments, and the operator does not receive a notice from EPA that the environmental documentation does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part, the operator will have no further obligations pursuant to the applicable requirements of this part provided that any appropriate measures, which may include monitoring, are put in place to assess and verify the impact of the activity. Alternatively, following final response from the operator, the EPA, in consultation with other federal agencies and with the concurrence of the National Science Foundation, will inform the operator that EPA finds that the environmental documentation does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part. If the operator then proceeds with the expedition without fulfilling the requirements of

this part, the operator is subject to enforcement proceedings pursuant to sections 7, 8, and 9 of the Antarctic Conservation Act, as amended by the Act; 16 U.S.C. 2407, 2408, 2409, and 45 CFR part 672.

(b) The EPA may waive or modify deadlines pursuant to this part where EPA determines an operator is acting in good faith and that circumstances outside the control of the operator created delays, provided that the environmental documentation fully meets deadlines under the Protocol.

§ 8.6 Preliminary environmental review.

(a) Unless an operator has determined to prepare an IEE or CEE, the operator shall conduct a preliminary environmental review that assesses the potential direct and reasonably foreseeable indirect impacts on the Antarctic environment of the proposed expedition. A Preliminary Environmental Review Memorandum (PERM) shall contain sufficient detail to assess whether the proposed activity may have less than a minor or transitory impact, and shall be submitted to the EPA for review no less than 180 days before the proposed departure of the expedition. The EPA, in consultation with other interested federal agencies, will review the PERM to determine if it is sufficient to demonstrate that the activity will have less than a minor or transitory impact or whether additional environmental documentation, *i.e.*, an IEE or CEE, is required to meet the obligations of Article 8 and Annex I of the Protocol. The EPA will provide its comments to the operator within fifteen (15) days of receipt of the PERM, and the operator shall have seventy-five (75) days to prepare a revised PERM or an IEE, if necessary. Following the final response from the operator, EPA may make a finding that the environmental documentation submitted does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part. This finding will be made with the concurrence of the National Science Foundation. If EPA does not provide such notice within thirty (30) days, the operator will be deemed to have met the requirements of this part provided that any required procedures, which may include appropriate monitoring, are put in place to assess and verify the impact of the activity.

(b) If EPA recommends an IEE and one is prepared and submitted within the seventy-five (75) day response period, it will be reviewed under the time frames set out for an IEE in §8.7. If EPA recommends a CEE and one is prepared, it will be reviewed under the time frames set out for a CEE in §8.8.

§ 8.7 Initial environmental evaluation.

(a) *Submission of IEE to the EPA.* Unless a PERM has been submitted pursuant to §8.6 which meets the environmental documentation requirements under Article 8 and Annex I to the Protocol and the provisions of this part or a CEE is being prepared, an IEE shall be submitted by the operator to the EPA no fewer than ninety (90) days before the proposed departure of the expedition.

(b) *Contents.* An IEE shall contain sufficient detail to assess whether a proposed activity may have more than a minor or transitory impact on the Antarctic environment and shall include the following information:

(1) A description of the proposed activity, including its purpose, location, duration, and intensity; and

(2) Consideration of alternatives to the proposed activity and any impacts that the proposed activity may have on the Antarctic environment, including consideration of cumulative impacts in light of existing and known proposed activities.

(c) *Further environmental review.* (1) The EPA, in consultation with other interested federal agencies, will review an IEE to determine whether the IEE meets the requirements under Annex I to the Protocol and the provisions of this part. The EPA will provide its comments to the operator within thirty (30) days of receipt of the IEE, and the operator will have forty-five (45) days to prepare a revised IEE, if necessary. Following the final response from the operator, EPA may make a finding that the documentation submitted does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part. This

finding will be made with the concurrence of the National Science Foundation. If such a notice is required, EPA will provide it within fifteen (15) days of receiving the final IEE from the operator or, if the operator does not provide a final IEE, within sixty (60) days following EPA's comments on the original IEE. If EPA does not provide notice within these time limits, the operator will be deemed to have met the requirements of this part provided that any required procedures, which may include appropriate monitoring, are put in place to assess and verify the impact of the activity.

(2) If a CEE is required, the operator must adhere to the time limits applicable to such documentation. (See: §8.8.) In this event EPA, at the operator's request, will consult with the operator regarding possible changes in the proposed activity which would allow preparation of an IEE.

§ 8.8 Comprehensive environmental evaluation.

(a) *Preparation of a CEE.* Unless a PERM or an IEE has been submitted and determined to meet the environmental documentation requirements of this part, the operator shall prepare a CEE. A CEE shall contain sufficient information to enable informed consideration of the reasonably foreseeable potential environmental effects of a proposed activity and possible alternatives to that proposed activity. A CEE shall include the following:

(1) A description of the proposed activity, including its purpose, location, duration and intensity, and possible alternatives to the activity, including the alternative of not proceeding, and the consequences of those alternatives;

(2) A description of the initial environmental reference state with which predicted changes are to be compared and a prediction of the future environmental reference state in the absence of the proposed activity;

(3) A description of the methods and data used to forecast the impacts of the proposed activity;

(4) Estimation of the nature, extent, duration and intensity of the likely direct impacts of the proposed activity;

(5) A consideration of possible indirect or second order impacts from the proposed activity;

(6) A consideration of cumulative impacts of the proposed activity in light of existing activities and other known planned activities;

(7) Identification of measures, including monitoring programs, that could be taken to minimize or mitigate impacts of the proposed activity and to detect unforeseen impacts and that could provide early warning of any adverse effects of the activity as well as to deal promptly and effectively with accidents;

(8) Identification of unavoidable impacts of the proposed activity;

(9) Consideration of the effects of the proposed activity on the conduct of scientific research and on other existing uses and values;

(10) An identification of gaps in knowledge and uncertainties encountered in compiling the information required under this section;

(11) A non-technical summary of the information provided under this section; and

(12) The name and address of the person or organization which prepared the CEE and the address to which comments thereon should be directed.

(b) *Submission of Draft CEE to the EPA and Circulation to Other Parties.* (1) Any operator who plans a nongovernmental expedition that would require a CEE must submit a draft of the CEE by December 1 of the preceding year. Within fifteen (15) days of receipt of the draft CEE, EPA will: send it to the Department of State which will circulate it to all Parties to the Protocol and forward it to the Committee for Environmental Protection established by the Protocol, and publish notice of receipt of the CEE and request for comments on the CEE in the FEDERAL REGISTER, and will provide copies to any person upon request. The EPA will accept public comments on the CEE for a period of ninety (90) days following notice in the FEDERAL REGISTER. The EPA, in consultation with other interested federal agencies, will evaluate the CEE to determine if the CEE meets the requirements under Article 8 and Annex I to the Protocol and the provisions of this part and will transmit its comments to

the operator within 120 days following publication in the FEDERAL REGISTER of the notice of availability of the CEE.

(2) The operator shall send a final CEE to EPA at least seventy-five (75) days before commencement of the proposed activity in the Antarctic Treaty area. The CEE must address and must include (or summarize) any comments on the draft CEE received from EPA, the public, and the Parties. Following the final response from the operator, the EPA will inform the operator if EPA, with the concurrence of the National Science Foundation, makes the finding that the environmental documentation submitted does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part. This notification will occur within fifteen (15) days of submittal of the final CEE by the operator if the final CEE is submitted by the operator within the time limits set out in this section. If no final CEE is submitted or the operator fails to meet these time limits, EPA will provide such notification sixty (60) days prior to departure of the expedition. If EPA does not provide such notice, the operator will be deemed to have met the requirements of this part provided that procedures, which include appropriate monitoring, are put in place to assess and verify the impact of the activity. The EPA will transmit the CEE, along with a notice of any decisions by the operator relating thereto, to the Department of State which shall circulate it to all Parties no later than sixty (60) days before commencement of the proposed activity in the Antarctic Treaty area. The EPA will also publish a notice of availability of the final CEE in the FEDERAL REGISTER.

(3) No final decision shall be taken to proceed with any activity for which a CEE is prepared unless there has been an opportunity for consideration of the draft CEE by the Antarctic Treaty Consultative Meeting on the advice of the Committee for Environmental Protection, provided that no expedition need be delayed through the operation of paragraph 5 of Article 3 to Annex I of the Protocol for longer than 15 months from the date of circulation of the draft CEE.

(c) *Decisions based on CEE.* The decision to proceed, based on environmental documentation that meets the requirements under Article 8 and Annex I to the Protocol and the provisions of this part, rests with the operator. Any decision by an operator on whether to proceed with or modify a proposed activity for which a CEE was required shall be based on the CEE and other relevant considerations.

§ 8.9 Measures to assess and verify environmental impacts.

(a) The operator shall conduct appropriate monitoring of key environmental indicators as proposed in the CEE to assess and verify the potential environmental impacts of activities which are the subject of a CEE. The operator may also need to carry out monitoring in order to assess and verify the impact of an activity for which an IEE has been prepared.

(b) All proposed activities for which an IEE or CEE has been prepared shall include procedures designed to provide a regular and verifiable record of the impacts of these activities, in order, *inter alia,* to:

(1) Enable assessments to be made of the extent to which such impacts are consistent with the Protocol; and

(2) Provide information useful for minimizing and mitigating those impacts, and, where appropriate, information on the need for suspension, cancellation, or modification of the activity.

§ 8.10 Cases of emergency.

This part shall not apply to activities taken in cases of emergency relating to the safety of human life or of ships, aircraft, equipment and facilities of high value, or the protection of the environment, which require an activity to be undertaken without completion of the procedures set out in this part. Notice of any such activities which would have otherwise required the preparation of a CEE shall be provided within fifteen (15) days to the Department of State, as provided in this paragraph, for circulation to all Parties to the Protocol and to the Committee on Environmental Protection, and a full explanation of the activities carried out shall be provided within forty-five

(45) days of those activities. Notification shall be provided to: The Director, The Office of Oceans Affairs, OES/OA, Room 5805, Department of State, 2201 C Street, NW, Washington, DC 20520–7818.

§ 8.11 Prohibited acts, enforcement and penalties.

(a) It shall be unlawful for any operator to violate this part.

(b) An operator who violates any of this part is subject to enforcement, which may include civil and criminal enforcement proceedings, and penalties, pursuant to sections 7,8, and 9 of the Antarctic Conservation Act, as amended by the Act; 16 U.S.C. 2407, 2408, 2409, and 45 CFR part 672.

§ 8.12 Coordination of reviews from other Parties.

(a) Upon receipt of a draft CEE from another Party, the Department of State shall publish notice in the FEDERAL REGISTER and shall circulate a copy of the CEE to all interested federal agencies. The Department of State shall coordinate responses from federal agencies to the CEE and shall transmit the coordinated response to the Party which has circulated the CEE. The Department of State shall make a copy of the CEE available upon request to the public.

(b) Upon receipt of the annual list of IEEs from another Party prepared in accordance with Article 2 of Annex I and any decisions taken in consequence thereof, the Department of State shall circulate a copy to all interested federal agencies. The Department of State shall make a copy of the list of IEEs prepared in accordance with Article 2 and any decisions taken in consequence thereof available upon request to the public.

(c) Upon receipt of a description of appropriate national procedures for environmental impact assessments from another Party, the Department of State shall circulate a copy to all interested federal agencies. The Department of State shall make a copy of these descriptions available upon request to the public.

(d) Upon receipt from another Party of significant information obtained, and any action taken in consequence therefrom from procedures put in place with regard to monitoring pursuant to Articles 2(2) and 5 of Annex I to the Protocol, the Department of State shall circulate a copy to all interested federal agencies. The Department of State shall make a copy of this information available upon request to the public.

(e) Upon receipt from another Party of a final CEE, the Department of State shall circulate a copy to all interested federal agencies. The Department of State shall make a copy available upon request to the public.

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

AUTHORITY: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

§ 9.1 OMB approvals under the Paperwork Reduction Act.

This part consolidates the display of control numbers assigned to collections of information in certain EPA regulations by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). No person is required to respond to an information collection request regulated by the PRA unless a valid control number assigned by OMB is displayed in either this part, another part of the Code of Federal Regulations, a valid FEDERAL REGISTER notice, or by other appropriate means.

40 CFR citation	OMB control No.
Public Information	
Part 2, subpart B	2020–0003
Environmental Impact Assessment of Nongovernmental Activities in Antarctica	
Part 3	2025–0003
8.5–8.10	2020–0007
Protection of Human Subjects	
26.1125	2070–0169
26.1303	2070–0169

40 CFR citation	OMB control No.
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30.530	2030–0020
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31.40	2030–0020
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35.2114	2040–0027
35.2118	2040–0027
35.2120	2040–0027
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35.2218	2040–0027
35.3010	2040–0095
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35.3135	2040–0118
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35.3550 (a)–(p)	2040–0185
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35.3565 (a)–(f)	2040–0185
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35.6055(a)(2)	2050–0179
35.6055(b)(1)	2050–0179
35.6055(b)(2)(i)–(ii)	2050–0179
35.6105(a)(2)(i)–(v), (vii)	2050–0179
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35.6300(a)(3)	2050–0179
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35.6585	2050–0179
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46.230(a)	2030–0020
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49.126(e)(1)(iii)	2060–0558
49.126(e)(1)(v)	2060–0558
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49.130(f)(1)–(2)	2060–0558
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51.365–51.366	2060–0252
51.370–51.371	2060–0252
51.850–51.860	2060–0279
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53.16(a)–(d), (f)	2080–0005
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60.42b	2060–0072
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600.006–86	2060–0104
600.006–89	2060–0104
600.007–80	2060–0104
600.010–86	2060–0104
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600.507–86	2060–0104
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721.160	2070–0012, 2070–0038
721.170	2070–0012, 2070–0038
721.185	2070–0012, 2070–0038
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1045.825	2060–0321
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1048.825	2060–0338
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[1] The ICRs referenced in this section of the table encompass the applicable general provisions contained in 40 CFR part 60, subpart A, which are not independent information collection requirements.

[2] The ICRs referenced in this section of the table encompass the applicable general provisions contained in 40 CFR part 61, subpart A, which are not independent information collection requirements.

[3] The ICRs referenced in this section of the table encompass the applicable general provisions contained in 40 CFR part 63, subpart A, which are not independent information collection requirements.

[58 FR 27472, May 10, 1993]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting §9.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

2. At 65 FR 76745, Dec. 7, 2000, the table in §9.1 was amended, but amendments could not

be incorporated because of inaccurate amendatory instructions.

3. At 71 FR 767, Jan. 5, 2006, the table was amended under the heading ''National Primary Drinking Water Regulations Implementation'' by removing the entry for §142.15(c); however, the amendment could not be incorporated because that entry does not exist.

PART 10—ADMINISTRATIVE CLAIMS UNDER FEDERAL TORT CLAIMS ACT

Subpart A—General

Sec.

Subpart B—Procedures

AUTHORITY: Sec. 1, 80 Stat. 306; 28 U.S.C. 2672; 28 CFR part 14.

SOURCE: 38 FR 16868, June 27, 1973, unless otherwise noted.

Subpart A—General

§ 10.1 Scope of regulations.

The regulations in this part apply only to claims asserted under the Federal Tort Claims Act, as amended, 28 U.S.C. 2671–2680, for money damages against the United States because of damage to or loss of property or personal injury or death, caused by the negligent or wrongful act or omission of any employee of the Environmental Protection Agency (EPA) while acting within the scope of his/her employment.

[51 FR 25832, July 16, 1986]

Subpart B—Procedures

§ 10.2 Administrative claim; when presented; place of filing.

(a) For purpose of the regulations in this part, a claim shall be deemed to have been presented when the Environmental Protection Agency receives, at a place designated in paragraph (c) of this section, an executed Standard Form 95 or other written notification of an incident accompanied by a claim for money damages in a sum certain for damage to or loss of property, for personal injury, or for death, alleged to have occurred by reason of the incident. A claim which should have been presented to EPA, but which was mistakenly addressed to or filed with another Federal agency, shall be deemed to be presented to EPA as of the date that the claim is received by EPA. A claim mistakenly addressed to or filed with EPA shall forthwith be transferred to the appropriate Federal agency, if ascertainable, or returned to the claimant.

(b) A claim presented in compliance with paragraph (a) of this section may be amended by the claimant at any time prior to final action by the Administrator, or his designee, or prior to the exercise of the claimant's option to bring suit under 28 U.S.C. 2675(a). Amendments shall be submitted in writing and signed by the claimant or his duly authorized agent or legal representative. Upon the timely filing of an amendment to a pending claim, EPA shall have 6 months in which to make a final disposition of the claim as amended and the claimant's option under 28 U.S.C. 2675(a) shall not accrue until 6 months after the filing of an amendment.

(c) Forms may be obtained and claims may be filed with the EPA office having jurisdiction over the employee involved in the accident or incident, or with the EPA Claims Officer, Office of General Counsel (2311), 1200 Pennsylvania Ave., NW., Washington, DC 20460.

[38 FR 16868, June 27, 1973, as amended at 51 FR 25832, July 16, 1986]

§ 10.3 Administrative claims; who may file.

(a) A claim for injury to or loss of property may be presented by the owner of the property interest which is the subject of the claim, his duly authorized agent, or his legal representative.

(b) A claim for personal injury may be presented by the injured person, his duly authorized agent, or his legal representative.

(c) A claim based on death may be presented by the executor or administrator of the decedent's estate or by any other person legally entitled to assert such a claim under applicable State law.

(d) A claim for loss wholly compensated by an insurer with the rights of a subrogee may be presented by the insurer. A claim for loss partially compensated by an insurer with the rights of a subrogee may be presented by the insurer or the insured individually as their respective interests appear, or jointly. Whenever an insurer presents a claim asserting the rights of a subrogee, he shall present with his claim appropriate evidence that he has the rights of a subrogee.

(e) A claim presented by an agent or legal representative shall be presented in the name of the claimant, be signed by the agent or legal representative, show the title or legal capacity of the person signing, and be accompanied by evidence of his authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian, or other representative.

§ 10.4 Evidence to be submitted.

(a) *Death.* In support of a claim based on death, the claimant may be required to submit the following evidence or information:

(1) An authenticated death certificate or other competent evidence showing cause of death, date of death, and age of the decedent.

(2) Decedent's employment or occupation at time of death, including his monthly or yearly salary or earnings (if any), and the duration of his last employment or occupation.

(3) Full names, addresses, birth dates, kinship, and marital status of the decedent's survivors, including identification of those survivors who were dependent for support upon the decedent at the time of his death.

(4) Degree of support afforded by the decendent to each survivor dependent upon him for support at the time of his death.

(5) Decedent's general physical and mental condition before death.

(6) Itemized bills for medical and burial expenses incurred by reason of the incident causing death, or itemized receipts of payments for such expenses.

(7) If damages for pain and suffering prior to death are claimed, a physician's detailed statement specifying the injuries suffered, duration of pain and suffering, any drugs administered for pain and the decedent's physical condition in the interval between injury and death.

(8) Any other evidence or information which may have a bearing on either the responsibility of the United States for the death or the damages claimed.

(b) *Personal Injury.* In support of a claim for personal injury, including pain and suffering, the claimant may be required to submit the following evidence or information:

(1) A written report by his attending physician or dentist setting forth the nature and extent of the injury, nature and extent of treatment, any degree of temporary or permanent disability, the prognosis, period of hospitalization, and any diminished earning capacity. In addition, the claimant may be required to submit to a physical or mental examination by a physician employed or designated by EPA. A copy of the report of the examining physician shall be made available to the claimant upon the claimant's written request provided that the claimant has, upon request, furnished the report referred to in the first sentence of this subparagraph and has made or agrees in writing to make available to EPA any other physician's reports previously or thereafter made of the physical or mental condition which is the subject matter of his claim.

(2) Itemized bills for medical, dental, hospital and related expenses incurred, or itemized receipts of payment for such expenses.

(3) If the prognosis reveals the necessity for future treatment, a statement

of expected duration of and expenses for such treatment.

(4) If a claim is made for loss of time from employment, a written statement from his employer showing actual time lost from employment, whether he is a full or part-time employee, and wages or salary actually lost.

(5) If a claim is made for loss of income and the claimant is self-employed, documentary evidence showing the amount of earnings actually lost.

(6) Any other evidence or information which may have a bearing on the responsibility of the United States for either the personal injury or the damages claimed.

(c) *Property Damage.* In support of a claim for damage to or loss of property, real or personal, the claimant may be required to submit the following evidence or information:

(1) Proof of ownership.

(2) A detailed statement of the amount claimed with respect to each item of property.

(3) An itemized receipt of payment for necessary repairs or itemized written estimates of the cost of such repairs.

(4) A statement listing date of purchase, purchase price, market value of the property as of date of damage, and salvage value, where repair is not economical.

(5) Any other evidence or information which may have a bearing on the responsibility of the United States either for the injury to or loss of property or for the damage claimed.

(d) *Time limit.* All evidence required to be submitted by this section shall be furnished by the claimant within a reasonable time. Failure of a claimant to furnish evidence necessary to a determination of his claim within three months after a request therefor has been mailed to his last known address may be deemed an abandonment of the claim. The claim may be thereupon disallowed.

§ 10.5 Investigation, examination, and determination of claims.

The EPA Claims Officer adjusts, determines, compromises and settles all administrative tort claims filed with EPA. In carrying out these functions, the EPA Claims Officer makes such investigations as are necessary for a determination of the validity of the claim. The decision of the EPA Claims Officer is a final agency decision of purposes of 28 U.S.C. 2675.

[51 FR 25832, July 16, 1986]

§ 10.6 Final denial of claim.

(a) Final denial of an administrative claim shall be in writing and sent to the claimant, his attorney, or legal representative by certified or registered mail. The notification of final denial may include a statement of the reasons for the denial and shall include a statement that, if the claimant is dissatisfied with EPA's action, he may file suit in an appropriate U.S. District Court not later than 6 months after the date of mailing of the notification.

(b) Prior to the commencement of suit and prior to the expiration of the 6-month period after the date of mailing by certified or registered mail of notice of final denial of the claim as provided in 28 U.S.C. 2401(b), a claimant, his duly authorized agent, or legal representative, may file a written request with the EPA for reconsideration of a final denial of a claim under paragraph (a) of this section. Upon the timely filing of a request for reconsideration, EPA shall have 6 months from the date of filing in which to make a final disposition of the claim and the claimant's option under 28 U.S.C. 2675(a) to bring suit shall not accrue until 6 months after the filing of a request for reconsideration. Final action on a request for reconsideration shall be effected in accordance with the provisions of paragraph (a) of this section.

§ 10.7 Payment of approved claim.

(a) Upon allowance of his claim, claimant or his duly authorized agent shall sign the voucher for payment, Standard Form 1145, before payment is made.

(b) When the claimant is represented by an attorney, the voucher for payment (SF 1145) shall designate both the claimant and his attorney as ''payees.'' The check shall be delivered to the attorney whose address shall appear on the voucher.

(c) No attorney shall charge fees in excess of 25 percent of a judgment or settlement after litigation, or in excess

of 20 percent of administrative settlements (28 U.S.C. 2678).

§ 10.8 Release.

Acceptance by the claimant, his agent or legal representative of any award, compromise or settlement made hereunder, shall be final and conclusive on the claimant, his agent or legal representative and any other person on whose behalf or for whose benefit the claim has been presented, and shall constitute a complete release of all claims against either the United States or any employee of the Government arising out of the same subject matter.

§ 10.9 Penalties.

A person who files a false claim or makes a false or fraudulent statement in a claim against the United States may be liable to a fine of not more than $10,000 or to imprisonment of not more than 5 years, or both (18 U.S.C. 287,1001), and, in addition, to a forfeiture of $2,000 and a penalty of double the loss or damage sustained by the United States (31 U.S.C. 3729).

[38 FR 16868, June 27, 1973, as amended at 51 FR 25832, July 16, 1986]

§ 10.10 Limitation on Environmental Protection Agency's authority.

(a) An award, compromise or settlement of a claim hereunder in excess of $25,000 shall be effected only with the prior written approval of the Attorney General or his designee. For the purposes of this paragraph, a principal claim and any derivative or subrogated claim shall be treated as a single claim.

(b) An administrative claim may be adjusted, determined, compromised or settled hereunder only after consultation with the Department of Justice when, in the opinion of the Environmental Protection Agency:

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and the Agency is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed $25,000.

(c) An administrative claim may be adjusted, determined, compromised, or settled by EPA hereunder only after consultation with the Department of Justice when EPA is informed or is otherwise aware that the United States or an employee, agent, or cost-plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

§ 10.11 Relationship to other agency regulations.

The regulations in this part supplement the Attorney General's regulations in part 14 of chapter 1 of title 28, CFR, as amended. Those regulations, including subsequent amendments thereto, and the regulations in this part apply to the consideration by the Environmental Protection Agency of administrative claims under the Federal Tort Claims Act.

[38 FR 16868, June 27, 1973, as amended at 51 FR 25832, July 16, 1986]

PART 11—SECURITY CLASSIFICATION REGULATIONS PURSUANT TO EXECUTIVE ORDER 11652

Sec.

AUTHORITY: Executive Order 11652 (37 FR 5209, March 10, 1972) and the National Security Directive of May 17, 1972 (37 FR 10053, May 19, 1972).

SOURCE: 37 FR 23541, Nov. 4, 1972, unless otherwise noted.

§ 11.1 Purpose.

These regulations establish policy and procedures governing the classification and declassification of national security information. They apply also to information or material designated under the Atomic Energy Act of 1954, as amended, as ''Restricted Data,'' or ''Formerly Restricted Data'' which, additionally, is subject to the

provisions of the Act and regulations of the Atomic Energy Commission.

§ 11.2 Background.

While the Environmental Protection Agency does not have the authority to originally classify information or material in the interest of the national security, it may under certain circumstances downgrade or declassify previously classified material or generate documents incorporating classified information properly originated by other agencies of the Federal Government which must be safeguarded. Agency policy and procedures must conform to applicable provisions of Executive Order 11652, and the National Security Council Directive of May 17, 1972, governing the safeguarding of national security information.

§ 11.3 Responsibilities.

(a) Classification and Declassification Committee: This committee, appointed by the Administrator, has the authority to act on all suggestions and complaints with respect to EPA's administration of this order. It shall establish procedures to review and act within 30 days upon all applications and appeals regarding requests for declassification. The Administrator, acting through the committee, shall be authorized to overrule previous determinations in whole or in part when, in its judgment, continued protection is no longer required. If the committee determines that continued classification is required under section 5(B) of Executive Order 11652, it shall promptly so notify the requester and advise him that he may appeal the denial to the Interagency Classification Review Committee.

(b) Director, Security and Inspection Division, Office of Administration: The Director, Security and Inspection Division, is responsible for the overall management and direction of a program designed to assure the proper handling and protection of classified information, and that classified information in the Agency's possession bears the appropriate classification markings. He also will assure that the program operates in accordance with the policy established herein, and will serve as Secretary of the Classification and Declassification Committee.

(c) Assistant Administrators, Regional Administrators, Heads of Staff Offices, Directors of National Environmental Research Centers are responsible for designating an official within their respective areas who shall be responsible for:

(1) Serving as that area's liaison with the Director, Security and Inspection Division, for questions or suggestions concerning security classification matters.

(2) Reviewing and approving, as the representative of the contracting offices, the DD Form 254, Contract Security Classification Specification, issued to contractors.

(d) Employees; (1) Those employees generating documents incorporating classified information properly originated by other agencies of the Federal Government are responsible for assuring that the documents are marked in a manner consistent with security classification assignments.

(2) Those employees preparing information for public release are responsible for assuring that such information is reviewed to eliminate classified information.

(3) All employees are responsible for bringing to the attention of the Director, Security and Inspection Division, any security classification problems needing resolution.

§ 11.4 Definitions.

(a) *Classified information.* Official information which has been assigned a security classification category in the interest of the national defense or foreign relations of the United States.

(b) *Classified material.* Any document, apparatus, model, film, recording, or any other physical object from which classified information can be derived by study, analysis, observation, or use of the material involved.

(c) *Marking.* The act of physically indicating the classification assignment on classified material.

(d) *National security information.* As used in this order this term is synonymous with ''classified information.'' It is any information which must be protected against unauthorized disclosure in the interest of the national defense

or foreign relations of the United States.

(e) *Security classification assignment.* The prescription of a specific security classification for a particular area or item of information. The information involved constitutes the sole basis for determining the degree of classification assigned.

(f) *Security classification category.* The specific degree of classification (Top Secret, Secret or Confidential) assigned to classified information to indicate the degree of protection required.

(1) *Top Secret.* Top Secret refers to national security information or material which requires the highest degree of protection. The test for assigning Top Secret classification shall be whether its unauthorized disclosure could reasonably be expected to cause exceptionally grave damage to the national security. Examples of ''exceptionally grave damage'' include armed hostilities against the United States or its allies; disruption of foreign relations vitally affecting the national security; the compromise of vital national defense plans or complex cryptologic and communications intelligence systems; the revelation of sensitive intelligence operations; and the disclosure of scientific or technological developments vital to national security. This classification shall be used with the utmost restraint.

(2) *Secret.* Secret refers to that national security information or material which requires a substantial degree of protection. The test for assigning Secret classification shall be whether its unauthorized disclosure could reasonably be expected to cause serious damage to the national security. Examples of ''serious damage'' include disruption of foreign relations significantly affecting the national security; significant impairment of a program or policy directly related to the national security; revelation of significant military plans or intelligence operations; and compromise of scientific or technological developments relating to national security. The classification Secret shall be sparingly used.

(3) *Confidential.* Confidential refers to that national security information or material which requires protection. The test for assigning Confidential classification shall be whether its unauthorized disclosure could reasonably be expected to cause damage to the national security.

§ 11.5 Procedures.

(a) *General.* Agency instructions on access, marking, safekeeping, accountability, transmission, disposition, and destruction of classification information and material will be found in the EPA Security Manual for Safeguarding Classified Material. These instructions shall conform with the National Security Council Directive of May 17, 1972, governing the classification, downgrading, declassification, and safeguarding of National Security Information.

(b) *Classification.* (1) When information or material is originated within EPA and it is believed to require classification, the person or persons responsible for its origination shall protect it in the manner prescribed for protection of classified information. The information will then be transmitted under appropriate safeguards to the Director, Security and Inspection Division, who will forward it to the department having primary interest in it with a request that a classification determination be made.

(2) A holder of information or material which incorporates classified information properly originated by other agencies of the Federal Government shall observe and respect the classification assigned by the originator.

(3) If a holder believes there is unnecessary classification, that the assigned classification is improper, or that the document is subject to declassification, he shall so advise the Director, Security and Inspection Division, who will be responsible for obtaining a resolution.

(c) *Downgrading and declassification.* Classified information and material officially transferred to the Agency during its establishment, pursuant to Reorganization Plan No. 3 of 1970, shall be declassified in accordance with procedures set forth below. Also, the same procedures will apply to the declassification of any information in the Agency's possession which originated in departments or agencies which no

longer exist, except that no declassification will occur in such cases until other departments having an interest in the subject matter have been consulted. Other classified information in the Agency's possession may be downgraded or declassified by the official authorizing its classification, by a successor in capacity, or by a supervisory official of either.

(1) *General Declassification Schedule*—(i) *Top Secret*. Information or material originally classified Top Secret shall become automatically downgraded to Secret at the end of the second full calendar year following the year in which it was originated, downgraded to Confidential at the end of the fourth full calendar year following the year in which it was originated, and declassified at the end of the 10th full calendar year following the year in which it was originated.

(ii) *Secret*. Information and material originally classified Secret shall become automatically downgraded to Confidential at the end of the second full calendar year following the year in which it was originated, and declassified at the end of the eighth full calendar year following the year in which it was originated.

(iii) *Confidential*. Information and material originally classified Confidential shall become automatically declassified at the end of the sixth full calendar year following the year in which it was originated.

(2) *Exemption from the General Declassification Schedule*. Information or material classified before June 1, 1972, assigned to Group 4 under Executive Order No. 10501, as amended, shall be subject to the General Declassification Schedule. All other information or material classified before June 1, 1972, whether or not assigned to Groups 1, 2, or 3, of Executive Order No. 10501, as amended, shall be excluded from the General Declassification Schedule. However, at any time after the expiration of 10 years after the date of origin it shall be subject to a mandatory classification review and disposition in accordance with the following criteria and conditions:

(i) It shall be declassified unless it falls within one of the following criteria:

(*a*) Classified information or material furnished by foreign governments or international organizations and held by the United States on the understanding that it be kept in confidence.

(*b*) Classified information or material specifically covered by statute, or pertaining to cryptography, or disclosing intelligence sources or methods.

(*c*) Classified information or material disclosing a system, plan, installation, project, or specific foreign relations matter, the continuing protection of which is essential to the national security.

(*d*) Classified information or material the disclosure of which would place a person in immediate jeopardy.

(ii) *Mandatory review of exempted material*. All classified information and material originated after June 1, 1972, which is exempted under any of the above criteria shall be subject to a classification review by the originating department at any time after the expiration of 10 years from the date of origin provided:

(*a*) A department or member of the public requests a review;

(*b*) The request describes the document or record with sufficient particularity to enable the department to identify it; and

(*c*) The record can be obtained with a reasonable amount of effort.

(*d*) Information or material which no longer qualifies for exemption under any of the above criteria shall be declassified. Information or material which continues to qualify under any of the above criteria shall be so marked, and, unless impossible, a date for automatic declassification shall be set.

(iii) All requests for ''mandatory review'' shall be directed to:

Director, Security and Inspection Division, Environmental Protection Agency, Washington, DC 20460.

The Director, Security and Inspection Division shall promptly notify the action office of the request, and the action office shall immediately acknowledge receipt of the request in writing.

(iv) *Burden of proof for administrative determinations*. The burden of proof is on the originating Agency to show that continued classification is warranted

within the terms of this paragraph (c)(2).

(v) *Availability of declassified material.* Upon a determination under paragraph (ii) of this paragraph (c)(2), that the requested material no longer warrants classification, it shall be declassified and made promptly available to the requester, if not otherwise exempt from disclosure under section 552(b) of Title 5 U.S.C. (Freedom of Information Act) or other provision of law.

(vi) *Classification review requests.* As required by paragraph (ii) of this paragraph (c)(2) of this order, a request for classification review must describe the document with sufficient particularity to enable the Department or Agency to identify it and obtain it with a reasonable amount of effort. Whenever a request is deficient in its description of the record sought, the requester should be asked to provide additional identifying information whenever possible. Before denying a request on the ground that it is unduly burdensome, the requester should be asked to limit his request to records that are reasonably obtainable. If nonetheless the requester does not describe the records sought with sufficient particularity, or the record requested cannot be obtained with a reasonable amount of effort, the requester shall be notified of the reasons why no action will be taken and of his right to appeal such decision.

§ 11.6 Access by historical researchers and former Government officials.

(a) Access to classified information or material may be granted to historical researchers or to persons who formerly occupied policymaking positions to which they were appointed by the President: *Provided, however*, That in each case the head of the originating Department shall:

(1) Determine that access is clearly consistent with the interests of the national security; and

(2) Take appropriate steps to assure that classified information or material is not published or otherwise compromised.

(b) Access granted a person by reason of his having previously occupied a policymaking position shall be limited to those papers which the former official originated, reviewed, signed, or received while in public office, except as related to the ''Declassification of Presidential Papers,'' which shall be treated as follows:

(1) *Declassification of Presidential Papers.* The Archivist of the United States shall have authority to review and declassify information and material which has been classified by a President, his White House Staff or special committee or commission appointed by him and which the Archivist has in his custody at any archival depository, including a Presidential library. Such declassification shall only be undertaken in accord with:

(i) The terms of the donor's deed of gift;

(ii) Consultations with the Departments having a primary subject-matter interest; and

(iii) The provisions of §11.5(c).

(2) [Reserved]

PART 12—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE ENVIRONMENTAL PROTECTION AGENCY

Sec.

AUTHORITY: 29 U.S.C. 794.

SOURCE: 52 FR 30606, Aug. 14, 1987, unless otherwise noted.

§ 12.101 Purpose.

The purpose of this part is to effectuate section 119 of the Rehabilitation,

Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the U.S. Postal Service. Section 504 regulations applicable to recipients of financial assistance from the Environmental Protection Agency (EPA) may be found at 40 CFR part 7 (1986).

§ 12.102 Application.

This part applies to all programs or activities conducted by the agency, except for programs or activities conducted outside the United States that do not involve individuals with handicaps in the United States.

§ 12.103 Definitions.

For purposes of this part, the term—

Agency means Environmental Protection Agency.

Assistant Attorney General means the Assistant Attorney General, Civil Rights Division, U.S. Department of Justice.

Auxiliary aids means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the agency. For example, auxiliary aids useful for persons with impaired vision include readers, Brailled materials, audio recordings, and other similar services and devices. Auxiliary aids useful for persons with impaired hearing include telephone handset amplifiers, telephones compatible with hearing aids, telecommunication devices for deaf persons (TDD's), interpreters, notetakers, written materials, and other similar services and devices.

Complete complaint means a written statement that contains the complainant's name and address and describes the agency's alleged discriminatory action in sufficient detail to inform the agency of the nature and date of the alleged violation of section 504. It shall be signed by the complainant or by someone authorized to do so on his or her behalf. Complaints filed on behalf of classes or third parties shall describe or identify (by name, if possible) the alleged victims of discrimination.

Facility means all or any portion of buildings, structures, equipment, roads, walks, parking lots, rolling stock or other conveyances, or other real or personal property.

Individual with handicaps means any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment. As used in this definition, the phrase:

(1) *Physical or mental impairment* includes—

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive, digestive, genitourinary; hemic and lymphatic; skin, and endocrine; or

(ii) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term *physical or mental impairment* includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, and drug addiction and alcoholism.

(2) *Major life activities* includes functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) *Has a record of such an impairment* means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) *Is regarded as having an impairment* means—

(i) Has a physical or mental impairment that does not substantially limit major life activities but is treated by the agency as constituting such a limitation;

(ii) Has a physical or mental impairment that substantially limits major

life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined in subparagraph (1) of this definition but is treated by the agency as having such an impairment.

Qualified individual with handicaps means—

(1) With respect to any agency program or activity under which a person is required to perform services or to achieve a level of accomplishment, an individual with handicaps who meets the essential eligibility requirements and who can achieve the purpose of the program or activity, without modifications in the program or activity that the agency can demonstrate would result in a fundamental alteration in its nature; or

(2) With respect to any other program or activity an individual with handicaps who meets the essential eligibility requirements for participation in, or receipt of benefits from, that program or activity.

(3) *Qualified handicapped person* as that term is defined for purposes of employment in 29 CFR 1613.702(f), which is made applicable to this part by §12.140.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794)), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93–516, 88 Stat. 1617); and the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602, 92 Stat. 2955); and the Rehabilitation Act Amendments of 1986 (Pub. L. 99–506, 100 Stat. 1810). As used in this part, section 504 applies only to programs or activities conducted by Executive agencies and not to federally assisted programs.

§§ 12.104–12.109 [Reserved]

§ 12.110 Self-evaluation.

(a) The agency shall, by November 13, 1987, begin a nationwide evaluation, of its current policies and practices, and the effects thereof, that do not or may not meet the requirements of this part. The agency shall provide an opportunity to interested persons, including individuals with handicaps or organizations representing individuals with handicaps to, participate in the self-evaluation process by submitting comments (both oral and written).

(b) The evaluation shall be concluded by September 14, 1988, with a written report submitted to the Administrator that states the findings of the self-evaluation, any remedial action taken, and recommendations, if any, for further remedial action.

(c) The Administrator shall, within 60 days of the receipt of the report of the evaluation and recommendations, direct that certain remedial actions be taken as he/she deems appropriate.

(d) The agency shall, for at least three years following completion of the evaluation required under paragraph (b) of this section, maintain on file and make available for public inspection:

(1) A list of the interested persons consulted;

(2) A description of the areas examined and any problems identified; and

(3) A description of any modifications made.

§ 12.111 Notice.

The agency shall make available to employees, unions representing employees, applicants, participants, beneficiaries, and other interested persons such information regarding the provisions of this part and its applicability to the programs or activities conducted by the agency, and make such information available to them in such manner as the agency head finds necessary to apprise such persons of the protections against discrimination assured them by section 504 and this regulation.

§§ 12.112–12.129 [Reserved]

§ 12.130 General prohibitions against discrimination.

(a) No qualified individual with handicaps shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

(b)(1) The agency, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap—

(i) Deny a qualified individual with handicaps the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified individual with handicaps an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified individual with handicaps with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aid, benefits, or services to individuals with handicaps or to any class of individuals with handicaps than is provided to others unless such action is necessary to provide qualified individuals with handicaps with aid, benefits, or services that are as effective as those provided to others;

(v) Deny a qualified individual with handicaps the opportunity to participate as a member of planning or advisory boards; or

(vi) Otherwise limit a qualified individual with handicaps in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) The agency may not deny a qualified individual with handicaps the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) The agency may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would—

(i) Subject qualified individuals with handicaps to discrimination on the basis of handicap; or

(ii) Defeat or substantially impair accomplishment of individuals with handicaps.

(4) The agency may not, in determining the site or location of a facility, make selections the purpose or effect of which would—

(i) Exclude individuals with handicaps from, deny them the benefits of, or otherwise subject them to discrimination under any program or activity conducted by the agency; or

(ii) Defeat or substantially impair the accomplishment of the objectives of a program or activity with respect to individuals with handicaps.

(5) The agency, in the selection of procurement contractors, may not use criteria that subject qualified individuals with handicaps to discrimination on the basis of handicap.

(6) The agency may not administer a licensing or certification program in a manner that subjects qualified individuals with handicaps to discrimination on the basis of handicap, nor may the agency establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with handicaps to discrimination on the basis of handicap. However, the program or activities of entities that are licensed or certified by the agency are not, themselves, covered by this part.

(c) The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or Executive order to individuals with handicaps or the exclusion of a specific class of individuals with handicaps from a program limited by Federal statute or Executive order to a different class of individuals with handicaps is not prohibited by this part.

(d) The agency shall administer programs and activities in the most integrated setting appropriate to the needs of qualified individuals with handicaps.

§§ 12.131–12.139 [Reserved]

§ 12.140 Employment.

No qualified individual with handicaps shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity conducted by the agency. The definitions, requirements, and procedures of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791), as established by the Equal Employment Opportunity Commission in 29 CFR part 1613, shall apply to employment in federally conducted programs or activities.

§§ 12.141–12.148 [Reserved]

§ 12.149 Program accessibility: Discrimination prohibited.

Except as otherwise provided in § 12.150, no qualified individual with handicaps shall, because the agency's facilities are inaccessible to or unusable by individuals with handicaps, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

§ 12.150 Program accessibility: Existing facilities.

(a) *General.* The agency shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by individuals with handicaps. This paragraph does not—

(1) Necessarily require the agency to make each of its existing facilities accessible to and usable by individuals with handicaps; or

(2) Require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where agency personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the agency has the burden of proving that compliance with § 12.150(a) would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the agency head or designee after considering all agency resources available for use in the funding and operation of the conducted program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with handicaps receive the benefits and services of the program or activity.

(b) *Methods.* The agency may comply with the requirements of this section through such means as redesign of equipment, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock, or any other methods that result in making its programs or activities readily accessible to and usable by individuals with handicaps. The agency is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. The agency, in making alterations to existing buildings, shall meet accessibility requirements to the extent compelled by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), and any regulations implementing it. In choosing among available methods for meeting the requirements of this section, the agency shall give priority to those methods that offer programs and activities to qualified individuals with handicaps in the most integrated setting appropriate.

(c) *Time period for compliance.* The agency shall comply with the obligations established under this section by November 13, 1987, except that where structural changes in facilities are undertaken, such changes shall be made by September 14, 1990, but in any event as expeditiously as possible.

(d) *Transition plan.* In the event that structural changes to facilities will be undertaken to achieve program accessibility, the agency shall develop, by March 14, 1988, a transition plan setting forth the steps necessary to complete such changes. The agency shall provide an opportunity to interested persons, including individuals with handicaps or organizations representing individuals with handicaps to participate in the development of the transition plan by submitting comments (both oral and written). A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum—

(1) Identify physical obstacles in the agency's facilities that limit the accessibility of its programs or activities to individuals with handicaps;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve compliance with this section and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the official responsible for implementation of the plan.

§ 12.151 Program accessibility: New construction and alterations.

Each building or part of a building that is constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered so as to be readily accessible to and usable by individuals with handicaps. The definitions, requirements, and standards of the Architectural Barriers Act (42 U.S.C. 4151–4157), as established in 41 CFR 101–19.600 to 101–19.607, apply to buildings covered by this section.

§§ 12.152–12.159 [Reserved]

§ 12.160 Communications.

(a) The agency shall take appropriate steps to ensure effective communication with applicants, participants, personnel of other Federal entities, and members of the public.

(1) The agency shall furnish appropriate auxiliary aids where necessary to afford an individual with handicaps an equal opportunity to participate in, and enjoy the benefits of, a program or activity conducted by the agency.

(i) In determining what type of auxiliary aid is necessary, the agency shall give primary consideration to the requests of the individuals with handicaps.

(ii) The agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature.

(2) Where the agency communicates with applicants and beneficiaries by telephone, telecommunication devices for deaf persons (TDD's) or equally effective telecommunication systems shall be used.

(b) The agency shall ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of accessible services, activities, and facilities.

(c) The agency shall provide signage at a primary entrance to each of its inaccessible facilities, directing users to a location at which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each primary entrance of an accessible facility.

(d) This section does not require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where agency personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the agency has the burden of proving that compliance with § 12.160 would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the agency head or designee after considering all agency resources available for use in the funding and operation of the conducted program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with handicaps receive the benefits and services of the program or activity.

§§ 12.161–12.169 [Reserved]

§ 12.170 Compliance procedures.

(a) Except as provided in paragraph (b) of this section, this section applies to all allegations of discrimination on the basis of handicap in programs or activities conducted by the agency.

(b) The agency shall process complaints alleging violations of section 504 with respect to employment according to the procedures established by the Equal Employment Opportunity

Commission in 29 CFR part 1613 pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

(c) Responsibility for coordinating implementation of this section shall be vested in the Director of the Office of Civil Rights, EPA or his/her designate.

(d) The complainant may file a complete complaint at any EPA office. All complete complaints must be filed within 180 days of the alleged act of discrimination. The agency may extend this time period for good cause. The agency shall accept and investigate all complete complaints for which it has jurisdiction.

(e) If the agency receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Government entity.

(f) The agency shall notify the Architectural and Transportation Barriers Compliance Board upon receipt of any complaint alleging that a building of facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), is not readily accessible to and usable by individuals with handicaps.

(g) Within 180 days of the receipt of a complete complaint for which it has jurisdiction, the agency shall notify the complainant of the results of the investigation in a letter containing—

(1) Findings of fact and conclusions of law;

(2) A description of a remedy for each violation found; and

(3) A notice of the right to appeal.

(h) Appeals of the findings of fact and conclusions of law or remedies must be filed by the complainant within 90 days of receipt from the agency of the letter required by paragraph (g) of this section. The agency may extend this time for good cause.

(i) Timely appeals shall be accepted and processed by the Administrator or a designee.

(j) The Administrator or a designee shall notify the complainant of the results of the appeal within 60 days of the receipt of the request. If the Administrator or designee determines that additional information is needed from the complainant, he or she shall have 60 days from the date of receipt of the additional information to make his or her determination on the appeal.

(k) The time limits cited in paragraphs (g) and (j) of this section above may be extended with the permission of the Assistant Attorney General.

(l) The agency may delegate its authority for conducting complaint investigations to other Federal agencies, except that the authority for making the final determination may not be delegated to another agency.

§§ 12.171–12.999 [Reserved]

PART 13—CLAIMS COLLECTION STANDARDS

Subpart A—General

Subpart B—Collection

Subpart C—Administrative Offset

Subpart D—Compromise of Debts

AUTHORITY: 5 U.S.C. 552a, 5512, and 5514; 31 U.S.C. 3711 *et seq.* and 3720A; 4 CFR parts 101–10.

SOURCE: 53 FR 37270, Sept. 23, 1988, unless otherwise noted.

Subpart A—General

§ 13.1 Purpose and scope.

This regulation prescribes standards and procedures for the Environmental Protection Agency's (EPA's) collection and disposal of debts. These standards and procedures are applicable to all debts for which a statute, regulation or contract does not prescribe different standards or procedures. This regulation covers EPA's collection, compromise, suspension, termination, and referral of debts.

§ 13.2 Definitions.

(a) *Debt* means an amount owed to the United States from sources which include loans insured or guaranteed by the United States and all other amounts due the United States from fees, grants, contracts, leases, rents, royalties, services, sales of real or personal property, overpayments, fines, penalties, damages, interest, forfeitures (except those arising under the Uniform Code of Military Justice), and all other similar sources. As used in this regulation, the terms *debt* and *claim* are synonymous.

(b) *Delinquent debt* means any debt which has not been paid by the date specified by the Government for payment or which has not been satisfied in accordance with a repayment agreement.

(c) *Debtor* means an individual, organization, association, corporation, or a State or local government indebted to the United States or a person or entity with legal responsibility for assuming the debtor's obligation.

(d) *Agency* means the United States Environmental Protection Agency.

(e) *Administrator* means the Administrator of EPA or an EPA employee or official designated to act on the Administrator's behalf.

(f) *Administrative offset* means the withholding of money payable by the United States to, or held by the United States for, a person to satisfy a debt the person owes the Government.

(g) *Creditor agency* means the Federal agency to which the debt is owed.

(h) *Disposable pay* means that part of current basic pay, special pay, incentive pay, retired pay, retainer pay, or in the case of an employee not entitled to basic pay, other authorized pay remaining after the deduction of any amount described in 5 CFR 581.105 (b) through (f). These deductions include, but are not limited to: Social security withholdings; Federal, State and local tax withholdings; health insurance premiums; retirement contributions; and life insurance premiums.

(i) *Employee* means a current employee of the Federal Government including a current member of the Armed Forces.

(j) *Person* means an individual, firm, partnership, corporation, association and, except for purposes of administrative offsets under subpart C and interest, penalty and administrative costs under subpart B of this regulation, includes State and local governments and Indian tribes and components of tribal governments.

(k) *Employee salary offset* means the administrative collection of a debt by deductions at one or more officially established pay intervals from the current pay account of an employee without the employee's consent.

(l) *Waiver* means the cancellation, remission, forgiveness or non-recovery of a debt or debt-related charge as permitted or required by law.

§ 13.3 Interagency claims.

This regulation does not apply to debts owed EPA by other Federal agencies. Such debts will be resolved by negotiation between the agencies or by referral to the General Accounting Office (GAO).

§ 13.4 Other remedies.

(a) This regulation does not supersede or require omission or duplication of administrative proceedings required by contract, statute, regulation or other Agency procedures, e.g., resolution of audit findings under grants or contracts, informal grant appeals, formal appeals, or review under a procurement contract.

(b) The remedies and sanctions available to the Agency under this regulation for collecting debts are not intended to be exclusive. The Agency may impose, where authorized, other appropriate sanctions upon a debtor for inexcusable, prolonged or repeated failure to pay a debt. For example, the Agency may stop doing business with a grantee, contractor, borrower or lender; convert the method of payment under a grant or contract from an advance payment to a reimbursement method; or revoke a grantee's or contractor's letter-of-credit.

§ 13.5 Claims involving criminal activities or misconduct.

(a) The Administrator will refer cases of suspected criminal activity or misconduct to the EPA Office of Inspector General. That office has the responsibility for investigating or referring the matter, where appropriate, to the Department of Justice (DOJ), and/or returning it to the Administrator for further actions. Examples of activities which should be referred are matters involving fraud, anti-trust violations, embezzlement, theft, false claims or misuse of Government money or property.

(b) The Administrator will not administratively compromise, terminate, suspend or otherwise dispose of debts involving criminal activity or misconduct without the approval of DOJ.

§ 13.6 Subdivision of claims not authorized.

A claim will not be subdivided to avoid the $20,000 limit on the Agency's authority to compromise, suspend, or terminate a debt. A debtor's liability arising from a particular transaction or contract is a single claim.

§ 13.7 Omission not a defense.

Failure by the Administrator to comply with any provision of this regulation is not available to a debtor as a defense against payment of a debt.

Subpart B—Collection

§ 13.8 Collection rule.

(a) The Administrator takes action to collect all debts owed the United States arising out of EPA activities and to reduce debt delinquencies. Collection actions may include sending written demands to the debtor's last known address. Written demand may be preceded by other appropriate action, including immediate referral to DOJ for litigation, when such action is necessary to protect the Government's interest. The Administrator may contact the debtor by telephone, in person and/or in writing to demand prompt payment, to discuss the debtor's position regarding the existence, amount or repayment of the debt, to inform the debtor of its rights (e.g., to apply for waiver of the indebtedness or to have an administrative review) and of the basis for the debt and the consequences of nonpayment or delay in payment.

(b) The Administrator maintains an administrative file for each debt and/or debtor which documents the basis for the debt, all administrative collection actions regarding the debt (including communications to and from the debtor) and its final disposition. Information from a debt file relating to an individual may be disclosed only for purposes which are consistent with this regulation, the Privacy Act of 1974 and other applicable law.

§ 13.9 Initial notice.

(a) When the Administrator determines that a debt is owed EPA, he provides a written initial notice to the debtor. Unless otherwise provided by agreement, contract or order, the initial notice informs the debtor:

(1) Of the amount, nature and basis of the debt;

(2) That payment is due immediately upon receipt of the notice;

(3) That the debt is considered delinquent if it is not paid within 30 days of the date mailed or hand-delivered;

(4) That interest charges and, except for State and local governments and Indian tribes, penalty charges and administrative costs may be assessed against a delinquent debt;

(5) Of any rights available to the debtor to dispute the validity of the debt or to have recovery of the debt waived (citing the available review or waiver authority, the conditions for review or waiver, and the effects of the review or waiver request on the collection of the debt), and of the possibility of assessment of interest, penalty and administrative costs; and

(6) The address, telephone number and name of the person available to discuss the debt.

(b) EPA will respond promptly to communications from the debtor. Response generally will be within 20 days of receipt of communication from the debtor.

(c) Subsequent demand letters also will advise the debtor of any interest, penalty or administrative costs which have been assessed and will advise the debtor that the debt may be referred to a credit reporting agency (see § 13.14), a collection agency (see § 13.13) or to DOJ (see § 13.33) if it is not paid.

§ 13.10 Aggressive collection actions; documentation.

(a) EPA takes actions and effective follow-up on a timely basis to collect all claims of the United States for money and property arising out of EPA's activities. EPA cooperates with other Federal agencies in their debt collection activities.

(b) All administrative collection actions are documented in the claim file, and the bases for any compromise, termination or suspension of collection actions is set out in detail. This documentation, including the Claims Collection Litigation Report required § 13.33, is retained in the appropriate debt file.

§ 13.11 Interest, penalty and administrative costs.

(a) *Interest.* EPA will assess interest on all delinquent debts unless prohibited by statute, regulation or contract.

(1) Interest begins to accrue on all debts from the date of the initial notice to the debtor. EPA will not recover interest where the debt is paid within 30 days of the date of the notice. EPA will assess an annual rate of interest that is equal to the rate of the current value of funds to the United States Treasury (*i.e.*, the Treasury tax and loan account rate) as prescribed and published by the Secretary of the Treasury in the FEDERAL REGISTER and the Treasury Fiscal Requirements Manual Bulletins, unless a different rate is necessary to protect the interest of the Government. EPA will notify the debtor of the basis for its finding that a different rate is necessary to protect the interest of the Government.

(2) The Administrator may extend the 30-day period for payment where he determines that such action is in the best interest of the Government. A decision to extend or not to extend the payment period is final and is not subject to further review.

(3) The rate of interest, as initially assessed, remains fixed for the duration of the indebtedness. If a debtor defaults on a repayment agreement, interest may be set at the Treasury rate in effect on the date a new agreement is executed.

(4) Interest will not be assessed on interest charges, administrative costs or later payment penalties. However, where a debtor defaults on a previous repayment agreement and interest, administrative costs and penalties charges have been waived under the defaulted agreement, these charges can be reinstated and added to the debt principal under any new agreement and interest charged on the entire amount of the debt.

(b) *Administrative costs of collecting overdue debts.* The costs of the Agency's

administrative handling of overdue debts, based on either actual or average cost incurred, will be charged on all debts except those owed by State and local governments and Indian tribes. These costs include both direct and indirect costs. Administrative costs will be assessed monthly throughout the period the debt is overdue except as provided by §13.12.

(c) *Penalties*. As provided by 31 U.S.C. 3717(e)(2), a penalty charge will be assessed on all debts, except those owned by State and local governments and Indian tribes, more than 90 days delinquent. The penalty charge will be at a rate not to exceed 6% per annum and will be assessed monthly.

(d) *Allocation of payments*. A partial payment by a debtor will be applied first to outstanding administrative costs, second to penalty assessments, third to accrued interest and then to the outstanding debt principal.

(e) *Waiver*. (1) The Administrator may (without regard to the amount of the debt) waive collection of all or part of accrued interest, penalty or administrative costs, where he determines that—

(i) Waiver is justified under the criteria of §13.25;

(ii) The debt or the charges resulted from the Agency's error, action or inaction, and without fault by the debtor; or

(iii) Collection of these charges would be against equity and good conscience or not in the best interest of the United States.

(2) A decision to waive interest, penalty charges or administrative costs may be made at any time prior to payment of a debt. However, where these charges have been collected prior to the waiver decision, they will not be refunded. The Administrator's decision to waive or not waive collection of these charges is a final agency action.

§13.12 Interest and charges pending waiver or review.

Interest, penalty charges and administrative costs will continue to accrue on a debt during administrative appeal, either formal or informal, and during waiver consideration by the Agency; *except*, that interest, penalty charges and administrative costs will not be assessed where a statute or a regulation specifically prohibits collection of the debt during the period of the administrative appeal or the Agency review.

§13.13 Contracting for collection services.

EPA will use private collection services where it determines that their use is in the best interest of the Government. Where EPA determines that there is a need to contract for collection services it will—

(a) Retain sole authority to resolve any dispute by the debtor of the validity of the debt, to compromise the debt, to suspend or terminate collection action, to refer the debt to DOJ for litigation, and to take any other action under this part which does not result in full collection of the debt;

(b) Require the contractor to comply with the Privacy Act of 1974, as amended, to the extent specified in 5 U.S.C. 552a(m), with applicable Federal and State laws pertaining to debt collection practices (e.g., the Fair Debt Collection Practices Act (15 U.S.C. 1692 *et seq.*)), and with applicable regulations of the Internal Revenue Service;

(c) Require the contractor to account accurately and fully for all amounts collected; and

(d) Require the contractor to provide to EPA, upon request, all data and reports contained in its files relating to its collection actions on a debt.

§13.14 Use of credit reporting agencies.

EPA reports delinquent debts to appropriate credit reporting agencies.

(a) EPA provides the following information to the reporting agencies:

(1) A statement that the claim is valid and is overdue;

(2) The name, address, taxpayer identification number and any other information necessary to establish the identity of the debtor;

(3) The amount, status and history of the debt; and

(4) The program or pertinent activity under which the debt arose.

(b) Before disclosing debt information, EPA will:

(1) Take reasonable action to locate the debtor if a current address is not available; and

(2) If a current address is available, notify the debtor by certified mail, return receipt requested, that:

(i) The designated EPA official has reviewed the claim and has determined that it is valid and overdue;

(ii) That within 60 days EPA intends to disclose to a credit reporting agency the information authorized for disclosure by this subsection; and

(iii) The debtor can request a complete explanation of the claim, can dispute the information in EPA's records concerning the claim, and can file for an administrative review, waiver or reconsideration of the claim, where applicable.

(c) Before information is submitted to a credit reporting agency, EPA will provide a written statement to the reporting agency that all required actions have been taken. Additionally, EPA will, thereafter, ensure that the credit reporting agency is promptly informed of any substantive change in the conditions or amounts of the debt, and promptly verify or correct information relevant to the claim.

(d) If a debtor disputes the validity of the debt, the credit reporting agency will refer the matter to the appropriate EPA official. The credit reporting agency will exclude the debt from its reports until EPA certifies in writing that the debt is valid.

§ 13.15 Taxpayer information.

(a) The Administrator may obtain a debtor's current mailing address from the Internal Revenue Service.

(b) Addresses obtained from the Internal Revenue Service will be used by the Agency, its officers, employees, agents or contractors and other Federal agencies only to collect or dispose of debts, and may be disclosed to credit reporting agencies only for the purpose of their use in preparing a commercial credit report on the taxpayer for use by EPA.

§ 13.16 Liquidation of collateral.

Where the Administrator holds a security instrument with a power of sale or has physical possession of collateral, he may liquidate the security or collateral and apply the proceeds to the overdue debt. EPA will exercise this right where the debtor fails to pay within a reasonable time after demand, unless the cost of disposing of the collateral is disproportionate to its value or special circumstances require judicial foreclosure. However, collection from other businesses, including liquidation of security or collateral, is not a prerequisite to requiring payment by a surety or insurance company unless expressly required by contract or statute. The Administrator will give the debtor reasonable notice of the sale and an accounting of any surplus proceeds and will comply with any other requirements of law or contract.

§ 13.17 Suspension or revocation of license or eligibility.

When collecting statutory penalties, forfeitures, or debts for purposes of enforcement or compelling compliance, the Administrator may suspend or revoke licenses or other privileges for any inexcusable, prolonged or repeated failure of a debtor to pay a claim. Additionally, the Administrator may suspend or disqualify any contractor, lender, broker, borrower, grantee or other debtor from doing business with EPA or engaging in programs EPA sponsors or funds if a debtor fails to pay its debts to the Government within a reasonable time. Debtors will be notified before such action is taken and applicable suspension or debarment procedures will be used. The Administrator will report the failure of any surety to honor its obligations to the Treasury Department for action under 6 U.S.C. 11.

§ 13.18 Installment payments.

(a) Whenever, feasible, and except as otherwise provided by law, debts owed to the United States, together with interest, penalty and administrative costs, as required by § 13.11, will be collected in a single payment. However, where the Administrator determines that a debtor is financially unable to pay the indebtedness in a single payment or that an alternative payment mechanism is in the best interest of the United States, the Administrator may approve repayment of the debt in installments. The debtor has the burden of establishing that it is financially unable to pay the debt in a single payment or that an alternative

payment mechanism is warranted. If the Administrator agrees to accept payment by installments, the Administrator may require a debtor to execute a written agreement which specifies all the terms of the repayment arrangement and which contains a provision accelerating the debt in the event of default. The size and frequency of installment payments will bear a reasonable relation to the size of the debt and the debtor's ability to pay. The installment payments will be sufficient in size and frequency to liquidate the debt in not more than 3 years, unless the Administrator determines that a longer period is required. Installment payments of less than $50 per month generally will not be accepted, but may be accepted where the debtor's financial or other circumstances justify. If the debt is unsecured, the Administrator may require the debtor to execute a confess-judgment note with a tax carry-forward and a tax carry-back provision. Where the Administrator secures a confess-judgment note, the Administrator will provide the debtor a written explanation of the consequences of the debtor's signing the note.

(b) If a debtor owes more than one debt and designates how a voluntary installment payment is to be applied among the debts, that designation will be approved if the Administrator determines that the designation is in the best interest of the United States. If the debtor does not designate how the payment is to be applied, the Administrator will apply the payment to the various debts in accordance with the best interest of the United States, paying special attention to applicable statutes of limitations.

§ 13.19 Analysis of costs; automation; prevention of overpayments, delinquencies or defaults.

(a) The Administrator may periodically compare EPA's costs in handling debts with the amounts it collects,

(b) The Administrator may periodically consider the need, feasibility, and cost effectiveness of automated debt collection operations.

(c) The Administrator may establish internal controls to identify the causes of overpayments and delinquencies and may issue procedures to prevent future occurrences of the identified problems.

Subpart C—Administrative Offset

§ 13.20 Administrative offset of general debts.

This subpart provides for EPA's collection of debts by administrative offset under section 5 of the Debt Collection Act of 1982 (31 U.S.C. 3716), other statutory authorities and the common law. It does not apply to offsets against employee salaries covered by §§ 13.21, 13.22 and 13.23 of this subpart. EPA will collect debts by administrative offsets where it determines that such collections are feasible and are not otherwise prohibited by statute or contract.

EPA will decide, on a case-by-case basis, whether collection by administrative offset is feasible and that its use furthers and protects the interest of the United States.

(a) *Standards.* (1) The Administrator collects debts by administrative offset if—

(i) The debt is certain in amount;

(ii) Efforts to obtain direct payment from the debtor have been, or would most likely be, unsuccessful or the Administrator and the debtor agree to the offset;

(iii) Offset is not expressly or implicitly prohibited by statute, regulation or contract;

(iv) Offset is cost-effective or has significant deterrent value;

(v) Offset does not substantially impair or defeat program objectives; and

(vi) Offset is best suited to further and protect the Government's interest.

(2) The Administrator may, in determining the method and amount of the offset, consider the financial impact on the debtor.

(b) *Interagency offset.* The Administrator may offset a debt owed to another Federal agency from amounts due or payable by EPA to the debtor, or may request another Federal agency to offset a debt owed to EPA. The Administrator may request the Internal Revenue Service to offset an overdue debt from a Federal income tax refund due a debtor where reasonable attempts to obtain payment have failed. Interagency offsets from employee salaries will be made in accordance with

the procedures contained in §§ 13.22 and 13.23.

(c) *Multiple debts.* Where moneys are available for offset against multiple debts of a debtor, it will be applied in accordance with the best interest of the Government as determined by the Administrator on a case-by-case basis.

(d) *Statutory bar to offset.* Administrative offset will not be made more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the Government's right to collect the debt were not known and could not have been known through the exercise of reasonable care by the officer responsible for discovering or collecting the debt. For purposes of offset, the right to collect a debt accrues when the appropriate EPA official determines that a debt exists (e.g., contracting officer, grant award official, etc.), when it is affirmed by an administrative appeal or a court having jurisdiction, or when a debtor defaults on a payment agreement, whichever is latest. An offset occurs when money payable to the debtor is first withheld or when EPA requests offset from money held by another agency.

(e) *Pre-offset notice.* Before initiating offset, the Administrator sends the debtor written notice of:

(1) The basis for and the amount of the debt as well as the Agency's intention to collect the debt by offset if payment or satisfactory response has not been received within 30 days of the notice;

(2) The debtor's right to submit an alternative repayment schedule, to inspect and copy agency records pertaining to the debt, to request review of the determination of indebtedness or to apply for waiver under any available statute or regulation; and

(3) Applicable interest, penalty charges and administrative costs.

(f) *Alternative repayment.* The Administrator may, at the Administrator's discretion, enter into a repayment agreement with the debtor in lieu of offset. In deciding whether to accept payment of the debt by an alternative repayment agreement, the Administrator may consider such factors as the amount of the debt, the length of the proposed repayment period, whether the debtor is willing to sign a confession-judgment note, past Agency dealings with the debtor, documentation submitted by the debtor indicating that an offset will cause undue financial hardship, and the debtor's financial ability to adhere to the terms of a repayment agreement. The Administrator may require financial documentation from the debtor before considering the repayment arrangement.

(g) *Review of administrative determination.* (1) A debt will not be offset while a debtor is seeking either formal or informal review of the validity of the debt under this section or under another statute, regulation or contract. However, interest, penalty and administrative costs will continue to accrue during this period, unless otherwise waived by the Administrator. The Administrator may initiate offset as soon as practical after completion of review or after a debtor waives the opportunity to request review.

(2) The Administrator may administratively offset a debt prior to the completion of a formal or informal review where the determines that:

(i) Failure to take the offset would substantially prejudice EPA's ability to collect the debt; and

(ii) The time before the first offset is to be made does not reasonably permit the completion of the review procedures. (Offsets taken prior to completion of the review process will be followed promptly by the completion of the process. Amounts recovered by offset but later found not to be owed will be refunded promptly.)

(3) The debtor must provide a written request for review of the decision to offset the debt no later than 15 days after the date of the notice of the offset unless a different time is specifically prescribed. The debtor's request must state the basis for the request for review.

(4) The Administrator may grant an extension of time for filing a request for review if the debtor shows good cause for the late filing. A debtor who fails timely to file or to request an extension waives the right to review.

(5) The Administrator will issue, no later than 60 days after the filing of the request, a written final decision based on the evidence, record and applicable law.

§ 13.21 Employee salary offset—general.

(a) *Purpose.* This section establishes EPA's policies and procedures for recovery of debts owed to the United States by installment collection from the current pay account of an employee.

(b) *Scope.* The provisions of this section apply to collection by salary offset under 5 U.S.C. 5514 of debts owed EPA and debts owed to other Federal agencies by EPA employees. This section does not apply to debts owed EPA arising from travel advances under 5 U.S.C. 5705, employee training expenses under 5 U.S.C. 4108 and to other debts where collection by salary offset is explicitly provided for or prohibited by another statute.

(c) *References.* The following statutes and regulations apply to EPA's recovery of debts due the United States by salary offset:

(1) 5 U.S.C. 5514, as amended, governing the installment collection of debts;

(2) 31 U.S.C. 3716, governing the liquidation of debts by administrative offset;

(3) 5 CFR part 550, subpart K, setting forth the minimum requirements for executive agency regulations on salary offset; and

(4) 4 CFR parts 101–105, the Federal Claims Collection Standards.

§ 13.22 Salary offset when EPA is the creditor agency.

(a) *Entitlement to notice, hearing, written response and decision.* (1) Prior to initiating collection action through salary offset, EPA will first provide the employee with the opportunity to pay in full the amount owed, unless such notification will compromise the Government's ultimate ability to collect the debt.

(2) Except as provided in paragraph (b) of this section, each employee from whom the Agency proposes to collect a debt by salary offset under this section is entitled to receive a written notice as described in paragraph (c) of this section.

(3) Each employee owing a debt to the United States which will be collected by salary offset is entitled to request a hearing on the debt. This request must be filed as prescribed in paragraph (d) of this section. The Agency will make appropriate hearing arrangements which are consistent with law and regulations. Where a hearing is held, the employee is entitled to a written decision on the following issues:

(i) The determination of the Agency concerning the existence or amount of the debt; and

(ii) The repayment schedule, if it was not established by written agreement between the employee and the Agency.

(b) *Exceptions to entitlement to notice, hearing, written response and final decision.* The procedural requirements of paragraph (a) of this section are not applicable to any adjustment of pay arising out of an employee's election of coverage or a change in coverage under a Federal benefits program (such as health insurance) requiring periodic deductions from pay, if the amount to be recovered was accumulated over four pay periods or less. However, if the amount to be recovered was accumulated over more than four pay periods the full procedures prescribed under paragraph (d) of this section will be extended to the employee.

(c) *Notification before deductions begin.* Except as provided in paragraph (b) of this section, deductions will not be made unless the employee is first provided with a minimum of 30 calendar days written notice. Notice will be sent by certified mail (return receipt requested), and must include the following:

(1) The Agency's determination that a debt is owed, including the origin, nature, and amount of the debt;

(2) The Agency's intention to collect the debt by means of deductions from the employee's current disposable pay account;

(3) The amount, frequency, proposed beginning date and duration of the intended deductions. (The proposed beginning date for salary offset cannot be earlier than 30 days after the date of notice, unless this would compromise the Government's ultimate ability to resolve the debt);

(4) An explanation of the requirements concerning interest, penalty and administrative costs;

(5) The employee's right to inspect and copy all records relating to the debt or to request and receive a copy of such records;

(6) If not previously provided, the employee's right to enter into a written agreement for a repayment schedule differing from that proposed by the Agency where the terms of the proposed repayment schedule are acceptable to the Agency. (Such an agreement must be in writing and signed by both the employee and the appropriate EPA official and will be included in the employee's personnel file and documented in the EPA payroll system);

(7) The right to a hearing conducted by a hearing official not under the control of the Administrator, if a request is filed;

(8) The method and time for requesting a hearing;

(9) That the filing of a request for hearing within 15 days of receipt of the original notification will stay the assessment of interest, penalty and administrative costs and the commencement of collection proceedings;

(10) That a final decision on the hearing (if requested) will be issued at the earliest practical date, but no later than 60 days after the filing of the request, unless the employee requests and the hearing official grants a delay in the proceedings;

(11) That knowingly false or frivolous statements, representations or evidence may subject the employee to—

(i) Disciplinary procedures under 5 U.S.C. chapter 75 or any other applicable statutes or regulations;

(ii) Criminal penalties under 18 U.S.C. 286, 287, 1001 and 1002 or other applicable statutory authority; or

(iii) Penalties under the False Claims Act, 31 U.S.C. 3729–3731, or any other applicable statutory authority;

(12) Any other rights and remedies available under statutes or regulations governing the program for which the collection is being made; and

(13) That amounts paid or deducted for the debt, except administrative costs and penalty charges where the entire debt is not waived or terminated, which are later waived or found not owed to the United States will be promptly refunded to the employee.

(d) *Request for hearing.* An employee may request a hearing by filing a written request directly with the Director, Financial Management Division (2734R) , U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The request must state the bases upon which the employee disputes the proposed collection of the debt. The request must be signed by the employee and be received by EPA within 15 days of the employee's receipt of the notification of proposed deductions. The employee should submit in writing all facts, evidence and witnesses which support his/her position to the Director, Financial Management Division, within 15 days of the date of the request for a hearing. The Director, Financial Management Division, will arrange for the services of a hearing official not under the control of the Administrator and will provide the hearing official with all documents relating to the claim.

(e) *Requests for hearing made after time expires.* Late requests for a hearing may be accepted if the employee can show that the delay in filing the request for a hearing was due to circumstances beyond the employee's control.

(f) *Form of hearing, written response and final decision.* (1) Normally, a hearing will consist of the hearing official making a decision based upon a review of the claims file and any materials submitted by the debtor. However, in instances where the hearing official determines that the validity of the debt turns on an issue of veracity or credibility which cannot be resolved through review of documentary evidence, the hearing official at his discretion may afford the debtor an opportunity for an oral hearing. Such oral hearings will consist of an informal conference before a hearing official in which the employee and the Agency will be given the opportunity to present evidence, witnesses and argument. If desired, the employee may be represented by an individual of his/her choice. The Agency shall maintain a summary record of oral hearings provided under these procedures.

(2) Written decisions provided after a request for hearing will, at a minimum, state the facts evidencing the nature

and origin of the alleged debt; and the hearing official's analysis, findings and conclusions.

(3) The decision of the hearing official is final and binding on the parties.

(g) *Request for waiver.* In certain instances, an employee may have a statutory right to request a waiver of overpayment of pay or allowances, e.g., 5 U.S.C. 5584 or 5 U.S.C. 5724(i). When an employee requests waiver consideration under a right authorized by statute, further collection on the debt will be suspended until a final administrative decision is made on the waiver request. However, where it appears that the Government's ability to recover the debt may be adversely affected because of the employee's resignation, termination or other action, suspension of recovery is not required. During the period of the suspension, interest, penalty charges and administrative costs will not be assessed against the debt. The Agency will not duplicate, for purposes of salary offset, any of the procedures already provided the debtor under a request for waiver.

(h) *Method and source of collection.* A debt will be collected in a lump-sum or by installment deductions at established pay intervals from an employee's current pay account, unless the employee and the Agency agree to alternative arrangements for payment. The alternative payment schedule must be in writing, signed by both the employee and the Administrator and will be documented in the Agency's files.

(i) *Limitation on amount of deduction.* The size and frequency of installment deductions generally will bear a reasonable relation to the size of the debt and the employee's ability to pay. However, the amount deducted for any period may not exceed 15 percent of the disposable pay from which the deduction is made, unless the employee has agreed in writing to the deduction of a greater amount. If possible, the installment payments will be in amounts sufficient to liquidate the debt in three years or less. Installment payments of less than $25 normally will be accepted only in the most unusual circumstances.

(j) *Duration of deduction.* If the employee is financially unable to pay a debt in a lump-sum or the amount of the debt exceeds 15 percent of disposable pay, collection will be made in installments. Installment deductions will be made over the period of active duty or employment except as provided in paragraph (a)(1) of this section.

(k) *When deductions may begin.* (1) Deductions to liquidate an employee's debt will begin on the date stated in the Agency's notice of intention to collect from the employee's current pay unless the debt has been repaid or the employee has filed a timely request for hearing on issues for which a hearing is appropriate.

(2) If the employee has filed a timely request for hearing with the Agency, deductions will begin after the hearing official has provided the employee with a final written decision indicating the amount owed the Government. Following the decision by the hearing official, the employee will be given 30 days to repay the amount owed prior to collection through salary offset, unless otherwise provided by the hearing official.

(l) *Liquidation from final check.* If the employee retires, resigns, or the period of employment ends before collection of the debt is completed, the remainder of the debt will be offset from subsequent payments of any nature due the employee (e.g., final salary payment, lump-sum leave, etc.).

(m) *Recovery from other payments due a separated employee.* If the debt cannot be liquidated by offset from any final payment due the employee on the date of separation, EPA will liquidate the debt, where appropriate, by administrative offset from later payments of any kind due the former employee (e.g., retirement pay). Such administrative offset will be taken in accordance with the procedures set forth in §13.20.

(n) *Employees who transfer to another Federal agency.* If an EPA employee transfers to another Federal agency prior to repaying a debt owed to EPA, the following action will be taken:

(1) The appropriate debt-claim form specified by the Office of Personnel Management (OPM) will be completed and certified to the new paying office by EPA. EPA will certify: That the employee owes a debt; the amount and the

basis for the debt; the date on which payment is due; the date the Government's rights to collect the debt first accrued; and that EPA's regulations implementing 5 U.S.C. 5514 have been approved by OPM.

(2) The new paying agency will be advised of the amount which has already been collected, the number of installments and the commencement date for the first installment, if other than the next officially established pay period. EPA will also identify to the new paying agency the actions it has taken and the dates of such actions.

(3) EPA will place or will arrange to have placed in the employee's official personnel file the information required by paragraphs (n) (1) and (2) of this section.

(4) Upon receipt of the official personnel file from EPA, the new paying agency will resume collection from the employee's current pay account and will notify both the employee and EPA of the resumption.

(o) *Interest, penalty and administrative cost.* EPA will assess interest and administrative costs on debts collected under these procedures. The following guidelines apply to the assessment of these costs on debts collected by salary offset:

(1) A processing and handling charge will be assessed on debts collected through salary offset under this section. Where offset begun prior to the employee's receipt of the 30-day written notice of the proposed offset, processing and handling costs will only be assessed after the expiration of the 30-day notice period and after the completion of any hearing requested under paragraph (d) of this section or waiver consideration under paragraph (g) of this section.

(2) Interest will be assessed on all debts not collected within 30 days of either the date of the notice where the employee has not requested a hearing within the allotted time, completion of a hearing pursuant to paragraph (d) of this section, or completion of waiver consideration under paragraph (g) of this section, whichever is later. Interest will continue to accrue during the period of the recovery.

(3) Deductions by salary offset normally begin prior to the time for assessment of a penalty. Therefore, a penalty charge will not be assessed unless deductions occur more than 120 days from the date of notice to the debtor and penalty assessments have not been suspended because of waiver consideration by EPA.

(p) *Non-waiver of right by payment.* An employee's payment under protest of all or any portion of a debt does not waive any rights which the employee may have under either these procedures or any other provision of law.

(q) *Refunds.* EPA will promptly refund to the employee amounts paid or deducted pursuant to this section, the recovery of which is subsequently waived or otherwise found not owing to the United States. Refunds do not bear interest unless specifically authorized by law.

(r) *Time limit for commencing recovery by salary setoff.* EPA will not initiate salary offset to collect a debt more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the right to collect the debt were not known and could not have been known through the exercise of reasonable care by the Government official responsible for discovering and collecting such debts.

§ 13.23 Salary offset when EPA is not the creditor agency.

The requirements below apply when EPA has been requested to collect a debt owed by an EPA employee to another Federal agency.

(a) *Format for the request for recovery.* (1) The creditor agency must complete fully the appropriate claim form specified by OPM.

(2) The creditor agency must certify to EPA on the debt claim form: The fact that the employee owes a debt; the date that the debt first accrued; and that the creditor agency's regulations implementing 5 U.S.C. 5514 have been approved by OPM and send it to the Director, Financial Management Division (2734R), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(3) If the collection is to be made in installments, the creditor agency must also advise EPA of the number of installments to be collected, the amount

of each installment, and the commencement date of the first installment, if a date other than the next established pay period.

(4) Unless the employee has consented in writing to the salary deductions or signed a statement acknowledging receipt of the required procedures and this information is attached to the claim form, the creditor agency must indicate the actions it took under its procedures for salary offset and the dates of such actions.

(b) *Processing of the claim by EPA*—(1) *Incomplete claims.* If EPA receives an improperly completed claim form, the claim form and all accompanying material will be returned to the requesting (creditor) agency with notice that OPM procedures must be followed and a properly completed claim form must be received before any salary offset can be taken. The notice should identify specifically what is needed from the requesting agency for the claim to be processed.

(2) *Complete claims.* If the claim procedures in paragraph (a) of this section have been properly completed, deduction will begin on the next established pay period. EPA will not review the merits of the creditor agency's determinations with respect to the amount or validity of the debt as stated in the debt claim form. EPA will not assess a handling or any other related charge to cover the cost of its processing the claim.

(c) *Employees separating from EPA before a debt to another agency is collected*—(1) *Employees separating from Government service.* If an employee begins separation action before EPA collects the total debt due the creditor agency, the following actions will be taken:

(i) To the extent possible, the balance owed the creditor agency will be liquidated from subsequent payments of any nature due the employee from EPA in accordance with §13.22(1);

(ii) If the total amount of the debt cannot be recovered, EPA will certify to the creditor agency and the employee the total amount of EPA's collection; and

(iii) If EPA is aware that the employee is entitled to payments from the Civil Service Retirement and Disability Fund or other similar payments, it will forward a copy of the claim form to the agency responsible for making such payments as notice that a debt is outstanding. EPA will also send a copy of the claim form to the creditor agency so that it can file a certified claim against the payments.

(2) *Employees who transfer to another Federal agency.* If an EPA employee transfers to another Federal agency before EPA collects the total amount due the creditor agency, the following actions will be taken:

(i) EPA will certify the total amount of the collection made on the debt; and

(ii) The employee's official personnel folder will be sent to the new paying agency. (It is the responsibility of the creditor agency to ensure that the collection is resumed by the new paying agency.)

Subpart D—Compromise of Debts

§13.24 General.

EPA may compromise claims for money or property where the claim, exclusive of interest, penalty and administrative costs, does not exceed $20,000. Where the claim exceeds $20,000, the authority to accept the compromise rests solely with DOJ. The Administrator may reject an offer of compromise in any amount. Where the claim exceeds $20,000 and EPA recommends acceptance of a compromise offer, it will refer the claim with its recommendation to DOJ for approval. The referral will be in the form of the Claims Collection Litigation Report (CCLR) and will outline the basis for EPA's recommendation. EPA refers compromise offers for claims in excess of $100,000 to the Commercial Litigation Branch, Civil Division, Department of Justice, Washington, DC 20530, unless otherwise provided by Department of Justice delegations or procedures. EPA refers offers of compromise for claims of $20,000 to $100,000 to the United States Attorney in whose judicial district the debtor can be found. If the Administrator has a debtor's firm written offer for compromise which is substantial in amount but the Administrator is uncertain as to whether the offer should be accepted, he may refer

the offer and the supporting data to DOJ or GAO for action.

§ 13.25 Standards for compromise.

(a) EPA may compromise a claim pursuant to this section if EPA cannot collect the full amount because the debtor does not have the financial ability to pay the full amount of the debt within a reasonable time, or the debtor refuses to pay the claim in full and the Government does not have the ability to enforce collection in full within a reasonable time by enforced collection proceedings. In evaluating the acceptability of the offer, the Administrator may consider, among other factors, the following:

(1) *Individual debtors.* (i) Age and health of the debtor;

(ii) Present and potential income;

(iii) Inheritance prospects;

(iv) The possibility that assets have been concealed or improperly transferred by the debtor;

(v) The availability of assets or income which may be realized by enforced collection proceedings; or

(vi) The applicable exemptions available to the debtor under State and Federal law in determining the Government's ability to enforce collection.

(2) *Municipal and quasi-municipal debtors.* (i) The size of the municipality or quasi-municipal entity;

(ii) The availability of current and future resources sufficient to pay the debt (e.g., bonding authority, rate adjustment authority, or taxing authority); or

(iii) The ratio of liabilities (both short and long term) to assets.

(3) *Commercial debtors.* (i) Ratio of assets to liabilities;

(ii) Prospects of future income or losses; or

(iii) The availability of assets or income which may be realized by enforced collection proceedings.

(b) EPA may compromise a claim, or recommend acceptance of a compromise to DOJ, where there is substantial doubt concerning the Government's ability to prove its case in court for the full amount of the claim, either because of the legal issues involved or a bona fide dispute as to the facts. The amount accepted in compromise in such cases will fairly reflect the probability of prevailing on the legal issues involved, considering fully the availability of witnesses and other evidentiary data required to support the Government's claim. In determining the litigative risks involved, EPA will give proportionate weight to the likely amount of court costs and attorney fees the Government may incur if it is unsuccessful in litigation.

(c) EPA may compromise a claim, or recommend acceptance of a compromise to DOJ, if the cost of collection does not justify the enforced collection of the full amount of the debt. The amount accepted in compromise in such cases may reflect an appropriate discount for the administrative and litigative costs of collection, taking into consideration the time it will take to effect collection. Costs of collection may be a substantial factor in the settlement of small claims, but normally will not carry great weight in the settlement of large claims. In determining whether the cost of collection justifies enforced collection of the full amount, EPA may consider the positive effect that enforced collection of the claim may have on the collection of other similar claims.

(d) Statutory penalties, forfeitures or debts established as an aid to enforcement and to compel compliance may be compromised where the Administrator determines that the Agency's enforcement policy, in terms of deterrence and securing compliance (both present and future), will be adequately served by accepting the offer.

§ 13.26 Payment of compromised claims.

The Administrator normally will not approve a debtor's request to pay a compromised claim in installments. However, where the Administrator determines that payment of a compromise by installments is necessary to effect collection, a debtor's request to pay in installments may be approved. Normally, where installment repayment is approved, the debtor will be required to execute a confess-judgment agreement which accelerates payment of the balance due upon default.

§ 13.27 Joint and several liability.

When two or more debtors are jointly and severally liable, collection action will not be withheld against one debtor until the other or others pay their proportionate share. The amount of a compromise with one debtor is not precedent in determining compromises from other debtors who have been determined to be jointly and severally liable on the claim.

§ 13.28 Execution of releases.

Upon receipt of full payment of a claim or the amount compromised, EPA will prepare and execute a release on behalf of the United States. The release will include a provision which voids the release if it was procured by fraud, misrepresentation, a false claim or by mutual mistake of fact.

Subpart E—Suspension of Collection Action

§ 13.29 Suspension—general.

The Administrator may suspend the Agency's collection actions on a debt where the outstanding debt principal does not exceed $20,000, the Government cannot presently collect or enforce collection of any significant sum from the debtor, the prospects of future collection justify retention of the debt for periodic review and there is no risk of expiration of the statute of limitations during the period of suspension. Additionally, the Administrator may waive the assessment of interest, penalty charges and administrative costs during the period of the suspension. Suspension will be for an established time period and generally will be reviewed at least every six months to ensure the continued propriety of the suspension. DOJ approval is required to suspend debts exceeding $20,000. Unless otherwise provided by DOJ delegations or procedures, the Administrator refers requests for suspension of debts of $20,000 to $100,000 to the United States Attorney in whose district the debtor resides. Debts exceeding $100,000 are referred to the Commercial Litigation Branch, Civil Division, Department of Justice, for approval.

§ 13.30 Standards for suspension.

(a) *Inability to locate debtor.* The Administrator may suspend collection on a debt where he determines that the debtor cannot be located presently but that there is a reasonable belief that the debtor can be located in the future.

(b) *Financial condition of debtor.* The Administrator may suspend collection action on a claim when the debtor owns no substantial equity in real or personal property and is unable to make payment on the claim or effect a compromise but the debtor's future financial prospects justify retention of the claim for periodic review, provided that:

(1) The applicable statute of limitations will not expire during the period of the suspension, can be tolled or has started running anew;

(2) Future collection can be effected by offset, notwithstanding the 10-year statute of limitations for administrative offsets; or

(3) The debtor agrees to pay interest on the debt and suspension is likely to enhance the debtor's ability to fully pay the principal amount of the debt with interest at a later date.

(c) *Request for waiver or administrative review—mandatory.* The Administrator will suspend collection activity where a statute provides for mandatory waiver consideration or administrative review prior to agency collection of a debt. The Administrator will suspend EPA's collection actions during the period provided for the debtor to request review or waiver and during the period of the Agency's evaluation of the request.

(d) *Request for waiver or administrative review—permissive.* The Administrator may suspend collection activities on debts of $20,000 or less during the pendency of a permissive waiver or administrative review where he determines that:

(1) There is a reasonable possibility that waiver will be granted and the debtor may be found not owing the debt (in whole or in part);

(2) The Government's interest is protected, if suspension is granted, by the reasonable assurance that the debt can be recovered if the debtor does not prevail; or

(3) Collection of the debt will cause undue hardship to the debtor.

(e) *Refund barred by statute or regulation.* The Administrator will ordinarily suspend collection action during the pendency of his consideration of a waiver request or administrative review where statute and regulation preclude refund of amounts collected by the Agency should the debtor prevail. The Administrator may decline to suspend collection where he determines that the request for waiver or administrative review is frivolous or was made primarily to delay collection.

Subpart F—Termination of Debts

§ 13.31 Termination—general.

The Administrator may terminate collection actions and write-off debts, including accrued interest, penalty and administrative costs, where the debt principal does not exceed $20,000. If the debt exceeds $20,000, EPA obtains the approval of DOJ in order to terminate further collection actions. Unless otherwise provided for by DOJ regulations or procedures, requests to terminate collection on debts in excess of $100,000 are referred to the Commercial Litigation Branch, Civil Division, Department of Justice, for approval. Debts in excess of $20,000 but $100,000 or less are referred to the United States Attorney in whose judicial district the debtor can be found.

§ 13.32 Standards for termination.

A debt may be terminated where the Administrator determines that:

(a) The Government cannot collect or enforce collection of any significant sum from the debtor, having due regard for available judicial remedies, the debtor's ability to pay, and the exemptions available to the debtor under State and Federal law;

(b) The debtor cannot be located, there is no security remaining to be liquidated, the applicable statute of limitations has expired, and the prospects of collecting by offset are too remote to justify retention of the claim;

(c) The cost of further collection action is likely to exceed the amount recoverable;

(d) The claim is determined to be legally without merit; or

(e) The evidence necessary to prove the claim cannot be produced or the necessary witnesses are unavailable and efforts to induce voluntary payment have failed.

Subpart G—Referrals

§ 13.33 Referrals to the Department of Justice.

(a) *Prompt referral.* The Administrator refers to DOJ for litigation all claims on which aggressive collection actions have been taken but which could not be collected, compromised, suspended or terminated. Referrals are made as early as possible, consistent with aggressive agency collection action, and within the period for bringing a timely suit against the debtor.

(1) Unless otherwise provided by DOJ regulations or procedures, EPA refers for litigation debts of more than $100,000 to the Commercial Litigation Branch, Civil Division, Department of Justice, Washington, DC 20530.

(2) Unless otherwise provided by DOJ regulations or procedures, EPA refers for litigation debts of $100,000 or less to the United States Attorney in whose judicial district the debtor can be found.

(b) *Claims Collection Litigation Report (CCLR).* Unless an exception has been granted by DOJ, the CCLR is used for referrals of all administratively uncollectible claims to DOJ and is used to refer all offers of compromise.

Subpart H—Referral of Debts to IRS for Tax Refund Offset

SOURCE: 59 FR 651, Jan. 5, 1994, unless otherwise noted.

§ 13.34 Purpose.

This subpart establishes procedures for the Environmental Protection Agency (EPA) to refer past-due debts to the Internal Revenue Service (IRS) for offset against the income tax refunds of persons owing debts to EPA. It specifies the Agency procedures and the rights of the debtor applicable to claims for the payment of debts owed to EPA.

§ 13.35 Applicability and scope.

(a) This subpart implements 31 U.S.C. 3720A, which authorizes the IRS to reduce a tax refund by the amount of a past-due legally enforceable debt owed to the United States.

(b) For purposes of this section, a past-due legally enforceable debt referable to the IRS is a debt which is owed to the United States and:

(1) Except in the case of a judgment debt, has been delinquent for at least three months but has not been delinquent for more than ten years at the time the offset is made;

(2) Cannot be currently collected pursuant to the salary offset provisions of 5 U.S.C. 5514(a)(1);

(3) Is ineligible for administrative offset under 31 U.S.C. 3716(a) by reason of 31 U.S.C. 3716(c)(2) or cannot be collected by administrative offset under 31 U.S.C. 3716(a) by the Agency against amounts payable to or on behalf of the debtor by or on behalf of the Agency;

(4) With respect to which EPA has given the taxpayer at least 60 days from the date of notification to present evidence that all or part of the debt is not past-due or not legally enforceable, has considered evidence presented by such taxpayer, if any, and has determined that an amount of such debt is past-due and legally enforceable;

(5) Has been disclosed by EPA to a consumer reporting agency as authorized by 31 U.S.C. 3711(f), unless a consumer reporting agency would be prohibited from using such information by 15 U.S.C. 1681c, or unless the amount of the debt does not exceed $100.00;

(6) With respect to which EPA has notified or has made a reasonable attempt to notify the taxpayer that the debt is past-due and, unless repaid within 60 days thereafter, the debt will be referred to the IRS for offset against any overpayment of tax;

(7) Is at least $25.00; and

(8) All other requirements of 31 U.S.C. 3720A and the Department of the Treasury regulations at 26 CFR 301.6402–6 relating to the eligibility of a debt for tax return offset have been satisfied.

§ 13.36 Administrative charges.

In accordance with § 13.11, all administrative charges incurred in connection with the referral of a debt to the IRS shall be assessed on the debt and thus increase the amount of the offset.

§ 13.37 Notice requirement before offset.

A request for reduction of an IRS tax refund will be made only after EPA makes a determination that an amount is owed and past-due and provides the debtor with 60 days written notice. EPA's notice of intention to collect by IRS tax refund offset (Notice of Intent) will state:

(a) The amount of the debt;

(b) That unless the debt is repaid within 60 days from the date of EPA's Notice of Intent, EPA intends to collect the debt by requesting the IRS to reduce any amounts payable to the debtor as refunds of Federal taxes paid by an amount equal to the amount of the debt and all accumulated interest and other charges;

(c) That the debtor has a right to present evidence that all or part of the debt is not past-due or not legally enforceable; and

(d) A mailing address for forwarding any written correspondence and a contact name and phone number for any questions.

§ 13.38 Review within the Agency.

(a) *Notification by debtor.* A debtor who receives a Notice of Intent has the right to present evidence that all or part of the debt is not past-due or not legally enforceable. To exercise this right, the debtor must:

(1) Send a written request for a review of the evidence to the address provided in the notice;

(2) State in the request the amount disputed and the reasons why the debtor believes that the debt is not past-due or is not legally enforceable; and

(3) Include in the request any documents which the debtor wishes to be considered or state that additional information will be submitted within the remainder of the 60-day period.

(b) *Submission of evidence.* The debtor may submit evidence showing that all or part of the debt is not past-due or not legally enforceable along with the notification required by paragraph (a) of this section. Failure to submit the notification and evidence within 60

days will result in an automatic referral of the debt to the IRS without further action by EPA.

(c) *Review of the evidence.* EPA will consider all available evidence related to the debt. Within 30 days, if feasible, EPA will notify the debtor whether EPA has sustained, amended, or cancelled its determination that the debt is past-due and legally enforceable.

§ 13.39 Agency determination.

(a) Following review of the evidence, EPA will issue a written decision.

(b) If EPA either sustains or amends its determination, it shall notify the debtor of its intent to refer the debt to the IRS for offset against the debtor's Federal income tax refund. If EPA cancels its original determination, the debt will not be referred to IRS.

§ 13.40 Stay of offset.

If the debtor timely notifies the EPA that he or she is exercising the right described in §13.38(a) and timely submits evidence in accordance with §13.38(b), any notice to the IRS will be stayed until the issuance of a written decision which sustains or amends its original determination.

PART 14—EMPLOYEE PERSONAL PROPERTY CLAIMS

Sec.

AUTHORITY: Military Personnel and Civilian Employees' Claims Act of 1964, as amended (31 U.S.C. 3721).

SOURCE: 51 FR 24146, July 2, 1986, unless otherwise noted.

§ 14.1 Scope and purpose.

This part prescribes regulations for the Military Personnel and Civilian Employees' Claims Act of 1964 (the Act), 31 U.S.C. 3721. The Act allows the Administrator of the U.S. Environmental Protection Agency (EPA) to settle and pay claims of EPA employees for damage to or loss of their personal property which was incident to service. A claim under the Act is allowed only where the claim is substantiated and the Administrator determines that possession of the property was reasonable or proper under the circumstances existing at the time and place of the loss and no part of the loss was caused by any negligent or wrongful act or omission of the employee or his/her agent.

§ 14.2 Definitions.

As used in this part:

(a) *EPA Claims Officer* is the Agency official delegated the responsibility by the Administrator to carry out the provisions of the Act.

(b) *Claim* means a demand for payment by an employee or his/her representative for the value or the repair cost of an item of personal property damaged, lost or destroyed as an incident to government service.

(c) *Employee* means a person appointed to a position with EPA.

(d) *Settle* means the act of considering, ascertaining, adjusting, determining or otherwise resolving a claim.

(e) *Accrual date* means the date of the incident causing the loss or damage or the date on which the loss or damage should have been discovered by the employee through the exercise of reasonable care.

(f) *Depreciation* is the reduction in value of an item caused by the elapse of time between the date of acquisition and the date of loss or damage.

§ 14.3 Incident to service.

In order for a claim to be allowed under this part, the EPA Claims Officer must determine that the item of personal property, at the time of damage or loss, was used by the employee as an incident to government service. An item is incident to service when possession of the item by the employee had substantial relationship to the employee's performance of duty. Whether an item is incident to service is determined by the facts of each claim. The employee has the burden of showing

that the item was incident to his/her governmental service.

§ 14.4 Reasonable and proper.

EPA does not insure its employees from every loss or damage to personal property they may sustain. In order for a claim to be allowed, the item must not only have been incident to service, it must also have been reasonable and proper for the employee to possess the item at the time and place of its loss or damage. Generally, the possession of an item is reasonable and proper when the item is of a type and quantity which EPA reasonably expected its employees to possess at the time and place of the loss or damage. Consequently, items which are exceptionally expensive, excessive quantities of otherwise allowable items, personal items which are used in place of items usually provided to employees by EPA or items which are primarily of aesthetic value are not considered reasonable or proper items and are unallowable.

§ 14.5 Who may file a claim.

A claim may be filed by an employee or by his/her authorized agent or legal representative. If a claim is otherwise allowable under this part, a claim can be filed by a surviving spouse, child, parent, brother or sister of a deceased employee.

§ 14.6 Time limits for filing a claim.

A claim under this part is considered by the EPA Claims Officer only if it is in writing and received within two years after the claim accrues. The EPA Claims Officer may consider a claim not filed within this period when the claim accrued during a period of armed conflict and the requirements of 31 U.S.C. 3721(g) are met.

§ 14.7 Where to file a claim.

An employee or his/her representative may file a claim with his/her Administrative Office or the Safety Office for the facility. The employee should complete and submit to the Administrative Office or the Safety Office a completed EPA Form 3370–1, ''Employee Claim for Loss of or Damage to Personal Property.'' That Office then forwards the form and any other relevant information to the EPA Claims Officer, Office of General Counsel (2311), 1200 Pennsylvania Ave., NW., Washington, DC 20460.

§ 14.8 Investigation of claims.

The EPA Claims Officer investigates claims filed under this part. The EPA Claims Officer may request additional documentation from an employee (e.g., repair estimates and receipts), interview witnesses, and conduct any further investigation he believes is warranted by the facts of the claim.

§ 14.9 Approval and payment of claims.

(a) EPA's approval and payment of a claim is limited by the Act to $25,000. The EPA Claims Officer considers, adjusts, determines, compromises and settles all claims filed under this part. The decision of the EPA Claims Officer is final unless reconsideration under § 14.10 is granted.

(b) The EPA Claims Officer will approve and pay claims filed for a deceased employee by persons specified in § 14.5 in the following order:

(1) The spouse's claim.

(2) A child's claim.

(3) A parent's claim.

(4) A brother's or sister's claim.

§ 14.10 Procedures for reconsideration.

The EPA Claims Officer, at his discretion, may reconsider a decision when the employee establishes that an error was made in the computation of the award or that evidence or material facts were unavailable to the employee at the time of the filing of the claim and the failure to provide the information was not the result of the employee's lack of care. An employee seeking reconsideration of a decision must file, within 30 days of the date of the decision, a written request with the EPA Claims Officer for reconsideration. The request for reconsideration must specify, where applicable, the error, the evidence or material facts not previously considered by the EPA Claims Officer and the reason why the employee believes that the evidence or facts previously were not available.

§ 14.11 Principal types of allowable claims.

(a) *General.* A claim under this part is allowed for tangible personal property of a type and quantity that was reasonable and proper for the employee to possess under the circumstances at the time of the loss or damage. In evaluating whether a claim is allowable, the EPA Claims Officer may consider such factors as: The employee's use of the item; whether EPA generally is aware that such items are used by its employees; or whether the loss was caused by a failure of EPA to provide adequate protection against the loss.

(b) *Examples of claims which are allowable.* Claims which are ordinarily allowed include loss or damage which occurred:

(1) In a place officially designated for storage of property such as a warehouse, office, garage, or other storage place;

(2) In a marine, rail, aircraft, or other common disaster or natural disaster such as a fire, flood, or hurricane;

(3) When the personal property was subjected to an extraordinary risk in the employee's performance of duty, such as in connection with an emergency situation, a civil disturbance, common or natural disaster, or during efforts to save government property or human life;

(4) When the property was used for the benefit of the government at the specific direction of a supervisor;

(5) When the property was money or other valuables deposited with an authorized government agent for safekeeping; and

(6) When the property was a vehicle which was subjected to an extraordinary risk in the employee's performance of duty and the use of the vehicle was at the specific direction of the employee's supervisor.

(c) *Claims for articles of clothing.* Claims for loss or damage to clothing and accessories worn by an employee may be allowed where:

(1) The damage or loss occurred during the employee's performance of official duty in an unusual or extraordinary risk situation;

(2) The loss or damage occurred during the employee's response to an emergency situation, to a natural disaster such as fire, flood, hurricane, or to a man-made disaster such as a chemical spill;

(3) The loss or damage was caused by faulty or defective equipment or furniture maintained by EPA; or

(4) The item was stolen even though the employee took reasonable precautions to protect the item from theft.

(d) *Claims for loss or damage to household items.* (1) Claims for damages to household goods may be allowed where:

(i) The loss or damages occurred while the goods were being shipped pursuant to an EPA authorized change in duty station;

(ii) The employee filed a claim for the damages with the appropriate carrier; and

(iii) The employee substantiates that he/she has suffered a loss in excess of the amount paid by the carrier.

(2) Where a carrier has refused to make an award to an employee because of his/her failure to comply with the carrier's claims procedures, any award by EPA will be reduced by the maximum amount payable for the item by the carrier under its contract of shipment. Where an employee fails to notify the carrier of damages or loss, either at the time of delivery of the household goods or within a reasonable time after discovery, any award by EPA will be reduced by the amount of the carrier's maximum contractual liability for the damage or loss. The employee has the burden of proving his/her entitlement to reimbursement from EPA for amounts in excess of that allowed by the carrier.

§ 14.12 Principal types of unallowable claims.

Claims that ordinarily will not be allowed include:

(a) Loss or damage totaling less than $25;

(b) Money or currency, except when deposited with an authorized government agency for safekeeping;

(c) Loss or damage to an item of extraordinary value or to an antique where the item was shipped with household goods, unless the employee filed a valid appraisal or authentication with the carrier prior to shipment of the item;

(d) Loss of bankbooks, checks, notes, stock certifications, money orders, or travelers checks;

(e) Property owned by the United States unless the employee is financially responsible for it to another government agency;

(f) Claims for loss or damage to a bicycle or a private motor vehicle, unless allowable under §14.11(b)(6);

(g) Losses of insurers or subrogees;

(h) Losses recoverable from insurers or carriers;

(i) Losses recovered or recoverable pursuant to contract;

(j) Claims for damage or loss caused, in whole or in part, by the negligent or wrongful acts of the employee or his/her agent;

(k) Property used for personal business or profit;

(l) Theft from the possession of the employee unless the employee took reasonable precautions to protect the item from theft;

(m) Property acquired, possessed or transported in violation of law or regulations;

(n) Unserviceable property; or

(o) Damage or loss to an item during shipment of household goods where the damage or loss was caused by the employee's negligence in packing the item.

§ 14.13 Items fraudulently claimed.

Where the EPA Claims Officer determines that an employee has intentionally misrepresented the cost, condition, cost of repair or a material fact concerning a claim, he/she may, at his discretion, deny the entire amount claimed for the item. Further, where the EPA Claims Officer determines that the employee intentionally has materially misrepresented the costs, conditions or nature of repairs of the claim, he will refer it to appropriate officials (e.g., Inspector General, the employee's supervisor, etc.) for action.

§ 14.14 Computation of award.

(a) The amount awarded on any item may not exceed its adjusted cost. Adjusted cost is either the purchase price of the item or its value at the time of acquisition, less appropriate depreciation. The amount normally payable for property damaged beyond economical repair is its depreciated value immediately before the loss or damage, less any salvage value. If the cost of repair is less than the depreciated value, it will be considered to be economically repairable and only the cost of repair will be allowable.

(b) Notwithstanding a contract to the contrary, the representative of an employee is limited by 31 U.S.C. 3721(i) to receipt of not more than 10 percent of the amount of an award under this part for services related to the claim. A person violating this paragraph is subject to a fine of not more than $1,000. 31 U.S.C. 3721(i).

PART 16—IMPLEMENTATION OF PRIVACY ACT OF 1974

Sec.

AUTHORITY: 5 U.S.C. 301, 552a (as revised).

SOURCE: 71 FR 234, Jan. 4, 2006, unless otherwise noted.

§ 16.1 Purpose and scope.

(a) This part implements the Privacy Act of 1974 (5 U.S.C. 552a) (PA or Act) by establishing Environmental Protection Agency (EPA or Agency) policies and procedures that permit individuals to obtain access to and request amendment or correction of information about themselves that is maintained in Agency systems of records. This part also establishes policies and procedures for administrative appeals of requests for access to, or correction or amendment of, records. This part does not expand or restrict any rights granted under the PA.

(b) These procedures apply only to requests by individuals seeking their own

records and only to records maintained by EPA. These procedures do not apply to those systems specifically exempt under §§ 16.11 and 16.12 herein or to any government-wide systems maintained by other Federal agencies.

(c) Privacy Act requests made by individuals for records about themselves and which are processed under this Part, will also be treated as FOIA requests and processed as appropriate under 40 CFR Part 2 to ensure full disclosure.

§ 16.2 Definitions.

As used in this part:

(a) The terms *individual*, *maintain*, *record*, and *system of records* have the same meanings as specified in 5 U.S.C. 552a.

(b) *EPA* means the Environmental Protection Agency.

(c) *Working days* means calendar days excluding Saturdays, Sundays, and Federal holidays.

§ 16.3 Procedures for accessing, correcting, or amending personal records.

(a) Any individual who—

(1) Wishes to be informed whether a system of records maintained by EPA contains any record pertaining to him or her,

(2) Seeks access to an EPA record about him or her that is maintained in an EPA PA system of records, including an accounting of any disclosures of that record; or

(3) Seeks to amend or correct a record about him or her that is maintained in a system of records, may submit a written request to the EPA Privacy Act Officer, Environmental Protection Agency, Headquarters Freedom of Information Office, Office of Environmental Information (MC–2822T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460 or via the Agency's Privacy Act Web site at *http://www.epa.gov/privacy* or by fax, (202) 566–1639.

(b) All requests for access to, or the correction or amendment of personal records should cite the Privacy Act of 1974 and reference the type of request being made (*i.e.*, access, correction or amendment). Requests must include:

(1) The name and signature of the individual making the request;

(2) The name of the PA system of records (as set forth in EPA's FEDERAL REGISTER PA systems of records notices) to which the request relates; and

(3) A statement whether a personal inspection of the records or a copy of them by mail is desired.

(c) A statement declaring his or her identity and stipulating that he or she understands it is a misdemeanor punishable by fine up to $5,000 to knowingly and willfully seek or obtain access to records about another individual under false pretenses.

(d) A requester who cannot determine which PA system of records to request may ask for assistance by writing to the Headquarters Freedom of Information Office, Attention: Privacy Act Officer, Environmental Protection Agency, (MC–2822T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460 or via e-mail to *http://www.epa.gov/privacy* or by fax, (202) 566–1639.

§ 16.4 Times, places, and requirements for identification of individuals making requests.

(a) If an individual requesting access under § 16.3 asks for personal inspection of records, and if EPA grants the request, the individual may appear at the time and place specified in EPA's response or arrange another time with the appropriate Agency official.

(b) Before conducting a personal inspection of his or her records, an individual must present sufficient identification (e.g., driver's license, employee identification card, social security card, or credit card) to establish that he or she is the subject of the records. EPA reserves the right to determine the adequacy of the identification. An individual who is unable to provide such identification described under paragraph (b) of this section will complete and sign, in the presence of an agency official, a statement declaring his or her identity and stipulating that he or she understands it is a misdemeanor punishable by fine up to $5,000 to knowingly and willfully seek or obtain access to records about another individual under false pretenses.

(c) An individual may have another person accompany him or her during

inspection of the records, and the system manager may require the requesting individual to sign a statement authorizing disclosure of the record in the presence of that other person.

(d) An individual may request a copy of the requested record.

(e) No verification of identity will be required where the records sought have been determined to be publicly available under the Freedom of Information Act.

§ 16.5 Request for correction or amendment of record.

An individual may request correction or amendment of any record pertaining to him or her in a system of records maintained by EPA by submitting a request in writing to the Freedom of Information Office, or via the Agency's Privacy Act Web site at *http://www.epa.gov/privacy* or by fax, (202) 566–1639. The following information must be provided:

(a) The name and signature of the individual making the request;

(b) The name of the system of records;

(c) A description of the information sought to be corrected or amended and the specific reasons for the correction or amendment; and

(d) Sufficient documentation of identity as described under §16.4(b). (An individual who is unable to provide the identification under §16.4(b) or is submitting a request on line, must provide a statement declaring his or her identity and stipulating that he or she understands it is a misdemeanor punishable by fine up to $5,000 to knowingly and willfully seek or obtain access to records about another individual under false pretenses).

§ 16.6 Initial decision on request for access to, or correction or amendment of, records.

(a) Within 10 working days of receipt of a request, the Agency Privacy Act Officer will send a letter to the requester acknowledging receipt of the request and promptly forward it to the manager of the system of records where the requested record is located with instructions to:

(1) Make a determination whether to permit access to the record, or to make the requested correction or amendment;

(2) Inform the requester of that determination and, if the determination is to deny access to the record, or to not correct or amend it, the reason for that decision and the procedures for appeal.

(b) If the system manager is unable to decide whether to grant a request of access to, or amendment or correction of a record within 20 working days of the Agency's receipt of the request, he or she will inform the requester reasons for the delay, and an estimate of when a decision will be made.

(c) In reviewing a request for the correction or amendment of a record, the system manager will be guided by the requirements of 5 U.S.C. 552a(e)(1) and (e)(5).

(d) A system manager who decides to grant all or any portion of a request to correct or amend a record will inform any person or entity outside EPA that was provided the record of the correction or amendment, and, where there is an accounting of that disclosure, make a note of the action taken in the accounting.

(e) If a request pursuant to §16.3 for access to a record is in a system of records which is exempted, the records system manager or designee will decide whether any information will nonetheless be made available. If the decision is to deny access, the reason for denial and the appeal procedure will be given to the requester.

(f) A person whose request for access is initially denied may appeal that denial to EPA's Privacy Act Officer. EPA's General Counsel will decide the appeal within 30 working days. If an appeal concerns a system of records maintained by the Office of Inspector General, the Privacy Act Officer will forward the appeal to the Counsel to the Inspector General who will decide on the appeal in accordance with §16.7. The Counsel to the Inspector General will carry out all responsibilities with respect to the appeal that are otherwise assigned to EPA's General Counsel under §16.7.

(g) If the appeal under §16.7(e)(6) is denied, the requester will be notified of

the right to seek judicial review in accordance with subsection (g) of the Privacy Act.

§ 16.7 The appeal process.

(a) An individual whose request for access to, or correction or amendment of a record is initially denied and who wishes to appeal that denial may do so by sending a letter to EPA's Privacy Act Officer within 30 days of the receipt of the initial denial. The appeal must identify and restate the initial request. If an appeal concerns an adverse decision by the Office of Inspector General, the Privacy Act Officer will forward it to the Counsel to the Inspector General, or his or her designee, who will then act on the appeal. The Counsel to the Inspector General, or his or her designee, will carry out all responsibilities with respect to PA appeals that are otherwise assigned to EPA's General Counsel under this section; however, if the Counsel to the Inspector General has signed the initial adverse determination, the General Counsel, or his or her designee, will act on the appeal.

(b) EPA's General Counsel, or his or her designee, will make final decisions on PA appeals within 30 working days from the date on which the appeal is properly received in the Office of General Counsel, unless, for good cause shown, the 30-day period is extended and the requester is notified of the extension in writing. Such extensions will be utilized only in exceptional circumstances.

(c) In conducting PA appeals, the General Counsel, or his or her designee, will be guided by the requirements of 5 U.S.C. 552a(e)(1) and (e)(5).

(d) If an appeal is granted in whole or in part, the requester will be notified, in writing, and access to the record will be granted, or the correction or amendment of the record will be made. In all such cases, the Privacy Act Officer will ensure that § 16.7(d) is complied with.

(e) If the General Counsel or the Counsel to the Inspector General decides not to grant all or any portion of an appeal, the requester will be informed:

(1) Of the decision and its basis;

(2) Of the requester's right to file a concise statement of reasons for disagreeing with EPA's decision;

(3) Of the procedures for filing such statement of disagreement;

(4) That such statements of disagreements will be made available in subsequent disclosures of the record, together with an agency statement (if deemed appropriate) summarizing its refusal;

(5) That prior recipients of the disputed record will be provided with statements as in paragraph (e)(4) of this section, to the extent that an accounting of disclosures is maintained under 5 U.S.C. 552a(c); and

(6) Of the requester's right to seek judicial review under 5 U.S.C. 552a(g).

§ 16.8 Special procedures: Medical Records.

Should EPA receive a request for access to medical records (including psychological records) disclosure of which the system manager decides would be harmful to the individual to whom they relate, EPA may refuse to disclose the records directly to the individual and instead offer to transmit them to a physician designated by the individual.

§ 16.9 Fees.

No fees will be charged for providing the first copy of a record or any portion of a record to an individual to whom the record pertains. The fee schedule for reproducing other records is the same as that set forth in 40 CFR 21.07.

§ 16.10 Penalties.

The Act provides, in pertinent part: ''Any person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000.'' (5 U.S.C. 552a(i)(3))

§ 16.11 General exemptions.

(a) *Systems of records affected.*

EPA–17 OCEFT Criminal Investigative Index and Files.

EPA–40 Inspector General's Operation and Reporting (IGOR) System Investigative Files.

EPA–46 OCEFT/NEIC Master Tracking System.

EPA–63 eDiscovery Enterprise Tool Suite.

(b) *Authority.* Under 5 U.S.C. 552a(j)(2), the head of any Federal agency may by rule exempt any PA system of records within the agency from certain provisions of the Act, if the system of records is maintained by an agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws and which consists of:

(1) Information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status;

(2) Information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or

(3) Reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

(c) *Qualification for exemption.* (1) The Agency's system of records, EPA–17 system of records is maintained by the Criminal Investigation Division, Office of Criminal Enforcement, Forensics, and Training, a component of EPA which performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the Division's criminal law enforcement activities comes from Powers of Environmental Protection Agency, 18 U.S.C. 3063; Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9603; Resource Conservation and Recovery Act, 42 U.S.C. 6928; Federal Water Pollution Control Act, 33 U.S.C. 1319, 1321; Toxic Substances Control Act, 15 U.S.C. 2614, 2615; Clean Air Act, 42 U.S.C. 7413; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136j, 136l; Safe Drinking Water Act, 42 U.S.C. 300h–2, 300i–1; Noise Control Act of 1972, 42 U.S.C. 4912; Emergency Planning and Community Right-To-Know Act of 1986, 42 U.S.C. 11045; and the Marine Protection, Research, and Sanctuaries Act of 1972, 33 U.S.C. 1415.

(2) The Agency's system of records, EPA–40 system of records is maintained by the Office of Investigations of the Office of Inspector General (OIG), a component of EPA that performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the criminal law enforcement activities of the OIG's Office of Investigations is the Inspector General Act of 1978, as amended, 5 U.S.C. app. 3.

(3) The Agency's system of records, EPA–46 system of records is maintained by the National Enforcement Investigations Center, Office of Criminal Enforcement, Forensics, and Training, a component of EPA which performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the criminal law enforcement activities comes from Reorganization Plan No. 3 of 1970 (5 U.S.C. app. 1), effective December 2, 1970; Powers of Environmental Protection Agency, 18 U.S.C. 3063; Comprehensive Environmental Response Compensation and Liability Act , 42 U.S.C. 9603; Resource Conservation and Recovery Act, 42 U.S.C. 6928; Federal Water Pollution Control Act, 33 U.S.C. 1319, 1321; Toxic Substances Control Act, 15 U.S.C. 2614, 2615; Clean Air Act, 42 U.S.C. 7413; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136j, 136l; Safe Drinking Water Act, 42 U.S.C. 300h–2, 300i–1; Emergency Planning and Community Right-To-Know Act of 1986, 42 U.S.C. 11045; and the Marine Protection, Research, and Sanctuaries Act of 1972, 33 U.S.C. 1415.

(4) The Agency's system of records, EPA–63 system of records is maintained by the Office of Environmental Information, Office of Enterprise Information Programs, on behalf of the Criminal Investigation Division, Office of Criminal Enforcement, Forensics, and Training, a component of EPA which performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the Division's criminal law enforcement activities comes from Powers of Environmental Protection Agency, 18 U.S.C. 3063; Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9603; Resource Conservation and Recovery Act, 42

U.S.C. 6928; Federal Water Pollution Control Act, 33 U.S.C. 1319, 1321; Toxic Substances Control Act, 15 U.S.C. 2614, 2615; Clean Air Act, 42 U.S.C. 7413; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136j, 136l; Safe Drinking Water Act, 42 U.S.C. 300h–2, 300i–1; Noise Control Act of 1972, 42 U.S.C. 4912; Emergency Planning and Community Right-To-Know Act of 1986, 42 U.S.C. 11045; and the Marine Protection, Research, and Sanctuaries Act of 1972, 33 U.S.C. 1415.

(d) *Scope of Exemption.* EPA systems of records 17, 40, 46 and 63 are exempted from the following provisions of the PA: 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (2), (3), (4)(G), and (H), (5), and (8); (f)(2) through (5); and (g). To the extent that the exemption for EPA systems of records 17, 40, 46 and 63 claimed under 5 U.S.C. 552a(j)(2) of the Act is held to be invalid, then an exemption under 5 U.S.C. 552a(k)(2) is claimed for these systems of records from (c)(3), (d), (e)(1), (e)(4)(G), (H), and (f)(2) through (5). For Agency's system of records, EPA system 40, an exemption is separately claimed under 5 U.S.C. 552(k)(5) from (c)(3), (d), (e)(1), (e)(4)(G), (4)(H), and (f)(2) through (5).

(e) *Reasons for exemption.* EPA systems of records 17, 40, 46 and 63 are exempted from the above provisions of the PA for the following reasons:

(1) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of each disclosure of records available to the individual named in the record upon request. These accountings must state the date, nature, and purpose of each disclosure of a record and the name and address of the recipient. Accounting for each disclosure would alert the subjects of an investigation to the existence of the investigation and the fact that they are subjects of the investigation. The release of such information to the subjects of an investigation would provide them with significant information concerning the nature of the investigation, and could seriously impede or compromise the investigation, endanger the physical safety of confidential sources, witnesses, law enforcement personnel and their families, and lead to the improper influencing of witnesses, the destruction of evidence, or the fabrication of testimony.

(2) 5 U.S.C. 552a(c)(4) requires an agency to inform any person or other agency about any correction or notation of dispute made by the agency in accordance with subsection (d) of the Act. Since EPA is claiming that these systems of records are exempt from subsection (d) of the Act, concerning access to records, this section is inapplicable and is exempted to the extent that these systems of records are exempted from subsection (d) of the Act.

(3) 5 U.S.C. 552a(d) requires an agency to permit an individual to gain access to records pertaining to him or her, to request amendment to such records, to request a review of an agency decision not to amend such records, and to contest the information contained in such records. Granting access to records in these systems of records could inform the subject of an investigation of an actual or potential criminal violation of the existence of that investigation, of the nature and scope of the information and evidence obtained as to his activities, of the identity of confidential sources, witnesses, and law enforcement personnel, and could provide information to enable the subject to avoid detection or apprehension. Granting access to such information could seriously impede or compromise an investigation, endanger the physical safety of confidential sources, witnesses, law enforcement personnel and their families, lead to the improper influencing of witnesses, the destruction of evidence, or the fabrication of testimony, and disclose investigative techniques and procedures. In addition, granting access to such information could disclose classified, security-sensitive, or confidential business information and could constitute an unwarranted invasion of the personal privacy of others.

(4) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required by statute or by Executive order of the President. The application of this provision could impair investigations and law enforcement, because it is not always possible to detect the relevance or necessity of specific information in the early stages of an investigation.

Relevance and necessity are often questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established. In addition, during the course of the investigation, the investigator may obtain information which is incidental to the main purpose of the investigation but which may relate to matters under the investigative jurisdiction of another agency. Such information cannot readily be segregated. Furthermore, during the course of the investigation, the investigator may obtain information concerning the violation of laws other than those which are within the scope of his jurisdiction. In the interest of effective law enforcement, the EPA investigators should retain this information, since it can aid in establishing patterns of criminal activity and can provide valuable leads for other law enforcement agencies.

(5) 5 U.S.C. 552a(e)(2) requires an agency to collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privileges under Federal programs. The application of this provision could impair investigations and law enforcement by alerting the subject of an investigation of the existence of the investigation, enabling the subject to avoid detection or apprehension, to influence witnesses improperly, to destroy evidence, or to fabricate testimony. Moreover, in certain circumstances, the subject of an investigation cannot be required to provide information to investigators, and information must be collected from other sources. Furthermore, it is often necessary to collect information from sources other than the subject of the investigation to verify the accuracy of the evidence collected.

(6) 5 U.S.C. 552a(e)(3) requires an agency to inform each person whom it asks to supply information, on a form that can be retained by the person, of the authority under which the information is sought and whether disclosure is mandatory or voluntary; of the principal purposes for which the information is intended to be used; of the routine uses which may be made of the information; and of the effects on the person, if any, of not providing all or any part of the requested information. The application of this provision could provide the subject of an investigation with substantial information about the nature of that investigation, which could interfere with the investigation. Moreover, providing such a notice to the subject of an investigation could seriously impede or compromise on undercover investigation by revealing its existence and could endanger the physical safety of confidential sources, witnesses, and investigators by revealing their identities.

(7) 5 U.S.C. 552a(e)(4) (G) and (H) require an agency to publish a FEDERAL REGISTER notice concerning its procedures for notifying an individual at his request if the system of records contains a record pertaining to him or her, how to gain access to such a record, and how to contest its content. Since EPA is claiming that these systems of records are exempted from parts of subsection (f)(2) through (5) of the Act, concerning agency rules, and subsection (d) of the Act, concerning access to records, these requirements are inapplicable and are exempted to the extent that these systems of records are exempted from subsections (f) and (d) of the Act. Although EPA is claiming exemption from these requirements, the Agency has published such a notice concerning its notification, access, and contest procedures because, under certain circumstances, EPA might decide it is appropriate for an individual to have access to all or a portion of the individual's records in these systems of records.

(8) 5 U.S.C. 552a(e)(5) requires an agency to maintain its records with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in making any determination about the individual. Since the Act defines *maintain* to include the collection of information, complying with this provision would prevent the collection of any data not shown to be accurate, relevant, timely, and complete at the moment it is collected. In collecting information for criminal law enforcement purposes, it is not possible to determine in advance what information

is accurate, relevant, timely, and complete. Facts are first gathered and then placed into a logical order to prove or disprove objectively the criminal behavior of an individual. Material that may seem unrelated, irrelevant, or incomplete when collected may take on added meaning or significance as the investigation progresses. The restrictions of this provision could interfere with the preparation of a complete investigative report, thereby impeding effective law enforcement.

(9) 5 U.S.C. 552a(e)(8) requires an agency to make reasonable efforts to serve notice on an individual when any record on such individual is made available to any person under compulsory legal process when such process becomes a matter of public record. Complying with this provision could prematurely reveal an ongoing criminal investigation to the subject of the investigation.

(10) 5 U.S.C. 552a(f)(1) requires an agency to promulgate rules which shall establish procedures whereby an individual can be notified in response to his request if any system of records named by the individual contains a record pertaining to him or her. Since EPA is claiming that these systems of records are exempt from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that these systems of records are exempted from subsection (d) of the Act. Although EPA is claiming exemption from the requirements of subsection (f)(2) through (5) of the Act, EPA has promulgated rules which establish Agency procedures because, under certain circumstances, it might be appropriate for an individual to have access to all or a portion of his records in these systems of records. These procedures are described elsewhere in this part.

(11) 5 U.S.C. 552a(g) provides for civil remedies if an agency fails to comply with the requirements concerning access to records under subsections (d)(1) and (3) of the Act; maintenance of records under subsection (e)(5) of the Act; and any other provision of the Act, or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual. Since EPA is claiming that these systems of records are exempt from subsections (c)(3) and (4), (d), (e)(1), (2), (3), (4)(G), (H), and (I), (5), and (8), and (f) of the Act, the provisions of subsection (g) of the Act are inapplicable and are exempted to the extent that these systems of records are exempted from those subsections of the Act.

(f) *Exempt records provided by another agency.* Individuals may not have access to records maintained by the EPA if such records were provided by another Federal agency which has determined by regulation that such records are subject to general exemption under 5 U.S.C. 552a(j). If an individual requests access to such exempt records, EPA will consult with the source agency.

(g) *Exempt records included in a nonexempt system of records.* All records obtained from a system of records that has been determined by regulation to be subject to general exemption under 5 U.S.C. 552a(j) retain their exempt status even if such records are also included in a system of records for which a general exemption has not been claimed.

[71 FR 234, Jan. 4, 2006, as amended at 83 FR 62718, Dec. 6, 2018]

§ 16.12 Specific exemptions.

(a) *Exemption under 5 U.S.C. 552a(k)(2)*—(1) *Systems of records affected.* EPA–17 OCEFT Criminal Investigative Index and Files.

EPA–21 External Compliance Program Discrimination Complaint Files.

EPA–30 OIG Hotline Allegation System.

EPA–40 Inspector General's Operation and Reporting (IGOR) System Investigative Files.

EPA–41 Inspector General's Operation and Reporting (IGOR) System Personnel Security Files.

EPA–46 OCEFT/NEIC Master Tracking System.

EPA–63 eDiscovery Enterprise Tool Suite.

(2) *Authority.* Under 5 U.S.C. 552a(k)(2), the head of any Federal agency may by rule exempt any PA system of records within the agency

from certain provisions of the Act, if the system of records is investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of the Act. However, if any individual is denied any right, privilege, or benefit that the individual would otherwise be entitled to by Federal law, or for which he or she would otherwise be eligible, as a result of the maintenance of the material, the material must be provided, except to the extent that the disclosure would reveal the identify of a confidential source.

(3) *Qualification for exemption.* All of the affected PA systems of records contain investigatory material compiled for law enforcement purposes, material which is not within the scope of subsection (j)(2) of the Act.

(4) *Scope of exemption.* (i) EPA systems of records 17, 30, 40, 41, 46 and 63 are exempted from the following provisions of the PA, subject to the limitations set forth in 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(G) and (4)(H); and (f)(2) through (5). EPA system of records 21 is exempt from the following provisions of the PA, subject to the limitations set forth in 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3), (d), and (e)(1).

(ii) An individual is ''denied any right, privilege, or benefit that he or she would otherwise be entitled by Federal law, or for which he or she would otherwise be eligible, as a result of the maintenance of such material,'' only if EPA actually uses the material in denying or proposing to deny such right, privilege, or benefit.

(iii) EPA–17 OCEFT Criminal Investigative Index and Files, EPA–40 Inspector General's Operation and Reporting (IGOR) System Investigative Files, and EPA–46 OCEFT/NEIC Master Tracking System are exempted under 5 U.S.C. 552a(j)(2), and these systems are exempted under 5 U.S.C. 552a(k)(2) only to the extent that the (j)(2) exemption is held to be invalid.

(5) *Reasons for exemption.* EPA systems of records 17, 21, 30, 40, 41, 46 and 63 are exempted from the above provisions of the PA for the following reasons:

(i) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of each disclosure of records available to the individual named in the record at his or her request. These accountings must state the date, nature, and purpose of each disclosure of a record and the name and address of the recipient. Accounting for each disclosure would alert the subjects of an investigation to the existence of the investigation and the fact that they are subjects of the investigation. The release of such information to the subjects of an investigation would provide them with significant information concerning the nature of the investigation, and could seriously impede or compromise the investigation, endanger the physical safety of confidential sources, witnesses, law enforcement personnel and their families, and lead to the improper influencing of witnesses, the destruction of evidence, or the fabrication of testimony.

(ii) 5 U.S.C. 552a(d) requires an agency to permit an individual to gain access to records pertaining to him or her, to request amendment of such records, to request a review of an agency decision not to amend such records, and to contest the information contained in such records. Granting access to records in these affected PA systems of records could inform the subject of an investigation of an actual or potential criminal violation, of the existence of that investigation, of the nature and scope of the information and evidence obtained as to his or her activities, of the identity of confidential sources, witnesses, and law enforcement personnel, and could provide information to enable the subject to avoid detection or apprehension. Granting access to such information could seriously impede or compromise an investigation, endanger the physical safety of confidential sources, witnesses, law enforcement personnel and their families, lead to the improper influencing of witnesses, the destruction of evidence, or the fabrication of testimony, and disclose investigative techniques and procedures. In addition, granting access to such information could disclose classified, security-sensitive, or confidential business information and could constitute an unwarranted invasion of the personal privacy of others.

(iii) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required by statute or by Executive order of the President. Maintaining records in this way could impair investigations and law enforcement efforts, because it is not always possible to detect the relevance or necessity of specific information in the early stages of an investigation. The relevance and necessity of maintaining information are often questions of judgment and timing, and it is only after that information is evaluated that its relevance and necessity can be established. In addition, during the course of an investigation, the investigator may obtain information which is incidental to the main purpose of the investigation but which may relate to matters under the investigative jurisdiction of another agency. Such information cannot readily be segregated. Furthermore, during the course of an investigation, the investigator may obtain information concerning the violation of laws other than those within the scope of the agency's jurisdiction. In the interest of effective law enforcement, EPA investigators should retain this information, since it can aid in establishing patterns of criminal activity and can provide valuable leads for other law enforcement agencies.

(iv) 5 U.S.C. 552a(e)(4)(G) and (H) require an agency to publish a FEDERAL REGISTER notice concerning its procedures for notifying an individual upon request if the system of records contains a record pertaining to him or her, how the individual can gain access to the record, and how to contest its content. Since EPA is claiming that these systems of records are exempt from subsection (f)(2) through (5) of the Act, concerning agency rules, and subsection (d) of the Act, concerning access to records, these requirements are inapplicable and are exempted to the extent that these systems of records are exempted from subsections (f) and (d) of the Act. Although EPA is claiming exemption from these requirements, EPA has published such a notice concerning its notification, access, and contest procedures because, under certain circumstances, EPA might decide it is appropriate for an individual to have access to all or a portion of his records in these systems of records.

(v) 5 U.S.C. 552a(f)(1) requires an agency to promulgate rules which shall establish procedures whereby an individual can be notified in response to his or her request if any system of records named by the individual contains a record pertaining to him or her. Since EPA is claiming that these systems of records are exempt from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that these systems of records are exempted from subsection (d) of the Act. Although EPA is claiming exemption from the requirements of subsection (f)(2) through (5) of the Act, EPA has promulgated rules which establish Agency procedures because, under certain circumstances, it might be appropriate for an individual to have access to all or a portion of his records in these systems of records. These procedures are described elsewhere in this part.

(b) *Exemption under 5 U.S.C. 552a(k)(5)*—(1) *Systems of records affected.* EPA 36 Research Grant, Cooperative Agreement, and Fellowship Application Files.

EPA 40 Inspector General's Operation and Reporting (IGOR) System Investigative Files.

EPA 41 Inspector General's Operation and Reporting (IGOR) System Personnel Security Files.

(2) *Authority.* Under 5 U.S.C. 552a(k)(5), the head of any agency may by rule exempt any system of records within the agency from certain provisions of the PA, if the system of records is investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source

would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity would be held in confidence.

(3) *Qualification for exemption.* These systems contain investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information.

(4) *Scope of exemption.* (i) EPA 36 is exempted from 5 U.S.C. 552a(c)(3) and (d). EPA 40 and 41 are exempted from the following provisions of the PA, subject to the limitations of 5 U.S.C. 552a(k)(5); 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(H); and (f)(2) through (5).

(ii) To the extent that records in EPA 40 and 41 reveal a violation or potential violation of law, then an exemption under 5 U.S.C. 552a(k)(2) is also claimed for these records. EPA 40 is also exempt under 5 U.S.C. 552a(j)(2) of the Act.

(5) *Reasons for exemption.* EPA 36, 40, and 41 are exempted from the above provisions of the PA for the following reasons:

(i) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of each disclosure of records available to the individual named in the record at his or her request. These accountings must state the date, nature, and purpose of each disclosure of a record and the name and address of the recipient. Making such an accounting could cause the identity of a confidential source to be revealed, endangering the physical safety of the confidential source, and could impair the ability of the EPA to compile, in the future, investigatory material for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, Federal contracts, or access to classified information.

(ii) 5 U.S.C. 552a(d) requires an agency to permit an individual to gain access to records pertaining to him or her, to request amendment to such records, to request a review of an agency decision not to amend such records, and to contest the information contained in such records. Granting such access could cause the identity of a confidential source to be revealed, endangering the physical safety of the confidential source, and could impair the ability of the EPA to compile, in the future, investigatory material for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, Federal contracts, or access to classified information.

(iii) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required by statute or by Executive order of the President. The application of this provision could impair investigations, because it is not always possible to detect the relevance or necessity of specific information in the early stages of an investigation. Relevance and necessity are often questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established.

(iv) 5 U.S.C. 552a(e)(4)(H) requires an agency to publish a FEDERAL REGISTER notice concerning its procedures for notifying an individual upon request how to gain access to any record pertaining to him or her and how to contest its content. Since EPA is claiming that these systems of records are exempt from subsections (f)(2) through (5) of the Act, concerning agency rules, and subsection (b) of the Act, concerning access to records, these requirements are inapplicable and are exempted to the extent that these systems of records are exempted from subsections (f)(2) through (5) and (d) of the Act. Although EPA is claiming exemption from these requirements, EPA has published such a notice concerning its access and contest procedures because, under certain circumstances, EPA might decide it is appropriate for an individual to have access to all or a portion of his records in these systems of records.

(v) 5 U.S.C. 552a(f)(2) through (5) require an agency to promulgate rules for obtaining access to records. Since EPA is claiming that these systems of records are exempt from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act,

concerning agency rules for obtaining access to such records, are inapplicable and are exempt to the extent that this system of records is exempt from subsection (d) of the Act. Although EPA is claiming exemption from the requirements of subsections (f)(2) through (5) of the Act, EPA has promulgated rules which establish Agency procedures because, under certain circumstances, it might be appropriate for an individual to have access to all or a portion of his records in this system of records. These procedures are described elsewhere in this part.

(c) *Exemption under 5 U.S.C. 552a(k)(1)*—(1) *System of records affected.* EPA 41 Inspector General's Operation and Reporting (IGOR) System Personnel Security Files.

(2) *Authority.* Under 5 U.S.C. 552a(k)(1), the head of any agency may by rule exempt any system of records within the agency from certain provisions of the Privacy Act of 1974, if the system of records is subject to the provisions of 5 U.S.C. 552(b)(1). A system of records is subject to the provisions of 5 U.S.C. 552(b)(1) if it contains records that are specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive order.

(3) *Qualification for Exemption.* EPA 41 may contain some records that bear a national defense/foreign policy classification of Confidential, Secret, or Top Secret.

(4) *Scope of exemption.* To the extent that EPA 41 contains records provided by other Federal agencies that are specifically authorized under criteria established by Executive Order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified by other Federal agencies pursuant to that Executive Order, the system of records is exempted from the following provisions of the PA: 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(G) and (4)(H); and (f)(2) through (5) of the Act.

(5) *Reasons for exemption.* EPA 41 is exempted from the above provisions of the PA for the following reasons:

(i) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of each disclosure of records available to the individual named in the record at his request. These accountings must state the date, nature, and purpose of each disclosure of a record and the name and address of the recipient. Making such an accounting could result in the release of properly classified information, which would compromise the national defense or disrupt foreign policy.

(ii) 5 U.S.C. 552a(d) requires an agency to permit an individual to gain access to records pertaining to him or her, to request amendment to such records, to request a review of an agency decision not to amend such records, and to contest the information contained in such records. Granting such access could cause the release of properly classified information, which would compromise the national defense or disrupt foreign policy.

(iii) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required by statute or by Executive order of the President. The application of this provision could impair personnel security investigations which use properly classified information, because it is not always possible to know the relevance or necessity of specific information in the early stages of an investigation. Relevance and necessity are often questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established.

(iv) 5 U.S.C. 552a(e)(4) (G) and (H) require an agency to publish a FEDERAL REGISTER notice concerning its procedures for notifying an individual upon request if the system of records contains a record pertaining to him or her, how to gain access to such a record, and how to contest its content. Since EPA is claiming that this system of records is exempt from subsection (f) of the Act, concerning agency rules, and subsection (d) of the Act, concerning access to records, these requirements are inapplicable and are exempted to the extent that this system of records is exempted from subsections (f) and

(d) of the Act. Although EPA is claiming exemption from these requirements, EPA has published such a notice concerning its notification, access, and contest procedures because, under certain circumstances, EPA might decide it is appropriate for an individual to have access to all or a portion of his records in this system of records.

(v) 5 U.S.C. 552a(f)(1) requires an agency to promulgate rules which shall establish procedures whereby an individual can be notified in response to his request if any system of records named by the individual contains a record pertaining to him or her. Since EPA is claiming that this system of records is exempt from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that this system of records is exempt from subsection (d) of the Act. Although EPA is claiming exemption from the requirements of subsection (f) of the Act, EPA has promulgated rules which establish Agency procedures because, under certain circumstances, it might be appropriate for an individual to have access to all or a portion of his or her records in this system of records. These procedures are described elsewhere in this part.

(d) *Exempt records provided by another Federal agency*. Individuals may not have access to records maintained by the EPA if such records were provided by another Federal agency which has determined by regulation that such records are subject to general exemption under 5 U.S.C. 552a(j) or specific exemption under 5 U.S.C. 552a(k). If an individual requests access to such exempt records, EPA will consult with the source agency.

(e) *Exempt records included in a nonexempt system of records*. All records obtained from a system of records which has been determined by regulation to be subject to specific exemption under 5 U.S.C. 552a(k) retain their exempt status even if such records are also included in a system of records for which a specific exemption has not been claimed.

[71 FR 234, Jan. 4, 2006, as amended at 83 FR 62718, Dec. 6, 2018]

PART 17—IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN EPA ADMINISTRATIVE PROCEEDINGS

Subpart A—General Provisions

Sec.

Subpart B—Information Required From Applicants

Subpart C—Procedures for Considering Applications

AUTHORITY: Section 504, Title 5 U.S.C., as amended by sec. 203(a)(1), Equal Access to Justice Act (Title 2 of Pub. L. 96–481, 94 Stat. 2323).

SOURCE: 48 FR 39936, Sept. 2, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 17.1 Purpose of these rules.

These rules are adopted by EPA pursuant to section 504 of title 5 U.S.C., as added by section 203(a)(1) of the Equal Access to Justice Act, Public Law No. 96–481. Under the Act, an eligible party may receive an award for attorney's

fees and other expenses when it prevails over EPA in an adversary adjudication before EPA unless EPA's position as a party to the proceeding was substantially justified or special circumstances make an award unjust. The purpose of these rules is to establish procedures for the submission and consideration of applications for awards against EPA when the underlying decision is not reviewed by a court.

§ 17.2 Definitions.

As used in this part:

(a) *The Act* means section 504 of title 5 U.S.C., as amended by section 203(a)(1) of the Equal Access to Justice Act, Public Law No. 96–481.

(b) *Administrator* means the Administrator of the Environmental Protection Agency.

(c) *Adversary adjudication* means an adjudication required by statute to be held pursuant to 5 U.S.C. 554 in which the position of the United States is represented by counsel or otherwise, but excludes an adjudication for the purpose of granting or renewing a license.

(d) *EPA* means the Environmental Protection Agency, an Agency of the United States.

(e) *Presiding officer* means the official, without regard to whether he is designated as an administrative law judge or a hearing officer or examiner, who presides at the adversary adjudication.

(f) *Proceeding* means an adversary adjudication as defined in §17.2(b).

§ 17.3 Proceedings covered.

(a) These rules apply to adversary adjudications required by statute to be conducted by EPA under 5 U.S.C. 554. To the extent that they are adversary adjudications, the proceedings conducted by EPA to which these rules apply include:

(1) A hearing to consider the assessment of a noncompliance penalty under section 120 of the Clean Air Act as amended (42 U.S.C. 7420);

(2) A hearing to consider the termination of an individual National Pollution Discharge Elimination System permit under section 402 of the Clean Water Act as amended (33 U.S.C. 1342);

(3) A hearing to consider the assessment of any civil penalty under section 16(a) of the Toxic Substances Control Act (15 U.S.C. 2615(a));

(4) A hearing to consider ordering a manufacturer of hazardous chemical substances or mixtures to take actions under section 6(b) of the Toxic Substances Control Act (15 U.S.C. 2605(b)), to decrease the unreasonable risk posed by a chemical substance or mixture;

(5) A hearing to consider the assessment of any civil penalty under section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (7 U.S.C. 1361);

(6) A hearing to consider suspension of a registrant for failure to take appropriate steps in the development of registration data under section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (7 U.S.C. 136a);

(7) A hearing to consider the suspension or cancellation of a registration under section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (7 U.S.C. 136d);

(8) A hearing to consider the assessment of any civil penalty or the revocation or suspension of any permit under section 105(a) or 105(f) of the Marine Protection, Research, and Sanctuaries Act as amended (33 U.S.C. 1415(a), 33 U.S.C. 1415(f));

(9) A hearing to consider the issuance of a compliance order or the assessment of any civil penalty conducted under section 3008 of the Resource Conservation and Recovery Act as amended (42 U.S.C. 6928);

(10) A hearing to consider the issuance of a compliance order under section 11(d) of the Noise Control Act as amended (42 U.S.C. 4910(d)).

(b) If a proceeding includes both matters covered by the Act and matters specifically excluded from coverage, any award made will include only fees and expenses related to covered issues.

§ 17.4 Applicability to EPA proceedings.

The Act applies to an adversary adjudication pending before EPA at any time between October 1, 1981 and September 30, 1984. This includes proceedings begun before October 1, 1981 if final EPA action has not been taken before that date, and proceedings pending on September 30, 1984.

§ 17.5 Eligibility of applicants.

(a) To be eligible for an award of attorney's fees and other expenses under the Act, the applicant must be a prevailing party in the adversary adjudication for which it seeks an award. The term *party* is defined in 5 U.S.C. 551(3). The applicant must show that it meets all conditions of eligibility set out in this subpart and in subpart B.

(b) The types of eligible applicants are as follows:

(1) An individual with a net worth of not more than $1 million;

(2) The sole owner of an unincorporated business which has a net worth of not more than $5 million and not more than 500 employees;

(3) A charitable or other tax-exempt organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) with not more than 500 employees;

(4) A cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 114j(a)) with not more than 500 employees; and

(5) Any other partnership, corporation, association, or public or private organization with a net worth of not more than $5 million and not more than 500 employees.

(c) For the purpose of eligibility, the net worth and number of employees of an applicant shall be determined as of the date of adversary adjudication was initiated.

(d) An applicant who owns an unincorporated business will be considered as an *individual* rather than a *sole owner of an unincorporated business* if the issues on which the applicant prevails are related primarily to personal interests rather than to business interest.

(e) The employees of an applicant include all persons who regularly perform services for remuneration for the applicant under the applicant's direction and control. Part-time employees shall be included.

(f) The net worth and number of employees of the applicant and all of its affiliates shall be aggregated to determine eligibility. An individual or group of individuals, corporation, or other entity that directly or indirectly controls or owns a majority of the voting shares of another business' board of directors, trustees, or other persons exercising similar functions, shall be considered an affiliate of that business for purposes of this part. In addition, the Presiding Officer may determine that financial relationships of the applicant other than those described in this paragraph constitute special circumstances that would make an award unjust.

(g) An applicant is not eligible if it has participated in the proceeding on behalf of other persons or entities that are ineligible.

§ 17.6 Standards for awards.

(a) A prevailing applicant may receive an award for fees and expenses incurred in connection with a proceeding unless the position of the EPA as a party to the proceeding was substantially justified or unless special circumstances make the award sought unjust. No presumption arises that the agency's position was not substantially justified simply because the agency did not prevail.

(b) An award shall be reduced or denied if the applicant has unduly or unreasonably protracted the proceeding.

§ 17.7 Allowable fees and other expenses.

(a) The following fees and other expenses are allowable under the Act:

(1) Reasonable expenses of expert witnesses;

(2) The reasonable cost of any study, analysis, engineering report, test, or project which EPA finds necessary for the preparation of the party's case;

(3) Reasonable attorney or agent fees;

(b) The amount of fees awarded will be based upon the prevailing market rates for the kind and quality of services furnished, except that:

(1) Compensation for an expert witness will not exceed $24.09 per hour; and

(2) Attorney or agent fees will not be in excess of $75 per hour.

(c) In determining the reasonableness of the fee sought, the Presiding Officer shall consider the following:

(1) The prevailing rate for similar services in the community in which the attorney, agent, or witness ordinarily performs services;

(2) The time actually spent in the representation of the applicant;

(3) The difficulty or complexity of the issues raised by the application;

(4) Any necessary and reasonable expenses incurred;

(5) Such other factors as may bear on the value of the services performed.

§ 17.8 Delegation of authority.

The Administrator delegates to the Environmental Appeals Board authority to take final action relating to the Equal Access to Justice Act. The Environmental Appeals Board is described at 40 CFR 1.25(e). This delegation does not preclude the Environmental Appeals Board from referring any matter related to the Equal Access to Justice Act to the Administrator when the Environmental Appeals Board deems it appropriate to do so. When an appeal or motion is referred to the Administrator by the Environmental Appeals Board, all parties shall be so notified and the rules in this part referring to the Environmental Appeals Board shall be interpreted as referring to the Administrator.

[57 FR 5323, Feb. 13, 1992]

Subpart B—Information Required From Applicants

§ 17.11 Contents of application.

(a) An application for award of fees and expenses under the Act shall identify the applicant and the proceeding for which an award is sought. The application shall show that the applicant has prevailed and identify the position of EPA in the proceeding that the applicant alleges was not substantially justified.

(b) The application shall include a statement that the applicant's net worth as of the time the proceeding was initiated did not exceed $1 million if the applicant is an individual (other than a sole owner of an unincorporated business seeking an award in that capacity) or $5 million in the case of all other applicants. An applicant may omit this statement if:

(1) It attaches a copy of a ruling by the Internal Revenue Service that it qualifies as an organization described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Code or, in the case of such an organization not required to obtain a ruling from the Internal Revenue Service on its exempt status, a statement that describes the basis for the applicant's belief that it qualifies under section 501(c)(3) of the Code; or

(2) It states that it is a cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 114j(a)).

(c) If the applicant is a partnership, corporation, association, or organization, or a sole owner of an unincorporated business, the application shall state that the applicant did not have more than 500 employees at the time the proceeding was initiated, giving the number of its employees and describing briefly the type and purpose of its organization or business.

(d) The application shall itemize the amount of fees and expenses sought.

(e) The application may include any other matters that the applicant believes should be considered in determining whether and in what amount an award should be made.

(f) The application shall be signed by the applicant with respect to the eligibility of the applicant and by the attorney of the applicant with respect to fees and expenses sought. The application shall contain or be accompanied by a written verification under oath or affirmation or under penalty of perjury that the information provided in the application and all accompanying material is true and complete to the best of the signer's information and belief.

(Approved by the Office of Management and Budget under control number 2000–0403)

§ 17.12 Net worth exhibit.

(a) Each applicant except a qualified tax exempt organization or a qualified cooperative must submit with its application a detailed exhibit showing its net worth at the time the proceeding was initiated. If any individual, corporation, or other entity directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or if the applicant directly or indirectly owns or controls a majority of the voting shares or other

interest of any corporation or other entity, the exhibit must include a showing of the net worth of all such affiliates or of the applicant including the affiliates. The exhibit may be in any form that provides full disclosure of assets and liabilities of the applicant and any affiliates and is sufficient to determine whether the applicant qualifies under the standards of 5 U.S.C. 504(b)(1)(B)(i). The Presiding Officer may require an applicant to file additional information to determine the applicant's eligibility for an award.

(b) The net worth exhibit shall describe any transfers of assets from, or obligations incurred by, the applicant or any affiliate occurring in the one-year period prior to the date on which the proceeding was initiated that reduced the net worth of the applicant and its affiliates below the applicable net worth ceiling. If there were no such transactions, the applicant shall so state.

(c) The net worth exhibit shall be included in the public record of the proceeding.

(Approved by the Office of Management and Budget under control number 2000–0430)

§ 17.13 Documentation of fees and expenses.

(a) The application shall be accompanied by full documentation of fees and expenses, including the cost of any study, engineering report, test, or project, for which an award is sought.

(b) The documentation shall include an affidavit from any attorney, agent, or expert witness representing or appearing in behalf of the party stating the actual time expended and the rate at which fees and other expenses were computed and describing the specific services performed.

(1) The affidavit shall itemize in detail the services performed by the date, number of hours per date, and the services performed during those hours. In order to establish the hourly rate, the affidavit shall state the hourly rate which is billed and paid by the majority of clients during the relevant time periods.

(2) If no hourly rate is paid by the majority of clients because, for instance, the attorney or agent represents most clients on a contingency basis, the attorney or agent shall provide affidavits from two attorneys or agents with similar experience, who perform similar work, stating the hourly rate which they bill and are paid by the majority of their clients during a comparable time period.

(c) The documentation shall also include a description of any expenses for which reimbursement is sought and a statement of the amounts paid and payable by the applicant or by any other person or entity for the services provided.

(d) The Presiding Officer may require the applicant to provide vouchers, receipts, or other substantiation for any expenses claimed.

(Approved by the Office of Management and Budget under control number 2000–0430)

§ 17.14 Time for submission of application.

(a) An application must be filed no later than 30 days after final disposition of the proceeding. If agency review or reconsideration is sought or taken of a decision in which an applicant believes it has prevailed, action on the award of fees shall be stayed pending final agency disposition of the underlying controversy.

(b) Final disposition means the later of:

(1) The date on which the Agency decision becomes final, either through disposition by the Environmental Appeals Board of a pending appeal or through an initial decision becoming final due to lack of an appeal or

(2) The date of final resolution of the proceeding, such as settlement or voluntary dismissal, which is not subject to a petition for rehearing or reconsideration.

(c) If judicial review is sought or taken of the final agency disposition of the underlying controversy, then agency proceedings for the award of fees will be stayed pending completion of judicial review. If, upon completion of review, the court decides what fees to award, if any, then EPA shall have no authority to award fees.

[48 FR 39936, Sept. 2, 1983, as amended at 57 FR 5323, Feb. 13, 1992]

Subpart C—Procedures for Considering Applications

§ 17.21 Filing and service of documents.

An application for an award and any other pleading or document related to the application shall be filed and served on all parties to the proceeding in the same manner as other pleadings in the proceeding.

§ 17.22 Answer to application.

(a) Within 30 calendar days after service of the application, EPA counsel shall file an answer.

(b) If EPA counsel and the applicant believe that they can reach a settlement concerning the award, EPA counsel may file a statement of intent to negotiate. The filing of such a statement shall extend the time for filing an answer an additional 30 days.

(c) The answer shall explain in detail any objections to the award requested and identify the facts relied on to support the objection. If the answer is based on any alleged facts not already reflected in the record of the proceeding, EPA counsel shall include with the answer either a supporting affidavit or affidavits or request for further proceedings under § 17.25.

§ 17.23 Comments by other parties.

Any party to a proceeding other than the applicant and EPA counsel may file comments on an application within 30 calendar days after it is served or on an answer within 15 calendar days after it is served.

§ 17.24 Settlement.

A prevailing party and EPA counsel may agree on a proposed settlement of an award before final action on the application, either in connection with a settlement of the underlying proceeding or after the underlying proceeding has been concluded. If the party and EPA counsel agree on a proposed settlement of an award before an application has been filed, the application shall be filed with the proposed settlement.

§ 17.25 Extensions of time and further proceedings.

(a) The Presiding Officer may, on motion and for good cause shown, grant extensions of time, other than for filing an application for fees and expenses, after final disposition in the adversary adjudication.

(b) Ordinarily, the determination of an award will be made on the basis of the written record of the underlying proceeding and the filings required or permitted by the foregoing sections of these rules. However, the adjudicative officer may *sua sponte* or on motion of any party to the proceedings require or permit further filings or other action, such as an informal conference, oral argument, additional written submissions, or an evidentiary hearing. Such further action shall be allowed only when necessary for full and fair resolution of the issues arising from the application and shall take place as promptly as possible. A motion for further filings or other action shall specifically identify the information sought on the disputed issues and shall explain why the further filings or other action is necessary to resolve the issues.

(c) In the event that an evidentiary hearing is required or permitted by the adjudicative officer, such hearing and any related filings or other action required or permitted shall be conducted pursuant to the procedural rules governing the underlying adversary adjudication.

§ 17.26 Decision on application.

The Presiding Officer shall issue a recommended decision on the application which shall include proposed written findings and conclusions on such of the following as are relevant to the decision:

(a) The applicant's status as a prevailing party;

(b) The applicant's qualification as a ''party'' under 5 U.S.C. 504(b)(1)(B);

(c) Whether EPA's position as a party to the proceeding was substantially justified;

(d) Whether the special circumstances make an award unjust;

(e) Whether the applicant during the course of the proceedings engaged in conduct that unduly and unreasonably

protracted the final resolution of the matter in controversy; and

(f) The amounts, if any, awarded for fees and other expenses, explaining any difference between the amount requested and the amount awarded.

§ 17.27 Agency review.

The recommended decision of the Presiding Officer will be reviewed by EPA in accordance with EPA's procedures for the type of substantive proceeding involved.

§ 17.28 Judicial review.

Judicial review of final EPA decisions on awards may be sought as provided in 5 U.S.C. 504(c)(2).

§ 17.29 Payment of award.

An applicant seeking payment of an award shall submit a copy of the final decision granting the award to the Office of Financial Management for Processing. A statement that review of the underlying decision is not being sought in the United States courts or that the process for seeking review of the award has been completed must also be included.

PART 18—ENVIRONMENTAL PROTECTION RESEARCH FELLOWSHIPS AND SPECIAL RESEARCH CONSULTANTS FOR ENVIRONMENTAL PROTECTION

Sec.

AUTHORITY: 42 U.S.C. 209; Pub. L. 109–54, 119 Stat. 531.

SOURCE: 71 FR 16702, Apr. 4, 2006, unless otherwise noted.

§ 18.1 Definitions.

As used in this part, continental United States does not include Hawaii or Alaska. The Administrator means the Administrator of the EPA and any other officer or employee of the Agency to whom the authority involved may be delegated. An Environmental Protection Research Fellowship is one which requires the performance of services, either full or part time, for the EPA. A Special Research Consultant for Environmental Protection is a special consultant appointed to assist and advise in the operations of the research activities of the EPA.

§ 18.2 Applicability.

The regulations in this part apply to the establishment of Environmental Protection Research Fellowships, the designation of persons to receive such fellowships, the appointment of Environmental Protection Research fellows, and the appointment of Special Research Consultants for environmental protection in the EPA. The EPA's statutory authority for these actions is established in Title II of the Interior, Environmental and Related Agencies Appropriations Act of 2006 (Pub. L. 109–54). Under an administrative provision of Public Law 109–54 the Administrator may, after consultation with the Office of Personnel Management, make up to five (5) appointments in any fiscal year from 2006 to 2011 for the Office of Research and Development under the authority provided in 42 U.S.C. 209. Appointees under this statutory authority shall be employees of the EPA.

§ 18.3 Purpose of Environmental Protection Research Fellowships.

Environmental Protection Research Fellowships in the Agency are for the purpose of encouraging and promoting research, studies, and investigations related to the protection of human health and the environment. Such fellowships may be provided to secure the services of talented scientists and engineers for a period of limited duration for research that furthers the EPA's mission where the nature of the work or the character of the individual's services render customary employing

methods impracticable or less effective.

§ 18.4 Establishment of Environmental Protection Research Fellowships.

All Environmental Protection Research fellowships shall be established by the Administrator or designee. In establishing an Environmental Protection Research fellowship, or a series of Environmental Protection Research fellowships, the Administrator shall prescribe in writing the conditions (in addition to those provided in the regulations in this part) under which Environmental Protection Research fellows will be appointed and will hold their fellowships.

§ 18.5 Qualifications for Environmental Protection Research Fellowships.

Scholastic and other qualifications shall be prescribed by the Administrator or designee for each Environmental Protection Research fellowship, or series of Environmental Protection Research fellowships. Each individual appointed to an Environmental Protection Research fellowship shall: have presented satisfactory evidence of general suitability, including professional and personal fitness; possess any other qualifications as reasonably may be prescribed; and meet all requirements and standards for documentation and disclosure of conflicts of interest and ethical professional conduct.

§ 18.6 Method of Application.

Application for an Environmental Protection Research fellowship shall be made in accordance with procedures established by the Administrator or designee.

§ 18.7 Selection and appointment of Environmental Protection Research Fellows.

The Administrator or designee shall do the following: prescribe a suitable professional and personal fitness review and an examination of the applicant's qualifications; designate in writing persons to receive Environmental Protection Research fellowships; and establish procedures for the appointment of Environmental Protection Research fellows.

§ 18.8 Stipends, Allowances, and Benefits.

(a) *Stipends.* Each Environmental Protection Research fellow shall be entitled to such stipend as is authorized by the Administrator or designee.

(b) *Travel and transportation allowances.* Under conditions prescribed by the Administrator or designee, an individual appointed as an Environmental Protection Research fellow may be authorized travel and transportation or relocation allowances for his or her immediate family under subchapter I of chapter 57 of title 5 U.S.C. 5701, in conjunction with travel authorized by the Administrator or designee. Included under this part is travel from place of residence, within or outside the continental United States, to first duty station; for any change of duty station ordered by the Administrator or designee during the term of the fellowship; and from last duty station to the place of residence which the individual left to accept the fellowship, or to some other place at no greater cost to the Government. An Environmental Protection Research fellow shall be entitled to travel allowances or transportation and per diem while traveling on official business away from his or her permanent duty station during the term of the fellowship. Except as otherwise provided herein, an Environmental Protection Research fellow shall be entitled to travel and transportation allowances authorized in this part at the same rates as may be authorized by law and regulations for other civilian employees of the EPA. If an Environmental Protection Research fellow dies during the term of a fellowship, and the place of residence that was left by the fellow to accept the fellowship was outside the continental United States, the payment of expenses of preparing the remains for burial and transporting them to the place of residence for interment may be authorized. In the case of deceased fellows whose place of residence was within the continental United States, payment of the expenses of preparing the remains and transporting them to the place of residence for interment may be authorized as provided for other civilian employees of the Agency.

(c) *Benefits.* In addition to other benefits provided herein, Environmental Protection Research fellows shall be entitled to benefits as provided by law or regulation for other civilian employees of the Agency.

(d) *Training.* Environmental Protection Research fellows are eligible for training at Government expense on the same basis as other Agency employees.

§ 18.9 Duration of Environmental Protection Research Fellowships.

Initial appointments to Environmental Protection Research fellowships may be made for varying periods not in excess of 5 years. Such an appointment may be extended for varying periods not in excess of 5 years for each period in accordance with procedures and requirements established by the Administrator or designee.

§ 18.10 Appointment of Special Research Consultants for Environmental Protection.

(a) *Purpose.* When the EPA requires the services of consultants with expertise in environmental sciences or engineering who cannot be obtained when needed through regular civil service appointment or under the compensation provisions of the Classification Act of 1949, Special Research Consultants may be appointed to assist and advise in the operations of the EPA, subject to the provisions of the following paragraphs and in accordance with such instructions as may be issued from time to time by the Administrator or designee.

(b) *Appointments.* Appointments, pursuant to the provisions of this section, may be made by those officials in the EPA to whom authority has been delegated by the Administrator or designee.

(c) *Compensation.* The per diem or other rates of compensation shall be fixed by the appointing officer in accordance with criteria established by the Administrator or designee.

§ 18.11 Standards of Conduct and Financial Disclosure.

All individuals appointed to an Environmental Protection Research Fellowship or as a Special Research Consultant shall be subject to the same current standards and disclosure regulations and requirements as Title 5 appointees.

PART 19—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

Sec.

AUTHORITY: Pub. L. 101–410, Oct. 5, 1990, 104 Stat. 890, as amended by Pub. L. 104–134, title III, sec. 31001(s)(1), Apr. 26, 1996, 110 Stat. 1321–373; Pub. L. 105–362, title XIII, sec. 1301(a), Nov. 10, 1998, 112 Stat. 3293; Pub. L. 114–74, title VII, sec. 701(b), Nov. 2, 2015, 129 Stat. 599.

SOURCE: 73 FR 75345, Dec. 11, 2008, unless otherwise noted.

§ 19.1 Applicability.

This part applies to each statutory provision under the laws administered by the Environmental Protection Agency concerning the civil monetary penalties which may be assessed in either civil judicial or administrative proceedings.

§ 19.2 Effective date.

The statutory penalty levels in the last column of Table 1 to § 19.4 apply to all violations which occurred after December 6, 2013 through November 2, 2015, and to violations occurring after November 2, 2015, where penalties were assessed before August 1, 2016. The statutory civil penalty levels set forth in the fourth column of Table 2 of § 19.4 apply to all violations which occurred after November 2, 2015, where the penalties were assessed on or after August 1, 2016 and before January 15, 2017. The statutory civil penalty levels set forth in the fifth column of Table 2 of § 19.4 apply to all violations which occurred after November 2, 2015, where the penalties were assessed on or after January 15, 2017 but before January 15, 2018. The statutory civil penalty levels set forth in the sixth column of Table 2 of § 19.4 apply to all violations which occurred after November 2, 2015, where the penalties were assessed on or after January 15, 2018 but before February 6,

2019. The statutory civil penalty levels set forth in the seventh and last column of Table 2 of § 19.4 apply to all violations which occur or occurred after November 2, 2015, where the penalties are assessed on or after February 6, 2019.

[84 FR 2058, Feb. 6, 2019]

§ 19.3 [Reserved]

§ 19.4 Statutory civil penalties, as adjusted for inflation, and tables.

Table 1 to § 19.4 sets out the statutory civil penalty provisions of statutes administered by EPA, with the original statutory civil penalty levels, as enacted, and the operative statutory civil penalty levels, as adjusted for inflation, for violations that occurred on or before November 2, 2015, and for violations that occurred after November 2, 2015, where penalties were assessed before August 1, 2016. Table 2 to § 19.4 sets out the statutory civil penalty provisions of statutes administered by EPA, with the third column displaying the original statutory civil penalty levels, as enacted. The fourth column of Table 2 displays the operative statutory civil penalty levels where penalties were assessed on or after August 1, 2016 but before January 15, 2017, for violations that occurred after November 2, 2015. The fifth column displays the operative statutory civil penalty levels where penalties were assessed on or after January 15, 2017 but before January 15, 2018, for violations that occurred after November 2, 2015. The sixth column displays the operative statutory civil penalty levels where penalties were assessed on or after January 15, 2018 but before February 6, 2019, for violations that occurred after November 2, 2015. The seventh and last column displays the operative statutory civil penalty levels where penalties are assessed on or after February 6, 2019, for violations that occur or occurred after November 2, 2015.

TABLE 1 OF SECTION 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

U.S. Code Citation	Environmental statute	Statutory penalties, as enacted	Penalties effective after January 30, 1997 through March 15, 2004	Penalties effective after March 15, 2004 through January 12, 2009	Penalties effective after January 12, 2009 through December 6, 2013	Statutory civil penalties for violations that occurred after December 6, 2013 through November 2, 2015, or are assessed before August 1, 2016
7 U.S.C. 136*l*.(a)(1)	FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA).	$5,000	$5,500	$6,500	$7,500	$7,500
7 U.S.C. 136*l*.(a)(2)	FIFRA	$500/$1,000	$550/$1,000	$650/$1,100	$750/$1,100	$750/$1,100
15 U.S.C. 2615(a)(1)	TOXIC SUBSTANCES CONTROL ACT (TSCA).	$25,000	$27,500	$32,500	$37,500	$37,500
15 U.S.C. 2647(a)	TSCA	$5,000	$5,500	$6,500	$7,500	$7,500
15 U.S.C. 2647(g)	TSCA	$5,000	$5,000	$5,500	$7,500	$7,500
31 U.S.C. 3802(a)(1)	PROGRAM FRAUD CIVIL REMEDIES ACT (PFCRA).	$5,000	$5,500	$6,500	$7,500	$7,500
31 U.S.C. 3802(a)(2)	PFCRA	$5,000	$5,500	$6,500	$7,500	$7,500
33 U.S.C. 1319(d)	CLEAN WATER ACT (CWA).	$25,000	$27,500	$32,500	$37,500	$37,500
33 U.S.C. 1319(g)(2)(A)	CWA	$10,000/$25,000	$11,000/$27,500	$11,000/$32,500	$16,000/$37,500	$16,000/$37,500
33 U.S.C. 1319(g)(2)(B)	CWA	$10,000/$125,000	$11,000/$137,500	$11,000/$157,500	$16,000/$177,500	$16,000/$187,500
33 U.S.C. 1321(b)(6)(B)(i).	CWA	$10,000/$25,000	$11,000/$27,500	$11,000/$32,500	$16,000/$37,500	$16,000/$37,500
33 U.S.C. 1321(b)(6)(B)(ii).	CWA	$10,000/$125,000	$11,000/$137,500	$11,000/$157,500	$16,000/$177,500	$16,000/$187,500
33 U.S.C. 1321(b)(7)(A)	CWA	$25,000/$1,000	$27,500/$1,100	$32,500/$1,100	$37,500/$1,100	$37,500/$2,100
33 U.S.C. 1321(b)(7)(B)	CWA	$25,000	$27,500	$32,500	$37,500	$37,500
33 U.S.C. 1321(b)(7)(C)	CWA	$25,000	$27,500	$32,500	$37,500	$37,500
33 U.S.C. 1321(b)(7)(D)	CWA	$100,000/$3,000	$110,000/$3,300	$130,000/$4,300	$140,000/$4,300	$150,000/$5,300
33 U.S.C. 1414b(d)(1) [1]	MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT (MPRSA).	$600	$660	$760	$860	$860
33 U.S.C. 1415(a)	MPRSA	$50,000/$125,000	$55,000/$137,500	$65,000/$157,500	$70,000/$177,500	$75,000/$187,500

33 U.S.C. 1901 note (*see* 1409(a)(2)(A)).	CERTAIN ALASKAN CRUISE SHIP OPERATIONS (CACSO).	$10,000/$25,000	$10,000/$25,000 [2]	$10,000/$25,000	$11,000/$27,500	$11,000/$27,500
33 U.S.C. 1901 note (*see* 1409(a)(2)(B)).	CACSO	$10,000/$125,000	$10,000/$125,000	$10,000/$125,000	$11,000/$137,500	$11,000/$147,500
33 U.S.C. 1901 note (*see* 1409(b)(1)).	CACSO	$25,000	$25,000	$25,000	$27,500	$27,500
42 U.S.C. 300g–3(b)	SAFE DRINKING WATER ACT (SDWA).	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 300g–3(g)(3)(A).	SDWA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 300g–3(g)(3)(B).	SDWA	$5,000/$25,000	$5,000/$25,000	$6,000/$27,500	$7,000/$32,500	$7,000/$32,500
42 U.S.C. 300g–3(g)(3)(C).	SDWA	$25,000	$25,000	$27,500	$32,500	$32,500
42 U.S.C. 300h–2(b)(1)	SDWA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 300h–2(c)(1)	SDWA	$10,000/$125,000	$11,000/$137,500	$11,000/$157,500	$16,000/$177,500	$16,000/$187,500
42 U.S.C. 300h–2(c)(2)	SDWA	$5,000/$125,000	$5,500/$137,500	$6,500/$157,500	$7,500/$177,500	$7,500/$187,500
42 U.S.C. 300h–3(c)	SDWA	$5,000/$10,000	$5,500/$11,000	$6,500/$11,000	$7,500/$16,000	$7,500/$16,000
42 U.S.C. 300i(b)	SDWA	$15,000	$15,000	$16,500	$16,500	$21,500
42 U.S.C. 300i–1(c)	SDWA	$20,000/$50,000	$22,000/$55,000 [3]	$100,000/ $1,000,000	$110,000/ $1,100,000	$120,000/ $1,150,000
42 U.S.C. 300j(e)(2)	SDWA	$2,500	$2,750	$2,750	$3,750	$3,750
42 U.S.C. 300j–4(c)	SDWA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 300j–6(b)(2)	SDWA	$25,000	$25,000	$27,500	$32,500	$32,500
42 U.S.C. 300j–23(d)	SDWA	$5,000/$50,000	$5,500/$55,000	$6,500/$65,000	$7,500/$70,000	$7,500/$75,000
42 U.S.C. 4852d(b)(5)	RESIDENTIAL LEAD-BASED PAINT HAZARD REDUCTION ACT OF 1992.	$10,000	$11,000	$11,000	$16,000	$16,000
42 U.S.C. 4910(a)(2)	NOISE CONTROL ACT OF 1972.	$10,000	$11,000	$11,000	$16,000	$16,000
42 U.S.C. 6928(a)(3)	RESOURCE CONSERVATION AND RECOVERY ACT (RCRA).	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 6928(c)	RCRA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 6928(g)	RCRA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 6928(h)(2)	RCRA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 6934(e)	RCRA	$5,000	$5,500	$6,500	$7,500	$7,500
42 U.S.C. 6973(b)	RCRA	$5,000	$5,500	$6,500	$7,500	$7,500
42 U.S.C. 6991e(a)(3)	RCRA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 6991e(d)(1)	RCRA	$10,000	$11,000	$11,000	$16,000	$16,000

TABLE 1 OF SECTION 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code Citation	Environmental statute	Statutory penalties, as enacted	Penalties effective after January 30, 1997 through March 15, 2004	Penalties effective after March 15, 2004 through January 12, 2009	Penalties effective after January 12, 2009 through December 6, 2013	Statutory civil penalties for violations that occurred after December 6, 2013 through November 2, 2015, or are assessed before August 1, 2016
42 U.S.C. 6991e(d)(2) ..	RCRA	$10,000	$11,000	$11,000	$16,000	$16,000
42 U.S.C. 7413(b)	CLEAN AIR ACT (CAA)	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 7413(d)(1)	CAA	$25,000/$200,000	$27,500/$220,000	$32,500/$270,000	$37,500/$295,000	$37,500/$320,000
42 U.S.C. 7413(d)(3)	CAA	$5,000	$5,500	$6,500	$7,500	$7,500
42 U.S.C. 7524(a)	CAA	$2,500/$25,000	$2,750/$27,500	$2,750/$32,500	$3,750/$37,500	$3,750/$37,500
42 U.S.C. 7524(c)(1)	CAA	$200,000	$220,000	$270,000	$295,000	$320,000
42 U.S.C. 7545(d)(1)	CAA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 9604(e)(5)(B)	COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT (CERCLA).	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 9606(b)(1)	CERCLA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 9609(a)(1)	CERCLA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 9609(b)	CERCLA	$25,000/$75,000	$27,500/$82,500	$32,500/$97,500	$37,500/$107,500	$37,500/$117,500
42 U.S.C. 9609(c)	CERCLA	$25,000/$75,000	$27,500/$82,500	$32,500/$97,500	$37,500/$107,500	$37,500/$117,500
42 U.S.C. 11045(a)	EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT (EPCRA).	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 11045(b)(1)(A)[4].	EPCRA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 11045(b)(2) ..	EPCRA	$25,000/$75,000	$27,500/$82,500	$32,500/$97,500	$37,500/$107,500	$37,500/$117,500
42 U.S.C. 11045(b)(3) ..	EPCRA	$25,000/$75,000	$27,500/$82,500	$32,500/$97,500	$37,500/$107,500	$37,500/$117,500
42 U.S.C. 11045(c)(1) ..	EPCRA	$25,000	$27,500	$32,500	$37,500	$37,500
42 U.S.C. 11045(c)(2) ..	EPCRA	$10,000	$11,000	$11,000	$16,000	$16,000
42 U.S.C. 11045(d)(1) ..	EPCRA	$25,000	$27,500	$32,500	$37,500	$37,500

42 U.S.C. 14304(a)(1) ..	MERCURY-CONTAINING AND RECHARGEABLE BATTERY MANAGEMENT ACT (BATTERY ACT).	$10,000	$10,000	$11,000	$16,000	$16,000
42 U.S.C. 14304(g)	BATTERY ACT	$10,000	$10,000	$11,000	$16,000	$16,000

[1] Note that 33 U.S.C. 1414b (d)(1)(B) contains additional penalty escalation provisions that must be applied to the penalty amounts set forth in this Table. The amounts set forth in this Table reflect an inflation adjustment to the calendar year 1992 penalty amount expressed in section 104B(d)(1)(A), which is used to calculate the applicable penalty amount under MPRSA section 104B(d)(1)(B) for violations that occur in any subsequent calendar year.

[2] CACSO was passed on December 21, 2000 as part of Title XIV of the Consolidated Appropriations Act of 2001, Pub. L. 106–554, 33 U.S.C. 1901 note.

[3] The original statutory penalty amounts of $20,000 and $50,000 under section 1432(c) of the SDWA, 42 U.S.C. 300i–1(c), were subsequently increased by Congress pursuant to section 403 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law No. 107–188 (June 12, 2002), to $100,000 and $1,000,000, respectively. EPA did not adjust these new penalty amounts in its 2004 Civil Monetary Penalty Inflation Adjustment Rule ("2004 Rule"), 69 FR 7121 (February 13, 2004), because they had gone into effect less than two years prior to the 2004 Rule.

[4] Consistent with how the EPA's other penalty authorities are displayed under Part 19.4, this Table now delineates, on a subpart-by-subpart basis, the penalty authorities enumerated under section 325(b) of EPCRA, 42 U.S.C. 11045(b) (*i.e.,* 42 U.S.C. 11045(b)(1)(A), (b)(2), and (b)(3)).

TABLE 2 OF SECTION 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

U.S. Code citation	Environmental statute	Statutory civil penalties, as enacted	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after August 1, 2016 but before January 15, 2017	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 15, 2017 but before January 15, 2018	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 15, 2018 but before February 6, 2019	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties are assessed on or after February 6, 2019
7 U.S.C. 136*l*.(a)(1) ...	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).	$5,000	$18,750	$19,057	$19,446	$19,936
7 U.S.C. 136*l*.(a)(2)[1]	FIFRA	$1,000/$500/$1,000 ..	$2,750/$1,772/$2,750	$2,795/$1,801/$2,795	$2,852/$1,838/$2,852	$2,924/$1,884/$2,924
15 U.S.C. 2615(a)(1)	Toxic Substances Control Act (TSCA).	$25,000	$37,500	$38,114	$38,892	$39,873
15 U.S.C. 2647(a)	TSCA	$5,000	$10,781	$10,957	$11,181	$11,463
15 U.S.C. 2647(g)	TSCA	$5,000	$8,908	$9,054	$9,239	$9,472
31 U.S.C. 3802(a)(1)	Program Fraud Civil Remedies Act (PFCRA).	$5,000	$10,781	$10,957	$11,181	$11,463
31 U.S.C. 3802(a)(2)	PFCRA	$5,000	$10,781	$10,957	$11,181	$11,463
33 U.S.C. 1319(d)	Clean Water Act (CWA).	$25,000	$51,570	$52,414	$53,484	$54,833
33 U.S.C. 1319(g)(2)(A).	CWA	$10,000/$25,000	$20,628/$51,570	$20,965/$52,414	$21,393/$53,484	$21,933/$54,833
33 U.S.C. 1319(g)(2)(B).	CWA	$10,000/$125,000	$20,628/$257,848	$20,965/$262,066	$21,393/$267,415	$21,933/$274,159
33 U.S.C. 1321(b)(6)(B)(i).	CWA	$10,000/$25,000	$17,816/$44,539	$18,107/$45,268	$18,477/$46,192	$18,943/$47,357

TABLE 2 OF SECTION 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code citation	Environmental statute	Statutory civil penalties, as enacted	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after August 1, 2016 but before January 15, 2017	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 15, 2017 but before January 15, 2018	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 15, 2018 but before February 6, 2019	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties are assessed on or after February 6, 2019
33 U.S.C. 1321(b)(6)(B)(ii).	CWA	$10,000/$125,000	$17,816/$222,695	$18,107/$226,338	$18,477/$230,958	$18,943/$236,783
33 U.S.C. 1321(b)(7)(A).	CWA	$25,000/$1,000	$44,539/$1,782	$45,268/$1,811	$46,192/$1,848	$47,357/$1,895
33 U.S.C. 1321(b)(7)(B).	CWA	$25,000	$44,539	$45,268	$46,192	$47,357
33 U.S.C. 1321(b)(7)(C).	CWA	$25,000	$44,539	$45,268	$46,192	$47,357
33 U.S.C. 1321(b)(7)(D).	CWA	$100,000/$3,000	$178,156/$5,345	$181,071/$5,432	$184,767/$5,543	$189,427/$5,683
33 U.S.C. 1414b(d)(1)	Marine Protection, Research, and Sanctuaries Act (MPRSA).	$600	$1,187	$1,206	$1,231	$1,262
33 U.S.C. 1415(a)	MPRSA	$50,000/$125,000	$187,500/$247,336	$190,568/$251,382	$194,457/$256,513	$199,361/$262,982
33 U.S.C. 1901 note (*see* 1409(a)(2)(A)).	Certain Alaskan Cruise Ship Operations (CACSO).	$10,000/$25,000	$13,669/$34,172	$13,893/$34,731	$14,177$35,440	$14,535/$36,334
33 U.S.C. 1901 note (*see* 1409(a)(2)(B)).	CACSO	$10,000/$125,000	$13,669/$170,861	$13,893/$173,656	$14,177/$177,200	$14,535/$181,669
33 U.S.C. 1901 note (*see* 1409(b)(1)).	CACSO	$25,000	$34,172	$34,731	$35,440	$36,334
33 U.S.C. 1908(b)(1)	Act To Prevent Pollution From Ships (APPS).	$25,000	$70,117	$71,264	$72,718	$74,552
33 U.S.C. 1908(b)(2)	APPS	$5,000	$14,023	$14,252	$14,543	$14,910
42 U.S.C. 300g–3(b)	Safe Drinking Water Act (SDWA).	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 300g–3(g)(3)(A).	SDWA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 300g–3(g)(3)(B).	SDWA	$5,000/$25,000	$10,781/$37,561	$10,957/$38,175	$11,181/$38,954	$11,463/$39,936
42 U.S.C. 300g–3(g)(3)(C).	SDWA	$25,000	$37,561	$38,175	$38,954	$39,936
42 U.S.C. 300h–2(b)(1).	SDWA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 300h–2(c)(1).	SDWA	$10,000/$125,000	$21,563/$269,535	$21,916/$273,945	$22,363/$279,536	$22,927/$286,586
42 U.S.C. 300h–2(c)(2).	SDWA	$5,000/$125,000	$10,781/$269,535	$10,957/$273,945	$11,181/$279,536	$11,463/$286,586
42 U.S.C. 300h–3(c)	SDWA	$5,000/$10,000	$18,750/$40,000	$19,057/$40,654	$19,446/$41,484	$19,936/$42,530

42 U.S.C. 300(b)	SDWA	$15,000	$22,537	$22,906	$23,374	$23,963
42 U.S.C. 300–1(c)	SDWA	$100,000/$1,000,000	$131,185/$1,311,850	$133,331/$1,333,312	$136,052/$1,360,525	$139,483/$1,394,837
42 U.S.C. 300(e)(2)	SDWA	$2,500	$9,375	$9,528	$9,722	$9,967
42 U.S.C. 300j–4(c)	SDWA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 300j–6(b)(2).	SDWA	$25,000	$37,561	$38,175	$38,954	$39,936
42 U.S.C. 300j–23(d)	SDWA	$5,000/$50,000	$9,893/$98,935	$10,055/$100,554	$10,260/$102,606	$10,519/$105,194
42 U.S.C. 4852d(b)(5)	Residential Lead–Based Paint Hazard Reduction Act of 1992.	$10,000	$16,773	$17,047	$17,395	$17,834
42 U.S.C. 4910(a)(2)	Noise Control Act of 1972.	$10,000	$35,445	$36,025	$36,760	$37,687
42 U.S.C. 6928(a)(3)	Resource Conservation and Recovery Act (RCRA).	$25,000	$93,750	$95,284	$97,229	$99,681
42 U.S.C. 6928(c)	RCRA	$25,000	$56,467	$57,391	$58,562	$60,039
42 U.S.C. 6928(g)	RCRA	$25,000	$70,117	$71,264	$72,718	$74,552
42 U.S.C. 6928(h)(2)	RCRA	$25,000	$56,467	$57,391	$58,562	$60,039
42 U.S.C. 6934(e)	RCRA	$5,000	$14,023	$14,252	$14,543	$14,910
42 U.S.C. 6973(b)	RCRA	$5,000	$14,023	$14,252	$14,543	$14,910
42 U.S.C. 6991e(a)(3)	RCRA	$25,000	$56,467	$57,391	$58,562	$60,039
42 U.S.C. 6991e(d)(1)	RCRA	$10,000	$22,587	$22,957	$23,426	$24,017
42 U.S.C. 6991e(d)(2)	RCRA	$10,000	$22,587	$22,957	$23,426	$24,017
42 U.S.C. 7413(b)	Clean Air Act (CAA)	$25,000	$93,750	$95,284	$97,229	$99,681
42 U.S.C. 7413(d)(1)	CAA	$25,000/$200,000	$44,539/$356,312	$45,268/$362,141	$46,192/$369,532	$47,357/$378,852
42 U.S.C. 7413(d)(3)	CAA	$5,000	$8,908	$9,054	$9,239	$9,472
42 U.S.C. 7524(a)	CAA	$25,000/$2,500	$44,539/$4,454	$45,268/$4,527	$46,192/$4,619	$47,357/$4,735
42 U.S.C. 7524(c)(1)	CAA	$200,000	$356,312	$362,141	$369,532	$378,852
42 U.S.C. 7545(d)(1)	CAA	$25,000	$44,539	$45,268	$46,192	$47,357
42 U.S.C. 9604(e)(5)(B).	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 9606(b)(1)	CERCLA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 9609(a)(1)	CERCLA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 9609(b)	CERCLA	$25,000/$75,000	$53,907/$161,721	$54,789/$164,367	$55,907/$167,722	$57,317/$171,952
42 U.S.C. 9609(c)	CERCLA	$25,000/$75,000	$53,907/$161,721	$54,789/$164,367	$55,907/$167,722	$57,317/$171,952
42 U.S.C. 11045(a)	Emergency Planning and Community Right-To-Know Act (EPCRA).	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 11045(b)(1)(A).	EPCRA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 11045(b)(2)	EPCRA	$25,000/$75,000	$53,907/$161,721	$54,789/$164,367	$55,907/$167,722	$57,317/$171,952
42 U.S.C. 11045(b)(3)	EPCRA	$25,000/$75,000	$53,907/$161,721	$54,789/$164,367	$55,907/$167,722	$57,317/$171,952
42 U.S.C. 11045(c)(1)	EPCRA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 11045(c)(2)	EPCRA	$10,000	$21,563	$21,916	$22,363	$22,927

TABLE 2 OF SECTION 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code citation	Environmental statute	Statutory civil penalties, as enacted	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after August 1, 2016 but before January 15, 2017	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 15, 2017 but before January 15, 2018	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 15, 2018 but before February 6, 2019	Statutory civil penalties for violations that occurred after November 2, 2015, where penalties are assessed on or after February 6, 2019
42 U.S.C.11045(d)(1)	EPCRA	$25,000	$53,907	$54,789	$55,907	$57,317
42 U.S.C. 14304(a)(1)	Mercury-Containing and Rechargeable Battery Management Act (Battery Act).	$10,000	$15,025	$15,271	$15,583	$15,976
42 U.S.C. 14304(g)	Battery Act	$10,000	$15,025	$15,271	$15,583	$15,976

[1] Note that 7 U.S.C. 136*l*.(a)(2) contains three separate statutory maximum civil penalty provisions. The first mention of $1,000 and the $500 statutory maximum civil penalty amount were originally enacted in 1978 (Pub. L. 95–396), and the second mention of $1,000 was enacted in 1972 (Pub. L. 92–516).

[78 FR 66647, Nov. 6, 2013, as amended at 81 FR 43094, July 1, 2016; 82 FR 3635, Jan. 12, 2017; 83 FR 1192, Jan. 10, 2018; 84 FR 2058, Feb. 6, 2019]

PART 20—CERTIFICATION OF FACILITIES

AUTHORITY: Secs. 301, 704, 80 Stat. 379, 83 Stat. 667; 5 U.S.C. 301, 26 U.S.C. 169.

SOURCE: 36 FR 22382, Nov. 25, 1971, unless otherwise noted.

§ 20.1 Applicability.

The regulations of this part apply to certifications by the Administrator of water or air pollution control facilities for purposes of section 169 of the Internal Revenue Code of 1954, as amended, 26 U.S.C. 169, as to which the amortization period began after December 31, 1975. Certification of air or water pollution control facilities as to which the amortization period began before January 1, 1976, will continue to be governed by Environmental Protection Agency regulations published November 25, 1971, at 36 FR 22382. Applicable regulations of the Department of Treasury are at 26 CFR 1.169 *et seq*.

[43 FR 1340, Jan. 9, 1978]

§ 20.2 Definitions.

As used in this part, the following terms shall have the meaning indicated below:

(a) *Act* means, when used in connection with water pollution control facilities, the Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 *et seq*.) or, when used in connection with air pollution control facilities, the Clean Air Act, as amended (42 U.S.C. 1857 *et seq*.).

(b) *State certifying authority* means:

(1) For water pollution control facilities, the State pollution control agency as defined in section 502 of the Act.

(2) For air pollution control facilities, the air pollution control agency designated pursuant to section 302(b)(1) of the Act; or

(3) For both air and water pollution control facilities, any interstate agency authorized to act in place of the certifying agency of a State.

(c) *Applicant* means any person who files an application with the Administrator for certification that a facility is in compliance with the applicable regulations of Federal agencies and in furtherance of the general policies of the United States for cooperation with the States in the prevention and abatement of water or air pollution under the Act.

(d) *Administrator* means the Administrator, Environmental Protection Agency.

(e) *Regional Administrator* means the Regional designee appointed by the Administrator to certify facilities under this part.

(f) *Facility* means property comprising any new identifiable treatment facility which removes, alters, disposes of, stores, or prevents the creation of pollutants, contaminants, wastes, or heat.

(g) *State* means the States, the District of Columbia, the Commonwealth of Puerto Rico, the Canal Zone, Guam, American Samoa, the Virgin Islands, and the Trust Territory of the Pacific Islands.

[36 FR 22382, Nov. 25, 1971, as amended at 43 FR 1340, Jan. 9, 1978]

§ 20.3 General provisions.

(a) An applicant shall file an application in accordance with this part for each separate facility for which certification is sought; *Provided*, That one application shall suffice in the case of substantially identical facilities which the applicant has installed or plans to install in connection with substantially identical properties; *Provided further*, That an application may incorporate by reference material contained in an application previously submitted by the applicant under this part and pertaining to substantially identical facilities.

(b) The applicant shall, at the time of application to the State certifying authority, submit an application in the form prescribed by the Administrator

to the Regional Administrator for the region in which the facility is located.

(c) Applications will be considered complete and will be processed when the Regional Administrator receives the completed State certification.

(d) Applications may be filed prior or subsequent to the commencement of construction, acquisition, installation, or operation of the facility.

(e) An amendment to an application shall be submitted in the same manner as the original application and shall be considered a part of the original application.

(f) If the facility is certified by the Regional Administrator, notice of certification will be issued to the Secretary of the Treasury or his delegate, and a copy of the notice shall be forwarded to the applicant and to the State certifying authority. If the facility is denied certification, the Regional Administrator will advise the applicant and State certifying authority in writing of the reasons therefor.

(g) No certification will be made by the Regional Administrator for any facility prior to the time it is placed in operation and the application, or amended application, in connection with such facility so states.

(h) An applicant may appeal any decision of the Regional Administrator which:

(1) Denies certification;

(2) Disapproves the applicant's suggested method of allocating costs pursuant to § 20.8(e); or

(3) Revokes a certification pursuant to § 20.10.

Any such appeal may be taken by filing with the Administrator within 30 days from the date of the decision of the Regional Administrator a written statement of objections to the decision appealed from. Within 60 days after receipt of such appeal the Administrator shall affirm, modify, or revoke the decision of the Regional Administrator, stating in writing his reasons therefor.

[36 FR 22382, Nov. 25, 1971, as amended at 43 FR 1340, Jan. 9, 1978]

§ 20.4 Notice of intent to certify.

(a) On the basis of applications submitted prior to the construction, reconstruction, erection, acquisition, or operation of a facility, the Regional Administrator may notify applicants that such facility will be certified if:

(1) The Regional Administrator determines that such facility, if constructed, reconstructed, erected, acquired, installed, and operated in accordance with such application will be in compliance with requirements identified in § 20.8; and if

(2) The application is accompanied by a statement from the State certifying authority that such facility, if constructed, reconstructed, acquired, erected, installed, and operated in accordance with such application, will be in conformity with the State program or requirements for abatement or control of water or air pollution.

(b) Notice of actions taken under this section will be given to the appropriate State certifying authority.

§ 20.5 Applications.

Applications for certification under this part shall be submitted in such manner as the Administrator may prescribe, shall be signed by the applicant or agent thereof, and shall include the following information:

(a) Name, address, and Internal Revenue Service identifying number of the applicant;

(b) Type and narrative description of the new identifiable facility for which certification is (or will be) sought, including a copy of schematic or engineering drawings, and a description of the function and operation of such facility;

(c) Address (or proposed address) of facility location;

(d) A general description of the operation in connection with which the facility is (or will be) used and a description of the specific process or processes resulting in discharges or emissions which are (or will be) controlled or prevented by the facility.

(e) If the facility is (or will be) used in connection with more than one plant or other property, one or more of which were not in operation before January 1, 1976, a description of the operations of the facility in respect to each plant or other property, including a reasonable allocation of the costs of the facility among the plants being serviced, and a description of the reasoning and accounting method or

methods used to arrive at these allocations.

(f) A description of the effect of the facility in terms of type and quantity of pollutants, contaminants, wastes, or heat, removed, altered, stored, disposed of, or prevented by the facility.

(g) If the facility performs a function other than removal, alteration, storage, prevention, or disposal of pollutants, contaminants, wastes, or heat, a description of all functions performed by the facility, including a reasonable identification of the costs of the facility allocable to removal, alteration, storage, prevention, or disposal of pollutants, contaminants, wastes, or heat and a description of the reasoning and accounting method or methods used to arrive at the allocation.

(h) Date when such construction, reconstruction, or erection will be completed or when such facility was (or will be) acquired;

(i) Date when such facility is placed (or is intended to be placed) in operation;

(j) Identification of the applicable State and local water or air pollution control requirements and standards, if any;

(k) Expected useful life of facility;

(l) Cost of construction, acquisition, installation, operation, and maintenance of the facility;

(m) Estimated profits reasonably expected to be derived through the recovery of wastes or otherwise in the operation of the facility over the period referred to in paragraph (a)(6) of 26 CFR 1.169–2;

(n) The percentage (if any, and if the taxpayer claims that the percentage is 5 percent or less) by which the facility (1) increases the output or capacity, (2) extends the useful life, or (3) reduces the total operating costs of the operating unit of the plant or other property most directly associated with the pollution control facility and a description of the reasoning and accounting method or methods used to arrive at this percentage.

(o) Such other information as the Administrator deems necessary for certification.

[36 FR 22382, Nov. 25, 1971, as amended at 43 FR 1340, Jan. 9, 1978]

§ 20.6 State certification.

The State certification shall be by the State certifying authority having jurisdiction with respect to the facility in accordance with 26 U.S.C. 169(d)(1)(A) and (d)(2). The certification shall state that the facility described in the application has been constructed, reconstructed, erected, or acquired in conformity with the State program or requirements for abatement or control of water or air pollution. It shall be executed by an agent or officer authorized to act on behalf of the State certifying authority.

§ 20.7 General policies.

(a) The general policies of the United States for cooperation with the States in the prevention and abatement of water pollution are: To enhance the quality and value of our water resources; to eliminate or reduce the pollution of the nation's waters and tributaries thereof; to improve the sanitary condition of surface and underground waters; and to conserve such waters for public water supplies, propagation of fish and aquatic life and wildlife, recreational purposes, and agricultural, industrial, and other legitimate uses.

(b) The general policy of the United States for cooperation with the States in the prevention and abatement of air pollution is to cooperate with and to assist the States and local governments in protecting and enhancing the quality of the Nation's air resources by the prevention and abatement of conditions which cause or contribute to air pollution which endangers the public health or welfare.

§ 20.8 Requirements for certification.

(a) Subject to § 20.9, the Regional Administrator will certify a facility if he makes the following determinations:

(1) It has been certified by the State certifying authority.

(2) That the facility:

(i) Removes, alters, disposes of, stores, or prevents the creation of pollutants, contaminants, wastes, or heat, which, but for the facility, would be released into the environment;

(ii) Does not by a factor or more than 5 percent: (A) Increase the output or capacity, (B) extend the useful life, or (C) reduce the total operating costs of

the operating unit (of the plant or other property) most directly associated with the pollution control facility; and

(iii) Does not significantly alter the nature of the manufacturing or production process or facility.

(3) The applicant is in compliance with all regulations of Federal agencies applicable to use of the facility, including conditions specified in any NPDES permit issued to the applicant under section 402 of the Act.

(4) The facility furthers the general policies of the United States and the States in the prevention and abatement of pollution.

(5) The applicant has complied with all the other requirements of this part and has submitted all requested information.

(b) In determining whether use of a facility furthers the general policies of the United States and the States in the prevention and abatement of water pollution, the Regional Administrator shall consider whether such facility is consistent with the following, insofar as they are applicable to the waters which will be affected by the facility:

(1) All applicable water quality standards, including water quality criteria and plans of implementation and enforcement established pursuant to section 303 of the Act or State laws or regulations;

(2) Decisions issued pursuant to section 310 of the Act;

(3) Water pollution control programs required pursuant to any one or more of the following sections of the Act: Section 306, section 307, section 311, section 318, or section 405; or in order to be consistent with a plan under section 208.

(c) In determining whether use of a facility furthers the general policies of the United States and the States in the prevention and abatement of air pollution, the Regional Administrator shall consider whether such facility is consistent with and meets the following requirements, insofar as they are applicable to the air which will be affected by the facility;

(1) Plans for the implementation, maintenance, and enforcement of ambient air quality standards adopted or promulgated pursuant to section 110 of the Act;

(2) Recommendations issued pursuant to sections 103(e) and 115 of the Act which are applicable to facilities of the same type and located in the area to which the recommendations are directed;

(3) Local government requirements for control of air pollution, including emission standards;

(4) Standards promulgated by the Administrator pursuant to the Act.

(d) A facility that removes elements or compounds from fuels that would be released as pollutants when such fuels are burned is eligible for certification if the facility is—

(1) Used in connection with a plant or other property in operation before January 1, 1976 (whether located and used at a particular plant or as a centralized facility for one or more plants), and

(2) Is otherwise eligible for certification.

(e) Where a facility is used in connection with more than one plant or other property, one or more of which were not in operation before January 1, 1976, or where a facility will perform a function other than the removal, alteration, storage, disposal, or prevention of pollutants, contaminants, wastes, or heat, the Regional Administrator will so indicate on the notice of certification and will approve or disapprove the applicant's suggested method of allocating costs. If the Regional Administrator disapproves the applicant's suggested method, he shall identify the proportion of costs allocable to each such plant, or to the removal, alteration, storage, disposal, or prevention of pollutants, contaminants, wastes, or heat.

[36 FR 22382, Nov. 25, 1971, as amended at 43 FR 1341, Jan. 9, 1978]

§ 20.9 Cost recovery.

Where it appears that, by reason of estimated profits to be derived through the recovery of wastes, through separate charges for use of the facility in question, or otherwise in the operation of such facility, all or a portion of its costs may be recovered over the period referred to in paragraph (a)(6) of 26 CFR 1.169–2, the Regional Administrator shall so signify in the notice of

certification. Determinations as to the meaning of the term *estimated profits* and as to the percentage of the cost of a certified facility which will be recovered over such period shall be made by the Secretary of the Treasury, or his delegate: *Provided*, That in no event shall estimated profits be deemed to arise from the use or reuse by the applicant of recovered waste.

§ 20.10 Revocation.

Certification hereunder may be revoked by the Regional Administrator on 30 days written notice to the applicant, served by certified mail, whenever the Regional Administrator shall determine that the facility in question is no longer being operated consistent with the § 20.8 (b) and (c) criteria in effect at the time the facility was placed in service. Within such 30-day period, the applicant may submit to the Regional Administrator such evidence, data or other written materials as the applicant may deem appropriate to show why the certification hereunder should not be revoked. Notification of a revocation under this section shall be given to the Secretary of the Treasury or his delegate. See 26 CFR 1.169–4(b)(1).

APPENDIX A TO PART 20—GUIDELINES FOR CERTIFICATION

1. *General.* Section 2112 of the Tax Reform Act of 1976 (Pub. L. 94–455, October 4, 1976) amended section 169 of the Internal Revenue Code of 1954, ''Amortization of Pollution Control Facilities.'' The amendment made permanent the rapid amortization provisions of section 704 of the Tax Reform Act of 1969 (Pub. L. 91–172, December 30, 1969) and redefined eligibility limits to allow certification of facilities which prevent the creation or emission of pollutants.

The law defines a *certified pollution control facility* as *a new identifiable treatment facility* which is:

(a) Used in connection with a plant or other property in operation before January 1, 1976, to abate or control air or water pollution by removing, altering, disposing of, storing, or preventing the creation or emission of pollutants, contaminants, wastes, or heat;

(b) Constructed, reconstructed, erected or (if purchased) first placed in service by the taxpayer after December 31, 1975;

(c) Not to *significantly* increase the output or capacity, extend the useful life, alter the nature of the manufacturing or production process or facility or reduce the total operating costs of the operating unit of the plant or other property most directly associated with the pollution control facility (as suggested by the legislative history, EPA regulations define the term *significant* as any increase, reduction or extension greater than 5%); and

(d) Certified by both State and Federal authorities, as provided in section 169(d)(1) (A) and (B) of the Internal Revenue Code.

If the facility is a building, the statute requires that it be exclusively devoted to pollution control. Most questions as to whether a facility is a *building* and, if so, whether it is *exclusively* devoted to pollution control are resolved by § 1.169–2(b)(2) of the Treasury Department regulations.

Since a treatment facility is eligible only if it furthers the general policies of the United States under the Clean Air Act and the Clean Water Act, a facility will be certified only if its purpose is to improve the quality of the air or water outside the plant. Facilities to protect the health or safety of employees inside the plant are not eligible.

Facilities installed before January 1, 1976, in plants placed in operation after December 31, 1968, are ineligible for certification under the statute. 26 U.S.C. 169.

2. *Air pollution control facilities.*

a. *Pollution control or treatment facilities normally eligible for certification.* The following devices are illustrative of facilities for removal, alteration, disposal, storage or preventing the creation or emission of air pollution:

(1) Inertial separators (cyclones, etc.).
(2) Wet collection devices (scrubbers).
(3) Electrostatic precipitators.
(4) Cloth filter collectors (baghouses).
(5) Director fired afterburners.
(6) Catalytic afterburners.
(7) Gas absorption equipment.
(8) Vapor condensers.
(9) Vapor recovery systems.
(10) Floating roofs for storage tanks.
(11) Fuel cleaning equipment.
(12) Combinations of the above.

(b) *Air Pollution control facility boundaries.* Most facilities are systems consisting of several parts. A facility need not start at the point where the gaseous effluent leaves the last unit of the processing equipment, nor will it always extend to the point where the effluent is emitted to the atmosphere or existing stack, breeching, ductwork or vent. It includes all the auxiliary equipment used to operate the control system, such as fans, blowers, ductwork, valves, dampers and electrical equipment. It also includes all equipment used to handle, store, transport or dispose of the collected pollutants.

(c) *Examples of eligibility limits.* The amortization deduction is limited to new identifiable treatment facilities which remove, alter, destroy, dispose of, store, or prevent the creation or emission of pollutants, contaminants or wastes. It is not available for all expenditures for air pollution control and is limited to devices which are installed for the purpose of pollution control and which actually remove, alter, destroy, dispose of, store or prevent the creation or emission of pollutants by removing potential pollutants at any stage of the production process.

(1) *Boiler modifications or replacements.* Modifications of boilers to accommodate *cleaner* fuels are not eligible for rapid amortization: e.g., removal of stokers from a coal-fired boiler and the addition of gas or oil burners. The purpose of the burners is to produce heat, and they are not identifiable as treatment facilities nor do they prevent the creation or emission of pollutants by removing potential pollutants. A new gas or oil-fired boiler that replaces a coal-fired boiler would also be ineligible for certification.

(2) *Fuel processing.* Eligible air pollution control facilities include preprocessing equipment which removes potential air pollutants from fuels before they are burned. A desulfurization facility would thus be eligible provided it is used in connection with the plant where the desulfurized coal will be burned or is used as a centralized facility for one or more plants. However, fluidized bed facilities would generally not be eligible for rapid amortization. Such facilities would almost certainly increase output or capacity, reduce total operating costs, or extend the useful life of the plant or other property by more than 5%, since the boiler itself would be the operating unit of the plant most closely associated with the pollution control facility. Where the Regional Office and the taxpayer disagree as to the applicability of the 5% rule, the Regional office should nonetheless certify the facility if it is otherwise eligible and leave the ultimate determination to the Treasury Department. The certification should alert Treasury to the possibility that the facility is ineligible for rapid amortization.

(3) *Incinerators.* The addition of an afterburner, secondary combustion chamber or particulate collector would be eligible as would any device added to effect more efficient combustion.

(4) *Collection devices used to collect products or process material.* In some manufacturing operations, devices are used to collect product or process material, as in the case of the manufacture of carbon black. The baghouse would be eligible for certification, but the certification should notify the Treasury Department of the profitable waste recovery involved. (See paragraph 8 below.)

(5) *Intermittent control systems.* Measuring devices which inform the taxpayer that ambient air quality standards are being exceeded are not eligible for certification since they do not physically remove, alter, destroy, dispose of, store or prevent the creation or emission of pollutants, but merely act as a signal to curtail operations. Of course, measuring devices used in connection with an eligible pollution control facility would be eligible.

d. *Replacement of manufacturing process by another, nonpolluting process.* An installation does not qualify for certification where it uses a process known to be *cleaner* than an alternative, but which does not actually remove, alter, destroy, dispose of, store or prevent the creation or emission of pollutants by removing potential pollutants at any stage in the production process. For example, a minimally polluting electric induction furnace to melt cast iron which replaces, or is installed instead of, a heavily polluting iron cupola furnace would be ineligible for this reason and because it is not an identifiable treatment facility. However, if the replacement equipment has an air pollution control device added to it, the control device would be eligible even though the process equipment would not. For example, where a primary copper smelting reverberatory furnace is replaced by a flash smelting furnace, followed by the installation of a contact sulfuric acid plant, the acid plant would qualify since it is a control device not necessary to the production process. The flash smelting furnace would not qualify because its purpose is to produce copper matte.

3. *Water Pollution Control Facilities.*

a. *Pollution control or treatment facilities normally eligible for certification.* The following types of equipment are illustrative of facilities to remove, alter, destroy, store or prevent the creation of water pollution:

(1) Pretreatment facilities which neutralize or stabilize industrial or sanitary wastes, or both, from a point immediately preceding the point of such treatment to the point of disposal to, and acceptance by, a publicly-owned treatment works. The necessary pumping and transmitting facilities are also eligible.

(2) Treatment facilities which neutralize or stabilize industrial or sanitary wastes, or both, to comply with Federal, State or local

effluent or water quality standards, from a point immediately preceding the point of such treatment to the point of disposal, including necessary pumping and transmitting facilities, including those for recycle or segregation of wastewater.

(3) Ancillary devices and facilities such as lagoons, ponds and structures for storage, recycle, segregation or treatment, or any combination of these, of wastewaters or wastes from a plant or other property.

(4) Devices, equipment or facilities constructed or installed for the primary purpose of recovering a by-product of the operation (saleable or otherwise) previously lost either to the atmosphere or to the waste effluent. Examples are:

(A) A facility to concentrate and recover vaporous by-products from a process stream for reuse as raw feedstock or for resale, unless the estimated profits from resale exceed the cost of the facility (see paragraph 8 below).

(B) A facility to concentrate or remove *gunk* or similar *tars* or polymerized tar-like materials from the process waste effluent previously discharged in the plant effluents. Removal may occur at any stage of the production process.

(C) A device used to extract or remove insoluble constitutents from a solid or liquid by use of a selective solvent; an open or closed tank or vessel in which such extraction or removal occurs; a diffusion battery of tanks or vessels for countercurrent decantation, extraction, or leaching, etc.

(D) A skimmer or similar device for removing grease, oils and fat-like materials from the process or effluent stream.

(b) *Examples of eligibility limits.* (1) In-plant process changes which may result in the reduction or elimination of pollution but which do not themselves remove, alter, destroy, dispose of, store or prevent the creation of pollutants by removing potential pollutants at some point in the process stream are not eligible for certification.

(2) A device, piece of equipment or facility is not eligible if it is associated with or included in a stream for subsurface injection of untreated or inadequately treated industrial or sanitary waste.

4. *Multiple-purpose facilities.* A facility can qualify for rapid amortization if it serves a function other than the abatement of pollution (unless it is a building). Otherwise, the effect might be to discourage installation of sensible pollution abatement facilities in favor of less efficient single-function facilities.

The regulations require applicants to state what percentage of the cost of a facility is properly allocable to its abatement function and to justify the allocation. The Regional Office will review these allocations, and the certification will inform the Treasury Department if the allocation appears to be incorrect. Although not generally necessary or desireable, site inspections may be appropriate in cases involving large sums of money or unusual types of equipment.

5. *Facilities serving both old and new plants.* The statute provides that pollution control facilities must be used in connection with a plant or other property in operation before January 1, 1976. When a facility is used in connection with both pre-1976 and newer property, it may qualify for rapid amortization to the extent it is used in connection with pre-1976 property.

Again, the applicant will submit a theory of allocation for review by the Regional Office. The usual method of allocation is to compare the effluent capacity of the pre-1976 plant to the treatment capacity of the control facility. For example, if the old plant has a capacity of 80 units of effluent (but an average output of 60 units), the new plant has a capacity of 40 units (but an average output of 20 units), and the control facility has a capacity of 150 units, then $^{80}/_{150}$ of the cost of the control facility would be eligible for rapid amortization.

If a taxpayer presents a seemingly reasonable method of allocation different from the foregoing, Regional Office personnel should consult with the Office of Air Quality Planning and Standards or the Office of Water Planning and Standards, and with the Office of General Counsel.

6. *State certification.* To qualify for rapid amortization under section 169, a facility must first be certified by the State as having been installed ''in conformity with the State program or requirements for abatement or control of water or atmospheric pollution or contamination.'' Significantly, the statute does not say that the State must require that a facility be installed. If use of a facility will not actually contravene a State requirement, the State may certify. However, since State certification is a prerequisite to EPA certification, EPA may not certify if the State has denied certification for whatever reason.

It should be noted that certification of a facility does not constitute the personal warranty of the certifying official that the conditions of the statute have been met. EPA certification is binding on the Government only to the extent the submitted facts are accurate and complete.

7. *Dispersal of pollutants.* Section 169 applies to facilities which remove, alter, destroy, dispose of, store or prevent the creation or emission of pollutants—including heat. Facilities which merely disperse pollutants (such as tall stacks) do not qualify. However, there is no way to *dispose of* heat other than by transferring B.t.u.'s to the environment. A cooling tower is therefore eligible for certification provided it is used in connection with a pre-1976 plant. A cooling pond or an

addition to an outfall structure which results in a decrease in the amount by which the temperature of the receiving water is raised and which meets applicable State standards is likewise eligible.

8. *Profit-making facilities.* The statute denies rapid amortization where the cost of pollution control facilities will be recovered from profits derived through the recovery or wastes *or otherwise.*

If a facility recovers marketable wastes, estimated profits on which are not sufficient to recover the entire cost of the facility, the amortization basis of the facility will be reduced in accordance with Treasury Department regulations. The responsibility of the Regional Offices is merely to identify for the Treasury Department those cases in which estimated profits will arise. The Treasury Department will determine the amount of such profits and the extent to which they can be expected to result in cost recovery, but the EPA certification should inform the Treasury whether cost recovery is possible.

The phrase *or otherwise* also includes situations where the taxpayer is in the business of renting the facility for a fee or charging for the treatment of waste. In such cases, the facility may theoretically qualify for EPA certification. The decision as to the extent of its profitability is for the Treasury Department. Situations may also arise where use of a facility is furnished at no additional charge to a number of users, or to the public, as part of a package of other services. In such cases, no profits will be deemed to arise from operation of the facility unless the other services included in the package are merely ancillary to use of the facility. Of course, the cost recovery provision does not apply where a taxpayer merely recovers the cost of a facility through general revenues; otherwise no profitable firm would ever be eligible for rapid amortization.

It should be noted that §20.9 of the EPA regulation is not meant to affect general principles of Federal income tax law. An individual other than the title holder of a piece of property may be entitled to take depreciation deductions on it if the arrangements by which such individual has use of the property may, for all practical purposes, be viewed as a purchase. In any such case, the facility could qualify for full rapid amortization, notwithstanding the fact that the title holder charges a separate fee for the use of the facility, so long as the taxpayer—in such a case, the user—does not charge a separate fee for use of the facility.

9. *Multiple applications.* Under EPA regulations, a multiple application may be submitted by a taxpayer who applies for certification of substantially identical pollution abatement facilities used in connection with substantially identical properties. It is not contemplated that the multiple application option will be used with respect to facilities in different States, since each such facility would require a separate application for certification to the State involved. EPA regulations also permit an applicant to incorporate by reference in an application material contained in an application previously filed. The purpose of this provision is to avoid the burden of furnishing detailed information (which may in some cases include portions of catalogs or process flow diagrams) which the certifying official has previously received. Accordingly, material filed with a Regional Office of EPA may be incorporated by reference only in an application subsequently filed with the same Regional Office.

[47 FR 38319, Aug. 31, 1982]

PART 21—SMALL BUSINESS

Sec.

AUTHORITY: 15 U.S.C. 636, as amended by Pub. L. 92–500.

SOURCE: 42 FR 8083, Feb. 8, 1977, unless otherwise noted.

§21.1 Scope.

This part establishes procedures for the issuance by EPA of the statements, referred to in section 7(g) of the Small Business Act and section 8 of the Federal Water Pollution Control Act Amendments of 1972, to the effect that additions to or alterations in the equipment, facilities (including the construction of pretreatment facilities and interceptor sewers), or methods of operations of small business concerns are necessary and adequate to comply with requirements established under the Federal Water Pollution Control Act, 33 U.S.C. 1151, *et seq.*

§21.2 Definitions.

(a) *Small business concern* means a concern defined by section 2[3] of the Small Business Act, 15 U.S.C. 632, 13 CFR part 121, and regulations of the

Small Business Administration promulgated thereunder.

(b) For purposes of paragraph 7(g)(2) of the Small Business Act, *necessary and adequate* refers to additions, alterations, or methods of operation in the absence of which a small business concern could not comply with one or more applicable standards. This can be determined with reference to design specifications provided by manufacturers, suppliers, or consulting engineers; including, without limitations, additions, alterations, or methods of operation the design specifications of which will provide a measure of treatment or abatement of pollution in excess of that required by the applicable standard.

(c) *Applicable Standard* means any requirement, not subject to an exception under §21.6, relating to the quality of water containing or potentially containing pollutants, if such requirement is imposed by:

(1) The Act;

(2) EPA regulations promulgated thereunder or permits issued by EPA or a State thereunder;

(3) Regulations by any other Federal Agency promulgated thereunder;

(4) Any State standard or requirement as applicable under section 510 of the Act;

(5) Any requirements necessary to comply with an areawide management plan approved pursuant to section 208(b) of the Act;

(6) Any requirements necessary to comply with a facilities plan developed under section 201 of the Act (see 35 CFR, subpart E);

(7) Any State regulations or laws controlling the disposal of aqueous pollutants that may affect groundwater.

(d) *Regional Administrator* means the Regional Administrator of EPA for the region including the State in which the facility or method of operation is located, or his designee.

(e) *Act* means the Federal Water Pollution Control Act, 33 U.S.C. 1151, *et seq.*

(f) *Pollutant* means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water. For the purposes of this section, the term also means sewage from vessels within the meaning of section 312 of the Act.

(g) *Permit* means any permit issued by either EPA or a State under the authority of section 402 of the Act; or by the Corps of Engineers under section 404 of the Act.

(h) *State* means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

Comment: As the SBA does not extend its programs to the Canal Zone, the listing of the Canal Zone as a State for the purposes of meeting a requirement imposed by section 311 or 312 of the Act is not effective in this regulation.

(i) *Statement* means a written approval by EPA, or if appropriate, a State, of the application.

(j) *Facility* means any building, structure, installation or vessel, or portion thereof.

(k) *Construction* means the erection, building, acquisition, alteration, remodeling, modification, improvement, or extension of any facility; *Provided,* That it does not mean preparation or undertaking of: Plans to determine feasibility; engineering, architectural, legal, fiscal, or economic investigations or studies; surveys, designs, plans, writings, drawings, specifications or procedures.

Comment: This provision would not later preclude SBA financial assistance being utilized for any planning or design effort conducted previous to construction.

(l) The term *additions and alterations* means the act of undertaking construction of any facility.

(m) The term *methods of operation* means the installation, emplacement, or introduction of materials, including those involved in construction, to achieve a process or procedure to control: Surface water pollution from nonpoint sources—that is, agricultural, forest practices, mining, construction; ground or surface water pollution from well, subsurface, or surface disposal operations; activities resulting in salt water intrusion; or changes in the

movement, flow, or circulation of navigable or ground waters.

(n) The term *vessel* means every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on the navigable waters of the United States other than a vessel owned or operated by the United States or a State or a political subdivision thereof, or a foreign nation; and is used for commercial purposes by a small business concern.

(o) *EPA* means the Environmental Protection Agency.

(p) *SBA* means the Small Business Administration.

(q) *Areawide agency* means an areawide management agency designated under section 208(c)(1) of the Act.

(r) *Lateral sewer* means a sewer which connects the collector sewer to the interceptor sewer.

(s) *Interceptor sewer* means a sewer whose primary purpose is to transport wastewaters from collector sewers to a treatment facility.

§ 21.3 Submission of applications.

(a) Applications for the statement described in § 21.5 of this part shall be made to the EPA Regional Office for the region covering the State in which the additions, alterations, or methods of operation covered by the application are located. A listing of EPA Regional Offices, with their mailing addresses, and setting forth the States within each region is as follows:

Region	Address	State
I	Regional Administrator, Region I, EPA, 5 Post Office Square—Suite 100, Boston, MA 02109–3912.	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
II	Regional Administrator, region II, EPA, 26 Federal Plaza, room 908, New York, NY 10007.	New Jersey, New York, Virgin Islands, and Puerto Rico.
III	Regional Administrator, region III, EPA, Curtis Bldg., 6th and Walnut Sts., Philadelphia, PA 19106.	Delaware, District of Columbia, Pennsylvania, Maryland, Virginia, and West Virginia.
IV	Regional Administrator, region IV, EPA, 345 Courtland St. NE., Atlanta, GA 30308.	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.
V	Regional Administrator, region V, EPA, 77 West Jackson Boulevard, Chicago, IL 60604.	Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.
VI	Regional Administrator, region VI, EPA, 1201 Elm St., 27th floor, First International Bldg., 70 Dallas, TX 75201.	Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.
VII	Regional Administrator, EPA Region VII, 11201 Renner Boulevard, Lenexa, Kansas 66219.	Iowa, Kansas, Missouri, and Nebraska.
VIII	Regional Administrator, region VIII, EPA, 1860 Lincoln St., Suite 900, Denver, CO 80203.	Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.
IX	Regional Administrator, Region IX, EPA, 75 Hawthorne St., San Francisco, CA 94105.	Arizona, California, Hawaii, Nevada, the territories of American Samoa and Guam; the Commonwealth of the Northern Mariana Islands; the territories of Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Atoll, Palmyra Atoll, and Wake Islands; and certain U.S. Government activities in the freely associated states of the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.
X	Regional Administrator, region X, EPA, 1200 6th Ave., Seattle, WA 98101.	Alaska, Idaho, Oregon, and Washington.

(b) An application described in paragraph (1) of § 21.3(c) may be submitted directly to the appropriate State, where a State has assumed responsibility for issuing the statement. Information on whether EPA has retained responsibility for certification or whether it has been assumed by the State may be obtained from either the appropriate Regional Administrator or the State Water Pollution Control Authority in which the facility is located.

(c) An application need be in no particular form, but it must be in writing and must include the following:

(1) Name of applicant (including business name, if different) and mailing address. Address of the affected facility or operation, if different, should also be included.

(2) Signature of the owner, partner, or principal executive officer requesting the statement.

(3) The Standard Industrial Classification number for the business for which an application is being submitted. Such SIC number shall be obtained from the Standard Industrial Classification Manual, 1972 edition. If the applicant does not know the SIC for the business, a brief description of the type of business activity being conducted should be provided.

(4) A description of the process or activity generating the pollution to be abated by the additions, alterations, or methods of operation covered by the application, accompanied by a schematic diagram of the major equipment and process, where practicable.

(5) A specific description of the additions, alterations, or methods of operation covered by the application. Where appropriate, such description will include a summary of the facility construction to be undertaken; a listing of the major equipment to be purchased or utilized in the operation of the facility; the purchase of any land or easements necessary to the operation of the facility; and any other items that the applicant deems pertinent. Any information that the applicant considers to be a trade secret shall be identified as such.

(6) A declaration of the requirement, or requirements, for compliance with which the alterations, additions, or methods of operation are claimed to be necessary and adequate.

(i) If the requirement results from a permit issued by EPA or a State under section 402 of the Act, the permit number shall be included.

(ii) If the requirement results from a permit issued by EPA or a State for a publicly-owned treatment works, the municipal permit number shall be included along with a written declaration from the authorized agent for the publicly owned treatment works that received the permit detailing the specific pretreatment requirements being placed upon the applicant.

(iii) If the requirement initiates from a plan to include the applicant's effluent in an existing municipal sewer system through the construction of lateral or interceptor sewers, a written declaration from the authorized agent for the publicly owned treatment works shall be included noting that the sewer construction is consistent with the integrity of the system; will not result in the capacity of the publicly owned treatment works being exceeded; and where applicable, is consistent with a facilities plan developed under section 201 of the Act (see 35 CFR part 917).

(iv) If the requirement results from a State order, regulation, or other enforceable authority controlling pollution from a vessel as provided by section 312(f)(3) of the Act, a written declaration from the authorized agent of the State specifying the control measures being required of the applicant shall be included.

(v) If the requirement is a result of a permit issued by the Corps of Engineers related to permits for dredged or fill material as provided by section 404 of the Act, a copy of the permit as issued shall be included.

(vi) If the requirement results from a standard of performance for control of sewage from vessels as promulgated by the Coast Guard under section 312(b) of the Act, the vessel registration number or documentation number shall be included.

(vii) If the requirement results from a plan to control or prevent the discharge or spill of pollutants as identified in section 311 of the Act, the title and date of that plan shall be included.

(viii) If the requirement is the result of an order by a State or an areawide management agency controlling the disposal of aqueous pollutants so as to protect groundwater, a copy of the order as issued shall be included.

(7) Additionally, if the applicant has received from a State Water Pollution Control Agency a permit issued by the State within the preceding two years, and if such permit was not issued under the authorities of section 402 of the Act, and where the permit directly relates to abatement of the discharge for which a statement is sought, a copy of that permit shall also be included.

Comment: Some States under State permit programs, separate and distinct from the NPDES permit program under the Act, conduct an engineering review of the facilities or equipment that would be used to control

pollution. The results of such a review would be materially helpful in determining the necessity and adequacy of any alterations or additions.

(8) Any written information from a manufacturer, supplier, or consulting engineer, or similar independent source, concerning the design capabilities of the additions or alterations covered by the application, including any warranty limitations or certifications obtained from or provided by such sources which would bear upon these design or performance capabilities. The Regional Administrator may waive the requirement for this paragraph if it appears that there is no independent source for the information described herein; as, for example, when the applicant has designed and constructed the additions or alterations with in-house capability.

(9) An estimated schedule for the construction or implementation of the alterations, additions, or methods of operation.

(10) An estimated cost of the alterations, additions, or methods of operation, and where practicable, the individual costs of major elements of the construction to be undertaken.

(11) Information on previously received loan assistance under this section for the facility or method of operation, including a description and dates of the activity funded.

(d) A separate application must be submitted for every addition, alteration, or method of operation that is at a separate geographical location from the initial application.

Comment: As an example, a chain has four dry cleaning establishments scattered through a community. A separate application would have to be filed for each.

(e) No statement shall be approved for any application that has not included the information or declaration requirements imposed by paragraph (c)(6) of § 21.3.

(f) All applications are to be submitted in duplicate.

(g) All applications are subject to the provisions of 18 U.S.C. 1001 regarding prosecution for the making of false statements or the concealing of material facts.

(h) Instructional guidelines to assist in the submission of applications for EPA certification are available from EPA or a certifying State.

[42 FR 8083, Feb. 8, 1977, as amended at 62 FR 1833, Jan. 14, 1997; 75 FR 69349, Nov. 12, 2010; 76 FR 49671, Aug. 11, 2011; 78 FR 37975, June 25, 2013]

§ 21.4 Review of application.

(a) The Regional Administrator or his designee will conduct a review of the application. This review will consist of a general assessment of the adequacy of the proposed alterations, additions, or methods of operation. The review will corroborate that the proposed alterations, additions, or methods of operation are required by an applicable standard. The review will identify any proposed alterations, additions, or methods of operation that are not required by an applicable standard, or that are extraneous to the achievement of an applicable standard.

(b) The assessment of adequacy will be conducted to ensure that the proposed additions, alterations, or methods of operation are sufficient to meet one or more applicable standards whether alone or in conjunction with other plans. The assessment will not generally examine whether other alternatives exist or would be more meritorious from a cost-effective, efficiency, or technological standpoint.

(c) An application which proposes additions, alterations, or methods of operation whose design, in anticipation of a future requirement, will achieve a level of performance above the requirements imposed by a presently applicable standard shall be reviewed and approved by EPA or a State without prejudice. The amount of financial assistance for such an application will be determined by SBA.

(d) The Regional Administrator shall retain one copy of the application and a summary of the action taken on it. Upon completion of his review, the Regional Administrator shall return the original application along with any other supporting documents or information provided to the applicant along with a copy to the appropriate SBA district office for processing.

§ 21.5 Issuance of statements.

(a) Upon application by a small business concern pursuant to § 21.3 the Regional Administrator will, if he finds that the additions, alterations, or methods of operation covered by the application are adequate and necessary to comply with an applicable standard, issue a written statement to the applicant to that effect, within 45 working days following receipt of the application, or within 45 working days following receipt of all information required to be submitted pursuant to § 21.3(c), whichever is later. Such a written statement shall be classified as a full approval. If an application is deficient in any respect, with regard to the specifications for submission listed in § 21.3(c), the Regional Administrator shall promptly, but in no event later than 30 working days following receipt of the application, notify the applicant of such deficiency.

(b)(1) If an application contains proposed alterations, additions, or methods of operation that are adequate and necessary to comply with an applicable standard but also contains proposed alterations, additions, or methods of operation that are not necessary to comply with an applicable standard, the Regional Administrator shall conditionally approve the application within the time limit specified in paragraph (a) of this section, and shall also identify in the approval those alterations, additions, or methods of operation that he determines are not necessary.

(2) Conditional approvals as contained in a statement will satisfy the requirements for approval by EPA for those alterations, additions, or methods of operation determined to be necessary and adequate. Such conditional approvals may be submitted to SBA in satisfaction of the requirements of section 7(g)(2)(B) of the Small Business Act.

(3) Conditional approvals will not satisfy the requirements for approval by EPA for those alterations, additions, or methods of operation included in the application that are determined not to be necessary. Unnecessary alterations, additions, or methods of operation are those which are extraneous to the achievement of an applicable standard.

(4) Conditional approvals may be appealed to the Deputy Administrator by an applicant in accordance with the procedures identified in § 21.8.

(c) If the Regional Administrator determines that the additions, alterations, or methods of operation covered by an application are not necessary and adequate to comply with an applicable standard, he shall disapprove the application and shall so advise the applicant of such determination within the time limit specified in paragraph (a) of this section, and shall state in writing the reasons for his determination.

(d) Any application shall be disapproved if the Regional Administrator determines that the proposed addition, alteration, or method of operation would result in the violation of any other requirement of this Act, or of any other Federal or State law or regulation with respect to the protection of the environment.

(e) An applicant need not demonstrate that its facility or method of operation will meet all applicable requirements established under the Act. The applicant need only demonstrate that the additions, alterations, or methods of operation will assist in ensuring compliance with one or more of the applicable standards for which financial assistance is being requested.

Comment: As an example, a small business has two discharge pipes—one for process water, the other for cooling water. The application for loan assistance is to control pollution from the process water discharge. However, EPA or a State may review the applicant's situation and identify for SBA that the applicant is subject to other requirements for which the applicant has not sought assistance.

(f) An application should not include major alternative designs significantly differing in scope, concept, or capability. It is expected that the applicant at the time of submission will have selected the most appropriate or suitable design for the addition, alteration, or method of operation.

(g) EPA will not provide assistance in the form of engineering, design, planning or other technical services to any applicant in the preparation of his application.

(h) An applicant may be issued a certification for additions, alterations, or methods of operation constructed or undertaken before loan assistance was applied for by the applicant. Any such applications would be reviewed by SBA for eligibility under SBA criteria, including refinancing and loan exposure.

§ 21.6 Exclusions.

(a) Statements shall not be issued for applications in the following areas:

(1) *Local requirements.* Applications for statements for additions, alterations, or methods of operation that result from requirements imposed by municipalities, counties or other forms of local or regional authorities and governments, except for areawide management agencies designated and approved under section 208 of the Act, shall not be approved; except for those requirements resulting from the application of pretreatment requirements under section 307(b) of the Act; or those resulting from an approved project for facilities plans, and developed under section 201 of the Act. (See 35 CFR, subpart E); or under a delegation of authority under the Act.

(2) *Cost recovery and user charges.* Applications for statements involving a request for financial assistance in meeting revenue and service charges imposed upon a small business by a municipality conforming to regulations governing a user charge or capital cost system under section 204(b)(2) of the Act (see 35 CFR 925–11 and 925–12) shall not be approved.

(3) *New facility sewer construction.* Applications for statements involving projects that involve the construction of a lateral, collection, or interceptor sewer, at a facility that was not in existence on October 18, 1972, shall not be approved. Applications for additions, alterations, or methods of operation for new facilities that do not involve sewer construction are not affected by this preclusion. Further, if an applicant is compelled to move as a result of a relocation requirement but operated at the facility prior to October 18, 1972, the cost of construction for a lateral, collection, or interceptor sewer can be approved for the new, relocated site. For the purpose of this exclusion lateral, collection, or interceptor sewer is determined as any sewer transporting waste from a facility or site to any publicly owned sewer.

(4) Other non-water related pollution abatement additions, alterations, or methods of operation which are not integral to meeting the requirements of the Act, although they may be achieving the requirements of another Federal or State law or regulation.

Comment: An example would be where stack emission controls were required on equipment that operated the water pollution control facility. This emission control equipment as an integral part of the water pollution control systems would be approvable. However, emission control equipment for a general purpose incinerator that only incidentally burned sewage sludge would not be approvable. The general purpose incinerator might also receive loan assistance but under separate procedures than those set out for water pollution control.

(5) *Privately owned treatment facility service or user costs.* Applications for statements involving financial assistance in meeting user cost or fee schedules related to participating in a privately owned treatment facility not under the ownership or control of the applicant shall not be approved.

(6) *Operation and maintenance charges.* Applications for statements containing a request for financial assistance in meeting the operations and maintenance costs of operating the applicant's additions, alterations, or methods of operation shall not be approved for any elements relating to such areas of cost.

(7) *Evidence of financial responsibility.* Applications for statements containing a request for financial assistance in meeting any requirements relating to evidence of financial responsibility as provided in section 311(p) of the Act shall not be approved.

§ 21.7 [Reserved]

COMMENT: Applications for a statement resulting from a requirement to control pollution from non-point sources as identified in section 304(e)(2)(A–F) of the Act and described in § 21.2(m) will not presently be issued a statement under § 21.5 unless the requirement is established through a permit under section 402. There is no requirement under the current Act that the Federal Government control pollution from such sources, and the nature and scope of State or areawide management agency proposals or

programs to control such sources cannot be determined at this time. As State and areawide plans for control of nonpoint sources being prepared under section 208 of the Act, will not be completed for several years, this section is being reserved pending a future determination on the eligibility of applications relating to non-profit sources to receive a statement under this part.

§ 21.8 Resubmission of application.

(a) A small business concern whose application is disapproved may submit an amended or corrected application to the Regional Administrator at any time. The applicant shall provide the date of any previous application.

(b) [Reserved]

§ 21.9 Appeals.

(a) An applicant aggrieved by a determination of a Regional Administrator under § 21.5 may appeal in writing to the Deputy Administrator of the Environmental Protection Agency, within 30 days of the date of the determination from which an appeal is taken; *Provided,* That the Deputy Administrator may, on good cause shown, accept an appeal at a later time.

(b) The applicant in requesting such an appeal shall submit to the Deputy Administrator a copy of the complete application as reviewed by the Regional Administrator.

(c) The applicant should also provide information as to why it believes the determination made by the Regional Administrator to be in error.

(d) The Deputy Administrator shall act upon such appeal within 60 days of receipt of any complete application for a review of the determination.

(e) Where a State has been delegated certification authority, the procedure for appeals shall be established in the State submission required in § 21.12.

§ 21.10 Utilization of the statement.

(a) Statements issued by the Regional Administrator will be mailed to the small business applicant and to the district office of the Small Business Administration serving the geographic area where the business is located. It is the responsibility of the applicant to also forward the statement to SBA as part of the application for a loan.

(b) Any statement or determination issued under § 21.5 shall not be altered, modified, changed, or destroyed by any applicant in the course of providing such statement to SBA. To do so can result in the revocation of any approval contained in the statement and subject the applicant to the penalties provided in 18 U.S.C. 1001.

(c) If an application for which a statement is issued under § 21.5 is substantively changed in scope, concept, design, or capability prior to the approval by SBA of the financial assistance requested, the statement as issued shall be revoked. The applicant must resubmit a revised application under § 21.3 and a new review must be conducted. Failure to meet the requirements of this paragraph could subject the applicant to the penalties specified in 18 U.S.C. 1001 and 18 U.S.C. 286. A substantive change is one which materially affects the performance or capability of the proposed addition, alteration, or method of operation.

(d) An agency, Regional Administrator, or State issuing a statement under § 21.5 shall retain a complete copy of the application for a period of five years after the date of issuance of the statement. The application shall be made available upon request for inspection or use at any time by any agency of the Federal Government.

(e) No application for a statement or for financial assistance under this section or statement issued under this section shall constitute or be construed as suspending, modifying, revising, abrogating or otherwise changing the requirements imposed on the applicant by the terms, conditions, limitations or schedules of compliance contained in an applicable standard, permit, or other provision established or authorized under the Act or any State or local statute, ordinance or code.

(f) No statement as issued and reviewed shall be construed as a waiver to the applicants fulfilling the requirements of any State or local law, statute, ordinance, or code (including building, health, or zoning codes).

(g) An amended application need not be submitted if the facility, property, or operation for which the statement is issued is sold, leased, rented, or transferred by the applicant to another party prior to approval by SBA of the financial assistance: *Provided,* That

there is or will be no substantive change in the scope, concept, design, capability, or conduct of the facility or operation.

Comment: However, eligibility for financial assistance would be reexamined by SBA with regard to any such sale, lease, rental or transfer.

(h) The Regional Administrator may include in any statement a date of expiration, after which date the approval by the Regional Administrator contained in the statement shall no longer apply. The date of expiration shall not become effective if the applicant has submitted the statement to the SBA, prior to the date of expiration, as part of the application for financial assistance.

§ 21.11 Public participation.

(a) Applications shall not generally be subject to public notice, public comment, or public hearings. Applications during the period of review as stated in § 21.5, or during the period of appeal as provided in § 21.8, shall be available for public inspection. Approved applications as provided in § 21.10(d) shall be available for public inspection at all times during the five year period.

(b) The Regional Administrator, if he believes that the addition, alteration, or method of operation may adversely and significantly affect an interest of the public, shall provide for a public notice and/or public hearing on the application. The public notice and/or public hearing shall be conducted in accordance with the procedures specified for a permit under 40 CFR 125.32 and 125.34(b).

(c) Where the applicant is able to demonstrate to the satisfaction of the Regional Administrator that disclosure of certain information or parts thereof as provided in § 21.3(c)(5) would result in the divulging of methods or processes entitled to protection as trade secrets, the Regional Administrator shall treat the information or the particular part as confidential in accordance with the purposes of section 1905 of Title 18 of the United States Code and not release it to any unauthorized person. *Provided, however,* That if access to such information is subsequently requested by any person, there will be compliance with the procedures specified in 40 CFR part 2. Such information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out the Act or when relevant in any proceeding under the Act.

§ 21.12 State issued statements.

(a) Any State after the effective date of these regulations may submit to the Regional Administrator for his approval an application to conduct a program for issuing statements under this section.

(1) A State submission shall specify the organizational, legal, financial, and administrative resources and procedures that it believes will enable it to conduct the program.

(2) The State program shall constitute an equivalent effort to that required of EPA under this section.

(3) The State organization responsible for conducting the program should be the State water pollution control agency, as defined in section 502 of the Act.

(4) The State submission shall propose a procedure for adjudicating applicant appeals as provided under § 21.9.

(5) The State submission shall identify any existing or potential conflicts of interest on the part of any personnel who will or may review or approve applications.

(i) A conflict of interest shall exist where the reviewing official is the spouse of or dependent (as defined in the Tax Code, 26 U.S.C. 152) of an owner, partner, or principal officer of the small business, or where he has or is receiving from the small business concern applicant 10 percent of gross personal income for a calendar year, except that it shall mean 50 percent gross personal income for a calendar year if the recipient is over 60 years of age and is receiving such portion pursuant to retirement, pension, or similar arrangements.

(ii) If the State is unable to provide alternative parties to review or approve any application subject to conflict of interest, the Regional Administrator shall review and approve the application.

(b) The Regional Administrator, within 60 days after such application, shall approve any State program that

conforms to the requirements of this section. Any such approval shall be after sufficient notice has been provided to the Regional Director of SBA.

(c) If the Regional Administrator disapproves the application, he shall notify the State, in writing, of any deficiency in its application. A State may resubmit an amended application at any later time.

(d) Upon approval of a State submission, EPA will suspend all review of applications and issuance of statements for small businesses in that State, pending transferral. *Provided, however,* That in the event of a State conflict of interest as identified in §21.12(a)(4) of this section, EPA shall review the application and issue the statement.

(e) Any applications shall, if received by an EPA Regional Office, be forwarded promptly to the appropriate State for action pursuant to section 7(g)(2) of the Small Business Act and these regulations.

(f)(1) EPA will generally not review or approve individual statements issued by a State. However, SBA, upon receipt and review of a State approved statement may request the Regional Administrator of EPA to review the statement. The Regional Administrator, upon such request can further approve or disapprove the State issued statement, in accordance with the requirements of §21.5.

(2) The Regional Administrator will periodically review State program performance. In the event of State program deficiencies the Regional Administrator will notify the State of such deficiencies.

(3) During that period that any State's program is classified as deficient, statements issued by a State shall also be sent to the Regional Administrator for review. The Regional Administrator shall notify the State, the applicant, and the SBA of any determination subsequently made, in accordance with §21.5, on any such statement.

(i) If within 60 days after notice of such deficiencies has been provided, the State has not taken corrective efforts, and if the deficiencies significantly affect the conduct of the program, the Regional Administrator, after sufficient notice has been provided to the Regional Director of SBA, shall withdraw the approval of the State program.

(ii) Any State whose program is withdrawn and whose deficiencies have been corrected may later reapply as provided in §21.12(a).

(g) Funds appropriated under section 106 of the Act may be utilized by a State agency authorized to receive such funds in conducting this program.

§21.13 Effect of certification upon authority to enforce applicable standards.

The certification by EPA or a State for SBA Loan purposes in no way constitutes a determination by EPA or the State that the facilities certified (a) will be constructed within the time specified by an applicable standard or (b) will be constructed and installed in accordance with the plans and specifications submitted in the application, will be operated and maintained properly, or will be applied to process wastes which are the same as described in the application. The certification in no way constitutes a waiver by EPA or a State of its authority to take appropriate enforcement action against the owner or operator of such facilities for violations of an applicable standard.

PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION/TERMINATION OR SUSPENSION OF PERMITS

Subpart A—General

Sec.

AUTHORITY: 7 U.S.C. 1361; 15 U.S.C. 2615; 33 U.S.C. 1319, 1342, 1361, 1415 and 1418; 42 U.S.C. 300g–3(g), 6912, 6925, 6928, 6991e and 6992d; 42 U.S.C. 7413(d), 7524(c), 7545(d), 7547, 7601 and 7607(a), 9609, and 11045.

SOURCE: 64 FR 40176, July 23, 1999, unless otherwise noted.

Subpart A—General

§ 22.1 Scope of this part.

(a) These Consolidated Rules of Practice govern all administrative adjudicatory proceedings for:

(1) The assessment of any administrative civil penalty under section 14(a) of the Federal Insecticide, Fungicide,

and Rodenticide Act as amended (7 U.S.C. 136*l*(a));

(2) The assessment of any administrative civil penalty under sections 113(d), 205(c), 211(d) and 213(d) of the Clean Air Act, as amended (42 U.S.C. 7413(d), 7524(c), 7545(d) and 7547(d)), and a determination of nonconforming engines, vehicles or equipment under sections 207(c) and 213(d) of the Clean Air Act, as amended (42 U.S.C. 7541(c) and 7547(d));

(3) The assessment of any administrative civil penalty or for the revocation or suspension of any permit under section 105(a) and (f) of the Marine Protection, Research, and Sanctuaries Act as amended (33 U.S.C. 1415(a) and (f));

(4) The issuance of a compliance order or the issuance of a corrective action order, the termination of a permit pursuant to section 3008(a)(3), the suspension or revocation of authority to operate pursuant to section 3005(e), or the assessment of any civil penalty under sections 3008, 9006, and 11005 of the Solid Waste Disposal Act, as amended (42 U.S.C. 6925(d), 6925(e), 6928, 6991e, and 6992d)), except as provided in part 24 of this chapter;

(5) The assessment of any administrative civil penalty under sections 16(a) and 207 of the Toxic Substances Control Act (15 U.S.C. 2615(a) and 2647);

(6) The assessment of any Class II penalty under sections 309(g) and 311(b)(6), or termination of any permit issued pursuant to section 402(a) of the Clean Water Act, as amended (33 U.S.C. 1319(g), 1321(b)(6), and 1342(a));

(7) The assessment of any administrative civil penalty under section 109 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9609);

(8) The assessment of any administrative civil penalty under section 325 of the Emergency Planning and Community Right-To-Know Act of 1986 (''EPCRA'') (42 U.S.C. 11045);

(9) The assessment of any administrative civil penalty under sections 1414(g)(3)(B), 1423(c), and 1447(b) of the Safe Drinking Water Act as amended (42 U.S.C. 300g–3(g)(3)(B), 300h–2(c), and 300j–6(b)), or the issuance of any order requiring both compliance and the assessment of an administrative civil penalty under section 1423(c);

(10) The assessment of any administrative civil penalty or the issuance of any order requiring compliance under Section 5 of the Mercury-Containing and Rechargeable Battery Management Act (42 U.S.C. 14304).

(11) The assessment of any administrative civil penalty under section 1908(b) of the Act To Prevent Pollution From Ships (''APPS''), as amended (33 U.S.C. 1908(b)).

(b) The supplemental rules set forth in subparts H and I of this part establish special procedures for proceedings identified in paragraph (a) of this section where the Act allows or requires procedures different from the procedures in subparts A through G of this part. Where inconsistencies exist between subparts A through G of this part and subpart H or I of this part, subparts H or I of this part shall apply.

(c) Questions arising at any stage of the proceeding which are not addressed in these Consolidated Rules of Practice shall be resolved at the discretion of the Administrator, Environmental Appeals Board, Regional Administrator, or Presiding Officer, as provided for in these Consolidated Rules of Practice.

[64 FR 40176, July 23, 1999, as amended at 65 FR 30904, May 15, 2000; 79 FR 65900, Nov. 6, 2014; 81 FR 73970, Oct. 25, 2016]

§ 22.2 Use of number and gender.

As used in these Consolidated Rules of Practice, words in the singular also include the plural and words in the masculine gender also include the feminine, and vice versa, as the case may require.

§ 22.3 Definitions.

(a) The following definitions apply to these Consolidated Rules of Practice:

Act means the particular statute authorizing the proceeding at issue.

Administrative Law Judge means an Administrative Law Judge appointed under 5 U.S.C. 3105.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his delegate.

Agency means the United States Environmental Protection Agency.

Business confidentiality claim means a confidentiality claim as defined in 40 CFR 2.201(h).

Clerk of the Board means an individual duly authorized to serve as Clerk of the Environmental Appeals Board.

Commenter means any person (other than a party) or representative of such person who timely:

(1) Submits in writing to the Regional Hearing Clerk that he is providing or intends to provide comments on the proposed assessment of a penalty pursuant to sections 309(g)(4) and 311(b)(6)(C) of the Clean Water Act or section 1423(c) of the Safe Drinking Water Act, whichever applies, and intends to participate in the proceeding; and

(2) Provides the Regional Hearing Clerk with a return address.

Complainant means any person authorized to issue a complaint in accordance with §§ 22.13 and 22.14 on behalf of the Agency to persons alleged to be in violation of the Act. The complainant shall not be a member of the Environmental Appeals Board, the Regional Judicial Officer or any other person who will participate or advise in the adjudication.

Consolidated Rules of Practice means the regulations in this part.

Environmental Appeals Board means the Board within the Agency described in 40 CFR 1.25.

Final order means:

(1) An order issued by the Environmental Appeals Board or the Administrator after an appeal of an initial decision, accelerated decision, decision to dismiss, or default order, disposing of the matter in controversy between the parties;

(2) An initial decision which becomes a final order under § 22.27(c); or

(3) A final order issued in accordance with § 22.18.

Hearing means an evidentiary hearing on the record, open to the public (to the extent consistent with § 22.22(a)(2)), conducted as part of a proceeding under these Consolidated Rules of Practice.

Hearing Clerk means the Hearing Clerk, Mail Code 1900, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Initial decision means the decision issued by the Presiding Officer pursuant to §§ 22.17(c), 22.20(b) or 22.27 resolving all outstanding issues in the proceeding.

Party means any person that participates in a proceeding as complainant, respondent, or intervenor.

Permit action means the revocation, suspension or termination of all or part of a permit issued under section 102 of the Marine Protection, Research, and Sanctuaries Act (33 U.S.C. 1412) or termination under section 402(a) of the Clean Water Act (33 U.S.C. 1342(a)) or section 3005(d) of the Solid Waste Disposal Act (42 U.S.C. 6925(d)).

Person includes any individual, partnership, association, corporation, and any trustee, assignee, receiver or legal successor thereof; any organized group of persons whether incorporated or not; and any officer, employee, agent, department, agency or instrumentality of the Federal Government, of any State or local unit of government, or of any foreign government.

Presiding Officer means an individual who presides in an administrative adjudication until an initial decision becomes final or is appealed. The Presiding Officer shall be an Administrative Law Judge, except where §§ 22.4(b), 22.16(c) or 22.51 allow a Regional Judicial Officer to serve as Presiding Officer.

Proceeding means the entirety of a single administrative adjudication, from the filing of the complaint through the issuance of a final order, including any action on a motion to reconsider under § 22.32.

Regional Administrator means, for a case initiated in an EPA Regional Office, the Regional Administrator for that Region or any officer or employee thereof to whom his authority is duly delegated.

Regional Hearing Clerk means an individual duly authorized to serve as hearing clerk for a given region, who shall be neutral in every proceeding. Correspondence with the Regional Hearing Clerk shall be addressed to the Regional Hearing Clerk at the address specified in the complaint. For a case initiated at EPA Headquarters, the term Regional Hearing Clerk means the Hearing Clerk.

Regional Judicial Officer means a person designated by the Regional Administrator under § 22.4(b).

Respondent means any person against whom the complaint states a claim for relief.

(b) Terms defined in the Act and not defined in these Consolidated Rules of Practice are used consistent with the meanings given in the Act.

[64 FR 40176, July 23, 1999, as amended at 65 FR 30904, May 15, 2000; 79 FR 65901, Nov. 6, 2014]

§ 22.4 Powers and duties of the Environmental Appeals Board, Regional Judicial Officer and Presiding Officer; disqualification, withdrawal, and reassignment.

(a) *Environmental Appeals Board.* (1) The Environmental Appeals Board rules on appeals from the initial decisions, rulings and orders of a Presiding Officer in proceedings under these Consolidated Rules of Practice, and approves settlement of proceedings under these Consolidated Rules of Practice commenced at EPA Headquarters. The Environmental Appeals Board may refer any case or motion to the Administrator when the Environmental Appeals Board, in its discretion, deems it appropriate to do so. When an appeal or motion is referred to the Administrator by the Environmental Appeals Board, all parties shall be so notified and references to the Environmental Appeals Board in these Consolidated Rules of Practice shall be interpreted as referring to the Administrator. If a case or motion is referred to the Administrator by the Environmental Appeals Board, the Administrator may consult with any EPA employee concerning the matter, provided such consultation does not violate § 22.8. Motions directed to the Administrator shall not be considered except for motions for disqualification pursuant to paragraph (d) of this section, or motions filed in matters that the Environmental Appeals Board has referred to the Administrator.

(2) In exercising its duties and responsibilities under these Consolidated Rules of Practice, the Environmental Appeals Board may do all acts and take all measures as are necessary for the efficient, fair and impartial adjudication of issues arising in a proceeding, including imposing procedural sanctions against a party who without adequate justification fails or refuses to comply with these Consolidated Rules of Practice or with an order of the Environmental Appeals Board. Such sanctions may include drawing adverse inferences against a party, striking a party's pleadings or other submissions from the record, and denying any or all relief sought by the party in the proceeding.

(b) *Regional Judicial Officer.* Each Regional Administrator shall delegate to one or more Regional Judicial Officers authority to act as Presiding Officer in proceedings under subpart I of this part, and to act as Presiding Officer until the respondent files an answer in proceedings under these Consolidated Rules of Practice to which subpart I of this part does not apply. The Regional Administrator may also delegate to one or more Regional Judicial Officers the authority to approve settlement of proceedings pursuant to § 22.18(b)(3). These delegations will not prevent a Regional Judicial Officer from referring any motion or case to the Regional Administrator. A Regional Judicial Officer shall be an attorney who is a permanent or temporary employee of the Agency or another Federal agency and who may perform other duties within the Agency. A Regional Judicial Officer shall not have performed prosecutorial or investigative functions in connection with any case in which he serves as a Regional Judicial Officer. A Regional Judicial Officer shall not knowingly preside over a case involving any party concerning whom the Regional Judicial Officer performed any functions of prosecution or investigation within the 2 years preceding the commencement of the case. A Regional Judicial Officer shall not prosecute enforcement cases and shall not be supervised by any person who supervises the prosecution of enforcement cases, but may be supervised by the Regional Counsel.

(c) *Presiding Officer.* The Presiding Officer shall conduct a fair and impartial proceeding, assure that the facts are fully elicited, adjudicate all issues, and avoid delay. The Presiding Officer may:

(1) Conduct administrative hearings under these Consolidated Rules of Practice;

(2) Rule upon motions, requests, and offers of proof, and issue all necessary orders;

(3) Administer oaths and affirmations and take affidavits;

(4) Examine witnesses and receive documentary or other evidence;

(5) Order a party, or an officer or agent thereof, to produce testimony, documents, or other non-privileged evidence, and failing the production thereof without good cause being shown, draw adverse inferences against that party;

(6) Admit or exclude evidence;

(7) Hear and decide questions of facts, law, or discretion;

(8) Require parties to attend conferences for the settlement or simplification of the issues, or the expedition of the proceedings;

(9) Issue subpoenas authorized by the Act; and

(10) Do all other acts and take all measures necessary for the maintenance of order and for the efficient, fair and impartial adjudication of issues arising in proceedings governed by these Consolidated Rules of Practice.

(d) *Disqualification, withdrawal and reassignment.* (1) The Administrator, the Regional Administrator, the members of the Environmental Appeals Board, the Regional Judicial Officer, or the Administrative Law Judge may not perform functions provided for in these Consolidated Rules of Practice regarding any matter in which they have a financial interest or have any relationship with a party or with the subject matter which would make it inappropriate for them to act. Any party may at any time by motion to the Administrator, Regional Administrator, a member of the Environmental Appeals Board, the Regional Judicial Officer or the Administrative Law Judge request that he or she disqualify himself or herself from the proceeding. If such a motion to disqualify the Regional Administrator, Regional Judicial Officer or Administrative Law Judge is denied, a party may appeal that ruling to the Environmental Appeals Board. If a motion to disqualify a member of the Environmental Appeals Board is denied, a party may appeal that ruling to the Administrator. There shall be no interlocutory appeal of the ruling on a motion for disqualification. The Administrator, the Regional Administrator, a member of the Environmental Appeals Board, the Regional Judicial Officer, or the Administrative Law Judge may at any time withdraw from any proceeding in which he deems himself disqualified or unable to act for any reason.

(2) If the Administrator, the Regional Administrator, the Regional Judicial Officer, or the Administrative Law Judge is disqualified or withdraws from the proceeding, a qualified individual who has none of the infirmities listed in paragraph (d)(1) of this section shall be assigned as a replacement. The Administrator shall assign a replacement for a Regional Administrator who withdraws or is disqualified. Should the Administrator withdraw or be disqualified, the Regional Administrator from the Region where the case originated shall replace the Administrator. If that Regional Administrator would be disqualified, the Administrator shall assign a Regional Administrator from another Region to replace the Administrator. The Regional Administrator shall assign a new Regional Judicial Officer if the original Regional Judicial Officer withdraws or is disqualified. The Chief Administrative Law Judge shall assign a new Administrative Law Judge if the original Administrative Law Judge withdraws or is disqualified.

(3) The Chief Administrative Law Judge, at any stage in the proceeding, may reassign the case to an Administrative Law Judge other than the one originally assigned in the event of the unavailability of the Administrative Law Judge or where reassignment will result in efficiency in the scheduling of hearings and would not prejudice the parties.

[64 FR 40176, July 23, 1999, as amended at 82 FR 2234, Jan. 9, 2017]

§ 22.5 Filing, service by the parties, and form of all filed documents; business confidentiality claims.

(a) *Filing of documents.* (1) The original and one copy of each document intended to be part of the record shall be

filed with the Headquarters or Regional Hearing Clerk, as appropriate, when the proceeding is before the Presiding Officer, or filed with the Clerk of the Board when the proceeding is before the Environmental Appeals Board. A document is filed when it is received by the appropriate Clerk. When a document is required to be filed with the Environmental Appeals Board, the document shall be sent to the Clerk of the Board by U.S. Mail, delivered by hand or courier (including delivery by U.S. Express Mail or by a commercial delivery service), or transmitted by the Environmental Appeal Board's electronic filing system, according to the procedures specified in 40 CFR 124.19 (i)(2)(i), (ii), and (iii). The Presiding Officer or the Environmental Appeals Board may by order authorize or require filing by facsimile or an electronic filing system, subject to any appropriate conditions and limitations.

(2) When the Presiding Officer corresponds directly with the parties, the original of the correspondence shall be filed with the Regional Hearing Clerk. Parties who correspond directly with the Presiding Officer shall file a copy of the correspondence with the Regional Hearing Clerk.

(3) A certificate of service shall accompany each document filed or served in the proceeding.

(b) *Service of documents.* Unless the proceeding is before the Environmental Appeals Board, a copy of each document filed in the proceeding shall be served on the Presiding Officer and on each party. In a proceeding before the Environmental Appeals Board, a copy of each document filed in the proceeding shall be served on each party.

(1) *Service of complaint.* (i) Complainant shall serve on respondent, or a representative authorized to receive service on respondent's behalf, a copy of the signed original of the complaint, together with a copy of these Consolidated Rules of Practice. Service shall be made personally, by certified mail with return receipt requested, or by any reliable commercial delivery service that provides written verification of delivery.

(ii)(A) Where respondent is a domestic or foreign corporation, a partnership, or an unincorporated association which is subject to suit under a common name, complainant shall serve an officer, partner, a managing or general agent, or any other person authorized by appointment or by Federal or State law to receive service of process.

(B) Where respondent is an agency of the United States complainant shall serve that agency as provided by that agency's regulations, or in the absence of controlling regulation, as otherwise permitted by law. Complainant should also provide a copy of the complaint to the senior executive official having responsibility for the overall operations of the geographical unit where the alleged violations arose. If the agency is a corporation, the complaint shall be served as prescribed in paragraph (b)(1)(ii)(A) of this section.

(C) Where respondent is a State or local unit of government, agency, department, corporation or other instrumentality, complainant shall serve the chief executive officer thereof, or as otherwise permitted by law. Where respondent is a State or local officer, complainant shall serve such officer.

(iii) Proof of service of the complaint shall be made by affidavit of the person making personal service, or by properly executed receipt. Such proof of service shall be filed with the Regional Hearing Clerk immediately upon completion of service.

(2) *Service of filed documents other than the complaint, rulings, orders, and decisions.* All documents filed by a party other than the complaint, rulings, orders, and decisions shall be served by the filing party on all other parties. Service may be made personally, by U.S. mail (including certified mail, return receipt requested, Overnight Express and Priority Mail), by any reliable commercial delivery service, or by facsimile or other electronic means, including but not necessarily limited to email, if service by such electronic means is consented to in writing. A party who consents to service by facsimile or email must file an acknowledgement of its consent (identifying the type of electronic means agreed to and the electronic address to be used) with the appropriate Clerk. In addition, the Presiding Officer or the Environmental Appeals Board may by order

authorize or require service by facsimile, email, or other electronic means, subject to any appropriate conditions and limitations.

(c) *Form of documents.* (1) Except as provided in this section, or by order of the Presiding Officer or of the Environmental Appeals Board there are no specific requirements as to the form of documents.

(2) The first page of every filed document shall contain a caption identifying the respondent and the docket number. All legal briefs and legal memoranda greater than 20 pages in length (excluding attachments) shall contain a table of contents and a table of authorities with page references.

(3) The original of any filed document (other than exhibits) shall be signed by the party filing or by its attorney or other representative. The signature constitutes a representation by the signer that he has read the document, that to the best of his knowledge, information and belief, the statements made therein are true, and that it is not interposed for delay.

(4) The first document filed by any person shall contain the name, mailing address, telephone number, and email address of an individual authorized to receive service relating to the proceeding on behalf of the person. Parties shall promptly file any changes in this information with the Headquarters or Regional Hearing Clerk or the Clerk of the Board, as appropriate, and serve copies on the Presiding Officer and all parties to the proceeding. If a party fails to furnish such information and any changes thereto, service to the party's last known address shall satisfy the requirements of paragraph (b)(2) of this section and § 22.6.

(5) The Environmental Appeals Board or the Presiding Officer may exclude from the record any document which does not comply with this section. Written notice of such exclusion, stating the reasons therefor, shall be promptly given to the person submitting the document. Such person may amend and resubmit any excluded document upon motion granted by the Environmental Appeals Board or the Presiding Officer, as appropriate.

(d) *Confidentiality of business information.* (1) A person who wishes to assert a business confidentiality claim with regard to any information contained in any document to be filed in a proceeding under these Consolidated Rules of Practice shall assert such a claim in accordance with 40 CFR part 2 at the time that the document is filed. A document filed without a claim of business confidentiality shall be available to the public for inspection and copying.

(2) Two versions of any document which contains information claimed confidential shall be filed with the Regional Hearing Clerk:

(i) One version of the document shall contain the information claimed confidential. The cover page shall include the information required under paragraph (c)(2) of this section and the words ''Business Confidentiality Asserted''. The specific portion(s) alleged to be confidential shall be clearly identified within the document.

(ii) A second version of the document shall contain all information except the specific information claimed confidential, which shall be redacted and replaced with notes indicating the nature of the information redacted. The cover page shall state that information claimed confidential has been deleted and that a complete copy of the document containing the information claimed confidential has been filed with the Regional Hearing Clerk.

(3) Both versions of the document shall be served on the Presiding Officer and the complainant. Both versions of the document shall be served on any party, non-party participant, or representative thereof, authorized to receive the information claimed confidential by the person making the claim of confidentiality. Only the redacted version shall be served on persons not authorized to receive the confidential information.

(4) Only the second, redacted version shall be treated as public information. An EPA officer or employee may disclose information claimed confidential in accordance with paragraph (d)(1) of this section only as authorized under 40 CFR part 2.

[64 FR 40176, July 23, 1999, as amended at 69 FR 77639, Dec. 28, 2004; 79 FR 65901, Nov. 6, 2014; 82 FR 2234, Jan. 9, 2017]

§ 22.6 Filing and service of rulings, orders and decisions.

All rulings, orders, decisions, and other documents issued by the Regional Administrator or Presiding Officer shall be filed with the Headquarters or Regional Hearing Clerk, as appropriate, in any manner allowed for the service of such documents. All rulings, orders, decisions, and other documents issued by the Environmental Appeals Board shall be filed with the Clerk of the Board. The Clerk of the Board, the Headquarters Hearing Clerk, or the Regional Hearing Clerk, as appropriate, must serve copies of such rulings, orders, decisions and other documents on all parties. Service may be made by U.S. mail (including by certified mail or return receipt requested, Overnight Express and Priority Mail), EPA's internal mail, any reliable commercial delivery service, or electronic means (including but not necessarily limited to facsimile and email).

[82 FR 2234, Jan. 9, 2017]

§ 22.7 Computation and extension of time.

(a) *Computation.* In computing any period of time prescribed or allowed in these Consolidated Rules of Practice, except as otherwise provided, the day of the event from which the designated period begins to run shall not be included. Saturdays, Sundays, and Federal holidays shall be included. When a stated time expires on a Saturday, Sunday or Federal holiday, the stated time period shall be extended to include the next business day.

(b) *Extensions of time.* The Environmental Appeals Board or the Presiding Officer may grant an extension of time for filing any document: upon timely motion of a party to the proceeding, for good cause shown, and after consideration of prejudice to other parties; or upon its own initiative. Any motion for an extension of time shall be filed sufficiently in advance of the due date so as to allow other parties reasonable opportunity to respond and to allow the Presiding Officer or Environmental Appeals Board reasonable opportunity to issue an order.

(c) *Completion of service.* Service of the complaint is complete when the return receipt is signed. Service of all other documents is complete upon mailing, when placed in the custody of a reliable commercial delivery service, or for facsimile or other electronic means, including but not necessarily limited to email, upon transmission. Where a document is served by U.S. mail, EPA internal mail, or commercial delivery service, including overnight or same-day delivery, 3 days shall be added to the time allowed by these Consolidated Rules of Practice for the filing of a responsive document. The time allowed for the serving of a responsive document is not expanded by 3 days when the served document is served by personal delivery, facsimile, or other electronic means, including but not necessarily limited to email.

[64 FR 40176, July 23, 1999, as amended at 82 FR 2234, Jan. 9, 2017]

§ 22.8 *Ex parte* discussion of proceeding.

At no time after the issuance of the complaint shall the Administrator, the members of the Environmental Appeals Board, the Regional Administrator, the Presiding Officer or any other person who is likely to advise these officials on any decision in the proceeding, discuss *ex parte* the merits of the proceeding with any interested person outside the Agency, with any Agency staff member who performs a prosecutorial or investigative function in such proceeding or a factually related proceeding, or with any representative of such person. Any *ex parte* memorandum or other communication addressed to the Administrator, the Regional Administrator, the Environmental Appeals Board, or the Presiding Officer during the pendency of the proceeding and relating to the merits thereof, by or on behalf of any party shall be regarded as argument made in the proceeding and shall be served upon all other parties. The other parties shall be given an opportunity to reply to such memorandum or communication. The requirements of this section shall not apply to any person who has formally recused himself from all adjudicatory functions in a proceeding, or who issues final orders only pursuant to § 22.18(b)(3).

§ 22.9 Examination of documents filed.

(a) Subject to the provisions of law restricting the public disclosure of confidential information, any person may, during Agency business hours inspect and copy any document filed in any proceeding. Such documents shall be made available by the Regional Hearing Clerk, the Hearing Clerk, or the Clerk of the Board, as appropriate.

(b) The cost of duplicating documents shall be borne by the person seeking copies of such documents. The Agency may waive this cost in its discretion.

Subpart B—Parties and Appearances

§ 22.10 Appearances.

Any party may appear in person or by counsel or other representative. A partner may appear on behalf of a partnership and an officer may appear on behalf of a corporation. Persons who appear as counsel or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

§ 22.11 Intervention and non-party briefs.

(a) *Intervention.* Any person desiring to become a party to a proceeding may move for leave to intervene. A motion for leave to intervene that is filed after the exchange of information pursuant to § 22.19(a) shall not be granted unless the movant shows good cause for its failure to file before such exchange of information. All requirements of these Consolidated Rules of Practice shall apply to a motion for leave to intervene as if the movant were a party. The Presiding Officer shall grant leave to intervene in all or part of the proceeding if: the movant claims an interest relating to the cause of action; a final order may as a practical matter impair the movant's ability to protect that interest; and the movant's interest is not adequately represented by existing parties. The intervenor shall be bound by any agreements, arrangements and other matters previously made in the proceeding unless otherwise ordered by the Presiding Officer or the Environmental Appeals Board for good cause.

(b) *Non-party briefs.* Any person who is not a party to a proceeding may move for leave to file a non-party brief. The motion shall identify the interest of the applicant and shall explain the relevance of the brief to the proceeding. All requirements of these Consolidated Rules of Practice shall apply to the motion as if the movant were a party. If the motion is granted, the Presiding Officer or Environmental Appeals Board shall issue an order setting the time for filing such brief. Any party to the proceeding may file a response to a non-party brief within 15 days after service of the non-party brief.

§ 22.12 Consolidation and severance.

(a) *Consolidation.* The Presiding Officer or the Environmental Appeals Board may consolidate any or all matters at issue in two or more proceedings subject to these Consolidated Rules of Practice where: there exist common parties or common questions of fact or law; consolidation would expedite and simplify consideration of the issues; and consolidation would not adversely affect the rights of parties engaged in otherwise separate proceedings. Proceedings subject to subpart I of this part may be consolidated only upon the approval of all parties. Where a proceeding subject to the provisions of subpart I of this part is consolidated with a proceeding to which subpart I of this part does not apply, the procedures of subpart I of this part shall not apply to the consolidated proceeding.

(b) *Severance.* The Presiding Officer or the Environmental Appeals Board may, for good cause, order any proceedings severed with respect to any or all parties or issues.

Subpart C—Prehearing Procedures

§ 22.13 Commencement of a proceeding.

(a) Any proceeding subject to these Consolidated Rules of Practice is commenced by filing with the Regional Hearing Clerk a complaint conforming to § 22.14.

(b) Notwithstanding paragraph (a) of this section, where the parties agree to settlement of one or more causes of action before the filing of a complaint, a proceeding may be simultaneously commenced and concluded by the issuance of a consent agreement and final order pursuant to § 22.18(b)(2) and (3).

§ 22.14 Complaint.

(a) *Content of complaint.* Each complaint shall include:

(1) A statement reciting the section(s) of the Act authorizing the issuance of the complaint;

(2) Specific reference to each provision of the Act, implementing regulations, permit or order which respondent is alleged to have violated;

(3) A concise statement of the factual basis for each violation alleged;

(4) A description of all relief sought, including one or more of the following:

(i) The amount of the civil penalty which is proposed to be assessed, and a brief explanation of the proposed penalty;

(ii) Where a specific penalty demand is not made, the number of violations (where applicable, days of violation) for which a penalty is sought, a brief explanation of the severity of each violation alleged and a recitation of the statutory penalty authority applicable for each violation alleged in the complaint;

(iii) A request for a Permit Action and a statement of its proposed terms and conditions; or

(iv) A request for a compliance or corrective action order and a statement of the terms and conditions thereof;

(5) Notice of respondent's right to request a hearing on any material fact alleged in the complaint, or on the appropriateness of any proposed penalty, compliance or corrective action order, or Permit Action;

(6) Notice if subpart I of this part applies to the proceeding;

(7) The address of the Regional Hearing Clerk; and

(8) Instructions for paying penalties, if applicable.

(b) *Rules of practice.* A copy of these Consolidated Rules of Practice shall accompany each complaint served.

(c) *Amendment of the complaint.* The complainant may amend the complaint once as a matter of right at any time before the answer is filed. Otherwise the complainant may amend the complaint only upon motion granted by the Presiding Officer. Respondent shall have 20 additional days from the date of service of the amended complaint to file its answer.

(d) *Withdrawal of the complaint.* The complainant may withdraw the complaint, or any part thereof, without prejudice one time before the answer has been filed. After one withdrawal before the filing of an answer, or after the filing of an answer, the complainant may withdraw the complaint, or any part thereof, without prejudice only upon motion granted by the Presiding Officer.

§ 22.15 Answer to the complaint.

(a) *General.* Where respondent: Contests any material fact upon which the complaint is based; contends that the proposed penalty, compliance or corrective action order, or Permit Action, as the case may be, is inappropriate; or contends that it is entitled to judgment as a matter of law, it shall file an original and one copy of a written answer to the complaint with the Regional Hearing Clerk and shall serve copies of the answer on all other parties. Any such answer to the complaint must be filed with the Regional Hearing Clerk within 30 days after service of the complaint.

(b) *Contents of the answer.* The answer shall clearly and directly admit, deny or explain each of the factual allegations contained in the complaint with regard to which respondent has any knowledge. Where respondent has no knowledge of a particular factual allegation and so states, the allegation is deemed denied. The answer shall also state: The circumstances or arguments which are alleged to constitute the grounds of any defense; the facts which respondent disputes; the basis for opposing any proposed relief; and whether a hearing is requested.

(c) *Request for a hearing.* A hearing upon the issues raised by the complaint and answer may be held if requested by respondent in its answer. If the respondent does not request a hearing,

the Presiding Officer may hold a hearing if issues appropriate for adjudication are raised in the answer.

(d) *Failure to admit, deny, or explain.* Failure of respondent to admit, deny, or explain any material factual allegation contained in the complaint constitutes an admission of the allegation.

(e) *Amendment of the answer.* The respondent may amend the answer to the complaint upon motion granted by the Presiding Officer.

§ 22.16 Motions.

(a) *General.* Motions shall be served as provided by § 22.5(b)(2). Upon the filing of a motion, other parties may file responses to the motion and the movant may file a reply to the response. Any additional responsive documents shall be permitted only by order of the Presiding Officer or Environmental Appeals Board, as appropriate. All motions, except those made orally on the record during a hearing, shall:

(1) Be in writing;

(2) State the grounds therefor, with particularity;

(3) Set forth the relief sought; and

(4) Be accompanied by any affidavit, certificate, other evidence or legal memorandum relied upon.

(b) *Response to motions.* A party's response to any written motion must be filed within 15 days after service of such motion. The movant's reply to any written response must be filed within 10 days after service of such response and shall be limited to issues raised in the response. The Presiding Officer or the Environmental Appeals Board may set a shorter or longer time for response or reply, or make other orders concerning the disposition of motions. The response or reply shall be accompanied by any affidavit, certificate, other evidence, or legal memorandum relied upon. Any party who fails to respond within the designated period waives any objection to the granting of the motion.

(c) *Decision.* The Regional Judicial Officer (or in a proceeding commenced at EPA Headquarters, an Administrative Law Judge) shall rule on all motions filed or made before an answer to the complaint is filed. Except as provided in §§ 22.29(c) and 22.51, an Administrative Law Judge shall rule on all motions filed or made after an answer is filed and before an initial decision becomes final or has been appealed. The Environmental Appeals Board shall rule as provided in § 22.29(c) and on all motions filed or made after an appeal of the initial decision is filed, except as provided pursuant to § 22.28.

(d) *Oral argument.* The Presiding Officer or the Environmental Appeals Board may permit oral argument on motions in its discretion.

[64 FR 40176, July 23, 1999, as amended at 82 FR 2234, Jan. 9, 2017]

§ 22.17 Default.

(a) *Default.* A party may be found to be in default: after motion, upon failure to file a timely answer to the complaint; upon failure to comply with the information exchange requirements of § 22.19(a) or an order of the Presiding Officer; or upon failure to appear at a conference or hearing. Default by respondent constitutes, for purposes of the pending proceeding only, an admission of all facts alleged in the complaint and a waiver of respondent's right to contest such factual allegations. Default by complainant constitutes a waiver of complainant's right to proceed on the merits of the action, and shall result in the dismissal of the complaint with prejudice.

(b) *Motion for default.* A motion for default may seek resolution of all or part of the proceeding. Where the motion requests the assessment of a penalty or the imposition of other relief against a defaulting party, the movant must specify the penalty or other relief sought and state the legal and factual grounds for the relief requested.

(c) *Default order.* When the Presiding Officer finds that default has occurred, he shall issue a default order against the defaulting party as to any or all parts of the proceeding unless the record shows good cause why a default order should not be issued. If the order resolves all outstanding issues and claims in the proceeding, it shall constitute the initial decision under these Consolidated Rules of Practice. The relief proposed in the complaint or the motion for default shall be ordered unless the requested relief is clearly inconsistent with the record of the proceeding or the Act. For good cause

shown, the Presiding Officer may set aside a default order.

(d) *Payment of penalty; effective date of compliance or corrective action orders, and Permit Actions.* Any penalty assessed in the default order shall become due and payable by respondent without further proceedings 30 days after the default order becomes final under § 22.27(c). Any default order requiring compliance or corrective action shall be effective and enforceable without further proceedings on the date the default order becomes final under § 22.27(c). Any Permit Action ordered in the default order shall become effective without further proceedings on the date that the default order becomes final under § 22.27(c).

§ 22.18 Quick resolution; settlement; alternative dispute resolution.

(a) *Quick resolution.* (1) A respondent may resolve the proceeding at any time by paying the specific penalty proposed in the complaint or in complainant's prehearing exchange in full as specified by complainant and by filing with the Regional Hearing Clerk a copy of the check or other instrument of payment. If the complaint contains a specific proposed penalty and respondent pays that proposed penalty in full within 30 days after receiving the complaint, then no answer need be filed. This paragraph (a) shall not apply to any complaint which seeks a compliance or corrective action order or Permit Action. In a proceeding subject to the public comment provisions of § 22.45, this quick resolution is not available until 10 days after the close of the comment period.

(2) Any respondent who wishes to resolve a proceeding by paying the proposed penalty instead of filing an answer, but who needs additional time to pay the penalty, may file a written statement with the Regional Hearing Clerk within 30 days after receiving the complaint stating that the respondent agrees to pay the proposed penalty in accordance with paragraph (a)(1) of this section. The written statement need not contain any response to, or admission of, the allegations in the complaint. Within 60 days after receiving the complaint, the respondent shall pay the full amount of the proposed penalty. Failure to make such payment within 60 days of receipt of the complaint may subject the respondent to default pursuant to § 22.17.

(3) Upon receipt of payment in full, the Regional Judicial Officer or Regional Administrator, or, in a proceeding commenced at EPA Headquarters, the Environmental Appeals Board, shall issue a final order. Payment by respondent shall constitute a waiver of respondent's rights to contest the allegations and to appeal the final order.

(b) *Settlement.* (1) The Agency encourages settlement of a proceeding at any time if the settlement is consistent with the provisions and objectives of the Act and applicable regulations. The parties may engage in settlement discussions whether or not the respondent requests a hearing. Settlement discussions shall not affect the respondent's obligation to file a timely answer under § 22.15.

(2) *Consent agreement.* Any and all terms and conditions of a settlement shall be recorded in a written consent agreement signed by all parties or their representatives. The consent agreement shall state that, for the purpose of the proceeding, respondent: Admits the jurisdictional allegations of the complaint; admits the facts stipulated in the consent agreement or neither admits nor denies specific factual allegations contained in the complaint; consents to the assessment of any stated civil penalty, to the issuance of any specified compliance or corrective action order, to any conditions specified in the consent agreement, and to any stated Permit Action; and waives any right to contest the allegations and its right to appeal the proposed final order accompanying the consent agreement. Where complainant elects to commence a proceeding pursuant to § 22.13(b), the consent agreement shall also contain the elements described at § 22.14(a)(1)-(3) and (8). The parties shall forward the executed consent agreement and a proposed final order to the Regional Judicial Officer or Regional Administrator, or, in a proceeding commenced at EPA Headquarters, the Environmental Appeals Board.

(3) *Conclusion of proceeding.* No settlement or consent agreement shall dispose of any proceeding under these Consolidated Rules of Practice without a final order from the Regional Judicial Officer or Regional Administrator, or, in a proceeding commenced at EPA Headquarters, the Environmental Appeals Board, ratifying the parties' consent agreement.

(c) *Scope of resolution or settlement.* Full payment of the penalty proposed in a complaint pursuant to paragraph (a) of this section or settlement pursuant to paragraph (b) of this section shall not in any case affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. Full payment of the penalty proposed in a complaint pursuant to paragraph (a) of this section or settlement pursuant to paragraph (b) of this section shall only resolve respondent's liability for Federal civil penalties for the violations and facts alleged in the complaint.

(d) *Alternative means of dispute resolution.* (1) The parties may engage in any process within the scope of the Alternative Dispute Resolution Act (''ADRA''), 5 U.S.C. 581 *et seq.*, which may facilitate voluntary settlement efforts. Such process shall be subject to the confidentiality provisions of the ADRA.

(2) Dispute resolution under this paragraph (d) does not divest the Presiding Officer of jurisdiction and does not automatically stay the proceeding. All provisions of these Consolidated Rules of Practice remain in effect notwithstanding any dispute resolution proceeding.

(3) The parties may choose any person to act as a neutral, or may move for the appointment of a neutral. If the Presiding Officer grants a motion for the appointment of a neutral, the Presiding Officer shall forward the motion to the Chief Administrative Law Judge, except in proceedings under subpart I of this part, in which the Presiding Officer shall forward the motion to the Regional Administrator. The Chief Administrative Law Judge or Regional Administrator, as appropriate, shall designate a qualified neutral.

§ 22.19 Prehearing information exchange; prehearing conference; other discovery.

(a) *Prehearing information exchange.* (1) In accordance with an order issued by the Presiding Officer, each party shall file a prehearing information exchange. Except as provided in § 22.22(a), a document or exhibit that has not been included in prehearing information exchange shall not be admitted into evidence, and any witness whose name and testimony summary has not been included in prehearing information exchange shall not be allowed to testify. Parties are not required to exchange information relating to settlement which would be excluded in the federal courts under Rule 408 of the Federal Rules of Evidence. Documents and exhibits shall be marked for identification as ordered by the Presiding Officer.

(2) Each party's prehearing information exchange shall contain:

(i) The names of any expert or other witnesses it intends to call at the hearing, together with a brief narrative summary of their expected testimony, or a statement that no witnesses will be called; and (ii) Copies of all documents and exhibits which it intends to introduce into evidence at the hearing.

(3) If the proceeding is for the assessment of a penalty and complainant has already specified a proposed penalty, complainant shall explain in its prehearing information exchange how the proposed penalty was calculated in accordance with any criteria set forth in the Act, and the respondent shall explain in its prehearing information exchange why the proposed penalty should be reduced or eliminated.

(4) If the proceeding is for the assessment of a penalty and complainant has not specified a proposed penalty, each party shall include in its prehearing information exchange all factual information it considers relevant to the assessment of a penalty. Within 15 days after respondent files its prehearing information exchange, complainant shall file a document specifying a proposed penalty and explaining how the proposed penalty was calculated in accordance with any criteria set forth in the Act.

(b) *Prehearing conference.* The Presiding Officer, at any time before the hearing begins, may direct the parties and their counsel or other representatives to participate in a conference to consider:

(1) Settlement of the case;

(2) Simplification of issues and stipulation of facts not in dispute;

(3) The necessity or desirability of amendments to pleadings;

(4) The exchange of exhibits, documents, prepared testimony, and admissions or stipulations of fact which will avoid unnecessary proof;

(5) The limitation of the number of expert or other witnesses;

(6) The time and place for the hearing; and

(7) Any other matters which may expedite the disposition of the proceeding.

(c) *Record of the prehearing conference.* No transcript of a prehearing conference relating to settlement shall be made. With respect to other prehearing conferences, no transcript of any prehearing conferences shall be made unless ordered by the Presiding Officer. The Presiding Officer shall ensure that the record of the proceeding includes any stipulations, agreements, rulings or orders made during the conference.

(d) *Location of prehearing conference.* The prehearing conference shall be held in the county where the respondent resides or conducts the business which the hearing concerns, in the city in which the relevant Environmental Protection Agency Regional Office is located, or in Washington, DC, unless the Presiding Officer determines that there is good cause to hold it at another location or by telephone.

(e) *Other discovery.* (1) After the information exchange provided for in paragraph (a) of this section, a party may move for additional discovery. The motion shall specify the method of discovery sought, provide the proposed discovery instruments, and describe in detail the nature of the information and/or documents sought (and, where relevant, the proposed time and place where discovery would be conducted). The Presiding Officer may order such other discovery only if it:

(i) Will neither unreasonably delay the proceeding nor unreasonably burden the non-moving party;

(ii) Seeks information that is most reasonably obtained from the non-moving party, and which the non-moving party has refused to provide voluntarily; and

(iii) Seeks information that has significant probative value on a disputed issue of material fact relevant to liability or the relief sought.

(2) Settlement positions and information regarding their development (such as penalty calculations for purposes of settlement based upon Agency settlement policies) shall not be discoverable.

(3) The Presiding Officer may order depositions upon oral questions only in accordance with paragraph (e)(1) of this section and upon an additional finding that:

(i) The information sought cannot reasonably be obtained by alternative methods of discovery; or

(ii) There is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.

(4) The Presiding Officer may require the attendance of witnesses or the production of documentary evidence by subpoena, if authorized under the Act. The Presiding Officer may issue a subpoena for discovery purposes only in accordance with paragraph (e)(1) of this section and upon an additional showing of the grounds and necessity therefor. Subpoenas shall be served in accordance with § 22.5(b)(1). Witnesses summoned before the Presiding Officer shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Any fees shall be paid by the party at whose request the witness appears. Where a witness appears pursuant to a request initiated by the Presiding Officer, fees shall be paid by the Agency.

(5) Nothing in this paragraph (e) shall limit a party's right to request admissions or stipulations, a respondent's right to request Agency records under the Federal Freedom of Information Act, 5 U.S.C. 552, or EPA's authority under any applicable law to conduct inspections, issue information request

letters or administrative subpoenas, or otherwise obtain information.

(f) *Supplementing prior exchanges.* A party who has made an information exchange under paragraph (a) of this section, or who has exchanged information in response to a request for information or a discovery order pursuant to paragraph (e) of this section, shall promptly supplement or correct the exchange when the party learns that the information exchanged or response provided is incomplete, inaccurate or outdated, and the additional or corrective information has not otherwise been disclosed to the other party pursuant to this section.

(g) *Failure to exchange information.* Where a party fails to provide information within its control as required pursuant to this section, the Presiding Officer may, in his discretion:

(1) Infer that the information would be adverse to the party failing to provide it;

(2) Exclude the information from evidence; or

(3) Issue a default order under §22.17(c).

§22.20 Accelerated decision; decision to dismiss.

(a) *General.* The Presiding Officer may at any time render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law. The Presiding Officer, upon motion of the respondent, may at any time dismiss a proceeding without further hearing or upon such limited additional evidence as he requires, on the basis of failure to establish a prima facie case or other grounds which show no right to relief on the part of the complainant.

(b) *Effect.* (1) If an accelerated decision or a decision to dismiss is issued as to all issues and claims in the proceeding, the decision constitutes an initial decision of the Presiding Officer, and shall be filed with the Regional Hearing Clerk.

(2) If an accelerated decision or a decision to dismiss is rendered on less than all issues or claims in the proceeding, the Presiding Officer shall determine what material facts exist without substantial controversy and what material facts remain controverted. The partial accelerated decision or the order dismissing certain counts shall specify the facts which appear substantially uncontroverted, and the issues and claims upon which the hearing will proceed.

Subpart D—Hearing Procedures

§22.21 Assignment of Presiding Officer; scheduling the hearing.

(a) *Assignment of Presiding Officer.* When an answer is filed, the Regional Hearing Clerk shall forward a copy of the complaint, the answer, and any other documents filed in the proceeding to the Chief Administrative Law Judge who shall serve as Presiding Officer or assign another Administrative Law Judge as Presiding Officer. The Presiding Officer shall then obtain the case file from the Chief Administrative Law Judge and notify the parties of his assignment.

(b) *Notice of hearing.* The Presiding Officer shall hold a hearing if the proceeding presents genuine issues of material fact. The Presiding Officer shall serve upon the parties a notice of hearing setting forth a time and place for the hearing not later than 30 days prior to the date set for the hearing. The Presiding Officer may require the attendance of witnesses or the production of documentary evidence by subpoena, if authorized under the Act, upon a showing of the grounds and necessity therefor, and the materiality and relevancy of the evidence to be adduced.

(c) *Postponement of hearing.* No request for postponement of a hearing shall be granted except upon motion and for good cause shown.

(d) *Location of the hearing.* The location of the hearing shall be determined in accordance with the method for determining the location of a prehearing conference under §22.19(d).

§22.22 Evidence.

(a) *General.* (1) The Presiding Officer shall admit all evidence which is not

irrelevant, immaterial, unduly repetitious, unreliable, or of little probative value, except that evidence relating to settlement which would be excluded in the federal courts under Rule 408 of the Federal Rules of Evidence (28 U.S.C.) is not admissible. If, however, a party fails to provide any document, exhibit, witness name or summary of expected testimony required to be exchanged under § 22.19 (a), (e) or (f) to all parties at least 15 days before the hearing date, the Presiding Officer shall not admit the document, exhibit or testimony into evidence, unless the non-exchanging party had good cause for failing to exchange the required information and provided the required information to all other parties as soon as it had control of the information, or had good cause for not doing so.

(2) In the presentation, admission, disposition, and use of oral and written evidence, EPA officers, employees and authorized representatives shall preserve the confidentiality of information claimed confidential, whether or not the claim is made by a party to the proceeding, unless disclosure is authorized pursuant to 40 CFR part 2. A business confidentiality claim shall not prevent information from being introduced into evidence, but shall instead require that the information be treated in accordance with 40 CFR part 2, subpart B. The Presiding Officer or the Environmental Appeals Board may consider such evidence in a proceeding closed to the public, and which may be before some, but not all, parties, as necessary. Such proceeding shall be closed only to the extent necessary to comply with 40 CFR part 2, subpart B, for information claimed confidential. Any affected person may move for an order protecting the information claimed confidential.

(b) *Examination of witnesses.* Witnesses shall be examined orally, under oath or affirmation, except as otherwise provided in paragraphs (c) and (d) of this section or by the Presiding Officer. Parties shall have the right to cross-examine a witness who appears at the hearing provided that such cross-examination is not unduly repetitious.

(c) *Written testimony.* The Presiding Officer may admit and insert into the record as evidence, in lieu of oral testimony, written testimony prepared by a witness. The admissibility of any part of the testimony shall be subject to the same rules as if the testimony were produced under oral examination. Before any such testimony is read or admitted into evidence, the party who has called the witness shall deliver a copy of the testimony to the Presiding Officer, the reporter, and opposing counsel. The witness presenting the testimony shall swear to or affirm the testimony and shall be subject to appropriate oral cross-examination.

(d) *Admission of affidavits where the witness is unavailable.* The Presiding Officer may admit into evidence affidavits of witnesses who are unavailable. The term ''unavailable'' shall have the meaning accorded to it by Rule 804(a) of the Federal Rules of Evidence.

(e) *Exhibits.* Where practicable, an original and one copy of each exhibit shall be filed with the Presiding Officer for the record and a copy shall be furnished to each party. A true copy of any exhibit may be substituted for the original.

(f) *Official notice.* Official notice may be taken of any matter which can be judicially noticed in the Federal courts and of other facts within the specialized knowledge and experience of the Agency. Opposing parties shall be given adequate opportunity to show that such facts are erroneously noticed.

§ 22.23 Objections and offers of proof.

(a) *Objection.* Any objection concerning the conduct of the hearing may be stated orally or in writing during the hearing. The party raising the objection must supply a short statement of its grounds. The ruling by the Presiding Officer on any objection and the reasons given for it shall be part of the record. An exception to each objection overruled shall be automatic and is not waived by further participation in the hearing.

(b) *Offers of proof.* Whenever the Presiding Officer denies a motion for admission into evidence, the party offering the information may make an offer of proof, which shall be included in the record. The offer of proof for excluded oral testimony shall consist of a brief statement describing the nature of the information excluded. The offer of

proof for excluded documents or exhibits shall consist of the documents or exhibits excluded. Where the Environmental Appeals Board decides that the ruling of the Presiding Officer in excluding the information from evidence was both erroneous and prejudicial, the hearing may be reopened to permit the taking of such evidence.

§ 22.24 Burden of presentation; burden of persuasion; preponderance of the evidence standard.

(a) The complainant has the burdens of presentation and persuasion that the violation occurred as set forth in the complaint and that the relief sought is appropriate. Following complainant's establishment of a prima facie case, respondent shall have the burden of presenting any defense to the allegations set forth in the complaint and any response or evidence with respect to the appropriate relief. The respondent has the burdens of presentation and persuasion for any affirmative defenses.

(b) Each matter of controversy shall be decided by the Presiding Officer upon a preponderance of the evidence.

§ 22.25 Filing the transcript.

The hearing shall be transcribed verbatim. Promptly following the taking of the last evidence, the reporter shall transmit to the Regional Hearing Clerk the original and as many copies of the transcript of testimony as are called for in the reporter's contract with the Agency, and also shall transmit to the Presiding Officer a copy of the transcript. A certificate of service shall accompany each copy of the transcript. The Regional Hearing Clerk shall notify all parties of the availability of the transcript and shall furnish the parties with a copy of the transcript upon payment of the cost of reproduction, unless a party can show that the cost is unduly burdensome. Any person not a party to the proceeding may receive a copy of the transcript upon payment of the reproduction fee, except for those parts of the transcript ordered to be kept confidential by the Presiding Officer. Any party may file a motion to conform the transcript to the actual testimony within 30 days after receipt of the transcript, or 45 days after the parties are notified of the availability of the transcript, whichever is sooner.

§ 22.26 Proposed findings, conclusions, and order.

After the hearing, any party may file proposed findings of fact, conclusions of law, and a proposed order, together with briefs in support thereof. The Presiding Officer shall set a schedule for filing these documents and any reply briefs, but shall not require them before the last date for filing motions under § 22.25 to conform the transcript to the actual testimony. All submissions shall be in writing, shall be served upon all parties, and shall contain adequate references to the record and authorities relied on.

Subpart E—Initial Decision, Motion To Reopen a Hearing, and Motion To Set Aside a Default Order

§ 22.27 Initial Decision.

(a) *Filing and contents.* After the period for filing briefs under § 22.26 has expired, the Presiding Officer shall issue an initial decision. The initial decision shall contain findings of fact, conclusions regarding all material issues of law or discretion, as well as reasons therefor, and, if appropriate, a recommended civil penalty assessment, compliance order, corrective action order, or Permit Action. Upon receipt of an initial decision, the Regional Hearing Clerk shall forward copies of the initial decision to the Environmental Appeals Board and the Assistant Administrator for the Office of Enforcement and Compliance Assurance.

(b) *Amount of civil penalty.* If the Presiding Officer determines that a violation has occurred and the complaint seeks a civil penalty, the Presiding Officer shall determine the amount of the recommended civil penalty based on the evidence in the record and in accordance with any penalty criteria set forth in the Act. The Presiding Officer shall consider any civil penalty guidelines issued under the Act. The Presiding Officer shall explain in detail in the initial decision how the penalty to be assessed corresponds to any penalty

criteria set forth in the Act. If the Presiding Officer decides to assess a penalty different in amount from the penalty proposed by complainant, the Presiding Officer shall set forth in the initial decision the specific reasons for the increase or decrease. If the respondent has defaulted, the Presiding Officer shall not assess a penalty greater than that proposed by complainant in the complaint, the prehearing information exchange or the motion for default, whichever is less.

(c) *Effect of initial decision.* The initial decision of the Presiding Officer shall become a final order 45 days after its service upon the parties and without further proceedings unless:

(1) A party moves to reopen the hearing;

(2) A party appeals the initial decision to the Environmental Appeals Board;

(3) A party moves to set aside a default order that constitutes an initial decision; or

(4) The Environmental Appeals Board elects to review the initial decision on its own initiative.

(d) *Exhaustion of administrative remedies.* Where a respondent fails to appeal an initial decision to the Environmental Appeals Board pursuant to § 22.30 and that initial decision becomes a final order pursuant to paragraph (c) of this section, respondent waives its rights to judicial review. An initial decision that is appealed to the Environmental Appeals Board shall not be final or operative pending the Environmental Appeals Board's issuance of a final order.

§ 22.28 Motion to reopen a hearing or to set aside a default order.

(a) *Motion to reopen a hearing*—(1) *Filing and content.* A motion to reopen a hearing to take further evidence must be filed no later than 20 days after service of the initial decision and shall state the specific grounds upon which relief is sought. Where the movant seeks to introduce new evidence, the motion shall: State briefly the nature and purpose of the evidence to be adduced; show that such evidence is not cumulative; and show good cause why such evidence was not adduced at the hearing. The motion shall be made to the Presiding Officer and filed with the Headquarters or Regional Hearing Clerk, as appropriate. A copy of the motion shall be filed with the Clerk of the Board in the manner prescribed by § 22.5(a)(1).

(2) *Disposition of motion to reopen a hearing.* Within 15 days following the service of a motion to reopen a hearing, any other party to the proceeding may file with the Headquarters or Regional Hearing Clerk, as appropriate, and serve on all other parties a response. A reopened hearing shall be governed by the applicable sections of these Consolidated Rules of Practice. The timely filing of a motion to reopen a hearing shall automatically toll the running of the time periods for an initial decision becoming final under § 22.27(c), for appeal under § 22.30, and for the Environmental Appeals Board to elect to review the initial decision on its own initiative pursuant to § 22.30(b). These time periods begin again in full when the Presiding Officer serves an order denying the motion to reopen the hearing or an amended decision. The Presiding Officer may summarily deny subsequent motions to reopen a hearing filed by the same party if the Presiding Officer determines that the motion was filed to delay the finality of the decision.

(b) *Motion to set aside default order*—(1) *Filing and content.* A motion to set aside a default order must be filed no later than 20 days after service of the initial decision and shall state the specific grounds upon which relief is sought. The motion shall be made to the Presiding Officer and filed with the Headquarters or Regional Hearing Clerk, as appropriate. A copy of the motion shall be filed with the Clerk of the Board in the manner prescribed by § 22.5(a)(1).

(2) *Effect of motion to set aside default.* The timely filing of a motion to set aside a default order automatically tolls the running of the time periods for an initial decision becoming final under § 22.27(c), for appeal under § 22.30(a), and for the Environmental Appeals Board to elect to review the initial decision on its own initiative pursuant to § 22.30(b). These time periods begin again in full when the Presiding Officer serves an order denying

the motion to set aside or an amended decision. The Presiding Officer may summarily deny subsequent motions to set aside a default order filed by the same party if the Presiding Officer determines that the motion was filed to delay the finality of the decision.

[82 FR 2235, Jan. 9, 2017]

Subpart F—Appeals and Administrative Review

§ 22.29 Appeal from or review of interlocutory orders or rulings.

(a) *Request for interlocutory appeal.* Appeals from orders or rulings other than an initial decision shall be allowed only at the discretion of the Environmental Appeals Board. A party seeking interlocutory appeal of such orders or rulings to the Environmental Appeals Board shall file a motion within 10 days of service of the order or ruling, requesting that the Presiding Officer forward the order or ruling to the Environmental Appeals Board for review, and stating briefly the grounds for the appeal.

(b) *Availability of interlocutory appeal.* The Presiding Officer may recommend any order or ruling for review by the Environmental Appeals Board when:

(1) The order or ruling involves an important question of law or policy concerning which there is substantial grounds for difference of opinion; and

(2) Either an immediate appeal from the order or ruling will materially advance the ultimate termination of the proceeding, or review after the final order is issued will be inadequate or ineffective.

(c) *Interlocutory review.* If the Presiding Officer has recommended review and the Environmental Appeals Board determines that interlocutory review is inappropriate, or takes no action within 30 days of the Presiding Officer's recommendation, the appeal is dismissed. When the Presiding Officer declines to recommend review of an order or ruling, it may be reviewed by the Environmental Appeals Board only upon appeal from the initial decision, except when the Environmental Appeals Board determines, upon motion of a party and in exceptional circumstances, that to delay review would be contrary to the public interest. Such motion shall be filed within 10 days of service of an order of the Presiding Officer refusing to recommend such order or ruling for interlocutory review.

§ 22.30 Appeal from or review of initial decision.

(a) *Notice of appeal and appeal brief—*(1) *Filing an appeal—*(i) *Filing deadline and who may appeal.* Within 30 days after the initial decision is served, any party may file an appeal from any adverse order or ruling of the Presiding Officer.

(ii) *Filing requirements.* Appellant must file a notice of appeal and an accompanying appellate brief with the Environmental Appeals Board as set forth in § 22.5(a). One copy of any document filed with the Clerk of the Board shall also be served on the Headquarters or Regional Hearing Clerk, as appropriate. Appellant also shall serve a copy of the notice of appeal upon the Presiding Officer. Appellant shall simultaneously serve one copy of the notice and brief upon all other parties and non-party participants.

(iii) *Content.* The notice of appeal shall summarize the order or ruling, or part thereof, appealed from. The appellant's brief shall contain tables of contents and authorities (with appropriate page references), a statement of the issues presented for review, a statement of the nature of the case and the facts relevant to the issues presented for review (with specific citation or other appropriate reference to the record (*e.g.*, by including the document name and page number)), argument on the issues presented, a short conclusion stating the precise relief sought, alternative findings of fact, and alternative conclusions regarding issues of law or discretion. If any appellant includes attachments to its notice of appeal or appellate brief, the notice of appeal or appellate brief shall contain a table that provides the title of each appended document and assigns a label identifying where it may be found in the record.

(iv) *Multiple appeals.* If a timely notice of appeal is filed by a party, any other party may file a notice of appeal and accompanying appellate brief on any issue within 20 days after the date on which the first notice of appeal was

served or within the time to appeal in paragraph (a)(1)(i) of this section, whichever period ends later.

(2) *Response brief.* Within 20 days of service of notices of appeal and briefs under paragraph (a)(1) of this section, any other party or non-party participant may file with the Environmental Appeals Board an original and one copy of a response brief responding to arguments raised by the appellant, together with specific citation or other appropriate reference to the record, initial decision, and opposing brief (*e.g.,* by including the document name and page number). Appellee shall simultaneously serve one copy of the response brief upon each party, non-party participant, and the Regional Hearing Clerk. Response briefs shall be limited to the scope of the appeal brief. If any responding party or non-party participant includes attachments to its response brief, the response brief shall contain a table that provides the title of each appended document and assigns a label identifying where it may be found in the record. Further briefs may be filed only with leave of the Environmental Appeals Board.

(3) *Length*—(i) *Briefs.* Unless otherwise ordered by the Environmental Appeals Board, appellate and response briefs may not exceed 14,000 words, and all other briefs may not exceed 7000 words. Filers may rely on the word-processing system used to determine the word count. As an alternative to this word limitation, filers may comply with a 30-page limit for appellate and response briefs, or a 15-page limit for replies. Headings, footnotes, and quotations count toward the word limitation. The table of contents, table of authorities, table of attachments (if any), statement requesting oral argument (if any), statement of compliance with the word limitation, and any attachments do not count toward the word or page-length limitation. The Environmental Appeals Board may exclude any appeal, response, or other brief that does not meet word or page-length limitations. Where a party can demonstrate a compelling and documented need to exceed such limitations, such party must seek advance leave of the Environmental Appeals Board to file a longer brief. Such requests are discouraged and will be granted only in unusual circumstances.

(ii) *Motions.* Unless otherwise ordered by the Environmental Appeals Board, motions and any responses or replies may not exceed 7000 words. Filers may rely on the word-processing system used to determine the word count. As an alternative to this word limitation, filers may comply with a 15-page limit. Headings, footnotes, and quotations count toward the word or page-length limitation. The Environmental Appeals Board may exclude any motion that does not meet word limitations. Where a party can demonstrate a compelling and documented need to exceed such limitations, such party must seek advance leave of the Environmental Appeals Board. Such requests are discouraged and will be granted only in unusual circumstances.

(b) *Review initiated by the Environmental Appeals Board.* Whenever the Environmental Appeals Board determines to review an initial decision on its own initiative, it shall issue an order notifying the parties and the Presiding Officer of its intent to review that decision. The Clerk of the Board shall serve the order upon the Regional Hearing Clerk, the Presiding Officer, and the parties within 45 days after the initial decision was served upon the parties. In that order or in a later order, the Environmental Appeals Board shall identify any issues to be briefed by the parties and establish a time schedule for filing and service of briefs.

(c) *Scope of appeal or review.* The parties' rights of appeal shall be limited to those issues raised during the course of the proceeding and by the initial decision, and to issues concerning subject matter jurisdiction. If the Environmental Appeals Board determines that issues raised, but not appealed by the parties, should be argued, it shall give the parties written notice of such determination to allow preparation of adequate argument. The Environmental Appeals Board may remand the case to the Presiding Officer for further proceedings.

(d) *Argument before the Environmental Appeals Board.* The Environmental Appeals Board may, at its discretion in response to a request or on its own initiative, order oral argument on any or

all issues in a proceeding. To request oral argument, a party must include in its substantive brief a statement explaining why oral argument is necessary. The Environmental Appeals Board may, by order, establish additional procedures governing any oral argument before the Environmental Appeals Board.

(e) *Motions on appeal*—(1) *General.* All motions made during the course of an appeal shall conform to § 22.16 unless otherwise provided. In advance of filing a motion, parties must attempt to ascertain whether the other party(ies) concur(s) or object(s) to the motion and must indicate in the motion the attempt made and the response obtained.

(2) *Disposition of a motion for a procedural order.* The Environmental Appeals Board may act on a motion for a procedural order at any time without awaiting a response.

(3) *Timing on motions for extension of time.* Parties must file motions for extensions of time sufficiently in advance of the due date to allow other parties to have a reasonable opportunity to respond to the request for more time and to provide the Environmental Appeals Board with a reasonable opportunity to issue an order.

(f) *Decision.* The Environmental Appeals Board shall adopt, modify, or set aside the findings of fact and conclusions of law or discretion contained in the decision or order being reviewed, and shall set forth in the final order the reasons for its actions. The Environmental Appeals Board may assess a penalty that is higher or lower than the amount recommended to be assessed in the decision or order being reviewed or from the amount sought in the complaint, except that if the order being reviewed is a default order, the Environmental Appeals Board may not increase the amount of the penalty above that proposed in the complaint or in the motion for default, whichever is less. The Environmental Appeals Board may adopt, modify or set aside any recommended compliance or corrective action order or Permit Action. The Environmental Appeals Board may remand the case to the Presiding Officer for further action.

[64 FR 40176, July 23, 1999, as amended at 68 FR 2204, Jan. 16, 2003; 69 FR 77639, Dec. 28, 2004; 79 FR 65901, Nov. 6, 2014; 80 FR 13252, Mar. 13, 2015; 82 FR 2235, Jan. 9, 2017]

Subpart G—Final Order

§ 22.31 Final order.

(a) *Effect of final order.* A final order constitutes the final Agency action in a proceeding. The final order shall not in any case affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. The final order shall resolve only those causes of action alleged in the complaint, or for proceedings commenced pursuant to § 22.13(b), alleged in the consent agreement. The final order does not waive, extinguish or otherwise affect respondent's obligation to comply with all applicable provisions of the Act and regulations promulgated thereunder.

(b) *Effective date.* A final order is effective upon filing. Where an initial decision becomes a final order pursuant to § 22.27(c), the final order is effective 45 days after the initial decision is served on the parties.

(c) *Payment of a civil penalty.* The respondent shall pay the full amount of any civil penalty assessed in the final order within 30 days after the effective date of the final order unless otherwise ordered. Payment shall be made by sending a cashier's check or certified check to the payee specified in the complaint, unless otherwise instructed by the complainant. The check shall note the case title and docket number. Respondent shall serve copies of the check or other instrument of payment on the Regional Hearing Clerk and on complainant. Collection of interest on overdue payments shall be in accordance with the Debt Collection Act, 31 U.S.C. 3717.

(d) *Other relief.* Any final order requiring compliance or corrective action, or a Permit Action, shall become effective and enforceable without further proceedings on the effective date of the final order unless otherwise ordered.

(e) *Final orders to Federal agencies on appeal.* (1) A final order of the Environmental Appeals Board issued pursuant to § 22.30 to a department, agency, or instrumentality of the United States shall become effective 30 days after its service upon the parties unless the head of the affected department, agency, or instrumentality requests a conference with the Administrator in writing and serves a copy of the request on the parties of record within 30 days of service of the final order. If a timely request is made, a decision by the Administrator shall become the final order.

(2) A motion for reconsideration pursuant to § 22.32 shall not toll the 30-day period described in paragraph (e)(1) of this section unless specifically so ordered by the Environmental Appeals Board.

§ 22.32 Motion to reconsider a final order.

Motions to reconsider a final order issued pursuant to § 22.30 shall be filed within 10 days after service of the final order. Motions must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Motions for reconsideration under this provision shall be directed to, and decided by, the Environmental Appeals Board. Motions for reconsideration directed to the Administrator, rather than to the Environmental Appeals Board, will not be considered, except in cases that the Environmental Appeals Board has referred to the Administrator pursuant to § 22.4(a) and in which the Administrator has issued the final order. A motion for reconsideration shall not stay the effective date of the final order unless so ordered by the Environmental Appeals Board.

Subpart H—Supplemental Rules

§ 22.33 [Reserved]

§ 22.34 Supplemental rules governing the administrative assessment of civil penalties under the Clean Air Act.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32, in administrative proceedings to assess a civil penalty conducted under sections 113(d), 205(c), 211(d), and 213(d) of the Clean Air Act, as amended (42 U.S.C. 7413(d), 7524(c), 7545(d), and 7547(d)), and a determination of nonconforming engines, vehicles or equipment under sections 207(c) and 213(d) of the Clean Air Act, as amended (42 U.S.C. 7541(c) and 7547(d)). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Issuance of notice.* Prior to the issuance of a final order assessing a civil penalty or a final determination of nonconforming engines, vehicles or equipment, the person to whom the order or determination is to be issued shall be given written notice of the proposed issuance of the order or determination. Service of a complaint or a consent agreement and final order pursuant to § 22.13 satisfies these notice requirements.

[81 FR 73971, Oct. 25, 2016]

§ 22.35 Supplemental rules governing the administrative assessment of civil penalties under the Federal Insecticide, Fungicide, and Rodenticide Act.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32, in administrative proceedings to assess a civil penalty conducted under section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (7 U.S.C. 136l(a)). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Venue.* The prehearing conference and the hearing shall be held in the county, parish, or incorporated city of the residence of the person charged, unless otherwise agreed in writing by all parties. For a person whose residence is outside the United States and outside any territory or possession of the United States, the prehearing conference and the hearing shall be held at the EPA office listed at 40 CFR 1.7 that is closest to either the person's primary place of business within the United States, or the primary place of business of the person's U.S. agent, unless otherwise agreed by all parties.

§ 22.36 [Reserved]

§ 22.37 Supplemental rules governing administrative proceedings under the Solid Waste Disposal Act.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32, in administrative proceedings under sections 3005(d) and (e), 3008, 9003 and 9006 of the Solid Waste Disposal Act (42 U.S.C. 6925(d) and (e), 6928, 6991b and 6991e) (''SWDA''). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Corrective action and compliance orders.* A complaint may contain a compliance order issued under section 3008(a) or section 9006(a), or a corrective action order issued under section 3008(h) or section 9003(h)(4) of the SWDA. Any such order shall automatically become a final order unless, no later than 30 days after the order is served, the respondent requests a hearing pursuant to § 22.15.

§ 22.38 Supplemental rules of practice governing the administrative assessment of civil penalties under the Clean Water Act.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32 and § 22.45, in administrative proceedings for the assessment of any civil penalty under section 309(g) or section 311(b)(6) of the Clean Water Act (''CWA'')(33 U.S.C. 1319(g) and 1321(b)(6)). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Consultation with States.* For proceedings pursuant to section 309(g), the complainant shall provide the State agency with the most direct authority over the matters at issue in the case an opportunity to consult with the complainant. Complainant shall notify the State agency within 30 days following proof of service of the complaint on the respondent or, in the case of a proceeding proposed to be commenced pursuant to § 22.13(b), no less than 40 days before the issuance of an order assessing a civil penalty.

(c) *Administrative procedure and judicial review.* Action of the Administrator for which review could have been obtained under section 509(b)(1) of the CWA, 33 U.S.C. 1369(b)(1), shall not be subject to review in an administrative proceeding for the assessment of a civil penalty under section 309(g) or section 311(b)(6).

§ 22.39 Supplemental rules governing the administrative assessment of civil penalties under section 109 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.10 through 22.32, in administrative proceedings for the assessment of any civil penalty under section 109 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9609). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Judicial review.* Any person who requested a hearing with respect to a Class II civil penalty under section 109(b) of CERCLA, 42 U.S.C. 9609(b), and who is the recipient of a final order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia or for any other circuit in which such person resides or transacts business. Any person who requested a hearing with respect to a Class I civil penalty under section 109(a)(4) of CERCLA, 42 U.S.C. 9609(a)(4), and who is the recipient of a final order assessing the civil penalty may file a petition for judicial review of such order with the appropriate district court of the United States. All petitions must be filed within 30 days of the date the order making the assessment was served on the parties.

(c) *Payment of civil penalty assessed.* Payment of civil penalties assessed in the final order shall be made by forwarding a cashier's check, payable to the ''EPA, Hazardous Substances Superfund,'' in the amount assessed, and noting the case title and docket number, to the appropriate regional Superfund Lockbox Depository.

§ 22.40 [Reserved]

§ 22.41 Supplemental rules governing the administrative assessment of civil penalties under Title II of the Toxic Substance Control Act, enacted as section 2 of the Asbestos Hazard Emergency Response Act (AHERA).

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32, in administrative proceedings to assess a civil penalty conducted under section 207 of the Toxic Substances Control Act (''TSCA'') (15 U.S.C. 2647). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Collection of civil penalty.* Any civil penalty collected under TSCA section 207 shall be used by the local educational agency for purposes of complying with Title II of TSCA. Any portion of a civil penalty remaining unspent after a local educational agency achieves compliance shall be deposited into the Asbestos Trust Fund established under section 5 of AHERA.

§ 22.42 Supplemental rules governing the administrative assessment of civil penalties for violations of compliance orders issued to owners or operators of public water systems under part B of the Safe Drinking Water Act.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32, in administrative proceedings to assess a civil penalty under section 1414(g)(3)(B) of the Safe Drinking Water Act, 42 U.S.C. 300g-3(g)(3)(B). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Choice of forum.* A complaint which specifies that subpart I of this part applies shall also state that respondent has a right to elect a hearing on the record in accordance with 5 U.S.C. 554, and that respondent waives this right unless it requests in its answer a hearing on the record in accordance with 5 U.S.C. 554. Upon such request, the Regional Hearing Clerk shall recaption the documents in the record as necessary, and notify the parties of the changes.

§ 22.43 Supplemental rules governing the administrative assessment of civil penalties against a federal agency under the Safe Drinking Water Act.

(a) *Scope.* This section shall apply, in conjunction with §§ 22.1 through 22.32, in administrative proceedings to assess a civil penalty against a federal agency under section 1447(b) of the Safe Drinking Water Act, 42 U.S.C. 300j-6(b). Where inconsistencies exist between this section and §§ 22.1 through 22.32, this section shall apply.

(b) *Effective date of final penalty order.* Any penalty order issued pursuant to this section and section 1447(b) of the Safe Drinking Water Act shall become effective 30 days after it has been served on the parties.

(c) *Public notice of final penalty order.* Upon the issuance of a final penalty order under this section, the Administrator shall provide public notice of the order by publication, and by providing notice to any person who requests such notice. The notice shall include:

(1) The docket number of the order;

(2) The address and phone number of the Regional Hearing Clerk from whom a copy of the order may be obtained;

(3) The location of the facility where violations were found;

(4) A description of the violations;

(5) The penalty that was assessed; and

(6) A notice that any interested person may, within 30 days of the date the order becomes final, obtain judicial review of the penalty order pursuant to section 1447(b) of the Safe Drinking Water Act, and instruction that persons seeking judicial review shall provide copies of any appeal to the persons described in 40 CFR 135.11(a).

§ 22.44 Supplemental rules of practice governing the termination of permits under section 402(a) of the Clean Water Act or under section 3008(a)(3) of the Resource Conservation and Recovery Act.

(a) *Scope of this subpart.* The supplemental rules of practice in this subpart shall also apply in conjunction with the Consolidated Rules of Practice in this part and with the administrative proceedings for the termination of permits under section 402(a) of the Clean Water Act or under section 3008(a)(3) of

the Resource Conservation and Recovery Act. Notwithstanding the Consolidated Rules of Practice, these supplemental rules shall govern with respect to the termination of such permits.

(b) In any proceeding to terminate a permit for cause under §122.64 or §270.43 of this chapter during the term of the permit:

(1) The complaint shall, in addition to the requirements of §22.14(b), contain any additional information specified in §124.8 of this chapter;

(2) The Director (as defined in §124.2 of this chapter) shall provide public notice of the complaint in accordance with §124.10 of this chapter, and allow for public comment in accordance with §124.11 of this chapter; and

(3) The Presiding Officer shall admit into evidence the contents of the Administrative Record described in §124.9 of this chapter, and any public comments received.

[65 FR 30904, May 15, 2000]

§22.45 Supplemental rules governing public notice and comment in proceedings under sections 309(g) and 311(b)(6)(B)(ii) of the Clean Water Act and section 1423(c) of the Safe Drinking Water Act.

(a) *Scope.* This section shall apply, in conjunction with §§22.1 through 22.32, in administrative proceedings for the assessment of any civil penalty under sections 309(g) and 311(b)(6)(B)(ii) of the Clean Water Act (33 U.S.C. 1319(g) and 1321(b)(6)(B)(ii)), and under section 1423(c) of the Safe Drinking Water Act (42 U.S.C. 300h-2(c)). Where inconsistencies exist between this section and §§22.1 through 22.32, this section shall apply.

(b) *Public notice*—(1) *General.* Complainant shall notify the public before assessing a civil penalty. Such notice shall be provided within 30 days following proof of service of the complaint on the respondent or, in the case of a proceeding proposed to be commenced pursuant to §22.13(b), no less than 40 days before the issuance of an order assessing a civil penalty. The notice period begins upon first publication of notice.

(2) *Type and content of public notice.* The complainant shall provide public notice of the complaint (or the proposed consent agreement if §22.13(b) is applicable) by a method reasonably calculated to provide notice, and shall also provide notice directly to any person who requests such notice. The notice shall include:

(i) The docket number of the proceeding;

(ii) The name and address of the complainant and respondent, and the person from whom information on the proceeding may be obtained, and the address of the Regional Hearing Clerk to whom appropriate comments shall be directed;

(iii) The location of the site or facility from which the violations are alleged, and any applicable permit number;

(iv) A description of the violation alleged and the relief sought; and

(v) A notice that persons shall submit comments to the Regional Hearing Clerk, and the deadline for such submissions.

(c) *Comment by a person who is not a party.* The following provisions apply in regard to comment by a person not a party to a proceeding:

(1) *Participation in proceeding.* (i) Any person wishing to participate in the proceedings must notify the Regional Hearing Clerk in writing within the public notice period under paragraph (b)(1) of this section. The person must provide his name, complete mailing address, and state that he wishes to participate in the proceeding.

(ii) The Presiding Officer shall provide notice of any hearing on the merits to any person who has met the requirements of paragraph (c)(1)(i) of this section at least 20 days prior to the scheduled hearing.

(iii) A commenter may present written comments for the record at any time prior to the close of the record.

(iv) A commenter wishing to present evidence at a hearing on the merits shall notify, in writing, the Presiding Officer and the parties of its intent at least 10 days prior to the scheduled hearing. This notice must include a copy of any document to be introduced, a description of the evidence to be presented, and the identity of any witness (and qualifications if an expert), and the subject matter of the testimony.

(v) In any hearing on the merits, a commenter may present evidence, including direct testimony subject to cross examination by the parties.

(vi) The Presiding Officer shall have the discretion to establish the extent of commenter participation in any other scheduled activity.

(2) *Limitations.* A commenter may not cross-examine any witness in any hearing and shall not be subject to or participate in any discovery or prehearing exchange.

(3) *Quick resolution and settlement.* No proceeding subject to the public notice and comment provisions of paragraphs (b) and (c) of this section may be resolved or settled under § 22.18, or commenced under § 22.13(b), until 10 days after the close of the comment period provided in paragraph (c)(1) of this section.

(4) *Petition to set aside a consent agreement and proposed final order.* (i) Complainant shall provide to each commenter, by certified mail, return receipt requested, but not to the Regional Hearing Clerk or Presiding Officer, a copy of any consent agreement between the parties and the proposed final order.

(ii) Within 30 days of receipt of the consent agreement and proposed final order a commenter may petition the Regional Administrator (or, for cases commenced at EPA Headquarters, the Environmental Appeals Board), to set aside the consent agreement and proposed final order on the basis that material evidence was not considered. Copies of the petition shall be served on the parties, but shall not be sent to the Regional Hearing Clerk or the Presiding Officer.

(iii) Within 15 days of receipt of a petition, the complainant may, with notice to the Regional Administrator or Environmental Appeals Board and to the commenter, withdraw the consent agreement and proposed final order to consider the matters raised in the petition. If the complainant does not give notice of withdrawal within 15 days of receipt of the petition, the Regional Administrator or Environmental Appeals Board shall assign a Petition Officer to consider and rule on the petition. The Petition Officer shall be another Presiding Officer, not otherwise involved in the case. Notice of this assignment shall be sent to the parties, and to the Presiding Officer.

(iv) Within 30 days of assignment of the Petition Officer, the complainant shall present to the Petition Officer a copy of the complaint and a written response to the petition. A copy of the response shall be provided to the parties and to the commenter, but not to the Regional Hearing Clerk or Presiding Officer.

(v) The Petition Officer shall review the petition, and complainant's response, and shall file with the Regional Hearing Clerk, with copies to the parties, the commenter, and the Presiding Officer, written findings as to:

(A) The extent to which the petition states an issue relevant and material to the issuance of the proposed final order;

(B) Whether complainant adequately considered and responded to the petition; and

(C) Whether a resolution of the proceeding by the parties is appropriate without a hearing.

(vi) Upon a finding by the Petition Officer that a hearing is appropriate, the Presiding Officer shall order that the consent agreement and proposed final order be set aside and shall establish a schedule for a hearing.

(vii) Upon a finding by the Petition Officer that a resolution of the proceeding without a hearing is appropriate, the Petition Officer shall issue an order denying the petition and stating reasons for the denial. The Petition Officer shall:

(A) File the order with the Regional Hearing Clerk;

(B) Serve copies of the order on the parties and the commenter; and

(C) Provide public notice of the order.

(viii) Upon a finding by the Petition Officer that a resolution of the proceeding without a hearing is appropriate, the Regional Administrator may issue the proposed final order, which shall become final 30 days after both the order denying the petition and a properly signed consent agreement are filed with the Regional Hearing Clerk, unless further petition for review is filed by a notice of appeal in the appropriate United States District

Court, with coincident notice by certified mail to the Administrator and the Attorney General. Written notice of appeal also shall be filed with the Regional Hearing Clerk, and sent to the Presiding Officer and the parties.

(ix) If judicial review of the final order is denied, the final order shall become effective 30 days after such denial has been filed with the Regional Hearing Clerk.

§§ 22.46–22.49 [Reserved]

Subpart I—Administrative Proceedings Not Governed by Section 554 of the Administrative Procedure Act

§ 22.50 Scope of this subpart.

(a) *Scope.* This subpart applies to all adjudicatory proceedings for:

(1) The assessment of a penalty under sections 309(g)(2)(A) and 311(b)(6)(B)(i) of the Clean Water Act (33 U.S.C. 1319(g)(2)(A) and 1321(b)(6)(B)(i)).

(2) The assessment of a penalty under sections 1414(g)(3)(B) and 1423(c) of the Safe Drinking Water Act (42 U.S.C. 300g–3(g)(3)(B) and 300h–2(c)), except where a respondent in a proceeding under section 1414(g)(3)(B) requests in its answer a hearing on the record in accordance with section 554 of the Administrative Procedure Act, 5 U.S.C. 554.

(b) *Relationship to other provisions.* Sections 22.1 through 22.45 apply to proceedings under this subpart, except for the following provisions which do not apply: §§ 22.11, 22.16(c), 22.21(a), and 22.29. Where inconsistencies exist between this subpart and subparts A through G of this part, this subpart shall apply. Where inconsistencies exist between this subpart and subpart H of this part, subpart H shall apply.

§ 22.51 Presiding Officer.

The Presiding Officer shall be a Regional Judicial Officer. The Presiding Officer shall conduct the hearing, and rule on all motions until an initial decision has become final or has been appealed.

§ 22.52 Information exchange and discovery.

Respondent's information exchange pursuant to § 22.19(a) shall include information on any economic benefit resulting from any activity or failure to act which is alleged in the administrative complaint to be a violation of applicable law, including its gross revenues, delayed or avoided costs. Discovery under § 22.19(e) shall not be authorized, except for discovery of information concerning respondent's economic benefit from alleged violations and information concerning respondent's ability to pay a penalty.

PART 23—JUDICIAL REVIEW UNDER EPA-ADMINISTERED STATUTES

Sec.

AUTHORITY: Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

SOURCE: 50 FR 7270, Feb. 21, 1985, unless otherwise noted.

§ 23.1 Definitions.

As used in this part, the term:

(a) *Federal Register document* means a document intended for publication in the FEDERAL REGISTER and bearing in its heading an identification code including the letters *FRL.*

(b) *Admininstrator* means the Administrator or any official exercising authority delegated by the Administrator.

(c) *General Counsel* means the General Counsel of EPA or any official exercising authority delegated by the General Counsel.

[50 FR 7270, Feb. 21, 1985, as amended at 53 FR 29322, Aug. 3, 1988]

§ 23.2 Timing of Administrator's action under Clean Water Act.

Unless the Administrator otherwise explicity provides in a particular promulgation or approval action, the time and date of the Administrator's action in promulgation (for purposes of sections 509(b)(1) (A), (C), and (E)), approving (for purposes of section 509(b)(1)(E)), making a determination (for purposes of section 509(b)(1) (B) and (D), and issuing or denying (for purposes of section 509(b)(1)(F)) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on (a) for a FEDERAL REGISTER document, the date that is two weeks after the date when the document is published in the FEDERAL REGISTER, or (b) for any other document, two weeks after it is signed.

§ 23.3 Timing of Administrator's action under Clean Air Act.

Unless the Administrator otherwise explicitly provides in a particular promulgation, approval, or action, the time and date of such promulgation, approval or action for purposes of the second sentence of section 307(b)(1) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on (a) for a FEDERAL REGISTER document, the date when the document is published in the FEDERAL REGISTER, or (b) for any other document, two weeks after it is signed.

§ 23.4 Timing of Administrator's action under Resource Conservation and Recovery Act.

Unless the Administrator otherwise explicitly provides in taking a particular action, for purposes of section 7006(b), the time and date of the Administrator's action in issuing, denying, modifying, or revoking any permit under section 3005, or in granting, denying, or withdrawing authorization or interim authorization under section 3006, shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is (a) for a FEDERAL REGISTER document, two weeks after the date when the document is published in the FEDERAL REGISTER, or (b) for any other document, two weeks after it is signed.

§ 23.5 Timing of Administrator's action under Toxic Substances Control Act.

Unless the Administrator otherwise explicitly provides in promulgating a particular rule or issuing a particular order, the time and date of the Administrator's promulgation or issuance for purposes of section 19(a)(1) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is (a) for a FEDERAL REGISTER document, two weeks after the date when the document is published in the FEDERAL REGISTER, or (b) for any other document, two weeks after it is signed.

§ 23.6 Timing of Administrator's action under Federal Insecticide, Fungicide and Rodenticide Act.

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of entry of an order issued by the Administrator following a public hearing for purposes of section 16(b) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after it is signed.

§ 23.7 Timing of Administrator's action under Safe Drinking Water Act.

Unless the Administrator otherwise explicitly provides in a particular promulgation action or determination, the time and date of the Administrator's promulgation, issuance, or determination for purposes of section 1448(a)(2)

shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is (a) for a FEDERAL REGISTER document, two weeks after the date when the document is published in the FEDERAL REGISTER or (b) for any other document, two weeks after it is signed.

§ 23.8 Timing of Administrator's action under Uranium Mill Tailings Radiation Control Act of 1978.

Unless the Administrator otherwise explicitly provides in a particular rule, the time and date of the Administrator's promulgation for purposes of 42 U.S.C. 2022(c)(2) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after the date when notice of promulgation is published in the FEDERAL REGISTER.

§ 23.9 Timing of Administrator's action under the Atomic Energy Act.

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of the entry of an order for purposes of 28 U.S.C. 2344 shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after the date when notice thereof is published in the FEDERAL REGISTER.

§ 23.10 Timing of Administrator's action under the Federal Food, Drug, and Cosmetic Act.

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of the issuance of a regulation under section 21 U.S.C. 346a(e)(1)(C), or any order under 21 U.S.C. 346a(f)(1)(C) or 21 U.S.C. 346a(g)(2)(C), or any regulation that is the subject of such an order, shall, for purposes of 28 U.S.C. 2112, be at 1 p.m. eastern time (standard or daylight, as appropriate) on the date that is for a FEDERAL REGISTER document, 2 weeks after the date when the document is published in the FEDERAL REGISTER, or for any other document, 2 weeks after it is signed.

[70 FR 33359, June 8, 2005]

§ 23.11 Holidays.

If the date determined under §§ 23.2 to 23.10 falls on a Federal holiday, then the time and date of the Administrator's action shall be at 1:00 p.m. eastern time on the next day that is not a Federal holiday.

§ 23.12 Filing notice of judicial review.

(a) For the purposes of 28 U.S.C. 2112(a), a copy of any petition filed in any United States Court of Appeals challenging a final action of the Administrator shall be sent by certified mail, return receipt requested, or by personal delivery to the General Counsel. The petition copy shall be time-stamped by the Clerk of the Court when the original is filed with the Court. The petition should be addressed to: Correspondence Control Unit, Office of General Counsel (2311), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(b) If the General Counsel receives two or more petitions filed in two or more United States Courts of Appeals for review of any Agency action within ten days of the effective date of that action for purposes of judicial review (as specified under §§ 23.2 through 23.10 of this part), the General Counsel will notify the United States Judicial Panel of Multidistrict Litigation of any petitions that were received within the ten day period, in accordance with the applicable rules of the Panel.

(c) For purposes of determining whether a petition for review has been received within the ten day period under paragraph (b) of this section, the petition shall be considered received on the date of service, if served personally. If service is accomplished by mail, the date of receipt shall be considered to be the date noted on the return receipt card.

[53 FR 29322, Aug. 3, 1988]

PART 24—RULES GOVERNING ISSUANCE OF AND ADMINISTRATIVE HEARINGS ON INTERIM STATUS CORRECTIVE ACTION ORDERS

Subpart A—General

Sec.

AUTHORITY: 42 U.S.C. sections 6912, 6928, 6991b.

SOURCE: 53 FR 12263, Apr. 13, 1988, unless otherwise noted.

Subpart A—General

§ 24.01 Scope of these rules.

(a) These rules establish procedures governing issuance of administrative orders for corrective action pursuant to sections 3008(h) and 9003(h) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (the Act), and conduct of administrative hearings on such orders, except as specified in paragraphs (b) and (c) of this section.

(b) The hearing procedures appearing at 40 CFR part 22 govern administrative hearings on any order issued pursuant to section 3008(h) of the Act which:

(1) Is contained within an administrative order that includes claims under section 3008(a) of the Act; or

(2) Includes a suspension or revocation of authorization to operate under section 3005(e) of the Act; or

(3) Seeks penalties under section 3008(h)(2) of the Act for non-compliance with a section 3008(h) order.

(c) The hearing procedures appearing at 40 CFR part 22 govern administrative hearings on any order issued pursuant to section 9003(h) of the Act that is contained within an administrative order that includes claims under section 9006 of the Act.

(d) Questions arising at any stage of the proceeding which are not addressed in these rules shall be resolved at the discretion of the Regional Administrator or Presiding Officer, as appropriate.

[53 FR 12263, Apr. 13, 1988, as amended at 56 FR 49380, Sept. 27, 1991]

§ 24.02 Issuance of initial orders; definition of final orders and orders on consent.

(a) An administrative action under section 3008(h) or 9003(h) of the Act shall be commenced by issuance of an administrative order. When the order is issued unilaterally, the order shall be referred to as an initial administrative order and may be referenced as a proceeding under section 3008(h) or 9003(h) of the Act. When the order has become effective, either after issuance of a final order following a final decision by the Regional Administrator, or after thirty days from issuance if no hearing is requested, the order shall be referred to as a final administrative order. Where the order is agreed to by the parties, the order shall be denominated as a final administrative order on consent.

(b) The initial administrative order shall be executed by an authorized official of EPA (petitioner), other than the Regional Administrator or the Assistant Administrator for the Office of Land and Emergency Management. For orders issued by EPA Headquarters, rather than by a Regional office, all references in these procedures to the

Regional Administrator shall be understood to be to the Assistant Administrator for Land and Emergency Management or his delegatee.

(c) The initial administrative order shall contain:

(1) A reference to the legal authority pursuant to which the order is issued,

(2) A concise statement of the factual basis upon which the order is issued, and

(3) Notification of respondent's right to request a hearing with respect to any issue of material fact or the appropriateness of the proposed corrective action.

[53 FR 12263, Apr. 13, 1988, as amended at 56 FR 49380, Sept. 27, 1991; 80 FR 77577, Dec. 15, 2015]

§ 24.03 Maintenance of docket and official record.

(a) A Clerk shall be designated by the Regional Administrator to receive all initial orders, final orders, decisions, responses, memoranda, and documents regarding the order and to maintain the official record and docket.

(b) On or before the date the initial order is served on respondent the EPA office issuing the order shall deliver to the Clerk (a copy of) the administrative record supporting the findings of fact, determinations of law, and relief sought in the initial administrative order. This record shall include all relevant documents and oral information (which has been reduced to writing), which the Agency considered in the process of developing and issuing the order, exclusive of privileged internal communications. The administrative record delivered to the Clerk must have an index and be available for review in the appropriate Agency Regional or Headquarters office during normal business hours after the order is issued.

§ 24.04 Filing and service of orders, decisions, and documents.

(a) *Filing of orders, decisions, and documents.* The original and one copy of the initial administrative order, the recommended decision of the Presiding Officer, the final decision and the final administrative order, and one copy of the administrative record and an index thereto must be filed with the Clerk designated for 3008(h) or 9003(h) orders. In addition, all memoranda and documents submitted in the proceeding shall be filed with the clerk.

(b) *Service of orders, decisions, and rulings.* The Clerk (or in the case of the initial administrative order, any other designated EPA employee) shall arrange for the effectuation of service of the initial administrative order, the recommended decision of the Presiding Officer, the final decision, and final administrative order. Service of a copy of the initial administrative order together with a copy of these procedures, the recommended decision of the Presiding Officer, the final decision, or a final administrative order, shall be made personally or by certified mail, return receipt requested or, if personal service cannot be effectuated or certified mail is returned refused or unsigned, by regular mail, on the respondent or his representative. The Clerk shall serve other documents from the Presiding Officer by regular mail.

(c) *Service of documents filed by the parties.* Service of all documents, filed by the parties, shall be made by the parties or their representatives on other parties or their representatives and may be regular mail, with the original filed with the Clerk. The original of any pleading, letter, or other document (other than exhibits) shall be signed by the party filing or by his counsel or other representative. The signature constitutes a representation by the signer that he has read the pleading, letter, or other document, that to the best of his knowledge, information, and belief, the statements made therein are true, and that it is not interposed for delay.

(d) *Service in general.* Service of orders, decisions, rulings, or documents by either the Clerk or the parties shall, in the case of a domestic or foreign corporation, a partnership, or other unincorporated association, which is subject to suit under a common name, be made, as prescribed in § 24.04 (b) and (c), upon an officer, partner, managing or general agent, or any person authorized by appointment or by Federal or State law to receive service of process.

(e) *Effective date of service.* Service of the initial administrative order and final administrative order is complete

upon receipt by respondent (or the respondent's agent, attorney, representative or other person employed by respondent and receiving such service), personally or by certified mail, or upon mailing by regular mail, if personal service or service by certified mail cannot be accomplished, in accordance with §24.04(b). Service of all other pleadings and documents is complete upon mailing, except as provided in §§24.10(b) and 24.14(e).

[53 FR 12263, Apr. 13, 1988, as amended at 56 FR 49380, Sept. 27, 1991]

§ 24.05 Response to the initial order; request for hearing.

(a) The initial administrative order becomes a final administrative order thirty (30) days after service of the order, unless the respondent files with the Clerk within thirty (30) days after service of the order, a response to the initial order and requests a hearing.

(b) The response to the initial order and request for a hearing must be in writing and mailed to, or personally served on, the Clerk of the Regional office which issued the order.

(c) The response to the initial order shall specify each factual or legal determination, or relief provision in the initial order the respondent disputes and shall briefly indicate the basis upon which it disputes such determination or provision.

(d) Respondent may include with its response to the initial order and request for a hearing a statement indicating whether it believes the subpart B or subpart C hearing procedures should be employed for the requested hearing and the reason(s) therefore.

§ 24.06 Designation of Presiding Officer.

Upon receipt of a request for a hearing, the Regional Administrator shall designate a Presiding Officer to conduct the hearing and preside over the proceedings.

§ 24.07 Informal settlement conference.

The respondent may request an informal settlement conference at any time by contacting the appropriate EPA employee, as specified in the initial administrative order. A request for an informal conference will not affect the respondent's obligations to timely request a hearing. Whether or not the respondent requests a hearing, the parties may confer informally concerning any aspect of the order. The respondent and respondent's representatives shall generally be allowed the opportunity at an informal conference to discuss with the appropriate Agency technical and legal personnel all aspects of the order, and in particular the basis for the determination that a release has occurred and the appropriateness of the ordered corrective action.

§ 24.08 Selection of appropriate hearing procedures.

(a) The hearing procedures set forth in subpart B of this part shall be employed for any requested hearing if the initial order directs the respondent—

(1) To undertake only a RCRA Facility Investigation and/or Corrective Measures Study, which may include monitoring, surveys, testing, information gathering, analyses, and/or studies (including studies designed to develop recommendations for appropriate corrective measures), or

(2) To undertake such investigations and/or studies and interim corrective measures, and if such interim corrective measures are neither costly nor technically complex and are necessary to protect human health and the environment prior to development of a permanent remedy, or

(3) To undertake investigations/studies with respect to a release from an underground storage tank.

(b) The hearing procedures set forth in subpart C of this part shall be employed if the respondent seeks a hearing on an order directing that—

(1) Corrective measures or such corrective measures together with investigations/studies be undertaken, or

(2) Corrective action or such corrective action together with investigations/studies be undertaken with respect to any release from an underground storage tank.

(c) The procedures contained in subparts A and D of this part shall be followed regardless of whether the initial order directs the respondent to undertake an investigation pursuant to the procedures in subpart B of this part, or requires the respondent to implement

corrective measures pursuant to the procedures in subpart C of this part.

[56 FR 49380, Sept. 27, 1991]

Subpart B—Hearings on Orders Requiring Investigations or Studies

§ 24.09 Qualifications of Presiding Officer; *ex parte* discussion of the proceeding.

The Presiding Officer shall be either the Regional Judicial Officer (as described in 40 CFR 22.04(b)) or another attorney employed by the Agency, who has had no prior connection with the case, including the performance of any investigative or prosecuting functions. At no time after issuance of the initial administrative order and prior to issuance of the final order shall the Regional Administrator, Presiding Officer, or any person who will advise these officials in the decision on the case, discuss *ex parte* the merits of the proceeding with any interested person outside the Agency, with any Agency staff member who performs a prosecutorial or investigative function in such proceeding or a factually related proceeding, or with any representative of such person. If, after issuance of the initial order and prior to issuance of the final order, the Regional Administrator, Presiding Officer, or any person who will advise these officials in the decision on the case receives from or on behalf of any party in an *ex parte* communication information which is relevant to the decision on the case and to which other parties have not had an opportunity to respond, a summary of such information shall be served on all other parties, who shall have an opportunity to reply to same within ten (10) days of service of the summary.

§ 24.10 Scheduling the hearing; prehearing submissions by respondent.

(a) *Date and time for hearing.* The Presiding Officer shall establish the date, time, location, and agenda for the requested public hearing and transmit this information to the parties. Subject to § 24.10(c), the hearing shall be scheduled and held within thirty (30) days of the Agency's receipt of the request for a public hearing.

(b) *Pre-hearing submissions by respondent.* At any time up to five (5) business days before the hearing respondent may, but is not required to, submit for inclusion in the administrative record information and argument supporting respondent's positions on the facts, law and relief, as each relates to the order in question. A copy of any information or argument submitted by respondent shall be served such that the Clerk and petitioner receive same at least five (5) business days before hearing.

(c) *Postponment of hearing.* The Presiding Officer may grant an extension of time for the conduct of the hearing upon written request of either party, for good cause shown, and after consideration of any prejudice to other parties. The Presiding Officer may not extend the date by which the request for hearing is due under § 24.05(a).

(d) *Location of hearing.* The hearing shall be held in the city in which the relevant EPA Regional Office is located, unless the Presiding Officer determines that there is good cause to hold it in another location.

§ 24.11 Hearing; oral presentations and written submissions by the parties.

The Presiding Officer shall conduct the hearing in a fair and impartial way, taking action as needed to avoid unnecessary delay, exclude redundant material and maintain order during the proceedings. Representatives of EPA shall introduce the administrative record and be prepared to summarize the basis for the order. The respondent shall have a reasonable opportunity to address relevant issues and present its views through legal counsel or technical advisors. The Presiding Officer may also allow technical and legal discussions and interchanges between the parties, including responses to questions to the extent deemed appropriate. It is not the Agency's intent to provide EPA or respondent an opportunity to engage in direct examination or cross-examination of witnesses. The Presiding Officer may address questions to the respondent's or EPA's representative(s) during the hearing. Each party shall insure that a representative(s) is (are) present at the hearing, who is (are) capable of responding to questions and articulating that party's position

on the law and facts at issue. Where respondent can demonstrate that through no fault of its own certain documents supportive of its position could not have been submitted before hearing in accordance with the requirements of § 24.10(b), it may submit such documents at the hearing. Otherwise no new documentary support may be submitted at hearing. The Presiding Officer may upon request grant petitioner leave to respond to submissions made by respondent pursuant to this section or § 24.10(b). The Presiding Officer shall have the discretion to order either party to submit additional information (including but not limited to posthearing briefs on undeveloped factual, technical, or legal matters) in whatever form he deems appropriate either at or after the hearing.

§ 24.12 Summary of hearing; Presiding Officer's recommendation.

(a) As soon as practicable after the conclusion of the hearing a written summary of the proceeding shall be prepared. This summary shall, at a minimum, identify:

(1) The dates of and known attendees at the hearing; and

(2) The bases upon which the respondent contested the terms of the order.

The summary must be signed by the Presiding Officer.

(b) The Presiding Officer will evaluate the entire administrative record and, on the basis of that review and the representations of EPA and respondent at the hearing, shall prepare and file a recommended decision with the Regional Administrator. The recommended decision must address all material issues of fact or law properly raised by respondent, and must recommend that the order be modified, withdrawn or issued without modification. The recommended decision must provide an explanation with citation to material contained in the record for any decision to modify a term of the order, to issue the order without change, or to withdraw the order. The recommended decision shall be based on the administrative record. If the Presiding Officer finds that any contested relief provision in the order is not supported by a preponderance of the evidence in the record, the Presiding Officer shall recommend that the order be modified and issued on terms that are supported by the record or withdrawn.

(c) At any time within twenty-one (21) days of service of the recommended decision on the parties, the parties may file comments on the recommended decision with the Clerk. The Clerk shall promptly transmit any such comments received to the Regional Administrator for his consideration in reaching a final decision.

Subpart C—Hearings on Orders Requiring Corrective Measures

§ 24.13 Qualifications of Presiding Officer; *ex parte* discussion of the proceeding.

(a) *Qualifications of Presiding Officer*. The Presiding Officer shall be either the Regional Judicial Officer (as described in 40 CFR 22.04(b)) of another attorney employed by the Agency, who has had no prior connection with the case, including the performance of any investigative or prosecuting functions.

(b) *Ex parte discussion of the proceeding*. At no time after issuance of the initial administrative order and prior to issuance of the final order shall the Regional Administrator, Presiding Officer, or any person who will advise these officials in the decision on the case, discuss *ex parte* the merits of the proceeding with any interested person outside the Agency, with any Agency staff member who performs a prosecutorial or investigative function in such proceeding or a factually related proceeding, or with any representative of such person. If, after issuance of the initial order and prior to issuance of the final order, the Regional Administrator, Presiding Officer, or any person who will advise these officials in the decision on the case receives from or on behalf of any party in an *ex parte* communication information which is relevant to the decision on the case and to which other parties have not had an opportunity to respond, a summary of such information shall be served on all other parties, who shall have an opportunity to reply to same within ten (10) days of service of the summary.

§ 24.14 Scheduling the hearing; pre-hearing submissions by the parties.

(a) The Presiding Officer shall establish an expeditious schedule for:

(1) The submission by respondent of a memorandum, with appropriate affidavits and exhibits, stating and supporting respondent's position on the facts, law and relief, specifying the bases upon and manner in which such determinations or relief provisions, if erroneous, require modification or withdrawal of the order:

(2) Submission of a response by EPA; and

(3) A public hearing.

Subject to § 24.14(b), a hearing shall be scheduled within 45 days of the order setting the schedule. The Presiding Officer shall establish the date, time, location and agenda for the hearing and shall transmit this information to the parties along with the schedule for the hearing.

(b) *Postponement of the hearing.* The Presiding Officer, as appropriate, may grant an extension of time for the filing of any document, other than a request for a hearing under § 24.05(a), or may grant an extension of time for the conduct of the hearing, upon written request of either party, for good cause shown and after consideration of any prejudice to other parties.

(c) *Respondent's pre-hearing submission.* In accordance with the schedule set by the Presiding Officer, the respondent shall file a memorandum stating and supporting respondent's position on the facts, law and relief. The memorandum must identify each factual allegation and all issues regarding the appropriateness of the terms of the relief in the initial order that respondent contests and for which respondent requests a hearing. The memorandum must clearly state respondent's position with respect to each such issue. Respondent must also include any proposals for modification of the order. The memorandum shall also present any arguments on the legal conclusions contained in the order.

(d) *Written questions to EPA.* The respondent may file a request with the Presiding Officer for permission to submit written questions to the EPA Regional Office issuing the order concerning issues of material fact in the order.

(1) Requests shall be accompanied by the proposed questions. In most instances, no more than twenty-five (25) questions, including subquestions and subparts, may be posed. The request and questions must be submitted to the Presiding Officer at least twenty-one (21) days before the hearing.

(2) The Presiding Officer may direct EPA to respond to such questions as he designates. In deciding whether or not to direct the Agency to respond to written questions the Presiding Officer should consider whether such responses are required for full disclosure and adequate resolution of the facts. No questions shall be allowed regarding privileged internal communications. The Presiding Officer shall grant, deny, or modify such requests expeditiously. If a request is granted the Presiding Officer may revise questions and may limit the number and scope of questions. Questions may be deleted or revised in the discretion of the Presiding Officer for reasons, which may include the fact that he finds the questions to be irrelevant, redundant, unnecessary, or an undue burden on the Agency. The Presiding Officer shall transmit the questions as submitted or as modified to EPA. EPA shall respond to the questions within fourteen (14) calendar days of service of the questions by the Presiding Officer, unless an extension is granted.

(e) *Submission of additional information.* The Presiding Officer shall have the discretion to order either party to submit additional information (including but not limited to post-hearing briefs on undeveloped factual, technical, or legal matters) in whatever form he deems appropriate either before, at, or after the hearing. The Presiding Officer may issue subpoenas for the attendance and testimony of persons and the production of relevant papers, books and documents. Since these hearing procedures provide elsewhere that the parties are not to engage in direct or cross-examination of witnesses, the subpoena power is to serve only as an adjunct to the Presiding Officer's authority to ask questions and otherwise take steps to clarify factual

matters which are in dispute. Upon request of the respondent the Presiding Officer may, in his discretion, allow submittal by the respondent of additional information in support of its claim, if it is received by the Clerk and petitioner at least five (5) business days before the hearing.

(f) *Location of hearing*. The hearing shall be held in the city in which the relevant EPA Regional Office is located, unless the Presiding Officer determines that there is good cause to hold it in another location.

§ 24.15 Hearing; oral presentations and written submissions by the parties.

(a) The Presiding Officer shall conduct the hearing in a fair and impartial manner, take action to avoid unnecessary delay in the disposition of the proceedings, and maintain order. The Presiding Officer shall permit oral statements on behalf of the respondent and EPA. The Presiding Officer may address questions to the respondent's or the EPA's representative(s) during the hearing. Each party shall ensure that a representative(s) is (are) present at the hearing, who is (are) capable of responding to questions and articulating that party's position on the law and facts at issue. Apart from questions by the Presiding Officer, no direct examination or cross-examination shall be allowed.

(b) Upon commencement of the hearing, a representative of EPA shall introduce the order and record supporting issuance of the order, and summarize the basis for the order. The respondent may respond to the administrative record and offer any facts, statements, explanations or documents which bear on any issue for which the hearing has been requested. Any such presentation by respondent may include new documents only to the extent that respondent can demonstrate that, through no fault of its own, such documents could not have been submitted before hearing in accordance with the requirements of § 24.14 (c) and (e). The Agency may then present matters solely in rebuttal to matters previously presented by the respondent. The Presiding Officer may allow the respondent to respond to any such rebuttal submitted. The Presiding Officer may exclude repetitive or irrelevant matter. The Presiding Officer may upon request grant petitioner leave to respond to submissions made by respondent pursuant to this paragraph or § 24.14(e).

§ 24.16 Transcript or recording of hearing.

(a) The hearing shall be either transcribed stenographically or tape recorded. Upon written request, such transcript or tape recording shall be made available for inspection or copying.

(b) The transcript or recording of the hearing and all written submittals filed with the Clerk by the parties subsequent to initial issuance of the order including post-hearing submissions will become part of the administrative record for the proceeding, for consideration by the Presiding Officer and Regional Administrator.

§ 24.17 Presiding Officer's recommendation.

(a) The Presiding Officer will, as soon as practicable after the conclusion of the hearing, evaluate the entire administrative record and, on the basis of the administrative record, prepare and file a recommended decision with the Regional Administrator. The recommended decision must address all material issues of fact or law properly raised by respondent, and must recommend that the order be modified, withdrawn or issued without modification. The recommended decision must provide an explanation, with citation to material contained in the record for any decision to modify a term of the order, to issue the order without change or to withdraw the order. The recommended decision shall be based on the administrative record. If the Presiding Officer finds that any contested relief provision in the order is not supported by a preponderance of the evidence in the record, the Presiding Officer shall recommend that the order be modified and issued on terms that are supported by the record, or withdrawn.

(b) At any time within twenty-one (21) days of service of the recommended decision on the parties, the parties

may file comments on the recommended decision with the Clerk. The Clerk shall promptly transmit any such comments received to the Regional Administrator for his consideration in reaching a final decision.

Subpart D—Post-Hearing Procedures

§ 24.18 Final decision.

As soon as practicable after receipt of the recommended decision, the Regional Administrator will either sign or modify such recommended decision, and issue it as a final decision. If the Regional Administrator modifies the recommended decision, he shall insure that the final decision indicates the legal and factual basis for the decision as modified. The Regional Administrator's decision shall be based on the administrative record.

§ 24.19 Final order.

If the Regional Administrator does not adopt portions of the initial order, or finds that modification of the order is necessary, the signatory official on the initial administrative order shall modify the order in accordance with the terms of the final decision and file and serve a copy of the final administrative order. If the Regional Administrator finds the initial order appropriate as originally issued, the final decision shall declare the initial administrative order to be a final order, effective upon service of the final decision. If the Regional Administrator declares that the initial order must be withdrawn, the signatory official on the initial administrative order will file and serve a withdrawal of the initial administrative order. This may be done without prejudice.

§ 24.20 Final agency action.

The final decision and the final administrative order are final agency actions that are effective on filing and service. These actions are not appealable to the Administrator.

PART 25—PUBLIC PARTICIPATION IN PROGRAMS UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT, THE SAFE DRINKING WATER ACT, AND THE CLEAN WATER ACT

Sec.

AUTHORITY: Sec. 101(e), Clean Water Act, as amended (33 U.S.C. 1251(e)); sec. 7004(b), Resource Conservation and Recovery Act (42 U.S.C. 6974(b)); sec. 1450(a)(1), Safe Drinking Water Act, as amended (42 U.S.C. 300j–9).

SOURCE: 44 FR 10292, Feb. 16, 1979, unless otherwise noted.

§ 25.1 Introduction.

This part sets forth minimum requirements and suggested program elements for public participation in activities under the Clean Water Act (Pub. L. 95–217), the Resource Conservation and Recovery Act (Pub. L. 94–580), and the Safe Drinking Water Act (Pub. L. 93–523). The applicability of the requirements of this part is as follows:

(a) Basic requirements and suggested program elements for public information, public notification, and public consultation are set forth in §25.4. These requirements are intended to foster public awareness and open processes of government decisionmaking. They are applicable to all covered activities and programs described in §25.2(a).

(b) Requirements and suggested program elements which govern the structure of particular public participation mechanisms (for example, advisory groups and responsiveness summaries)

are set forth in §§ 25.5, 25.6, 25.7, and 25.8. This part does not mandate the use of these public participation mechanisms. It does, however, set requirements which those responsible for implementing the mechanisms must follow if the mechanisms are required elsewhere in this chapter.

(c) Requirements which apply to Federal financial assistance programs (grants and cooperative agreements) under the three acts are set forth in §§ 25.10 and 25.12(a).

(d) Requirements for public involvement which apply to specific activities are set forth in § 25.9 (Permit enforcement), § 25.10 (Rulemaking), and § 25.12 (Assuring compliance with requirements).

§ 25.2 Scope.

(a) The activities under the three Acts which are covered by this part are:

(1) EPA rulemaking, except non-policy rulemaking (for example publication of funding allotments under statutory formulas); and State rulemaking under the Clean Water Act and Resource Conservation and Recovery Act;

(2) EPA issuance and modification of permits, and enforcement of permits as delineated by § 25.9;

(3) Development by EPA of major informational materials, such as citizen guides or handbooks, which are expected to be used over several years and which are intended to be widely distributed to the public;

(4) Development by EPA of strategy and policy guidance memoranda when a Deputy Assistant Administrator determines it to be appropriate;

(5) Development and implementation of plans, programs, standards, construction, and other activities supported with EPA financial assistance (grants and cooperative agreements) to State, interstate, regional and local agencies (herein after referred to as ''State, interstate, and substate agencies'');

(6) The process by which EPA makes a determination regarding approval of State administration of the Construction Grants program in lieu of Federal administration; and the administration of the Construction Grants Program by the State after EPA approval;

(7) The process by which EPA makes a determination regarding approval of State administration of the following programs in lieu of Federal administration: The State Hazardous Waste Program; the NPDES Permit Program; the Dredge and Fill Permit Program; and the Underground Injection Control Program;

(8) Other activities which the Assistant Administrator for Water and Waste Management, the Assistant Administrator for Enforcement, or any EPA Regional Administrator deems appropriate in view of the Agency's responsibility to involve the public in significant decisions.

(b) Activities which are not covered by this part, except as otherwise provided under (a)(8) or (c) of this section, are activities under parts 33 (Subagreements), 39 (Loan Guarantees for Construction of Treatment Works), 40 (Research and Development Grants), 45 (Training Grants and Manpower Forecasting) and 46 (Fellowships) of this chapter.

(c) Some programs covered by these regulations contain further provisions concerning public participation. These are found elsewhere in this chapter in provisions which apply to the program of interest. Regulations which govern the use and release of public information are set forth in part 2 of this chapter.

(d) Specific provisions of court orders which conflict with requirements of this part, such as court-established timetables, shall take precedence over the provisions in this part.

(e) Where the State undertakes functions in the construction grants program, the State shall be responsible for meeting these requirements for public participation, and any applicable public participation requirements found elsewhere in this chapter, to the same extent as EPA.

(f) Where the State undertakes functions in those programs specifically cited in § 25.2(a)(7), the State shall be responsible for meeting the requirements for public participation included in the applicable regulations governing those State programs. The requirements for public participation in State Hazardous Waste Programs, Dredge

and Fill Permit programs, Underground Injection Control programs and NPDES permit programs are found in part 123 of this chapter. These regulations embody the substantive requirements of this part.

(g) These regulations apply to the activities of all agencies receiving EPA financial assistance which is awarded after [the effective date of final regulations], and to all other covered activities of EPA, State, interstate, and substate agencies which occur after that date. These regulations will apply to ongoing grants or other covered activities upon any significant change in the activity (for example, upon a significant proposed increase in project scope of a construction grant). Parts 105 (Public Participation in Water Pollution Control) and 249 (Public Participation in Solid Waste Management) will no longer appear in the Code of Federal Regulations; however, they will remain applicable, in uncodified form, to grants awarded prior to the effective date of this part and to all other ongoing activities.

§ 25.3 Policy and objectives.

(a) EPA, State, interstate, and substate agencies carrying out activities described in § 25.2(a) shall provide for, encourage, and assist the participation of the public. The term, ''the public'' in the broadest sense means the people as a whole, the general populace. There are a number of identifiable ''segments of the public'' which may have a particular interest in a given program or decision. Interested and affected segments of the public may be affected directly by a decision, either beneficially or adversely; they may be affected indirectly; or they may have some other concern about the decision. In addition to private citizens, the public may include, among others, representatives of consumer, environmental, and minority associations; trade, industrial, agricultural, and labor organizations; public health, scientific, and professional societies; civic associations; public officials; and governmental and educational associations.

(b) Public participation is that part of the decision-making process through which responsible officials become aware of public attitudes by providing ample opportunity for interested and affected parties to communicate their views. Public participation includes providing access to the decision-making process, seeking input from and conducting dialogue with the public, assimilating public viewpoints and preferences, and demonstrating that those viewpoints and preferences have been considered by the decision-making official. Disagreement on significant issues is to be expected among government agencies and the diverse groups interested in and affected by public policy decisions. Public agencies should encourage full presentation of issues at an early stage so that they can be resolved and timely decisions can be made. In the course of this process, responsible officials should make special efforts to encourage and assist participation by citizens representing themselves and by others whose resources and access to decision-making may be relatively limited.

(c) The following are the objectives of EPA, State, interstate, and substate agencies in carrying out activities covered by this part:

(1) To assure that the public has the opportunity to understand official programs and proposed actions, and that the government fully considers the public's concerns;

(2) To assure that the government does not make any significant decision on any activity covered by this part without consulting interested and affected segments of the public;

(3) To assure that government action is as responsive as possible to public concerns;

(4) To encourage public involvement in implementing environmental laws;

(5) To keep the public informed about significant issues and proposed project or program changes as they arise;

(6) To foster a spirit of openness and mutual trust among EPA, States, substate agencies and the public; and

(7) To use all feasible means to create opportunities for public participation, and to stimulate and support participation.

§ 25.4 Information, notification, and consultation responsibilities.

(a) *General.* EPA, State, interstate, and substate agencies shall conduct a

continuing program for public information and participation in the development and implementation of activities covered by this part. This program shall meet the following requirements:

(b) *Information and assistance requirements.* (1) Providing information to the public is a necessary prerequisite to meaningful, active public involvement. Agencies shall design informational activities to encourage and facilitate the public's participation in all significant decisions covered by § 25.2(a), particularly where alternative courses of action are proposed.

(2) Each agency shall provide the public with continuing policy, program, and technical information and assistance beginning at the earliest practicable time. Informational materials shall highlight significant issues that will be the subject of decisionmaking. Whenever possible, consistent with applicable statutory requirements, the social, economic, and environmental consequences of proposed decisions shall be clearly stated in such material. Each agency shall identify segments of the public likely to be affected by agency decisions and should consider targeting informational materials toward them (in addition to the materials directed toward the general public). Lengthy documents and complex technical materials that relate to significant decisions should be summarized for public and media uses. Fact sheets, news releases, newsletters, and other similar publications may be used to provide notice that materials are available and to facilitate public understanding of more complex documents, but shall not be a substitute for public access to the full documents.

(3) Each agency shall provide one or more central collections of reports, studies, plans, and other documents relating to controversial issues or significant decisions in a convenient location or locations, for example, in public libraries. Examples of such documents are catalogs of documents available from the agency, grant applications, fact sheets on permits and permit applications, permits, effluent discharge information, and compliance schedule reports. Copying facilities at reasonable cost should be available at the depositories.

(4) Whenever possible, agencies shall provide copies of documents of interest to the public free of charge. Charges for copies should not exceed prevailing commercial copying costs. EPA requirements governing charges for information and documents provided to the public in response to requests made under the Freedom of Information Act are set forth in part 2 of this chapter. Consistent with the objectives of § 25.3(b), agencies may reserve their supply of free copies for private citizens and others whose resources are limited.

(5) Each agency shall develop and maintain a list of persons and organizations who have expressed an interest in or may, by the nature of their purposes, activities or members, be affected by or have an interest in any covered activity. Generally, this list will be most useful where subdivided by area of interest or geographic area. Whenever possible, the list should include representatives of the several categories of interests listed under § 25.3(a). Those on the list, or relevant portions if the list is subdivided, shall receive timely and periodic notification of the availability of materials under § 25.4(b)(2).

(c) *Public notification.* Each agency shall notify interested and affected parties, including appropriate portions of the list required by paragraph (b)(5) of this section, and the media in advance of times at which major decisions not covered by notice requirements for public meetings or public hearings are being considered. Generally, notices should include the timetable in which a decision will be reached, the issues under consideration, any alternative courses of action or tentative determinations which the agency has made, a brief listing of the applicable laws or regulations, the location where relevant documents may be reviewed or obtained, identification of any associated public participation opportunities such as workshops or meetings, the name of an individual to contact for additional information, and any other appropriate information. All advance notifications under this paragraph must be provided far enough in advance of agency action to permit

time for public response; generally this should not be less than 30 days.

(d) *Public consultation.* For the purposes of this part, ''public consultation'' means an exchange of views between governmental agencies and interested or affected persons and organizations in order to meet the objectives set forth in §25.3. Requirements for three common forms of public consultation (public hearings, public meetings, and advisory groups) are set forth in §§25.5, 25.6, and 25.7. Other less formal consultation mechanisms may include but are not limited to review groups, ad hoc committees, task forces, workshops, seminars and informal personal communications with individuals and groups. Public consultation must be preceded by timely distribution of information and must occur sufficiently in advance of decision-making to allow the agency to assimilate public views into agency action. EPA, State, interstate, and substate agencies shall provide for early and continuing public consultation in any significant action covered by this part. Merely conferring with the public after an agency decision does not meet this requirement. In addition to holding hearings and meetings as specifically required in this chapter, a hearing or meeting shall be held if EPA, the State, interstate, or substate agency determines that there is significant public interest or that a hearing or meeting would be useful.

(e) *Public information concerning legal proceedings.* EPA, State, interstate, and substate agencies shall provide full and open information on legal proceedings to the extent not inconsistent with court requirements, and where such disclosure would not prejudice the conduct of the litigation. EPA actions with regard to affording opportunities for public comment before the Department of Justice consents to a proposed judgment in an action to enjoin discharges of pollutants into the environment shall be consistent with the Statement of Policy issued by the Department of Justice (see title 28, CFR, chapter 1, §50.7).

§25.5 Public hearings.

(a) *Applicability.* Any non-adjudicatory public hearing, whether mandatory or discretionary, under the three Acts shall meet the following minimum requirements. These requirements are subordinate to any more stringent requirements found elsewhere in this chapter or otherwise imposed by EPA, State, interstate, or substate agencies. Procedures developed for adjudicatory hearings required by this chapter shall be consistent with the public participation objectives of this part, to the extent practicable.

(b) *Notice.* A notice of each hearing shall be well publicized, and shall also be mailed to the appropriate portions of the list of interested and affected parties required by §25.4(b)(5). Except as otherwise specifically provided elsewhere in this chapter, these actions must occur at least 45 days prior to the date of the hearing. However, where EPA determines that there are no substantial documents which must be reviewed for effective hearing participation and that there are no complex or controversial matters to be addressed by the hearing, the notice requirement may be reduced to no less than 30 days. EPA may further reduce or waive the hearing notice requirement in emergency situations where EPA determines that there is an imminent danger to public health. To the extent not duplicative, the agency holding the hearing shall also provide informal notice to all interested persons or organizations that request it. The notice shall identify the matters to be discussed at the hearing and shall include or be accompanied by a discussion of the agency's tentative determination on major issues (if any), information on the availability of a bibliography of relevant materials (if deemed appropriate), and procedures for obtaining further information. Reports, documents and data relevant to the discussion at the public hearing shall be available to the public at least 30 days before the hearing. Earlier availability of materials relevant to the hearing will further assist public participation and is encouraged where possible.

(c) *Locations and time.* Hearings must be held at times and places which, to the maximum extent feasible, facilitate attendance by the public. Accessibility of public transportation, and use of evening and weekend hearings,

should be considered. In the case of actions with Statewide interest, holding more than one hearing should be considered.

(d) *Scheduling presentations.* The agency holding the hearing shall schedule witnesses in advance, when necessary, to ensure maximum participation and allotment of adequate time for all speakers. However, the agency shall reserve some time for unscheduled testimony and may consider reserving blocks of time for major categories of witnesses.

(e) *Conduct of hearing.* The agency holding the hearing shall inform the audience of the issues involved in the decision to be made, the considerations the agency will take into account, the agency's tentative determinations (if any), and the information which is particularly solicited from the public. The agency should consider allowing a question and answer period. Procedures shall not unduly inhibit free expression of views (for example, by onerous written statement requirements or qualification of witnesses beyond minimum identification).

(f) *Record.* The agency holding the hearing shall prepare a transcript, recording or other complete record of public hearing proceedings and make it available at no more than cost to anyone who requests it. A copy of the record shall be available for public review.

§ 25.6 Public meetings.

Public meetings are any assemblies or gathering, (such as conferences, informational sessions, seminars, workshops, or other activities) which the responsible agency intends to be open to anyone wishing to attend. Public meetings are less formal than public hearings. They do not require formal presentations, scheduling of presentations and a record of proceedings. The requirements of § 25.5 (b) and (c) are applicable to public meetings, except that the agency holding the meeting may reduce the notice to not less than 30 days if there is good reason that longer notice cannot be provided.

§ 25.7 Advisory groups.

(a) *Applicability.* The requirements of this section on advisory groups shall be met whenever provisions of this chapter require use of an advisory group by State, interstate, or substate agencies involved in activities supported by EPA financial assistance under any of the three Acts.

(b) *Role.* Primary responsibility for decision-making in environmental programs is vested by law in the elected and appointed officials who serve on public bodies and agencies at various levels of government. However, all segments of the public must have the opportunity to participate in environmental quality planning. Accordingly, where EPA identifies a need for continued attention of an informed core group of citizens in relation to activities conducted with EPA financial assistance, program regulations elsewhere in this chapter will require an advisory group to be appointed by the financially assisted agency. Such advisory groups will not be the sole mechanism for public participation, but will complement other mechanisms. They are intended to assist elected or appointed officials with final decision-making responsibility by making recommendations to such officials on important issues. In addition, advisory groups should foster a constructive interchange among the various interests present on the group and enhance the prospect of community acceptance of agency action.

(c) *Membership.* (1) The agency receiving financial assistance shall assure that the advisory group reflects a balance of interests in the affected area. In order to meet this requirement, the assisted agency shall take positive action, in accordance with paragraph (c)(3) of this section, to establish an advisory group which consists of substantially equivalent proportions of the following four groups:

(i) *Private citizens.* No person may be included in this portion of the advisory group who is likely to incur a financial gain or loss greater than that of an average homeowner, taxpayer or consumer as a result of any action likely to be taken by the assisted agency.

(ii) *Representatives of public interest groups.* A ''public interest group'' is an organization which reflects a general civic, social, recreational, environmental or public health perspective in

the area and which does not directly reflect the economic interests of its membership.

(iii) Public officials.

(iv) Citizens or representatives of organizations with substantial economic interests in the plan or project.

(2) Generally, where the activity has a particular geographic focus, the advisory group shall be made up of persons who are residents of that geographic area.

(3) In order to meet the advisory group membership requirements of paragraph (c)(1) of this section, the assisted agency shall:

(i) Identify public interest groups, economic interests, and public officials who are interested in or affected by the assisted activity.

(ii) Make active efforts to inform citizens in the affected area, and the persons or groups identified under paragraph (c)(3)(i) of this section, of this opportunity for participation on the advisory group. This may include such actions as placing notices or announcements in the newspapers or other media, mailing written notices to interested parties, contacting organizations or individuals directly, requesting organizations to notify their members through meetings, newsletters, or other means.

(iii) Where the membership composition set forth in paragraph (c)(1) of this section is not met after the above actions, the assisted agency shall identify the causative problems and make additional efforts to overcome such problems. For example, the agency should make personal contact with prospective participants to invite their participation.

(iv) Where problems in meeting the membership composition arise, the agency should request advice and assistance from EPA.

(d) The assisted agency shall record the names and mailing addresses of each member of the advisory group, with the attributes of each in relation to the membership requirements set forth in paragraph (c)(1) of this section, provide a copy to EPA, and make the list available to the public. In the event that the membership requirements set forth in paragraph (c)(1) of this section are not met, the assisted agency shall append to the list a description of its efforts to comply with those requirements and an explanation of the problems which prevented compliance. EPA shall review the agency's efforts to comply and approve the advisory group composition or, if the agency's efforts were inadequate, require additional actions to achieve the required membership composition.

(e) *Responsibilities of the assisted agency.* (1) The assisted agency shall designate a staff contact who will be responsible for day-to-day coordination among the advisory group, the agency, and any agency contractors or consultants. The financial assistance agreement shall include a budget item for this staff contact. Where substantial portions of the assisted agency's responsibilities will be met under contract, the agency shall require a similar designation, and budget specification, of its contractor. In the latter event, the assisted agency does not have to designate a separate staff contact on its own staff, if the Regional Administrator determines that the contractor's designation will result in adequate coordination. The staff contact shall be located in the project area.

(2) The assisted agency has such responsibilities as providing the advisory group with information, identifying issues for the advisory group's consideration, consulting with the advisory group throughout the project, requesting the advisory group's recommendations prior to major decisions, transmitting advisory group recommendations to decision-making officials, and making written responses to any formal recommendation by the advisory group. The agency shall make any such written responses available to the public. To the maximum extent feasible, the assisted agency shall involve the advisory group in the development of the public participation program.

(3) The assisted agency shall identify professional and clerical staff time which the advisory group may depend upon for assistance, and provide the advisory group with an operating budget which may be used for technical assistance and other purposes agreed upon between the advisory group and the agency.

(4) The assisted agency shall establish a system to make costs of reasonable out-of-pocket expenses of advisory group participation available to group members. Time away from work need not be reimbursed; however, assisted agencies are encouraged to schedule meetings at times and places which will not require members to leave their jobs to attend.

(f) *Advisory group responsibilities and duties.* The advisory group may select its own chairperson, adopt its own rules of order, and schedule and conduct its own meetings. Advisory group meetings shall be announced well in advance and shall be open to the public. At all meetings, the advisory group shall provide opportunity for public comment. Any minutes of advisory group meetings and recommendations to the assisted agency shall be available to the public. The advisory group should monitor the progress of the project and become familiar with issues relevant to project development. In the event the assisted agency and the advisory group agree that the advisory group will assume public participation responsibilities, the group should undertake those responsibilities promptly. The advisory group should make written recommendations directly to the assisted agency and to responsible decision-making officials on major decisions (including approval of the public participation program) and respond to any requests from the agency or decision-making officials for recommendations. The advisory group should remain aware of community attitudes and responses to issues as they arise. As part of this effort, the advisory group may, within the limitations of available resources, conduct public participation activities in conjunction with the assisted agency; solicit outside advice; and establish, in conjunction with the assisted agency, subcommittees, ad hoc groups, or task forces to investigate and develop recommendations on particular issues as they arise. The advisory group should undertake its responsibilities fully and promptly in accordance with the policies and requirements of this part. Nothing shall preclude the right of the advisory group from requesting EPA to perform an evaluation of the assisted agency's compliance with the requirements of this part.

(g) *Training and assistance.* EPA will promptly provide appropriate written guidance and project information to the newly formed advisory group and may provide advice and assistance to the group throughout the life of the project. EPA will develop and, in conjunction with the State or assisted agency, carry out a program to provide a training session for the advisory group, and appropriate assisted agency representatives, promptly after the advisory group is formed. The assisted agency shall provide additional needed information or assistance to the advisory group.

§ 25.8 Responsiveness summaries.

Each agency which conducts any activities required under this part shall prepare a Responsiveness Summary at specific decision points as specified in program regulations or in the approved public participation work plan. Responsiveness Summaries are also required for rulemaking activities under § 25.10. Each Responsiveness Summary shall identify the public participation activity conducted; describe the matters on which the public was consulted; summarize the public's views, significant comments, criticisms and suggestions; and set forth the agency's specific responses in terms of modifications of the proposed action or an explanation for rejection of proposals made by the public. Responsiveness Summaries prepared by agencies receiving EPA financial assistance shall also include evaluations by the agency of the effectiveness of the public participation program. Assisted agencies shall request such evaluations from any advisory group and provide an opportunity for other participating members of the public to contribute to the evaluation. (In the case of programs with multiple responsiveness summary requirements, these analyses need only be prepared and submitted with the final summary required.) Responsiveness summaries shall be forwarded to the appropriate decision-making official and shall be made available to the public. Responsiveness Summaries

shall be used as part of evaluations required under this part or elsewhere in this chapter.

§ 25.9 Permit enforcement.

Each agency administering a permit program shall develop internal procedures for receiving evidence submitted by citizens about permit violations and ensuring that it is properly considered. Public effort in reporting violations shall be encouraged, and the agency shall make available information on reporting procedures. The agency shall investigate alleged violations promptly.

§ 25.10 Rulemaking.

(a) EPA shall invite and consider written comments on proposed and interim regulations from any interested or affected persons and organizations. All such comments shall be part of the public record, and a copy of each comment shall be available for public inspection. EPA will maintain a docket of comments received and any Agency responses. Notices of proposed and interim rulemaking, as well as final rules and regulations, shall be distributed in accordance with §25.4(c) to interested or affected persons promptly after publication. Each notice shall include information as to the availability of the full texts of rules and regulations (where these are not set forth in the notice itself) and places where copying facilities are available at reasonable cost to the public. Under Executive Order 12044 (March 23, 1978), further EPA guidance will be issued concerning public participation in EPA rulemaking. A Responsiveness Summary shall be published as part of the preamble to interim and final regulations. In addition to providing opportunity for written comments on proposed and interim regulations, EPA may choose to hold a public hearing.

(b) State rulemaking specified in §25.2(a)(1) shall be in accord with the requirements of paragraph (a) of this section or with the State's administrative procedures act, if one exists. However, in the event of conflict between a provision of paragraph (a) of this section and a provision of a State's administrative procedures act, the State's law shall apply.

§ 25.11 Work elements in financial assistance agreements.

(a) This section is applicable to activities under §25.2(a)(5) except as otherwise provided in parts 30 or 35.

(b) Each applicant for EPA financial assistance shall set forth in the application a public participation work plan or work element which reflects how public participation will be provided for, encouraged, and assisted in accordance with this part. This work plan or element shall cover the project period. At a minimum, the work plan or element shall include:

(1) Staff contacts and budget resources to be devoted to public participation by category;

(2) A proposed schedule for public participation activities to impact major decisions, including consultation points where responsiveness summaries will be prepared;

(3) An identification of consultation and information mechanisms to be used;

(4) The segments of the public targeted for involvement.

(c) All reasonable costs of public participation incurred by assisted agencies which are identified in an approved public participation work plan or element, or which are otherwise approved by EPA, shall be eligible for financial assistance.

(d) The work plan or element may be revised as necessary throughout the project period with approval of the Regional Administrator.

§ 25.12 Assuring compliance with public participation requirements.

(a) *Financial assistance programs*—(1) *Applications.* EPA shall review the public participation work plan (or, if no work plan is required by this chapter for the particular financial assistance agreement, the public participation element) included in the application to determine consistency with all policies and requirements of this part. No financial assistance shall be awarded unless EPA is satisfied that the public participation policies and requirements of this part and, any applicable public participation requirements found elsewhere in this chapter, will be met.

(2) *Compliance*—(i) *Evaluation.* EPA shall evaluate compliance with public

participation requirements using the work plan, responsiveness summary, and other available information. EPA will judge the adequacy of the public participation effort in relation to the objectives and requirements of § 25.3 and § 25.4 and other applicable requirements. In conducting this evaluation, EPA may request additional information from the assisted agency, including records of hearings and meetings, and may invite public comment on the agency's performance. The evaluation will be undertaken as part of any mid-project review required in various programs under this chapter; where no such review is required the review shall be conducted at an approximate mid-point in continuing EPA oversight activity. EPA may, however, undertake such evaluation at any point in the project period, and will do so whenever it believes that an assisted agency may have failed to meet public participation requirements.

(ii) *Remedial actions.* Whenever EPA determines that an assisted agency has not fully met public participation requirements, EPA shall take actions which it deems appropriate to mitigate the adverse effects of the failure and assure that the failure is not repeated. For ongoing projects, that action shall include, at a minimum, imposing more stringent requirements on the assisted agency for the next budget period or other period of the project (including such actions as more specific output requirements and milestone schedules for output achievement; interim EPA review of public participation activities and materials prepared by the agency, and phased release of funds based on compliance with milestone schedules.) EPA may terminate or suspend part or all financial assistance for non-compliance with public participation requirements, and may take any further actions that it determines to be appropriate in accordance with parts 30 and 35 of this chapter (see, in particular, §§ 30.340, Noncompliance and 30.615–3, Withholding of Payments, and subpart H of part 30, Modification, Suspension, and Termination).

(b) *State programs approved in lieu of Federal programs.* State compliance with applicable public participation requirements in programs specified in § 25.2(a) (6) and (7) and administered by approved States shall be monitored by EPA during the annual review of the State's program, and during any financial or program audit or review of these programs. EPA may withdraw an approved program from a State for failure to comply with applicable public participation requirements.

(c) *Other covered programs.* Assuring compliance with these public participation requirements for programs not covered by paragraphs (a) and (b) of this section is the responsibility of the Administrator of EPA. Citizens with information concerning alleged failures to comply with the public participation requirements should notify the Administrator. The Administrator will assure that instances of alleged non-compliance are promptly investigated and that corrective action is taken where necessary.

§ 25.13 Coordination and non-duplication.

The public participation activities and materials that are required under this part should be coordinated or combined with those of closely related programs or activities wherever this will enhance the economy, the effectiveness, or the timeliness of the effort; enhance the clarity of the issue; and not be detrimental to participation by the widest possible public. Hearings and meetings on the same matter may be held jointly by more than one agency where this does not conflict with the policy of this paragraph. Special efforts shall be made to coordinate public participation procedures under this part and applicable regulations elsewhere in this chapter with environmental assessment and analysis procedures under 40 CFR part 6. EPA encourages interstate agencies in particular to develop combined proceedings for the States concerned.

§ 25.14 Termination of reporting requirements.

All reporting requirements specifically established by this part will terminate on (5 years from date of publication) unless EPA acts to extend the requirements beyond that date.

PART 26—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA

Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

Subparts E–J [Reserved]

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

AUTHORITY: 5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Pub. L. 109–54, 119 Stat. 531; and 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

Subpart A—Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA

SOURCE: 82 FR 7273, Jan. 19, 2017, unless otherwise noted.

§ 26.101 To what does this policy apply?

(a) Except as detailed in § 26.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

(b) [Reserved]

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this

policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.[62]

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Federal department or agency but not otherwise covered by this policy comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report.[63] Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.

(j) Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible.

(k) [Reserved]

(l) Compliance dates and transition provisions:

(1) For purposes of this section, the *pre-2018 Requirements* means this subpart as published in the 2016 edition of the Code of Federal Regulations.

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The compliance date for § 26.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) Research initially approved by an IRB, for which such review was waived pursuant to § 26.101(i), or for which a determination was made that the research was exempt before July 19, 2018,

[62] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.– Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979.

[63] *Id.*

shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to § 26.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

(m) Severability: Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[82 FR 7273, Jan. 19, 2017, as amended at 83 FR 2893, Jan. 22, 2018]

§ 26.102 Definitions for purposes of this policy.

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

(c) *Department or agency head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

(d) *Federal department or agency* refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.*, the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) *Interaction* includes communication or interpersonal contact between investigator and subject.

(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.*, a medical record).

(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(7) Federal departments or agencies implementing this policy shall:

(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of ''identifiable private information,'' as defined in paragraph (e)(5) of this section, and ''identifiable biospecimen,'' as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate ''identifiable private information,'' as defined in paragraph (e)(5) of this section, or an ''identifiable biospecimen,'' as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the FEDERAL REGISTER after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

(f) *Institution* means any public or private entity, or department or agency (including federal, state, and other agencies).

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(j) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(k) *Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) *Written,* or *in writing*, for purposes of this part, refers to writing on a tangible medium (*e.g.*, paper) or in an electronic format.

§ 26.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.

(a) Each institution engaged in research that is covered by this policy, with the exception of research eligible for exemption under § 26.104, and that is conducted or supported by a Federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for Federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office. Federal departments and agencies will conduct or support research covered by this policy only if the institution has provided an assurance that it will comply with the requirements of this policy, as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB (if such certification is required by § 26.103(d)).

(b) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(c) The department or agency head may limit the period during which any assurance shall remain effective or otherwise condition or restrict the assurance.

(d) Certification is required when the research is supported by a Federal department or agency and not otherwise waived under § 26.101(i) or exempted under § 26.104. For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research. Under no condition shall research covered by this section be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB.

(e) For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to § 26.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the

IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (*e.g.*, in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

(Approved by the Office of Management and Budget under Control Number 0990–0260)

§ 26.104 Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B.* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C.* The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D.* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 26.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §26.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such

projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §26.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §26.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §26.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §26.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

§§ 26.105–26.106 [Reserved]

§ 26.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 26.108 IRB functions and operations.

(a) In order to fulfill the requirements of this policy each IRB shall:

(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

(3) Establish and follow written procedures for:

(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

(iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of

(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

(ii) Any suspension or termination of IRB approval.

(b) Except when an expedited review procedure is used (as described in § 26.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

§ 26.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § 26.104 for which limited IRB review is a condition of exemption (under § 26.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 26.116. The IRB may require that information, in addition to that specifically mentioned in § 26.116, be given to the subjects when in the IRB's judgment the information

would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 26.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 26.109(f).

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with § 26.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in § 26.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

(2) [Reserved.]

(g) An IRB shall have authority to observe or have a third party observe the consent process and the research.

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§ 26.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary of HHS has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the FEDERAL REGISTER for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption under § 26.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in § 26.108(b).

(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ 26.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.*, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § 26.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § 26.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) [Reserved]

(8) For purposes of conducting the limited IRB review required by § 26.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § 26.116(a)(1)–(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § 26.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 26.112 Review by Institution

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 26.113 Suspension or Termination of IRB Approval of Research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval

shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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§ 26.114 Cooperative Research.

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

§ 26.115 IRB Records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in § 26.109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 26.108(a)(2).

(6) Written procedures for the IRB in the same detail as described in § 26.108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by § 26.116(c)(5).

(8) The rationale for an expedited reviewer's determination under § 26.110(b)(1)(i) that research appearing on the expedited review list described in § 26.110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in § 26.103(e).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

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§ 26.116 General Requirements for Informed Consent.

(a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical

treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.* Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or

identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials*—(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(A) Public benefit or service programs;

(B) Procedures for obtaining benefits or services under those programs;

(C) Possible changes in or alternatives to those programs or procedures; or

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and

(ii) The research could not practicably be carried out without the waiver or alteration.

(f) *General waiver or alteration of consent*—(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad

consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) *Screening, recruiting, or determining eligibility.* An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) *Posting of clinical trial consent form.* (1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) *Preemption.* The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) *Emergency medical care.* Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

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§ 26.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

(1) A written informed consent form that meets the requirements of § 26.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by § 26.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by § 26.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

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§ 26.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under § 26.101(i) or exempted under § 26.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy,

and certification submitted, by the institution, to the Federal department or agency component supporting the research.

§ 26.119 Research undertaken without the intention of involving human subjects.

Except for research waived under § 26.101(i) or exempted under § 26.104, in the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

§ 26.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the Federal department or agency through such officers and employees of the Federal department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 26.121 [Reserved]

§ 26.122 Use of Federal funds.

Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 26.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that Federal department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 26.124 Conditions.

With respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.201 To what does this subpart apply?

(a) This subpart applies to all research involving intentional exposure of any human subject who is a pregnant woman (and her fetus) or a child conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 26.202 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) are applicable to this subpart.

(a) *Research involving intentional exposure of a human subject* means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(b) A *child* is a person who has not attained the age of 18 years.

§ 26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or child.

Notwithstanding any other provision of this part, under no circumstances shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[71 FR 36175, June 23, 2006]

Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.301 To what does this subpart apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all observational research involving human subjects who are pregnant women (and therefore their fetuses) conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The exemptions at § 26.101(b)(1) through (b)(6) are applicable to this subpart.

(c) The provisions of § 26.101(c) through (i) are applicable to this subpart. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 26.302 Definitions.

The definitions in §§ 26.102 and 26.202 shall be applicable to this subpart as well. In addition, *observational research* means any human research that does not meet the definition of *research involving intentional exposure of a human subject* in § 26.202(a).

§ 26.303 Duties of IRBs in connection with observational research involving pregnant women and fetuses.

The provisions of 45 CFR 46.203 are applicable to this section.

§ 26.304 Additional protections for pregnant women and fetuses involved in observational research.

The provisions of 45 CFR 46.204 are applicable to this section.

§ 26.305 Protections applicable, after delivery, to the placenta, the dead fetus, or fetal material.

The provisions of 45 CFR 46.206 are applicable to this section.

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.401 To what does this subpart apply?

(a) This subpart applies to all observational research involving children as subjects, conducted or supported by EPA. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments. This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) Exemptions at § 26.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 26.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 26.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 26.101(c) through (i) are applicable to this subpart.

§ 26.402 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the following terms are defined:

(a) For purposes of this subpart, *Administrator* means the Administrator of the Environmental Protection Agency and any other officer or employee of the Environmental Protection Agency to whom authority has been delegated by the Administrator.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State, Tribal, or local law to consent on behalf of a child to general medical care.

(f) *Observational research* means any research with human subjects that does not meet the definition of research involving intentional exposure of a human subject in § 26.202(a).

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

§ 26.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review observational research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

§ 26.404 Observational research not involving greater than minimal risk.

EPA will conduct or fund observational research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 26.406.

§ 26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

If the IRB finds that an intervention or procedure presents more than minimal risk to children, EPA will not conduct or fund observational research that includes such an intervention or procedure unless the IRB finds and documents that:

(a) The intervention or procedure holds out the prospect of direct benefit

to the individual subject or is likely to contribute to the subject's well-being;

(b) The risk is justified by the anticipated benefit to the subjects;

(c) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 26.406.

§ 26.406 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the observational research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the observational research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 26.116(d).

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 26.116, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 26.404 or § 26.405.

(c) In addition to the provisions for waiver contained in § 26.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may replace the consent requirements in subpart A of this part and paragraph (b) of this section with provided an appropriate, equivalent mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate, equivalent mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 26.117.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Subparts E–J [Reserved]

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1101 To what does this subpart apply?

(a) Except as provided in paragraph (c) of this section, this subpart applies to all research initiated on or after April 15, 2013 involving intentional exposure of a human subject to:

(1) Any substance if, at any time prior to initiating such research, any

person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136–136y) or section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a), or to hold the results of the research for later inspection by EPA under FIFRA or section 408 of FFDCA; or

(2) A pesticide if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section, or to hold the results of the research for later inspection by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section.

(b) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available and relevant information. EPA must rebuttably presume the existence of intent if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the research was initiated, the results of such research would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

(c) Unless otherwise required by the Administrator, research is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(d) The EPA Administrator retains final judgment as to whether a particular activity is covered by this subpart.

(e) Compliance with this subpart requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This subpart does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. Reference to State or local laws in this subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(g) This subpart does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10543, Feb. 14, 2013]

§ 26.1102 Definitions.

(a) *Administrator* means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including Federal, State, and other agencies).

(c) *Pesticide* means any substance or mixture of substances meeting the definition in 7 U.S.C. 136(u) (Federal Insecticide, Fungicide, and Rodenticide Act, section 2(u)).

(d) *Research* means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this subpart, whether or not they are considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(3) ''Intervention'' includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. ''Private information'' includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(f) *IRB* means an institutional review board established in accord with and for the purposes expressed in this part.

(g) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(h) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) *Research involving intentional exposure of a human subject means* a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(j) *Person* means any person, as that term is defined in FIFRA section 2(s) (7 U.S.C. 136), except:

(1) A federal agency that is subject to the provisions of the Federal Policy for the Protection of Human Subjects of Research, and

(2) A person when performing human research supported by a federal agency covered by paragraph (j)(1) of this section.

(k) *Common Rule* refers to the Federal Policy for the Protection of Human Subjects that was established in 1991 by the Office of Science and Technology Policy and codified in 1991 by EPA and 14 other Federal departments and agencies (see the FEDERAL REGISTER issue of June 18, 1991 (56 FR 28003)) and subsequently codified by other Federal departments and agencies. The Common Rule contains a widely accepted set of standards for conducting ethical research with human subjects, together with a set of procedures designed to ensure that the standards are met. Once codified by a Federal department or agency, the requirements of the Common Rule apply to research conducted or sponsored by that Federal department or agency. EPA's codification of the Common Rule appears in 40 CFR part 26, subpart A.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10543, Feb. 14, 2013]

§§ 26.1103–26.1106 [Reserved]

§ 26.1107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities which are presented for its approval. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB

regularly reviews research that involves a vulnerable category of subjects, such as prisoners or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 26.1108 IRB functions and operations.

In order to fulfill the requirements of this subpart each IRB shall:

(a) Follow written procedures:

(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(2) For determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(3) For ensuring prompt reporting to the IRB of proposed changes in research activity; and

(4) For ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Environmental Protection Agency of:

(1) Any unanticipated problems involving risks to human subjects or others;

(2) Any instance of serious or continuing noncompliance with this subpart of the requirements or determinations of the IRB; or

(3) Any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see § 26.1110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 26.1109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this subpart.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 26.1116. The IRB may require that information, in addition to that specifically mentioned in § 26.1116 be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with § 26.1117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this subpart at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review either or both of the following:

(i) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(ii) Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 26.1108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Administrator may restrict, suspend, or terminate, an institution's or IRB's use of the expedited review procedure for research covered by this subpart.

§ 26.1111 Criteria for IRB approval of research.

(a) In order to approve research covered by this subpart the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject, in accordance with, and to the extent required by § 26.1116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 26.1117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10543, Feb. 14, 2013]

§ 26.1112 Review by institution.

Research covered by this subpart that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 26.1113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Administrator of EPA.

§ 26.1114 Cooperative research.

In complying with this subpart, sponsors, investigators, or institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 26.1115 IRB records.

(a) An IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).

(7) Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).

(b) The records required by this subpart shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of EPA at reasonable times and in a reasonable manner.

§ 26.1116 General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject. An investigator must seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject must be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in this subpart are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(d) Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(e) If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10543, Feb. 14, 2013]

§ 26.1117 Documentation of informed consent.

(a) Informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject. A copy shall be given to the subject.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 26.1116. This form may be read to the subject, but in any event, the investigator must give the subject adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 26.1116 have been presented orally to the subject. When this method is used, there must be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject. Only the short form itself is to be signed by the subject. However, the witness must sign both the short form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary. A copy of the summary must be given to the subject, in addition to a copy of the short form.

[78 FR 10543, Feb. 14, 2013]

§§ 26.1118–26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by § 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by § 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L—Prohibition of Third-Party Research involving Intentional Exposure to a Pesticide of Human Subjects who are Children or Pregnant or Nursing Women

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1201 To what does this subpart apply?

This subpart applies to any research subject to subpart K of this part.

[78 FR 10544, Feb. 14, 2013]

§ 26.1202 Definitions.

The definitions in § 26.1102 shall be applicable to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) are applicable to this subpart. In addition, a child is a person who has not attained the age of 18 years.

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or support research covered by § 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[71 FR 36175, June 23, 2006]

Subpart M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA on or after April 15, 2013 either of the following:

(a) A report containing the results of any human research for consideration in connection with an action that may be performed by EPA under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a).

(b) A report containing the results of any human research on or with a pesticide for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA.

[78 FR 10544, Feb. 14, 2013]

§ 26.1302 Definitions.

The definitions in § 26.102 apply to this subpart as well.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10544, Feb. 14, 2013]

§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by § 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in § 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by § 26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N [Reserved]

Subpart O—Administrative Actions for Noncompliance

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§ 26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the

operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection, EPA may send a letter describing the noncompliance to the IRB and to the parent institution. EPA will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, EPA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, EPA may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10544, Feb. 14, 2013]

§ 26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the Agency under § 26.1502(a) and the EPA Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate, the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in § 26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in § 26.1706.

§ 26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are disclosable to the public under 40 CFR part 2.

§ 26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 26.1502(b)(4).

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10544, Feb. 14, 2013]

§ 26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 2 CFR part 1532.

[71 FR 6168, Feb. 6, 2006, as amended at 72 FR 2427, Jan. 19, 2007]

§ 26.1507 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other statutorily authorized proceedings or actions. EPA may, at any time, on its own initiative or through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. EPA may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10544, Feb. 14, 2013]

Subpart P—Review of Proposed and Completed Human Research

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1601 To what does this subpart apply?

This subpart applies to both of the following:

(a) Reviews by EPA and by the Human Studies Review Board of proposals to conduct new research subject to § 26.1125.

(b) Reviews by EPA on or after April 15, 2013 and, to the extent required by § 26.1604, by the Human Studies Review Board of reports of completed research subject to § 26.1701.

[78 FR 10544, Feb. 14, 2013]

§ 26.1602 Definitions.

The definitions in § 26.1102 also apply to this subpart.

[78 FR 10544, Feb. 14, 2013]

§ 26.1603 EPA review of proposed human research.

(a) EPA must review all proposals for new human research submitted under § 26.1125 in a timely manner.

(b) In reviewing proposals for new human research submitted under § 26.1125, the EPA Administrator must consider and make determinations regarding the scientific validity and reliability of the proposed research, including:

(1) Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research.

(2) Whether the proposed research is designed in accordance with current scientific standards and practices to:

(i) Address the research question.

(ii) Include representative study populations for the endpoint in question.

(iii) Have adequate statistical power to detect appropriate effects.

(3) Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.

(c) In reviewing proposals for new research submitted under §26.1125, the EPA Administrator must consider and make determinations regarding ethical aspects of the proposed research, including:

(1) Whether adequate information is available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research.

(2) Whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence, minimizes identified risks to human subjects, and identifies likely benefits of the research and their distribution.

(3) Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the EPA Administrator will also consider the process laid out and the attendant discussion for evaluating that type of study as provided in Recommendation 4–1 of the 2004 Report from the National Research Council of the National Academy of Sciences (NAS), entitled ''Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues.''

(4) Whether subject selection will be equitable.

(5) Whether subjects' participation would follow free and fully informed consent.

(6) Whether an appropriately constituted IRB or its foreign equivalent has approved the proposed research.

(7) If any person from a vulnerable population may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate.

(8) If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate.

(9) Whether any proposed payments to subjects are consistent with the principles of justice and respect for persons, and whether they are so high as to constitute undue inducement or so low as to be attractive only to individuals who are socioeconomically disadvantaged.

(10) Whether the sponsor or investigator would provide needed medical care for injuries incurred in the proposed research, without cost to the human subjects.

(d) With respect to any research or any class of research subject to this subpart, the EPA Administrator may recommend additional conditions which, in the judgment of the EPA Administrator, are necessary for the protection of human subjects.

(e) In reviewing proposals covered by this subpart, the Administrator may take into account factors such as whether the applicant has been subject to a termination or suspension under §26.123(a) or §26.1123 and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Administrator, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(f) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

(g) Following initial evaluation of the protocol by Agency staff, EPA shall submit the protocol and all supporting materials, together with the

staff evaluation, to the Human Studies Review Board.

(h) EPA must provide the submitter of the proposal copies of the EPA and Human Studies Review Board reviews.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78 FR 10544, Feb. 14, 2013 and amended at 78 FR 10544, Feb. 14, 2013]

§ 26.1604 EPA review of completed human research.

(a) When considering, under any regulatory statute it administers, data from completed research involving intentional exposure of humans to a pesticide, EPA must thoroughly review the material submitted under § 26.1303, if any, and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall notify the submitter of the research of the results of the EPA and Human Studies Review Board reviews.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78 FR 10544, Feb. 14, 2013 and amended at 78 FR 10545, Feb. 14, 2013]

§ 26.1605 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) *Membership.* The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) *Responsibilities.* The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78 FR 10544, Feb. 14, 2013]

§ 26.1606 Human Studies Review Board review of proposed human research.

In commenting on proposals for new research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the proposed research, including all elements required in § 26.1603(b) and (c) and any additional conditions recommended pursuant to § 26.1603(d).

[78 FR 10545, Feb. 14, 2013]

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the completed research, and must apply the appropriate standards in subpart Q of this part.

[78 FR 10545, Feb. 14, 2013]

Subpart Q—Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1701 To what does this subpart apply?

(a) For decisions under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a), this subpart applies to research involving intentional exposure of human subjects to any substance.

(b) For decisions under any regulatory statute administered by EPA other than those statutes designated in paragraph (a) of this section, this subpart applies to research involving intentional exposure of human subjects to a pesticide.

[78 FR 10545, Feb. 14, 2013]

§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 also apply to this subpart.

[78 FR 10545, Feb. 14, 2013]

§ 26.1703 Prohibitions applying to all research subject to this subpart.

(a) Prohibition of reliance on scientifically invalid research. EPA must not rely on data from research subject to this subpart unless EPA determines that the data are relevant to a scientific or policy question important for EPA decisionmaking, that the data were derived in a manner that makes them scientifically valid and reliable, and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA must consider:

(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted.

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question.

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data.

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research subject to this subpart involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children. Except as provided in § 26.1706, EPA must not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[78 FR 10545, Feb. 14, 2013]

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults.

(a) This section applies to research subject to this subpart that is not subject to § 26.1705.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section if there is clear and convincing evidence that:

(1) The conduct of the research was fundamentally unethical (*e.g.*, the research was intended to seriously harm participants or failed to obtain informed consent); or

(2) The conduct of the research was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(c) The prohibition in this section is in addition to the prohibitions in § 26.1703.

[78 FR 10545, Feb. 14, 2013]

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated after April 7, 2006.

(a) This section applies to research subject to this subpart, that:

(1) Was initiated after April 7, 2006.

(2) Was subject, at the time it was conducted, either to subparts A through L of this part, or to the codification of the Common Rule by another Federal department or agency.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) All applicable provisions of subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency; or

(2) If the research was conducted outside the United States, with procedures at least as protective of subjects as

those in subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

(c) Except as provided in §26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) A proposal that was found to be acceptable under §26.1603(c), and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under §26.1603(c), EPA must not rely on that data.

(2) A proposal that would have been found to be acceptable under §26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(d) The prohibition in this section is in addition to the prohibitions in §26.1703.

[78 FR 10545, Feb. 14, 2013]

§26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA has published a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10546, Feb. 14, 2013]

PART 27—PROGRAM FRAUD CIVIL REMEDIES

Sec.

AUTHORITY: 31 U.S.C. 3801–3812; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note; Pub. L. 104–134, 110 Stat. 1321, 31 U.S.C. 3701 note.

SOURCE: 53 FR 15182, Apr. 27, 1988, unless otherwise noted.

§ 27.1 Basis and purpose.

(a) *Basis.* This part implements the Program Fraud Civil Remedies Act of 1986, Public Law No. 99–509, sections 6101–6104, 100 Stat. 1874 (October 21, 1986), to be codified at 31 U.S.C. 3801–3812. 31 U.S.C. 3809 of the statute requires each authority head to promulgate regulations necessary to implement the provisions of the statute.

(b) *Purpose.* This part (1) establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to the Environmental Protection Agency, and (2) specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 27.2 Definitions.

Administrative Law Judge means an administrative law judge in the Authority appointed pursuant to 5 U.S.C. 3105 or detailed to the Authority pursuant to 5 U.S.C. 3344.

Administrator means the Administrator of the United States Environmental Protection Agency.

Authority means the United States Environmental Protection Agency.

Benefit means, in the context of ''statement,'' anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.

Claim means any request, demand, or submission—

(a) Made to the Authority for property, services, or money (including money representing grants, loans, insurance, or benefits);

(b) Made to a recipient of property, services, or money from the Authority or to a party to a contract with the Authority—

(1) For property or services if the United States—

(i) Provided such property or services;

(ii) Provided any portion of the funds for the purchase of such property or services; or

(iii) Will reimburse such recipient or party for the purchase of such property or services; or

(2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

(i) Provided any portion of the money requested or demanded; or

(ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or

(c) Made to the Authority which has the effect of decreasing an obligation to pay or account for property, services, or money.

Complaint means the administrative complaint served by the reviewing official on the defendant under § 27.7.

Defendant means any person alleged in a complaint under § 27.7 to be liable for a civil penalty or assessment under § 27.3.

Environmental Appeals Board means the Board within the Agency described in § 1.25 of this title.

Government means the United States Government.

Hearing Clerk means the Office of the Hearing Clerk (1900), United States Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Individual means a natural person.

Initial decision means the written decision of the presiding officer required by § 27.10 or § 27.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating official means the Inspector General of the United States

Environmental Protection Agency or an officer or employee of the Office of Inspector General designated by the Inspector General and serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–16 under the General Schedule.

Knows or has reason to know means that a person, with respect to a claim or statement—

(a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(b) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(c) Acts in reckless disregard of the truth or falsity of the claim or statement.

Makes, wherever it appears, shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, *making* or *made* shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association, or private organization, and includes the plural of those terms.

Presiding officer means the administrative law judge designated by the Chief administrative law judge to serve as presiding officer.

Representative means an attorney who is a member in good standing of the bar of any State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico, or other representative who must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

Reviewing official means the General Counsel of the Authority or his designee who is—

(a) Not subject to supervision by, or required to report to, the investigating official;

(b) Not employed in the organizational unit of the Authority in which the investigating official is employed; and

(c) Serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–16 under the General Schedule.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—

(a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or

(b) With respect to (including relating to eligibility for)—

(1) A contract with, or a bid or proposal for a contract with; or

(2) A grant, loan, or benefit from,

the Authority, or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5326, Feb. 13, 1992]

§ 27.3 Basis for civil penalties and assessments.

(a) *Claims.* (1) Except as provided in paragraph (c) of this section, any person who makes a claim that the person knows or has reason to know—

(i) Is false, fictitious, or fraudulent;

(ii) Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes, or is supported by, any written statement that—

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of such omission; and

(C) Is a statement in which the person making such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than the operative effective statutory maximum amount, as provided in 40 CFR 19.4, [1] for each such claim.

[1] As adjusted in accordance with the Federal Civil Penalties Inflation Adjustment

Continued

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to the Authority, recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the Authority, recipient, or party.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section, shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1) of this section. Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(b) *Statements.* (1) Except as provided in paragraph (c) of this section, any person who makes a written statement that—

(i) The person knows or has reason to know—

(A) Asserts a material fact which is false, factitious, or fraudulent; or

(B) Is false, factitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and

(ii) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than the operative effective statutory maximum amount, as provided in 40 CFR 19.4,[2] for each such statement.

(2) Each written representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to the Authority when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of such Authority.

(c) No proof of specific intent to defraud is required to establish liability under this section.

(d) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty under this section.

(e) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons.

[53 FR 15182, Apr. 27, 1988, as amended at 61 FR 69366, Dec. 31, 1996; 69 FR 7126, Feb. 13, 2004; 73 FR 75346, Dec. 11, 2008]

§ 27.4 Investigation.

(a) If the investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted—

(1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued and shall identify the records or documents sought;

(2) The investigating official may designate a person to act on his or her behalf to receive the documents sought; and

(3) The person receiving such subpoena shall be required to tender to the investigating official or the person designated to receive the documents a certification that the documents sought have been produced, or that such documents are not available and the reasons therefor, or that such documents,

Act of 1990 (Pub. L. 101–410, 104 Stat. 890), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, 110 Stat. 1321).

[2] As adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, 110 Stat. 1321).

suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.

(c) Nothing in this section shall preclude or limit an investigating official's discretion to defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution.

(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

§ 27.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under § 27.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under § 27.3 of this part, the reviewing official shall transmit to the Attorney General a written notice of the reviewing official's intention to issue a complaint under § 27.7.

(b) Such notice shall include—

(1) A statement of the reviewing official's reasons for issuing a complaint;

(2) A statement specifying the evidence that supports the allegations of liability;

(3) A description of the claims or statements upon which the allegations of liability are based;

(4) An estimate of the amount of money or the value of property, services, or other benefits requested or demanded in violation of § 27.3 of this part;

(5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and

(6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

§ 27.6 Prerequisites for issuing a complaint.

(a) The reviewing official may issue a complaint under § 27.7 only if—

(1) The Department of Justice approves the issuance of a complaint in written statement described in 31 U.S.C. 3803(b)(1), and

(2) In the case of allegations of liability under § 27.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money or the value of property or services demanded or requested in violation of § 27.3(a) does not exceed $150,000.

(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person, claims that are unrelated or were not submitted simultaneously, regardless of the amount of money, or the value of property or services, demanded or requested.

§ 27.7 Complaint.

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing official may serve a complaint on the defendant, as provided in § 27.8.

(b) The complaint shall state—

(1) The allegations of liability against the defendant, including the statuory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant's right

to request a hearing by filing an answer and to be represented by a representative; and

(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the maximum amount of penalties and assessments without right to appeal as provided in § 27.10.

(c) At the same time the reviewing official serves the complaint, he or she shall serve the defendant with a copy of these regulations.

§ 27.8 Service of complaint.

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by Rule 4(d) of the Federal Rules of Civil Procedure. Service is complete upon receipt.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by—

(1) Affidavit of the individual serving the complaint by delivery;

(2) A United States Postal Service return receipt card acknowledging receipt; or

(3) Written acknowledgment of receipt by the defendant or his or her representative.

§ 27.9 Answer.

(a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for hearing.

(b) In the answer, the defendant—

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant's representative, if any.

(c) If the defendant is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the defendant may, before the expiration of 30 days from service of the complaint, file with the reviewing official a general answer denying liability and requesting a hearing, and a request for an extension of time within which to file an answer meeting requirements of paragraph (b) of this section. The reviewing official shall file promptly with the hearing clerk the complaint, the general answer denying liability, and the request for an extension of time as provided in § 27.11. Upon assignment to a presiding officer, the presiding officer may, for good cause shown, grant the defendant up to 30 additional days within which to file an answer meeting the requirements of paragraph (b) of this section.

§ 27.10 Default upon failure to file an answer.

(a) If the defendant does not file an answer within the time prescribed in § 27.9(a), the reviewing official may file the complaint with the hearing clerk as provided in § 27.11.

(b) Upon assignment of the complaint to a presiding officer, the presiding officer shall promptly serve on defendant in the manner prescribed in § 27.8, a notice that an initial decision will be issued under this section.

(c) The presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under § 27.3, the presiding officer shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the presiding officer's decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file

a timely answer, the presiding officer shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the presiding officer denying a defendant's motion under paragraph (e) of this section, is not subject to reconsideration under § 27.38.

(h) The defendant may appeal to the Environmental Appeals Board the decision denying a motion to reopen by filing a notice of appeal within 15 days after the presiding officer denies the section. The timely filing of a notice of appeal shall stay the initial decision the Environmental Appeals Board decides the issue.

(i) If the defendant files a timely notice of appeal, the presiding officer shall forward the record of the proceeding to the Environmental Appeals Board.

(j) The Environmental Appeals Board shall decide expeditiously whether extraordinary circumstances excuse the defendant's failure to file a timely answer based solely on the record before the presiding officer.

(k) If the Environmental Appeals Board decides that extraordinary circumstances excused the defendant's failure to file a timely answer, the Environmental Appeals Board shall remand the case to the presiding officer with instructions to grant the defendant an opportunity to answer.

(l) If the Environmental Appeals Board decides that the defendant's failure to file a timely answer is not excused, the Environmental Appeals Board shall reinstate the initial decision of the presiding officer, which shall become final and binding upon the parties 30 days after the Environmental Appeals Board issues such decision.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5326, Feb. 13, 1992]

§ 27.11 Referral of complaint and answer to the presiding officer.

(a) Upon receipt of an answer, the reviewing official shall file the complaint and answer with the hearing clerk.

(b) The hearing clerk shall forward the complaint and answer to the Chief administrative law judge who shall assign himself or herself or another administrative law judge as presiding officer. The presiding officer shall then obtain the complaint and answer from the Chief administrative law judge and notify the parties of his or her assignment.

§ 27.12 Notice of hearing.

(a) When the presiding officer obtains the complaint and answer, the presiding officer shall promptly serve a notice of hearing upon the defendant in the manner prescribed by § 27.8. At the same time, the presiding officer shall send a copy of such notice to the representative for the Government.

(b) Such notice shall include—

(1) The date, time and place, and the nature of the hearing;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The matters of fact and law to be asserted;

(4) A description of the procedures for the conduct of the hearing;

(5) The name, address, and telephone number of the representative of the Government and of the defendant, if any; and

(6) Such other matters as the presiding officer deems appropriate.

(c) The presiding officer shall issue the notice of hearing at least twenty (20) days prior to the date set for the hearing.

§ 27.13 Parties to the hearing.

(a) The parties to the hearing shall be the defendant and the Authority.

(b) Pursuant to 31 U.S.C. 3730(c)(5), a private plaintiff under the False Claims Act may participate in these proceedings to the extent authorized by the provisions of that Act.

§ 27.14 Separation of functions.

(a) The investigating official, the reviewing official, and any employee or agent of the Authority who takes part in investigating, preparing, or presenting a particular case, may not, in such case or a factually related case—

(1) Participate in the hearing as the presiding officer;

(2) Participate or advise in the initial decision or the review of the initial decision by the Environmental Appeals

Board, except as a witness or representative in public proceedings; or

(3) Make the collection of penalties and assessments under 31 U.S.C. 3806.

(b) Neither the presiding officer nor the members of the Environmental Appeals Board shall be responsible to, or subject to, the supervision or direction of the investigating official or the reviewing official.

(c) Except as provided in paragraph (a) of this section, the representative for the Government may be employed anywhere in the authority, including in the offices of either the investigating official or the reviewing official.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5326, Feb. 13, 1992]

§ 27.15 *Ex parte* contacts.

No party or person (except employees of the presiding officer's office) shall communicate in any way with the presiding officer on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine question concerning administrative functions or procedures.

§ 27.16 Disqualification of the reviewing official or presiding officer.

(a) A reviewing official or presiding officer in a particular case may disqualify himself or herself at any time.

(b) A party may file a motion for disqualification of a reviewing official or presiding officer with the hearing clerk. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.

(c) Such motion and affidavit shall be filed within 15 days of the party's discovery of reasons requiring disqualification, or such objections shall be deemed waived.

(d) Such affidavit shall state specific facts that support the party's belief that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.

(e) Upon the filing of such a motion and affidavit, the presiding officer shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with paragraph (f) of this section.

(f)(1) If the presiding officer determines that the reviewing official is disqualified because the reviewing official could not have made an impartial determination pursuant to §27.5(a), the presiding officer shall dismiss the complaint without prejudice.

(2) If the presiding officer disqualifies himself or herself, the case shall be reassigned promptly to another presiding officer.

(3) If the presiding officer denies a motion to disqualify, the Environmental Appeals Board may determine the matter only as part of its review of the initial decision upon appeal, if any.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5326, Feb. 13, 1992]

§ 27.17 Rights of parties.

Except as otherwise limited by this part, all parties may—

(a) Be accompanied, represented, and advised by a representative;

(b) Participate in any conference held by the presiding officer;

(c) Conduct discovery;

(d) Agree to stipulations of fact or law, which shall be made part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral arguments at the hearing as permitted by the presiding officer; and

(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 27.18 Authority of the presiding officer.

(a) The presiding officer shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The presiding officer has the authority to—

(1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;
(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
(4) Administer oaths and affirmations;
(5) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;
(6) Rule on motions and other procedural matters;
(7) Regulate the scope and timing of discovery;
(8) Regulate the course of the hearing and the conduct of representatives and parties;
(9) Examine witnesses;
(10) Receive, rule on, exclude, or limit evidence;
(11) Upon motion of a party, take official notice of facts;
(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;
(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and
(14) Exercise such other authority as is necessary to carry out the responsibilities of the presiding officer under this part.
(c) The presiding officer does not have the authority to find Federal statutes or regulations invalid.

§ 27.19 Prehearing conferences.

(a) The presiding officer may schedule prehearing conferences as appropriate.
(b) Upon the motion of any party, the presiding officer shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.
(c) The presiding officer may use prehearing conferences to discuss the following:
(1) Simplification of the issues;
(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
(3) Stipulations and admissions of fact as to the contents and authenticity of documents;
(4) Whether the parties can agree to submission of the case on a stipulated record;
(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;
(6) Limitation of the number of witnesses;
(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;
(8) Discovery;
(9) The time and place for the hearing; and
(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.
(d) The presiding officer may issue an order containing all matters agreed upon by the parties or ordered by the presiding officer at a prehearing conference.

§ 27.20 Disclosure of documents.

(a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under § 27.4(b) are based, unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.
(b) Upon written request to the reviewing official, the defendant also may obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.
(c) The notice sent to the Attorney General from the reviewing official as described in § 27.5 is not discoverable under any circumstances.
(d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed

following the filing of an answer pursuant to § 27.9.

§ 27.21 Discovery.

(a) The following types of discovery are authorized:

(1) Requests for production of documents for inspection and copying;

(2) Requests for admissions of the authenticity of any relevant document or of the truth of any relevant fact;

(3) Written interrogatories; and

(4) Depositions.

(b) For the purpose of this section and §§ 27.22 and 27.23, the term *documents* includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the presiding officer. The presiding officer shall regulate the timing of discovery.

(d) *Motions for discovery.* (1) A party seeking discovery may file a motion which shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(2) Within ten days of service, a party may file an opposition to the motion and/or a motion for protective order as provided in § 27.24.

(3) The presiding officer may grant a motion for discovery only if he finds that the discovery sought—

(i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;

(ii) Is not unduly costly or burdensome;

(iii) Will not unduly delay the proceeding; and

(iv) Does not seek privileged information.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

(5) The presiding officer may grant discovery subject to a protective order under § 27.24.

(e) *Depositions.* (1) If a motion for deposition is granted, the presiding officer shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will be held.

(2) The party seeking to depose shall serve the subpoena in the manner prescribed in § 27.8.

(3) The deponent may file a motion to quash the subpoena or a motion for a protective order within ten days of service.

(4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition, which it shall make available to all other parties for inspection and copying.

(f) Each party shall bear its own costs of discovery.

§ 27.22 Exchange of witness lists, statements, and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the presiding officer, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 27.33(b). At the time the above documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the presiding officer, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the presiding officer shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the presiding officer finds good cause for the failure or that there is not prejudice to the objecting party.

(c) Unless another party objects within the time set by the presiding officer, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 27.23 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the presiding officer issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 15 days before the date fixed for the hearing unless otherwise allowed by the presiding officer for good cause shown. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in §27.8. A subpoena on a party or upon an individual under the control of a party may be served by first class mail.

(f) A party or the individual to whom the subpoena is directed may file a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§27.24 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by a party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the presiding officer may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery other than that requested;

(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;

(5) That discovery be conducted with no one present except persons designated by the presiding officer;

(6) That the contents of discovery or evidence be sealed;

(7) That a deposition after being sealed be opened only by order of the presiding officer;

(8) That a trade secret or other confidential research, development, or commercial information, or facts pertaining to any criminal investigation, proceeding, or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the presiding officer.

§27.25 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of the Authority, a check for witness fees and mileage need not accompany the subpoena.

§27.26 Form, filing and service of papers.

(a) *Form.* (1) Documents filed with the hearing clerk shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the hearing clerk, and a designation of the paper (e.g., motion to quash subpoena).

(3) Every pleading and paper shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.

(b) *Service.* A party filing a document with the hearing clerk shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than those required to be served as prescribed in §27.8, shall be made by delivering a copy or by placing a copy of the document in the United States mail, postage prepaid and addressed, to the party's last known address. When a party is represented by a representative, service shall be made upon such representative in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

§ 27.27 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government shall be excluded from the computation.

(c) When a document has been served or issued by placing it in the mail, an additional five days will be added to the time permitted for any response.

§ 27.28 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with hearing clerk and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The presiding officer shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 27.29 Sanctions.

(a) The presiding officer may sanction a person, including any party or representative for—

(1) Failing to comply with an order, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission, the presiding officer may—

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The presiding officer may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§ 27.30 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under § 27.3 and, if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) The Authority shall prove defendant's liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer for good cause shown.

§ 27.31 Determining the amount of penalties and assessments.

(a) In determining an appropriate amount of civil penalties and assessments, the presiding officer and the Environmental Appeals Board, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, ordinarily double damages and a significant civil penalty should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the presiding officer and the Environmental Appeals Board in determining the amount of penalties and assessments to impose with respect to the misconduct (*i.e.*, the false, fictitious, or fraudulent claims or statements) charged in the complaint:

(1) The number of false, fictitious, or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the defendant's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;

(6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations, including particularly the impact on the intended beneficiaries of such programs;

(8) Whether the defendant has engaged in a pattern of the same or similar misconduct;

(9) Whether the defendant attempted to conceal the misconduct;

(10) The degree to which the defendant has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees or agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;

(12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;

(13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of the defendant's prior participation in the program or in similar transactions;

(15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly; and

(16) The need to deter the defendant and others from engaging in the same or similar misconduct.

(c) Nothing in this section shall be construed to limit the presiding officer or the Environmental Appeals Board from considering any other factors

that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5327, Feb. 13, 1992]

§ 27.32 Location of hearing.

(a) The hearing may be held—

(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which the claim or statement in issue was made; or

(3) In such other place as may be agreed upon by the defendant and the presiding officer.

(b) Each party shall have the opportunity to present argument with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the presiding officer.

§ 27.33 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the presiding officer, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in § 27.22(a).

(c) The presiding officer shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The presiding officer shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the presiding officer, a witness may be cross-examined on matters relevant to the proceeding without regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the presiding officer shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or empoyee of the party appearing for the entity *pro se* or designated by the party's representative; or

(3) an individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by the Government engaged in assisting the representative for the Government.

§ 27.34 Evidence.

(a) The presiding officer shall determine the admissibility of evidence.

(b) Except as provided in this part, the presiding officer shall not be bound by the Federal Rules of Evidence. However, the presiding officer may apply the Federal Rules of Evidence when appropriate, e.g., to exclude unreliable evidence.

(c) The presiding officer shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The presiding officer shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the presiding officer pursuant to § 27.24.

§ 27.35 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the hearing clerk at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the presiding officer and the Environmental Appeals Board.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the presiding officer pursuant to § 27.24.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5327, Feb. 13, 1992]

§ 27.36 Post-hearing briefs.

The presiding officer may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The presiding officer shall fix the time for filing such briefs, not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The presiding officer may permit the parties to file responsive briefs.

§ 27.37 Initial decision.

(a) The presiding officer shall issue an initial decision based only on the record. The decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the claims or statements identified in the complaint, or any portions thereof, violate § 27.3;

(2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments considering any mitigating or aggravating factors that he or she finds in the case, such as those described in § 27.31.

(c) The presiding officer shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and responsive briefs (if permitted) has expired. The presiding officer shall at the same time serve all parties with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration or a notice of appeal. If the presiding officer fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the presiding officer is timely appealed to the Environmental Appeals Board, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the Environmental Appeals Board and shall be final and binding on the parties 30 days after it is issued by the presiding officer.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5327, Feb. 13, 1992]

§ 27.38 Reconsideration of initial decision.

(a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of the presiding officer.

(d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.

(e) The presiding officer may dispose of a motion for reconsideration by denying it or by issuing a revised intial decision.

(f) If the presiding officer denies a motion for reconsideration, the initial decision shall constitute the final decision of the Environmental Appeals Board and shall be final and binding on the parties 30 days after the presiding officer denies the motion, unless the initial decision is timely appealed to the Environmental Appeals Board in accordance with § 27.39.

(g) If the presiding officer issued a revised initial decision, that decision shall constitute the final decision of the Environmental Appeals Board and shall be final and binding on the parties 30 days after it is issued, unless it is timely appealed to the Environmental Appeals Board in accordance with § 27.39.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5327, Feb. 13, 1992]

§ 27.39 Appeal to authority head.

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the Environmental Appeals Board by filing a notice of appeal with the hearing clerk in accordance with this section.

(b)(1) A notice of appeal may be filed at any time within 30 days after the presiding officer issues an initial decision. However, if another party files a motion for reconsideration under § 27.38, consideration of the appeal shall be stayed automatically pending resolution of the motion for reconsideration.

(2) If a motion for reconsideration is timely filed, a notice of appeal may be filed within 30 days after the presiding officer denies the motion or issues a revised initial decision, whichever applies.

(3) The Environmental Appeals Board may extend the initial 30 day period for an additional 30 days if the defendant files a request for an extension within the initial 30 day period and shows good cause.

(c) If the defendant filed a timely notice of appeal, and the time for filing motions for reconsideration under § 27.38 has expired, the presiding officer shall forward the record of the proceeding to the Environmental Appeals Board.

(d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.

(e) The representative for the Government may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.

(f) There is no right to appear personally before the Environmental Appeals Board.

(g) There is no right to appeal any interlocutory ruling by the presiding officer.

(h) In reviewing the initial decision, the Environmental Appeals Board shall not consider any objection that was not raised before the presiding officer unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) If any party demonstrates to the satisfaction of the Environmental Appeals Board that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure to present such evidence at such hearing, the Environmental Appeals Board shall remand the matter to the presiding officer for consideration of such additional evidence.

(j) The Environmental Appeals Board may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment, determined by the presiding officer in any initial decision.

(k) The Environmental Appeals Board shall promptly serve each party to the appeal with a copy of the decision of the Environmental Appeals Board and a statement describing the right of any person determined to be liable for a civil penalty or assessment to seek judicial review.

(l) Unless a petition for review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the Environmental Appeals Board serves the defendant with a copy of the Environmental Appeals Board's decision, a determination that a defendant

is liable under § 27.3 is final and is not subject to judicial review.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5327, Feb. 13, 1992]

§ 27.40 Stay ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the Environmental Appeals Board a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the Environmental Appeals Board shall stay the process immediately. The Environmental Appeals Board may order the process resumed only upon receipt of the written authorization of the Attorney General.

[57 FR 5327, Feb. 13, 1992]

§ 27.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the Environmental Appeals Board.

(b) No administrative stay is available following a final decision of the Environmental Appeals Board.

[57 FR 5327, Feb. 13, 1992]

§ 27.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the Environmental Appeals Board imposing penalties or assessments under this part and specifies the procedures for such review.

[57 FR 5327, Feb. 13, 1992]

§ 27.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 27.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under §§ 27.42 or 27.43, or any amount agreed upon in a compromise or settlement under § 27.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under this section against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

§ 27.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 27.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the presiding officer issues an initial decision.

(c) The Environmental Appeals Board has exclusive authority to compromise or settle a case under this part at any time after the date on which the presiding officer issues an initial decision, except during the pendency of any review under § 27.42 or during the pendency of any action to collect penalties and assessments under § 27.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 27.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the Environmental Appeals Board, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the Environmental Appeals Board or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

[53 FR 15182, Apr. 27, 1988, as amended at 57 FR 5327, Feb. 13, 1992]

§ 27.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 27.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 27.10(b) shall be deemed a notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

§ 27.48 Delegated functions.

The Administrator delegates authority to the Environmental Appeals Board to issue final decisions in appeals filed under this part. An appeal directed to the Administrator, rather than the Environmental Appeals Board, will not be considered. This delegation of authority to the Environmental Appeals Board does not preclude the Environmental Appeals Board from referring an appeal or motion filed under this part to the Administrator for decision when the Environmental Appeals Board, in its descretion, deems it appropriate to do so. When an appeal or motion is referred to the Administrator, all parties shall be so notified and the rules in this part referring to the Environmental Appeals Board shall be interpreted as referring to the Administrator. If a case or motion is referred to the Administrator by the Environmental Appeals Board, the Administrator may consult with any EPA employee concerning the matter, provided such consultation does not violate the *ex parte* contacts restrictions set forth in §§ 27.14 and 27.15 of this part.

[57 FR 5328, Feb. 13, 1992]

PART 29—INTERGOVERNMENTAL REVIEW OF ENVIRONMENTAL PROTECTION AGENCY PROGRAMS AND ACTIVITIES

Sec.

AUTHORITY: E.O. 12372, July 14, 1982 (47 FR 30959), as amended Apr. 8, 1983 (48 FR 15887); sec. 401 of the Intergovernmental Cooperation Act of 1968 as amended (31 U.S.C. 6506); sec. 204 of the Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3334).

SOURCE: 48 FR 29300, June 24, 1983, unless otherwise noted.

§ 29.1 What is the purpose of these regulations?

(a) The regulations in this part implement Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' issued July 14, 1982, and amended, on April 8, 1983. These regulations also implement applicable provisions of section 401 of the Intergovernmental Cooperation Act of 1968, as amended and section 204 of the Demonstration Cities and Metropolitan Development Act of 1966, as amended.

(b) These regulations are intended to foster an intergovernmental partnership and a strengthened federalism by relying on State processes and on State, areawide, regional and local coordination for review of proposed Federal financial assistance and direct Federal development.

(c) These regulations are intended to aid the internal management of the Environmental Protection Agency (EPA) and are not intended to create

any right or benefit enforceable at law by a party against EPA or its officers.

§ 29.2 What definitions apply to these regulations?

Administrator means the Administrator of the U.S. Environmental Protection Agency or an official or employee of the Agency acting for the Administrator under a delegation of authority.

Agency means the U.S. Environmental Protection Agency (EPA).

Order means Executive Order 12372, issued July 14, 1982, and amended April 8, 1983, and titled ''Intergovernmental Review of Federal Programs.''

States means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, or the Trust Territory of the Pacific Islands.

§ 29.3 What programs and activities of the Environmental Protection Agency are subject to these regulations?

The Administrator publishes in the FEDERAL REGISTER a list of the EPA programs and activities that are subject to these regulations and identifies which of these are subject to the requirements of section 204 of the Demonstration Cities and Metropolitan Development Act.

§ 29.4 What are the Administrator's general responsibilities under the Order?

(a) The Administrator provides opportunities for consultation by elected officials of those State and local governments that would provide the non-Federal funds for, or that would be directly affected by, proposed Federal financial assistance from, or direct Federal development by, the EPA.

(b) If a State adopts a process under the Order to review and coordinate proposed Federal financial assistance and direct Federal development, the Administrator to the extent permitted by law:

(1) Uses the State process to determine official views of State and local elected officials;

(2) Communicates with State and local elected officials as early in a program planning cycle as is reasonably feasible to explain specific plans and actions;

(3) Makes efforts to accommodate State and local elected officials' concerns with proposed Federal financial assistance and direct Federal development that are communicated through the State process;

(4) Allows the States to simplify and consolidate existing federally required State plan submissions;

(5) Where State planning and budgeting systems are sufficient and where permitted by law, encourages the substitution of State plans for federally required State plans;

(6) Seeks the coordination of views of affected State and local elected officials in one State with those of another State when proposed Federal financial assistance or direct Federal development has an impact on interstate metropolitan urban centers or other interstate areas; and

(7) Supports State and local governments by discouraging the reauthorization or creation of any planning organization which is federally-funded, which has a limited purpose, and which is not adequately representative of, or accountable to, State or local elected officials,

§ 29.5 What is the Administrator's obligation with respect to Federal interagency coordination?

The Administrator, to the extent practicable, consults with and seeks advice from all other substantially affected Federal departments and agencies in an effort to assure full coordination between such agencies and EPA regarding programs and activities covered under these regulations.

§ 29.6 What procedures apply to the selection of programs and activities under these regulations?

(a) A State may select any program or activity published in the FEDERAL REGISTER in accordance with § 29.3 of this part for intergovernmental review under these regulations. Each State, before selecting programs and activities, shall consult with local elected officials.

(b) Each State that adopts a process shall notify the Administrator of EPA

programs and activities selected for that process.

(c) A State may notify the Administrator of changes in its selections at any time. For each change, the State shall submit an assurance to the Administrator that the State has consulted with local elected officials regarding the change. EPA may establish deadlines by which States are required to inform the Administrator of changes in their program selections.

(d) The Administrator uses a State's process as soon as feasible, depending on individual programs and activities, after the Administrator is notified of its selections.

§ 29.7 How does the Administrator communicate with State and local officials concerning the EPA programs and activities?

(a) For those programs and activities covered by a State process under § 29.6, the Administrator, to the extent permitted by law:

(1) Uses the State process to determine views of State and local elected officials; and

(2) Communicates with State and local elected officials, through the State process, as early in a program planning cycle as is reasonably feasible to explain specific plans and actions.

(b) The Administrator provides notice of proposed Federal financial assistance or direct Federal development to directly affected State, areawide, regional, and local entities in a State if:

(1) The State has not adopted a process under the Order; or

(2) The assistance or development involves a program or activity not selected for the State process.

This notice may be published in the FEDERAL REGISTER or issued by other means which EPA, in its discretion deems appropriate.

§ 29.8 How does the Administrator provide States an opportunity to comment on proposed Federal financial assistance and direct Federal development?

(a) Except in unusual circumstances, the Administrator gives State processes or directly affected State, areawide, regional and local officials and entities:

(1) At least 30 days from the date established by the Administrator to comment on proposed Federal financial assistance in the form of noncompeting continuation awards; and

(2) At least 60 days from the date established by the Administrator to comment on proposed direct Federal development or Federal financial assistance, other than noncompeting continuation awards.

(b) This section also applies to comments in cases in which the review, coordination, and communication with the Environmental Protection Agency have been delegated.

(c) Applicants for programs and activities subject to section 204 of the Demonstration Cities and Metropolitan Development Act shall allow areawide agencies a 60-day opportunity for review and comment.

§ 29.9 How does the Administrator receive and respond to comments?

(a) The Administrator follows the procedures in § 29.10 if:

(1) A State office or official is designated to act as a single point of contact between a State process and all Federal agencies, and

(2) That office or official transmits a State process recommendation for a program selected under § 29.6.

(b) The single point of contact is not obligated to transmit comments from State, areawide, regional or local officials and entities where there is no State process recommendation. However, if a State process recommendation is transmitted by a single point of contact, all comments from State, area-wide, regional, and local officials and entities that differ from it must also be transmitted.

(c) If a State has not established a process, or is unable to submit a State process recommendation, the State, areawide, regional and local officials and entities may submit comments directly either to the applicant or to EPA.

(d) If a program or activity is not selected for a State process, the State, areawide, regional and local officials and entities may submit comments either directly to the applicant or to EPA. In addition, if a State process

recommendation for a nonselected program or activity is transmitted to EPA by the single point of contact, the Administrator follows the procedures of § 29.10 of this part.

(e) The Administrator *considers* comments which do not constitute a State process recommendation submitted under these regulations and for which the Administrator is not required to apply the procedures of § 29.10 of this part, when such comments are provided by a single point of contact, by the applicant, or directly to the Agency by a commenting party.

§ 29.10 How does the Administrator make efforts to accommodate intergovernmental concerns?

(a) If a State process provides a State process recommendation to the Agency through the State's single point of contact, the Administrator either:

(1) Accepts the recommendation;

(2) reaches a mutually agreeable solution with the State process; or

(3) Provides the single point of contact with such written explanation of the decision, as the Administrator, in his or her discretion, deems appropriate. The Administrator may also supplement the written explanation by providing the explanation to the single point of contact by telephone, other telecommunication, or other means.

(b) In any explanation under paragraph (a)(3) of this section, the Administrator informs the single point of contact that:

(1) EPA will not implement its decision for at least ten days after the single point of contact receives the explanation; or

(2) The Administrator has reviewed the decision and determined that, because of unusual circumstances, the waiting period of at least ten days is not feasible.

(c) For purposes of computing the waiting period under paragraph (b)(1) of this section, a single point of contact is presumed to have received written notification 5 days after the date of mailing of such notification.

§ 29.11 What are the Administrator's obligations in interstate situations?

(a) The Administrator is responsible for:

(1) Identifying proposed Federal financial assistance and direct Federal development that have an impact on interstate areas;

(2) Notifying appropriate officials and entities in States which have adopted a process and selected an EPA program or activity.

(3) Making efforts to identify and notify the affected State, areawide, regional, and local officials and entities in those States that do not adopt a process under the Order or do not select an EPA program or activity;

(4) Responding in accordance with § 29.10 of this part to a recommendation received from a designated areawide agency transmitted by a single point of contact, in cases in which the review, coordination, and communication with EPA were delegated.

(b) The Administrator uses the procedures in § 29.10 if a State process provides a State process recommendation to the Agency through a single point of contact.

§ 29.12 How may a State simplify, consolidate, or substitute federally required State plans?

(a) As used in this section:

(1) *Simplify* means that a State may develop its own format, choose its own submission date, and select the planning period for a State plan.

(2) *Consolidate* means that a State may meet statutory and regulatory requirements by combining two or more plans into one document and that the State can select the format, submission date, and planning period for the consolidated plan.

(3) *Substitute* means that a State may use a plan or other document that it has developed for its own purposes to meet Federal requirements.

(b) If not inconsistent with law, a State may decide to try to simplify, consolidate, or substitute federally required State plans without prior approval by the Administrator.

(c) The Administrator reviews each State plan that a State has simplified, consolidated, or substituted and accepts the plan only if its contents meet Federal requirements.

§ 29.13 May the Administrator waive any provision of these regulations?

In an emergency, the Administrator may waive any provision of these regulations.