

Models (Revised)” (1986), including supplements (EPA publication no. 450/2–78–027R)<sup>2</sup>, unless:

(1) The guideline techniques are inappropriate, in which case the model may be modified or another model substituted on a case-by-case basis or, where appropriate, on a generic basis for a specific Federal agency program; and

(2) Written approval of the EPA Regional Administrator is obtained for any modification or substitution.

(d) The analyses required under this subpart, except §93.158(a)(1), must be based on the total of direct and indirect emissions from the action and must reflect emission scenarios that are expected to occur under each of the following cases:

(1) The Act mandated attainment year or, if applicable, the farthest year for which emissions are projected in the maintenance plan;

(2) The year during which the total of direct and indirect emissions from the action is expected to be the greatest on an annual basis; and

(3) Any year for which the applicable SIP specifies an emissions budget.

**§93.160 Mitigation of air quality impacts.**

(a) Any measures that are intended to mitigate air quality impacts must be identified and the process for implementation and enforcement of such measures must be described, including an implementation schedule containing explicit timelines for implementation.

(b) Prior to determining that a Federal action is in conformity, the Federal agency making the conformity determination must obtain written commitments from the appropriate persons or agencies to implement any mitigation measures which are identified as conditions for making conformity determinations.

(c) Persons or agencies voluntarily committing to mitigation measures to facilitate positive conformity determinations must comply with the obligations of such commitments.

(d) In instances where the Federal agency is licensing, permitting or oth-

erwise approving the action of another governmental or private entity, approval by the Federal agency must be conditioned on the other entity meeting the mitigation measures set forth in the conformity determination.

(e) When necessary because of changed circumstances, mitigation measures may be modified so long as the new mitigation measures continue to support the conformity determination. Any proposed change in the mitigation measures is subject to the reporting requirements of §93.156 and the public participation requirements of §93.157.

(f) The implementation plan revision required in §93.151 shall provide that written commitments to mitigation measures must be obtained prior to a positive conformity determination and that such commitments must be fulfilled.

(g) After a State revises its SIP to adopt its general conformity rules and EPA approves that SIP revision, any agreements, including mitigation measures, necessary for a conformity determination will be both State and federally enforceable. Enforceability through the applicable SIP will apply to all persons who agree to mitigate direct and indirect emissions associated with a Federal action for a conformity determination.

**PART 94 [RESERVED]**

**PART 95—MANDATORY PATENT LICENSES**

Sec.

95.1 Definitions.

95.2 Petition for mandatory license.

95.3 Findings prior to application to Attorney General.

95.4 Limitations on mandatory licenses.

AUTHORITY: 42 U.S.C. 7609; Sec. 104, Pub. L. 103–182, 107 Stat. 2057, 2064.

SOURCE: 59 FR 67638, Dec. 30, 1994, unless otherwise noted.

**§95.1 Definitions.**

(a) As used in this part, all terms not defined in this section shall have the meaning given them by the Act.

(b) *Act* means the Clean Air Act, as amended (42 U.S.C. §§ 7401–7671).

<sup>2</sup> See footnote 1 at §93.159(b)(2).

(c) *Agency* means the Environmental Protection Agency.

(d) *Administrator* means the Administrator of the Environmental Protection Agency.

**§ 95.2 Petition for mandatory license.**

(a) Any party required to comply with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521) may petition to the Administrator for a mandatory patent license pursuant to section 308 of the Act (42 U.S.C. 7608), under a patent that the petitioner maintains is necessary to enable the petitioner to comply with Sections 111, 112 or 202 of the Act.

(b)(1) Each petition shall be signed by the petitioner and shall state the petitioner's name and address. If the petitioner is a corporation, the petition shall be signed by an authorized officer of the corporation, and the petition shall indicate the state of incorporation. Where the petitioner elects to be represented by counsel, a signed notice to that effect shall be included with the petition at the time of filing.

(2) Each petition shall include a copy of the patent under which a mandatory patent license is sought. The petition shall identify all current owners of the patent and shall include a copy of all assignment documents relevant to the patent that are available from the United States Patent and Trademark Office.

(3) Each petition must identify any person whose interest the petitioner believes may be affected by the grant of the license to which the petition is directed.

(4) Each petition must contain a concise statement of all of the essential facts upon which it is based. No particular form of statement is required. Each petition shall be verified by the petitioner or by the person having the best knowledge of such facts. In the case of facts stated on information and belief, the source of such information and grounds of belief shall be given. The statement of facts shall include the following:

(i) An identification of the provisions of the Act and/or regulations thereunder that the petitioner maintains petitioner will be able to comply with if the petitioner is granted the patent li-

cense that is the subject of the petition;

(ii) An identification of the nature and purpose of the petitioner's intended use of the patent license;

(iii) An explanation of the relationship between the patented technology and the activities to which petitioner proposes to apply the patented technology, including an estimate of the effect on such activities stemming from the grant or denial of the patent license;

(iv) A summary of facts demonstrating that the patent under which a mandatory patent license is sought is being used or is intended for public or commercial use;

(v) An explanation of why a mandatory patent license is necessary for the petitioner to comply with the requirements of sections 111, 112 or 202 of the Act, and why the patented technology is not otherwise available;

(vi) An explanation of why there are no other reasonable alternatives for accomplishing compliance with sections 111, 112 or 202 of the Act;

(vii) An explanation of why the unavailability of a mandatory patent license may result in a substantial lessening of competition or a tendency to create a monopoly in any line of commerce in any section of the United States;

(viii) A summary of efforts made by the petitioner to obtain a patent license from the owner of the patent, including the terms and conditions of any patent license proposed by petitioner to the patent owner; and

(ix) The terms, if any, on which the owner of the patent has proposed to grant the petitioner a patent license.

(5) Each petition shall include a proposed patent license that states all of the terms and conditions that the petitioner proposes for the patent license.

(6) Petitions shall be addressed to the Assistant Administrator for Air and Radiation, Mail Code 6101, U.S. Environmental Protection Agency, Washington, DC 20460.

(c) Petitions that do not include all of the information required in paragraph (b) of this section shall be returned to the petitioner. The petitioner may supplement the petition and resubmit the petition.

(d) If the Administrator, or the Administrator's designee, finds that the criteria in §95.3 are not met, or otherwise decides to deny the petition, a denial of the petition shall be sent to the petitioner, along with an explanation of the reasons for the denial.

(e) If the Administrator, or the Administrator's designee, finds that the criteria in §95.3 are met and decides to apply to the Attorney General for a patent license under section 308 of the Act, notice of such application shall be given to the petitioner, along with a copy of the application sent to the Attorney General.

**§95.3 Findings prior to application to Attorney General.**

The Administrator, or the Administrator's designee, may apply to the Attorney General for a mandatory patent license pursuant to section 308 of the Act (42 U.S.C. 7608) either in response to a petition under §95.2 or on the Administrator's or designee's own initiative, only after expressly finding that each one of the following mandatory criteria is met:

(a) The application is for a patent license covering no more than one patent;

(b) The party to whom the proposed patent license is to be granted has presented the Administrator or designee with evidence that such party has made reasonable efforts to obtain a patent license from the patent owner with terms similar to the license terms to be proposed in the application to the Attorney General;

(c) The patent under which a patent license is sought in the application to the Attorney General is being used or is intended for public or commercial use;

(d) The mandatory patent license is necessary for a party to comply with the requirements of sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521);

(e) The patented technology is not otherwise reasonably available, and there are no other reasonable alternatives for accomplishing compliance with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521); and

(f) The unavailability of a mandatory patent license may result in a substantial lessening of competition or a tendency to create a monopoly in any line of commerce in any section of the United States.

**§95.4 Limitations on mandatory licenses**

(a) If the Administrator, or the Administrator's designee, decides to apply to the Attorney General for a mandatory patent license in accordance with §95.3, the application shall include a proposed patent license with the following limitations:

(1) The scope and duration of the patent license shall be limited to that necessary to permit the proposed licensee to comply with the requirements the Act;

(2) The patent license shall be non-exclusive;

(3) The patent license shall be non-signable, except with that part of the enterprise or goodwill that enjoys the license;

(4) The patent license shall be for use of the licensed technology in the United States only;

(5) The patent license shall extend only to those uses necessary to enable the licensee to comply with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521);

(6) The patent license shall provide for termination, subject to adequate protections of the legitimate interests of the licensed party, when the circumstances that made the compulsory patent license necessary cease to exist and are unlikely to recur; and

(7) The patent license shall provide for adequate remuneration that takes into account the economic value of the license.

(b) The Administrator, or the Administrator's designee, may decide as appropriate to include additional conditions, terms or limitations on the scope of the patent license for which application is made to the Attorney General.

**PARTS 96–99 [RESERVED]**