

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-assignable, 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]**

**SUBCHAPTER D—WATER PROGRAMS**

**PART 100—[RESERVED]**

**PART 104—PUBLIC HEARINGS ON EFFLUENT STANDARDS FOR TOXIC POLLUTANTS**

- Sec.
- 104.1 Applicability.
- 104.2 Definitions.
- 104.3 Notice of hearing; objection; public comment.
- 104.4 Statement of basis and purpose.
- 104.5 Docket and record.
- 104.6 Designation of Presiding Officer.
- 104.7 Powers of Presiding Officer.
- 104.8 Prehearing conferences.
- 104.9 Admission of evidence.
- 104.10 Hearing procedures.
- 104.11 Briefs and findings of fact.
- 104.12 Certification of record.
- 104.13 Interlocutory and post-hearing review of rulings of the Presiding Officer; motions.
- 104.14 Tentative and final decision by the Administrator.
- 104.15 Promulgation of standards.
- 104.16 Filing and time.

AUTHORITY: Secs. 501 and 307(a) of the Federal Water Pollution Control Act, as amend-

ed (33 U.S.C. 1251 *et seq.*, Pub. L. 92-500, 86 Stat. 816).

SOURCE: 41 FR 17902, Apr. 29, 1976, unless otherwise noted.

**§ 104.1 Applicability.**

This part shall be applicable to hearings required by statute to be held in connection with the establishment of toxic pollutant effluent standards under section 307(a) of the Act.

**§ 104.2 Definitions.**

As used in this part, the term:

(a) *Act* means the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 *et seq.*, Public Law 92-500, 86 Stat. 816.

(b) *Administrator* means the Administrator of the Environmental Protection Agency, or any employee of the Agency to whom the Administrator may by order delegate his authority to carry out his functions under section 307(a) of the Act, or any person who shall by operation of law be authorized to carry out such functions.