

## § 25.11

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

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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 midpoint 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-compli-

ance 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**

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- 26.102 Definitions.
- 26.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
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- 26.111 Criteria for IRB approval of research.
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