

information relevant to such an assessment?

6. *How should the Agency implement standards of acceptability?*—a. To what extent and how should the submitter of research with human subjects to EPA be required to document or otherwise demonstrate compliance with appropriate standards for the protection of human research subjects, e.g., fully informed and fully voluntary participation, and independent oversight of research design and conduct by an Institutional Review Board or comparable entity?

b. How should the Agency determine compliance with an appropriate standard for human research data which is not submitted, but which it obtains from the scientific literature or other sources?

c. To what extent should new standards be applied to research which has already been conducted, or is underway? Should a different standard be applied to such research? Does fairness require a period of transition to any new rule or standards of acceptability, or do other considerations override that factor?

d. Should the Agency apply the same standard of acceptability to research already submitted to or obtained by EPA and to research newly submitted to or obtained by EPA? Does it matter if the submitted research was conducted for the specific regulatory purpose at hand or for other purposes (even though the study was conducted after EPA issued a policy on human testing)? Does fairness require a period of transition to any new rule or standards of acceptability, or do other considerations override that factor?

e. Is rulemaking needed at all? Would it be better to address the issues surrounding acceptance of human research, or some of them, by other means, such as policy statements or internal guidelines?

IV. Statutory and Executive Order Reviews

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this ANPR is a “significant regulatory action” under section 3(f) of the Executive Order. The Agency therefore submitted this document to OMB for the 10-day review period afforded under this Executive Order. Any changes made in response to OMB comments during that review have been documented in the public docket as required by the Executive Order.

Since this ANPR does not impose any requirements, and instead seeks

comments and suggestions for the Agency to consider in developing a subsequent notice of proposed rulemaking, the various other review requirements that apply when an agency imposes requirements do not apply to this action.

As part of your comments on this ANPR you may include any comments or information that you have regarding these requirements. In particular, any comments or information that would help the Agency to assess the potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note); or to consider environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). The Agency will consider such comments during the development of any subsequent notice of proposed rulemaking as it takes appropriate steps to address any applicable requirements.

List of Subjects

Environmental protection, Protection of human research subjects.

Dated: April 29, 2003.

Christine T. Whitman,
Administrator.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD136-3091b; FRL-7484-1]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendments to State II Vapor Recovery at Gasoline Dispensing Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland for the purpose of amending the regulations pertaining to Stage II Vapor Recovery at Gasoline Dispensing Stations. In the Final Rules section of this **Federal Register**, EPA is approving the State’s SIP submittal as a direct final

rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by June 6, 2003.

ADDRESSES: Written comments should be addressed to Makeba Morris, Acting Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Kathleen Anderson, (215) 814-2173, or by e-mail at anderson.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the “Rules and Regulations” section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: April 9, 2003.

James W. Newsom,

Regional Administrator, Region III.

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