country,'' as defined in 18 U.S.C. 1151. Indian country includes:

1. All lands within the exterior boundaries of Indian reservations within or abutting the State of Ohio;

2. Any land held in trust by the U.S. for an Indian tribe; and

3. Any other land, whether on or off an Indian reservation that qualifies as Indian country. Therefore, this action has no effect on Indian country. EPA retains the authority to implement and administer the RCRA program in Indian country. However, at this time, there is no Indian country within the State of Ohio.

I. What Is Codification and Is EPA Codifying Ohio's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing a state's statutes and regulations that comprise the state's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized state rules in 40 CFR part 272. We reserve the amendment of 40 CFR part 272, subpart P, for authorization of Ohio's program revisions until a later date.

J. Administrative Requirements

The Office of Management and Budget has exempted RCRA authorization from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. Furthermore, this action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by state law. This authorization will effectively suspend the applicability of certain federal regulations in favor of Ohio's program, thereby eliminating duplicate requirements in the state. Authorization will not impose any new burdens on small entities. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This action does not have tribal implications within the meaning of Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes state requirements as part of the state RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action does not include environmental justice-related issues that require consideration under Executive Order 12898 (59 FR 7929, February 16, 1994).

Under RCRA section 3006(b), EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings' issued under the executive order. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: January 9, 2003.

Bharat Mathur,

Deputy Regional Administrator, Region 5.

[FR Doc. 03–1626 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 312

[FRL–7442–4]

RIN 2050–AF05

Clarification to Interim Standards and Practices for All Appropriate Inquiry Under CERCLA and Notice of Future Rulemaking Action

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to clarify a provision included in recent amendments to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Specifically, today's direct final rule addresses the interim standard set by Congress in the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Law'') for conducting ''all appropriate inquiry'' to establish that a landowner had no reason to know of contamination at a property under CERCLA liability provisions prior to purchasing the property. Today's action clarifies that, in the case of property purchased on or after May 31, 1997, the requirements for conducting ''all appropriate inquiry,'' including the

conduct of such activities to establish an innocent landowner defense under CERCLA, also will be satisfied through the use of ASTM Standard E1527–2000, entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process.'' In addition, recipients of brownfields site assessment grants will be in compliance with the all appropriate inquiry requirements if they comply with the ASTM Standard E1527–2000.

DATES: This rule is effective on March 25, 2003, without further notice, unless EPA receives adverse comment by February 24, 2003. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments on today's direct final rule may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions provided in paragraph B of the **SUPPLEMENTARY INFORMATION** section below. Please reference Docket number SFUND–2002–0007 when submitting your comments.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/CERCLA Call Center at 800–424–9346 or TDD 800–553–7672 (hearing impaired). In the Washington, DC metropolitan area, call 703–412–9810 or TDD 703–412–3323.

For more detailed information on specific aspects of this rule, contact Patricia Overmeyer, Office of Brownfields Clean up and Redevelopment (5105T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0002, 202–566–2774. *overmeyer.patricia@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

A. How Can I Get Copies of the Background Materials Supporting Today's Direct Final Rule or Other Related Information?

1. EPA has established an official public docket for this direct final rule under Docket ID No. SFUND–2002–0007. The official public docket consists of the documents specifically referenced in this rule and other information related to this direct final rule. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center located at 1301 Constitution Ave. NW, Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling (202) 566–0276. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

You may use EPA Dockets at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI, and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified above.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff. For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

B. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA will not consider late comments in formulating a final decision.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the party submitting the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. To access EPA's electronic public

docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. SFUND–2002–0007. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

2. E-mail. Comments may be sent by electronic mail (e-mail) to *Superfund.Docket@epamail.epa.gov.* Make sure this electronic copy is in an ASCII format that does not use special characters or encryption. Cite the docket Number SFUND–2002–0007 in your electronic file. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

3. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified above. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

4. By Mail. Send two (2) copies of your comments to: EPA Docket Center, U.S. Environmental Protection Agency Headquarters, Mail Code 5305T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. SFUND–2002–0007.

5. By Hand Delivery or Courier. Deliver your comments to: EPA Docket Center, EPA West Building, Room B–102, 1301 Constitution Ave., NW., Washington, DC, 20007. Attention Docket ID No. SFUND–2002–0007. Such deliveries are only accepted during the Docket's normal hours of operation as identified above.

Regulated Entities

Entities potentially regulated by this action include public and private parties who, as bona fide prospective purchasers, contiguous property owners, or innocent landowners, purchase property and intend to claim a limitation on CERCLA liability in conjunction with the property purchase. In addition, any entity conducting a site characterization or assessment with a brownfields grant awarded under CERCLA section104(k)(2)(B)(ii) will be affected by today's action. This includes state, local and Tribal governments that receive brownfields site assessment grants. A summary of the potentially affected industry sectors (by NAICS codes) is displayed in the table below.

Industry category	NAICS code
Real Estate	531
Insurance	52412
Banking/Real Estate Credit	52292
Environmental Consulting Services	54162
State, Local and Tribal Government	N/A

The list of potentially affected entities in the above table may not be exhaustive. Our aim is to provide a guide for readers regarding those entities that EPA is aware potentially could be affected by this action. However, this action may affect other entities not listed in the table. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT.**

Preamble

I. Statutory Authority

This direct final rule clarifies provisions included in section 223 of the Small Business Liability Relief and Brownfields Revitalization Act which amends section 101(35)(B) of CERCLA (42 U.S.C. 9601(35)) and clarifies interim standards for the conduct of ''all appropriate inquiry'' for obtaining CERCLA liability relief and for conducting site characterizations and assessments with the use of brownfields grant monies.

II. Background

On January 11, 2002, President Bush signed the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Law''). In general, the Act amends CERCLA and provides funds to assess and clean up brownfields sites; clarifies CERCLA liability provisions related to innocent purchasers of contaminated properties; and provides funding to enhance State and Tribal clean up programs. In part, subtitle B of Title II of the Act revises some of the provisions of CERCLA section 101(35) and provides some Superfund liability limitations for bona fide prospective purchasers and contiguous property owners, in addition to clarifying the requirements necessary to establish the innocent landowner defense under CERCLA. Among the requirements added to CERCLA is the requirement that such parties undertake ''all appropriate inquiry'' into prior ownership and use of certain property.

The Act requires EPA to develop regulations within two years which will establish standards and practices for how to conduct all appropriate inquiry. In addition, in the Brownfields Law, Congress established, as the Federal interim standard for conducting all appropriate inquiry, the procedures of the American Society for Testing and Materials (ASTM) including Standard E1527–97 (entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process''). This interim standard applies to properties purchased on or after May 31, 1997 until EPA promulgates Federal regulations establishing standards and practices for conducting all appropriate inquiry.

Today's direct final rule clarifies that persons may use the current ASTM standard, E1527–2000 for conducting all appropriate inquiry and establishing the innocent landowner defense under CERCLA section 101(35)(B) for properties purchased on or after May 31, 1997, while continuing also to recognize use of ASTM's previous standard, E1527–97.

Following enactment of the Brownfields Law, EPA received inquiries from interested parties expressing concerns that the ASTM standard for all appropriate inquiry that was cited in the Act (*i.e.*, ASTM's 1997 standard) has been updated and consequently is no longer available from ASTM. The ASTM standard cited in the Brownfields Law has been updated and replaced with ASTM's revised standard, ''Standard E1527–2000.'' The revised standard has the same name as the previous standard. The revised standard is not significantly different from the previous standard. Revisions to the 1997 standard that are incorporated into the E1527–2000 updated standard include provisions for potential expansion of an assessment, guidance for better identification of the purpose of the assessment, a provision for inquiring about historical remediation, a provision for facilitating reconstruction of the assessment by a different assessor, and amended guidance for selecting an environmental professional. A summary of the revisions made to the 1997 ASTM standard and included in the 1527–2000 standard is provided in the document ''Overview of Additions and Modifications to ASTM 1527–2000

Standard from the 1997 ASTM Standard.'' A copy of this document, as well as an annotated copy of the 1997 ASTM standard identifying the specific modifications incorporated into the ASTM 2000 standard, is included in the regulatory docket for today's rule.

EPA believes that it is consistent with Congressional intent to require the use of the most current standards available until EPA has promulgated its standard and not to require the use of standards that have been superseded or that generally are not available. In addition, Congress did not intend to place an undue burden on interested parties seeking to obtain and implement the standard. Given that the version of the ASTM standard cited in the Brownfields Law is no longer available, such an undue burden may occur, if EPA does not undertake today's action. In particular, recipients of grant monies awarded under the new Brownfields Law may experience an undue burden, if required to comply with the ASTM standard that no longer is available or recognized as the current industry standard. Therefore, with today's action, EPA is clarifying that for the purposes of CERCLA section 101 (35)(B), until the Agency promulgates regulations implementing standards for all appropriate inquiry, parties may use either the procedures provided in ASTM E1527–2000, entitled ''Standard Practice for Environmental Site Assessment: Phase I Environmental Site Assessment Process,'' or the standard ASTM E1527–97. EPA has determined that it is reasonable to promulgate this clarification as a direct final rule that is effective immediately, rather than delay promulgation of the clarification until after receipt and consideration of public comments, to avoid any further confusion with regard to the acceptable standard for conducting all appropriate inquiry and to ensure that new grant recipients are not placed under any undue burden.

III. Today's Action

EPA is publishing this direct final rule because the Agency wants to reduce any undue burden placed upon grant recipients. In addition, the Agency views this as a noncontroversial action and anticipates no adverse comment. We believe that today's action is reasonable and can be promulgated without consideration of public comment because it: (1) Allows for the use of the updated version of the standard cited in the Brownfields Law, while also allowing the use of the former version, and the updated version of the standard is similar to, and not significantly different than, the previous standard; (2) reduces the burden of obtaining an appropriate standard, given that the standard cited in the Brownfields Law is no longer available; and (3) this action merely clarifies an interim standard that is effective only until EPA promulgates a final rule replacing the interim standard.

Although we view today's action as noncontroversial, in the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate proposed rule containing the clarification summarized above. That proposed rule will serve as the proposal to be revised, if adverse comments are received. If EPA does not receive adverse comment in response to this rule prior to February 24, 2003, this rule will become effective on March 25, 2003, without further notice. If EPA receives adverse comment, we will publish a timely withdrawal of this rule in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time and before February 24, 2003.

IV. Future Rulemaking Setting Standards for ''All Appropriate Inquiry''

EPA also is announcing today its progress in developing regulatory standards for conducting ''all appropriate inquiry.'' The Brownfields Law requires that EPA promulgate such standards within two years of enactment of the law, or by January 2004. Congress included in the Brownfields Law a list of criteria that the Agency must address in the regulations establishing standards and practices for conducting all appropriate inquiry (section 101(35)(2)(B)(ii)). The Act also requires that parties receiving funding under the Federal brownfields program to conduct site assessments must conduct the site assessment in accordance with the standards and practices for all appropriate inquiry established under the same provision of the Act.

EPA is soliciting the advice and input of public and private stakeholder groups in developing the regulations for conducting all appropriate inquiry in accordance with the criteria set forth by Congress. We understand that voluntary standards developed by standards developing organizations, such as the ASTM 1527–2000 standard, are available and are currently being used to conduct all appropriate inquiry in conjunction with private real estate property transactions. In addition, site assessment protocols have been established under the Federal Superfund remedial action and RCRA corrective action programs, as well as within State clean up programs. We intend to develop Federal regulations that build upon the depth of experience accrued in both the public and private sectors in implementing these standards and programs. We believe that building upon currently available private sector standards for undertaking all appropriate inquiry as well as building on the experience of state and Federal government site assessment programs is the most efficient and economical way to develop Federal regulatory standards that will both meet the criteria set in the Brownfields Law and ensure minimal disruption to the private market and State and Federal site assessment programs.

To ensure that we obtain a diverse array of input from both private sector stakeholders and state program officials, EPA is developing the federal regulations by soliciting private and public sector input under the convening stage of the negotiated rulemaking process, and may supplement our information gathering through the conduct of public meetings. We initiated the convening stage of a negotiated rulemaking process to identify appropriate stakeholder groups and solicit advice and input from experienced public and private sector users of similar standards. Following an evaluation of stakeholder interests and input during the convening process, we either will announce our intent to continue with a negotiated rulemaking process, or announce our intent to solicit public input, by way of an additional notice or a public meeting, on options for a proposed rulemaking that will set standards for all appropriate inquiry. We anticipate announcing our intended approach for the development of a proposed rulemaking in the **Federal Register** during the winter of 2003. Any questions regarding our future regulatory effort should be directed to the parties listed above in the section entitled **FOR FURTHER INFORMATION CONTACT.**

V. Statutory and Executive Order Reviews

a. Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget.

b. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 FR U.S.C. 3501 *et seq.*)

c. The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the APA or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This action will not have a significant impact on a substantial number of small entities because it does not create any new requirements.

d. Because the purpose of today's action is to make a clarification that does not create any new requirements it has no economic impact and is not subject to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pubic Law 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA.

e. This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

f. This rule does not have tribal implications, as specified by Executive Order 13175 (65 FR 67249, November 6, 2000).

g. This rule is not subject to Executive Order 13045 (62 FR 1985, April 23, 1997), because it is not economically significant.

h. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

i. This action does involve technical standards; therefore, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) apply. The NTTAA was signed into law on March 7, 1996 and, among other things, directs the National Institute of Standards and Technology (NIST) to bring together federal agencies as well as state and local governments to achieve greater reliance on voluntary standards and decreased dependence on in-house standards. It states that use of such standards, whenever practicable and appropriate, is intended to achieve the following goals: (a) Eliminate the cost to the government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation; (b) provide incentives and opportunities to establish standards that serve national needs; (c) encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards; and (d) further the policy of reliance upon the private sector to supply Government needs for goods and services. The Act requires that federal agencies adopt private sector standards, particularly those developed by standards developing organizations (SDOs), wherever possible in lieu of creating proprietary, non-consensus standards. Today's action is compliant with the spirit and requirements of the NTTAA, given that the interim standard for all appropriate inquiry that is the subject of today's action is a private sector standard developed by a standard developing organization. Today's action allows for the use of the American Society for Testing and Materials (ASTM) standard known as Standard E1527–2000 and entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process'' as the interim standard for conducting all appropriate inquiry for properties purchased on or after May 31, 1997, or in the alternative, the use of Standard E1527–97, and entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process.''

j. Today's action does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

k. The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 25, 2003 unless EPA publishes a withdrawal in the **Federal Register**.

List of Subjects in 40 CFR Part 312

Environmental protection, Administrative practice and procedure, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 17, 2003.

Christine Todd Whitman,

Administrator.

For the reasons set out in the preamble, title 40 chapter J of the code of Federal Regulations is amended as follows:

1. Title 40 Chapter J is amended by adding new part 312 to read as follows:

PART 312—INNOCENT LANDOWNERS, STANDARDS FOR CONDUCTING ALL APPROPRIATE INQUIRY

Subpart A—Introduction

Sec.

Subpart B—[Reserved]

Authority: Section 101(35)(B) of CERCLA, as amended, 42 U.S.C. 9601(3)(B).

Subpart A—Introduction

§ 312.1 Purpose and applicability.

(a) *Purpose.* The purpose of this section is to provide standards and procedures for ''all appropriate inquiry'' for the purposes of CERCLA section 101(35)(B).

(b) *Applicability.* This section is applicable to: potential innocent landowners conducting all appropriate inquiry under section 101(35)(B) of CERCLA; bona fide prospective purchasers defined under section 101(40) of CERCLA; contiguous property owners under section 107(q) of CERCLA; and persons conducting site characterization and assessments with the use of a grant awarded under CERCLA section 104(k)(2)(B)(ii).

§ 312.2 Standards and practices for all appropriate inquiry.

(a) With respect to property purchased on or after May 31, 1997, the procedures of the American Society for Testing and Materials (ASTM)1527–97 and the procedures of the American Society for Testing and Materials (ASTM) 1527–2000, both entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process,'' shall satisfy the requirements for conducting ''all appropriate inquiry'' under section 101(35)(B)(i)(I) of CERCLA, as amended

by the Small Business Liability Relief and Brownfields Revitalization Act.

[FR Doc. 03–1631 Filed 1–23–03; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3050–F]

RIN 0938–AK40

Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule requires hospitals to develop and maintain a quality assessment and performance improvement (QAPI) program. In the December 19, 1997 **Federal Register**, we published a proposed rule to revise the hospitals conditions of participation (CoPs). The QAPI CoP was one of the conditions included in the proposed rule. We separated the QAPI CoP from the larger set of hospital CoPs so that it could be published in advance of the remaining CoPs to implement the Administration's initiatives regarding medical errors. QAPI focuses provider efforts on the actual care delivered to patients, the performance of the hospital as an organization, and the impact of treatment furnished by the hospital on the health status of its patients. Specifically, it is important to note that a QAPI is not designed to measure a hospital's quality, but rather a minimum requirement that the hospital systematically examine its quality and implement specific improvement projects on an ongoing basis. State agencies (SAs) during their surveys, review all aspects of a hospital's operations and this review provides a framework in which the SA can assess a hospital's QAPI program. In addition, the QAPI entails all activities required for measuring quality of care and maintaining it at acceptable levels. This typically includes—

• Identifying and verifying quality-related problems and their underlying cause;

• Designing and implementing corrective action activities to address deficiencies; and

• Following up to determine the degree of success of an intervention and to detect new problems and opportunities for improvement.

Performance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance. Under performance improvement framework, hospitals will continuously study and improve the processes of healthcare and delivery of service.

EFFECTIVE DATE: These regulations are effective on March 25, 2003.

FOR FURTHER INFORMATION CONTACT: Nancy Archer, (410) 786–0596; Mary Collins, (410) 786–3189; Monique Howard, (410) 786–3869; Jeannie Miller, (410) 786–3164;

SUPPLEMENTARY INFORMATION:

I. Background

A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' to revise the entire set of Conditions of Participation (CoPs) for hospitals. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the State Operations Manual (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore, are not routinely surveyed for compliance by the SAs. However, all Medicare and Medicaid participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

B. Patient Safety and Medical Errors

In 1999, the Institute of Medicine (IOM) published a report entitled ''To Err is Human: Building a Safer Health System,'' which highlighted patient injuries associated with medical errors. In this report, the IOM defined an error as the following: ''An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.'' The IOM report also indicated that an estimated 44,000 to 98,000 Americans die annually as a result of preventable medical errors. The results of the report have generated substantial media, public, Congressional, and Departmental concerns regarding patients health and safety.

As recommended by the IOM, the Quality Interagency Coordination Task Force (QuIC), evaluated and responded to the recommendations in the IOM report with a strategy to identify patient safety issues and to reduce the number of errors by 50 percent over the next 5 years. In an effort to thoroughly consider all of the relevant issues related to medical errors, the QuIC expanded the IOM's definition to read as follows: ''An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.'' We have adopted the QuIC revised definition of an error.

Accordingly, the QAPI CoP has been separated from the larger set of CoPs and published in an accelerated timeframe because it provides the framework to implement the Administration's initiatives designed to help distinguish and avoid mistakes in the healthcare delivery system. In addition, we are requiring that a hospital's QAPI program be an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors. The remaining provisions of the hospital CoPs will be published at a later date.

Many people believe that medical errors involve medication (for example, an incorrect or improper dosage of medicine) or surgical errors (for example, incorrect site amputation). However, there are many other types of medical errors including—

• Diagnostic errors (for example, misdiagnoses leading to an incorrect choice of therapy or treatment, failure to use an indicated diagnostic test, misinterpretation of test results, and