

LOUISIANA-OZONE—Continued  
[1-Hour Standard]

Designated area	Designation		Classification	
	Date <sup>1</sup>	Type	Date <sup>1</sup>	Type
* * * * *				

<sup>1</sup> This date is October 18, 2000, unless otherwise noted.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[FRL-7383-9]

**National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final notice of deletion of a portion of the Department of Energy (DOE) Mound Superfund Site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA), Region V is publishing a direct final notice of deletion of Parcel 4 of the Department of Energy (DOE) Mound Superfund Site (Mound Site), located in Miamisburg, Ohio, from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Ohio, through the Ohio Environmental Protection Agency (OEPA), because EPA and the OEPA have determined that the Department of Energy has implemented all appropriate response actions required with respect to Parcel 4. This deletion does not preclude future actions under Superfund or relieve DOE of their Long-Term Stewardship or Operation and Maintenance responsibilities.

**DATES:** This direct final notice of partial deletion will be effective December 2, 2002 unless EPA receives adverse comments by October 31, 2002. If adverse comments are received, EPA will publish a timely withdrawal of the direct final notice of deletion in the

**Federal Register** informing the public that the deletion will not take effect. **ADDRESSES:** Comments may be mailed, telephoned, or e-mailed to: Timothy Fischer, Remedial Project Manager at (312) 886-5787, *Fischer.Timothy@EPA.Gov* or Gladys Beard, State NPL Deletion Process Manager at (312) 886-7254, *Beard.Gladys@EPA.Gov*, Superfund Division, U.S. EPA Region, 5, 77 W. Jackson Blvd. (SR-6J), Chicago, IL 60604.

**Information Repositories:** Comprehensive information about the Site is available for viewing and copying at the Site information repositories located at: EPA Region V Library, 77 W. Jackson Boulevard, Chicago, IL 60604, (312) 353-5821, Monday through Friday 8 a.m. to 4 p.m.; The CERCLA Public Reading Room, Miamisburg Senior Adult Center, 305 Central Avenue, Miamisburg, OH 45342.

**FOR FURTHER INFORMATION CONTACT:** Timothy Fischer, Remedial Project Manager at (312) 886-5787, *Fischer.Timothy@EPA.GOV* or Gladys Beard, State NPL Deletion Process Manager at (312) 886-7253, *Beard.Gladys@EPA.Gov* or 1-800-621-8431, EPA Region V, 77 W. Jackson Boulevard, Mail Code SR-6J, Chicago, IL 60604.

**SUPPLEMENTARY INFORMATION:**

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**I. Introduction**

EPA Region V is publishing this direct final notice of deletion of a portion of the Department of Energy Mound Superfund Site (Mound Site), from the NPL.

EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in section 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be non-controversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective December 2, 2002 unless EPA receives adverse comments by November 1, 2002 on this document. If adverse comments are received within the 30-day public comment period on this document, EPA will publish a timely withdrawal of this direct final deletion before the effective date of the deletion and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses Parcel 4 of the DOE Mound Superfund Site and demonstrates how a portion of the Site meets the deletion criteria. Section V discusses EPA's action to delete a portion of the Site from the NPL unless adverse comments are received during the public comment period.

**II. NPL Deletion Criteria**

Section 300.425(e) of the NCP provides that releases may be deleted from the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

- i. Responsible parties or other persons have implemented all appropriate response actions required;
- ii. All appropriate Fund-financed (Hazardous Substance Superfund Response Trust Fund) responses under CERCLA have been implemented, and no further response action by responsible parties is appropriate; or
- iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Even if a site or portions of a site are deleted from the NPL, where hazardous

substances, pollutants, or contaminants remain at the deleted site above levels that allow for unlimited use and unrestricted exposure, CERCLA section 121(c), 42 U.S.C. 9621(c), requires that a subsequent review of the site be conducted at least every five years after the initiation of the remedial action at the deleted site to ensure that the action remains protective of public health and the environment. If new information becomes available which indicates a need for further action, DOE or EPA may initiate remedial actions. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

### III. Deletion Procedures

The following procedures apply to the partial deletion of this Site:

(1) The EPA consulted with Ohio on the partial deletion of the Site from the NPL prior to developing this direct final notice of deletion.

(2) Ohio concurred with the partial deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final notice of partial deletion, a notice of intent to partially delete is published today in the "Proposed Rules" section of the **Federal Register**, as well as in a major local newspaper of general circulation at or near the Site, and is being distributed to appropriate federal, state, and local government officials and other interested parties. The newspaper notice announces the 30-day public comment period concerning the notice of intent to partially delete the Site from the NPL.

(4) The EPA placed copies of documents supporting the partial deletion in the site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this document EPA will publish a timely notice of withdrawal of this direct final notice of partial deletion before its effective date and will prepare a response to comments and continue with a decision on the partial deletion based on the notice of intent to partially delete and the comments already received.

Deletion or partial deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion or partial deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a

site from the NPL does not preclude eligibility for future response actions should future conditions warrant such actions.

### IV. Basis for Partial Site Deletion

The following information provides EPA's rationale for deleting Parcel 4 of the Mound Site from the NPL and EPA's finding that the criteria in 40 CFR 300.425(e) are satisfied:

#### *Site Location*

The Mound Site is located in Miamisburg, Ohio, about 10 miles south of Dayton and 45 miles north of Cincinnati. The 306-acre site consists of a number of industrial buildings in the northern portion of the Mound Site, and open land in the southern portion. The Mound Site is located near an ancient Indian mound; hence the name of the DOE facility—the Mound Plant. Parcel 4 is generally bound to the north by the operational area of the plant, to the east by off-site residences, to the south by Benner Road, and to the west by the Miami-Erie Canal. A legal description of Parcel 4 is included in the Record of Decision for Parcel 4, and in the administrative record for the partial deletion decision.

#### *Site History*

Most of the Site is owned by the United States Department of Energy, which began operations there in 1948 involving the manufacture of triggering devices for nuclear weapons. As a result of past disposal practices and contaminant releases to the environment, including radioactive contaminants, the Mound Site was listed on the NPL on November 21, 1989 (54 FR 48184). DOE signed a CERCLA Section 120 Federal Facility Agreement (FFA) with EPA in October, 1990. In 1993, this agreement was modified and expanded to include OEPA. DOE serves as the lead agency for CERCLA-related activities at the Mound Site.

#### *Remedial Investigation and Feasibility Study (RI/FS)*

DOE, EPA, and OEPA originally planned to address the Mound Site's environmental restoration issues under a set of Operable Units (OUs), each of which would include a number of Potential Release Sites (RRSs). For each OU, the site would follow the traditional CERCLA Process: A Remedial Investigation/Feasibility Study (RI/FS), followed by a Record of Decision (ROD) and Remedial Design/Remedial Action (RD/RA). In 1995, after beginning remedial investigations for several OUs, DOE and its regulators concluded that the OU approach was

inefficient for Mound due to the number and variety of contaminants on the Site. DOE, EPA, and OEPA agreed that it would be better to evaluate each PRS or building separately, use removal action authority to remediate each one as needed, and establish a goal of no additional remediation other than institutional controls for the final remedy. Following completion of removal actions, a residual risk evaluation would be conducted to ensure that industrial use of the block or building would be safe. DOE, EPA, and OEPA called this approach the "Mound 2000 Process."

The Mound 2000 Process established a Core Team consisting of representatives of DOE, EPA, and OEPA. The Core Team evaluates each of the potential contamination problems at the Mound Site and recommends the appropriate response. It uses information gathered from site visits, existing data, and knowledge of Mound Plant processes to determine whether or not any action is warranted for potential release sites. If a decision cannot be made based on the information on hand, the Core Team identifies the specific, additional information needed. The Core Team also receives input from technical experts and from the public. Thus, all stakeholders have an opportunity to express their opinions or suggestions for each potential problem area.

In February 2001, DOE conducted a residual risk evaluation for Parcel 4 of the Mound Site. The purpose of the risk evaluation was to assess risks associated with levels of contamination that exist after completion of removal action. The residual risk evaluation method was consistent with the CERCLA baseline risk assessment method to ensure that future users of the land would not be exposed to contaminant levels that would pose unacceptable risks. The residual risk assessment for Parcel 4 determined that limiting use of Parcel 4 to industrial/commercial uses was protective of human health and the environment.

#### *Record of Decision Finding*

The ROD was signed for Parcel 4 of the Mound Site on March 8, 2001. The selected remedy included institutional controls in the form of deed restrictions on future land and groundwater use. DOE, or its successors, as the lead agency for this ROD, has the responsibility to monitor, maintain and enforce these institutional controls. In order to maintain protection of human health and the environment at Parcel 4 in the future, the institutional controls ensure:

1. Maintenance of industrial/commercial land use;
2. Prohibition against residential use;
3. Prohibition against the use of groundwater;
4. Site access for federal and state agencies for the purpose of sampling and monitoring; and
5. Prohibition against removal of Parcel 4 soils from the DOE Mound property boundary (as owned in 1998) without approval from the Ohio Department of Health (ODH) and the Ohio Environmental Protection Agency (OEPA).

#### *ROD Implementation*

DOE has implemented the ROD for Parcel 4 by placing restrictions in the deed for the Parcel. DOE conveyed Parcel 4 to the Miamisburg Mound Community Improvement Corporation (MMCIC) on April 19, 2001. Because the restrictions have been placed in a Quit Claim Deed for Parcel 4 and that deed has been executed with the transfer of the land to the MMCIC, the restrictions are enforceable and the remedy is considered "implemented".

While EPA does not believe that any future response actions for Parcel 4 will be needed, if future conditions warrant such action, this area of the Mound Site would be eligible for Fund-financed response actions. This partial deletion affects Parcel 4 only. The remainder of the Site, save for those portions deleted in a previous action (see 66 FR 10371–10374), remain on the NPL.

#### *Operation and Maintenance of Institutional Controls*

Under the ROD signed on March 8, 2001, the Department of Energy committed itself to monitor and maintain the institutional controls for Parcel 4 required by the ROD, and to enforce them if necessary. The ROD also required DOE to provide U.S. EPA and Ohio EPA with periodic compliance assessments. Deletion of Parcel 4 from the NPL does not alter in any way DOE's Operation and Maintenance or Long-Term Stewardship obligations under the Parcel 4 ROD. A Long-Term Stewardship Plan is under development for the DOE Mound Plant. Long-Term Stewardship (LTS) is defined as "the physical controls, institutions, information and other mechanisms needed to ensure protection of people and the environment at sites where DOE has completed or plans to complete 'cleanup' (e.g., landfill closures,

remedial actions, removal actions, and facility stabilization). This concept of long-term stewardship includes, inter alia, land use controls, monitoring, maintenance, and information management (This definition of long-term stewardship comes from the 1998 settlement agreement DOE entered into; *NRDC, et al. v. Richardson, et al.*, Civ. No. 97–963)." The LTS Plan for DOE Mound covers all the above concepts and refers to the processes set up to ensure the effectiveness of the institutional controls. For more information, contact Dann Bird, Miamisburg Mound Community Improvement Corporation, at (937) 865–4266 or Sue Smiley, Department of Energy, at (937) 865–3984.

#### *Five-Year Review*

Because the remedy for Parcel 4 does not allow unlimited use of and unrestricted exposure to the property, DOE is required by Section 121(c) of CERCLA to review the remedy to assure that it continues to protect human health and the environment. While CERCLA requires a review at least once every 5 years after the initiation of remedial action, DOE committed itself to conduct such reviews annually. DOE also committed itself to consult with U.S. EPA, Ohio EPA, and the Ohio Department of Health on these reviews. The first Five-Year Review of the Mound Plant was completed on September 28, 2001. It concluded that the Parcel 4 remedy remains protective of human health and the environment. An additional walkover inspection of the Parcel 4 property was accomplished on May 21, 2002, and no violations of the deed restrictions were documented.

#### *Community Involvement*

Public participation activities with respect to any response actions in Parcel 4 have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k), and CERCLA section 117, 42 U.S.C. 9617. Documents in the deletion docket which EPA relied on for recommendation of the partial deletion of this Site from the NPL are available to the public in the information repositories.

#### *Federal Facility Agreement*

Deletion of Parcel 4 from the NPL in no way alters the obligations of the Department of Energy under the Federal Facility Agreement under CERCLA Section 120, signed by U.S. EPA, Ohio

EPA, and DOE in 1993, including Long-Term Stewardship or Operation and Maintenance responsibilities.

#### **V. Deletion Action**

The EPA, with concurrence of the State of Ohio, has determined that the Department of Energy has implemented all appropriate response actions required, and that no further CERCLA response is appropriate to provide protection of human health and the environment. Therefore, EPA is deleting Parcel 4 of the Site from the NPL.

Because EPA considers this action to be non-controversial and routine, EPA is taking it without prior publication. This action will be effective December 2, 2002, unless EPA receives adverse comments by November 1, 2002. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will not take effect. EPA will prepare a response to comments and as appropriate continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

#### **List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 17, 2002.

**Norman Niedergang,**

*Acting Regional Administrator, Region V.*

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

#### **PART 300—[AMENDED]**

1. The authority citation for part 300 continues to read as follows:

**Authority:** 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

#### **Appendix B—[Amended]**

2. Table 2 of Appendix B to Part 300 is amended under Ohio "OH" by revising the entry for "Mound Plant (USDOE)" and the city "Miamisburg."

TABLE 2.—FEDERAL FACILITIES SECTION

State	Site name	City/County	(Notes) <sup>a</sup>
OH	Mound Plant (USDOE)	Miamisburg	P

<sup>(a)</sup>

P=Sites with partial deletion(s).

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[FR Doc. 02-24641 Filed 10-1-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicaid & Medicare Services

#### 42 CFR Part 482

[CMS-3018-N]

RIN 0938-AL15

#### Medicare and Medicaid Programs; Hospital Conditions of Participation: Clarification of the Regulatory Flexibility Analysis for Patients' Rights

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

**ACTION:** Interim final rule; clarification of regulatory flexibility analysis.

**SUMMARY:** On July 2, 1999, we published an interim final rule with comment period introducing a new Patients' Rights Condition of Participation (CoP) that hospitals must meet to be approved for, or to continue participation in, the Medicare and Medicaid programs. Several aspects of that interim final rule with comment period were challenged, including its regulatory flexibility analysis (RFA). As a result of this action, a Federal court, without enjoining continued enforcement of the rule, ordered the Secretary of the Department Health and Human Services (DHHS) to complete a compliant RFA to accompany the interim final rule with comment period. This document addresses the court's order.

**FOR FURTHER INFORMATION CONTACT:** Jeannie Miller, RN, (410) 786-3164.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

###### A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule that detailed our plans to

revise all of the hospital conditions of participation (CoPs), emphasizing lessening Federal regulations to eliminate unnecessary structural and process requirements, focus on outcomes of care, allow greater flexibility to hospitals and practitioners to meet quality standards, and place a stronger emphasis on quality assessment and performance improvement. The proposed rule introduced our intent to include a new Patients' Rights CoP for hospitals. We solicited comments and received strong support for the establishment of the new CoP from the public, mental health advocacy groups, the media, and the Congress.

After the proposed rule was published, reports of injuries and deaths associated with the use of restraints and seclusion increased our concern about patient safety. State surveyors, patient advocacy groups, the media, and the public also brought complaints about hospital violations of patients' rights to our attention. These violations included denying or frustrating patients' access to care, denying patients' full involvement in their treatment, disregarding patients' advance directives, and denying patients access to their records. In the July 2, 1999 **Federal Register** (64 FR 36070), we published an interim final rule with comment period to address these concerns and assure patient safety. The rule set forth requirements supporting and protecting patients' rights in the hospital setting, specifically, the right to be free from the inappropriate use of seclusion and restraint, with requirements to protect the patient when use of either intervention is necessary.

###### B. Legal Challenge of the Interim Final With Comment Period

The interim final rule with comment period was challenged in United States District Court for the District of Columbia by the National Association of Psychiatric Health Systems, the American Hospital Association, the Sheppard and Enoch Pratt Foundation, Incorporated, and Acadia Hospital. (See

*National Association of Psychiatric Health Sys. v. Shalala*, 120 F.Supp.2d 33 (D.D.C. 2000).) Plaintiffs challenged one provision of the new CoP, the requirement that hospitals must provide for an in-person evaluation of a patient by a physician or other licensed independent practitioner (LIP) within 1 hour of initiating the use of restraint or placing the patient in seclusion to address the patients' violent or aggressive behavior. (See § 482.13(f)(3)(ii)(C).)

On September 14, 2000, the Court ruled in favor of the Secretary with respect to the plaintiffs' challenge under the Administrative Procedures Act; however, the Court ruled against the Secretary with respect to the plaintiffs' claim that the rule failed to fulfill certain requirements of the Regulatory Flexibility Act (RFA). In its decision, the Court noted that the RFA requires—

- A succinct statement of the need for and objectives of the rule;
- A summary of and response to the significant issues raised by public comments to the RFA assessment in the notice of proposed rulemaking;
- A description and estimate of the number of small entities to which the rule will be applied;
- A description of the projected reporting and recordkeeping requirements of the rule, including an estimate of the effect that the recordkeeping requirements will have on small entities; and
- A description of the efforts the agency has taken to minimize the significant economic impact of the rule on small businesses, including a discussion of the less restrictive alternatives considered and rejected.

The Court, noting that the Secretary had not made a "reasonable good faith effort to canvass major options and weigh their probable effects," concluded that the agency failed to satisfy the fifth element of the Regulatory Flexibility Act. The case was remanded to the Department of Health and Human Services for completion of a compliant RFA without enjoining continued enforcement of the requirements of the