

Natural Resource Damage Assessment Plan for the Ashtabula River and Harbor

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Prepared by:

**U.S. Fish and Wildlife Service, Region 3
B.H.W. Federal Building, 1 Federal Drive
Ft. Snelling, MN 55111-4096**

With Assistance from:

**Stratus Consulting Inc.
P.O. Box 4059
Boulder, CO 80306-4059**

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1. Introduction

The Ohio Environmental Protection Agency (Ohio EPA), the U.S. Fish and Wildlife Service (Service) of the Department of Interior (DOI), and the National Oceanic and Atmospheric Administration (NOAA) of the Department of Commerce (DOC) (collectively, the trustees) are preparing to assess damages to natural resources that have resulted from releases of hazardous substances to the Ashtabula River, Ashtabula Harbor, Lake Erie, and other areas where hazardous substances have come to be located (collectively known as the assessment area).

1.1 Authority to Conduct a Natural Resource Damage Assessment

The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) as amended, [42 U.S.C. §§ 9607 *et seq.*] and the Federal Water Pollution Control Act (Clean Water Act, or CWA), as amended [33 U.S.C. §§ 1321 *et seq.*], authorize the federal government, states, and Indian tribes to recover, on behalf of the public, damages for injuries to natural resources belonging to, managed by, held in trust by, appertaining to, or otherwise controlled by them (referred to as “managed or controlled”). Under the authority of the CERCLA and the CWA, the DOI issued federal regulations at 43 CFR Part 11 to guide trustees in the assessment of natural resource injuries, damages, and restoration following the release of hazardous substances. The purpose of these regulations is to provide standardized and cost effective procedures for assessing natural resource damages [43 CFR § 11.11]. This Assessment Plan is designed to be in accordance with the regulations promulgated by the DOI at 43 CFR Part 11.¹

In accordance with 42 U.S.C. 9607(f)(2)(B) and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) [40 CFR § 300.600], the Governor of Ohio has delegated the Director of the Ohio EPA as the natural resource trustee for the State of Ohio by Executive Order 2000-20T, June 26, 2000. The Ohio EPA acts on behalf of the State as trustee for natural resources, and their supporting ecosystems, within the boundaries of Ohio or managed or controlled by Ohio.

The NCP and Executive Order 12580, dated January 23, 1987, designate federal natural resource trustees. The Secretary of the DOI acts as trustee for natural resources, and their supporting ecosystems, managed or controlled by the DOI. In this matter, the Service is acting on behalf of

1. The application of these regulations is not mandatory, and the trustees have the option of diverging from them as appropriate. However, assessments performed in compliance with these regulations have the force and effect of a rebuttable presumption in any administrative or judicial proceeding under CERCLA [42 U.S.C. § 9607 (f)(2)(C)].

the Secretary of the DOI as trustee. The official authorized to act on behalf of the DOI at the Ashtabula assessment area is the Regional Director of Region 3 of the Service. The Secretary of the DOC acts as trustee for natural resources, and their supporting ecosystems, managed or controlled by the DOC. The Secretary of the DOC also acts as trustee for natural resources, and their supporting ecosystems, managed or controlled by other federal agencies when those natural resources are found in, under, or using waters navigable by deep draft vessels, tidally influenced waters, or waters of the contiguous zone and the exclusive economic zone. The Secretary of the DOC has delegated his authority to act as trustee to the Administrator of NOAA.

1.2 Justification

The trustees completed a preassessment screen (PAS) in accordance with federal regulations at 43 CFR §§ 11.23-11.25 for the Ashtabula assessment area on May 18, 2001. The PAS is based on a review of the readily available data, and it documents that the trustees have a reasonable probability of making a successful claim for natural resource damages. Specifically, the PAS concluded the following:

- ▶ Releases of hazardous substances have occurred.
- ▶ Natural resources for which the trustees may assert trusteeship under the CERCLA and the CWA have been or are likely to have been adversely affected by the discharge or release of hazardous substances.
- ▶ The quantity and concentration of the released hazardous substances are sufficient to potentially cause injury to natural resources.
- ▶ Data sufficient to pursue an assessment are readily available or likely to be obtained at a reasonable cost.
- ▶ Response actions carried out or planned do not or will not sufficiently remedy the injury to natural resources without further action.

Therefore, the trustees determined that further investigation and assessment is warranted at the Ashtabula assessment area in accordance with federal regulations at 43 CFR Part 11, Subparts C and E.

1.3 Purpose of the Assessment Plan

The purpose of this Assessment Plan is to describe the trustees' approach for conducting a natural resource damage assessment (NRDA) of the Ashtabula assessment area and to propose initial work that may be conducted during the current or next field season. The Assessment Plan (and possibly addenda describing additional work in subsequent field seasons) helps the trustees ensure that the NRDA will be completed at a reasonable cost relative to the magnitude of likely damage. The trustees also intend for this plan to communicate the assessment approach to the public and the potentially responsible parties (PRPs) in an effective manner so that these groups can productively participate in, or comment on, assessment activities.

1.4 Decision to Perform a Type B Assessment

Trustees may select between a "Type A" and a "Type B" assessment [43 CFR § 11.33]. Type A procedures are simplified procedures that require minimal field observation [43 CFR § 11.33(a)]. A model has been developed for Type A assessments in Great Lakes environments ("NRDAM/GLE") [43 CFR § 11.33(a)]. Under 43 CFR § 11.34, an authorized official may use a Type A assessment if the release occurred over a short duration, was a minor event, was relatively homogenous, and involved a limited number of hazardous substances.

Releases of hazardous substances in the assessment area have occurred since the 1940s, with contamination extending over more than 500 acres of the Ashtabula River and Harbor and, possibly, an undefined area of Lake Erie. Hazardous substances have been transmitted through the food chain, affecting several different trophic levels. Over 50 listed hazardous substances have been detected in the assessment area. Consequently, the releases cannot be considered of short duration, minor, or resulting from a single event and are therefore not readily amenable to simplified models. The spatial and temporal extent and heterogeneity of exposure conditions and potentially affected resources are not suitable for application of simplifying assumptions and the averaged data and conditions inherent in Type A procedures.

The trustees have determined that 1) a Type A NRDAM/GLE is not appropriate given the long term, spatially and temporally complex nature of the releases and exposures to hazardous substances in the assessment area, 2) substantial site-specific data already exist to support the assessment, and 3) additional site-specific data can probably be collected at reasonable cost. As a result, the trustees have determined to use the Type B procedures.

1.5 Preliminary Estimate of Damages

As part of the planning process for a Type B assessment, the trustees are required to prepare a Preliminary Estimate of Damages (PED) [43 CFR § 11.38]. The purpose of this estimate is to guide the trustees in selecting approaches and methods that are likely to cost less than the value of damages. The trustees are not required to release the PED until the Report of Assessment at the conclusion of the NRDA. The trustees have completed a PED, determined that a Type B assessment is justified, in part because existing information will reduce assessment costs, and will release the PED as part of any Report of Assessment at the conclusion of the NRDA.

1.6 Participation by the Public in the Assessment

The trustees invite public participation in this NRDA. The trustees intend to hold public comment periods on at least the following documents.

- ▶ this Assessment Plan
- ▶ the Restoration and Compensation Determination Plan
- ▶ any other significant additions or modifications to this Assessment Plan
- ▶ the Restoration Plan (after settlement or award).

Each public comment period will last for at least 30 days, with reasonable extensions granted as appropriate. The public comment period for this Assessment Plan begins on the day the notice of availability is published in the Federal Register and lasts for 30 calendar days. Comments may be submitted in writing to either:

David DeVault
U.S. Fish and Wildlife Service, Region 3
B.H.W. Federal Building, 1 Federal Drive
Ft. Snelling, MN 55111-4096

or

Sheila Abraham
Ohio Environmental Protection Agency
North East District Office
2110 East Aurora Road
Twinsburg, OH 44087

In addition, the trustees will open a public reading room that will provide access to documents used by the trustees for the NRDA. This will be located at:

**U.S. Fish and Wildlife Service
6950 Americana Parkway
Reynoldsburg, OH 43068
Phone: 614-469-6923**

1.7 Organization of the Assessment Plan

The remaining sections of this Assessment Plan contain the following information. Section 2 provides background information about the site. Section 3 describes the general approaches that the trustees propose to follow to document hazardous substance releases, pathways, and injuries, and to scale appropriate restoration through quantification of injuries, damages, and restoration. Additional approaches may be proposed in one or more Assessment Plan addenda to be released to the public in the future. Section 4 describes initial assessment activities that may be undertaken this field season as part of this plan. Additional assessment activities may be described in subsequent addenda. Section 5 describes general quality assurance procedures to be used in any assessment activities.

2. Background Information

This NRDA will address injuries to natural resources that result from releases of hazardous substances into the Ashtabula River, Ashtabula Harbor, or Lake Erie from PRP discharges directly or indirectly into Fields Brook, the Ashtabula River, or Ashtabula Harbor (Figure 1). The NRDA will initially focus on the following natural resources: 1) surface waters and sediments, 2) benthic invertebrates and supporting habitats, 3) fishery resources and supporting habitats, and 4) avian and mammalian resources and supporting habitats. The NRDA will initially focus on the following classes of hazardous substances: 1) organochlorines, 2) other organic compounds, and 3) metals. PRPs have been identified by the U.S. Environmental Protection Agency in conjunction with the Fields Brook Superfund action. The trustees may modify the focus of the NRDA with respect to natural resources, hazardous substances, or PRPs, based on the results of initial assessment activities described in this plan.

2.1 Other Activities in the Assessment Area

The U.S. Environmental Protection Agency (Agency) placed Fields Brook on the National Priorities List in 1983. In 1985, the International Joint Commission designated the lower

Ashtabula River and Harbor as a Great Lakes Area of Concern. The Ashtabula Partnership formed in 1994 to facilitate voluntary cleanup as an alternative to an impending designation of the Ashtabula River as an operable unit of the Fields Brook Superfund Site. The Partnership comprises approximately 50 public and private entities, including the U.S. Army Corps of Engineers (ACOE), the Agency, the Service, the Ohio EPA, the Ohio Department of Natural Resources, the Ohio Department of Health, local governments, and local businesses and industries, some of which are PRPs.

2.2 Geographic Scope of the Assessment Area

This NRDA will initially focus on the water, sediment, shoreline, and biological resources of the Ashtabula River from the Upper Turning Basin to the harbor mouth, as well as the Lake Erie shoreline in the immediate vicinity of the Ashtabula River (see Figure 1). If data warrant, the assessment boundaries may be expanded to include other areas where hazardous substances have come to be located.

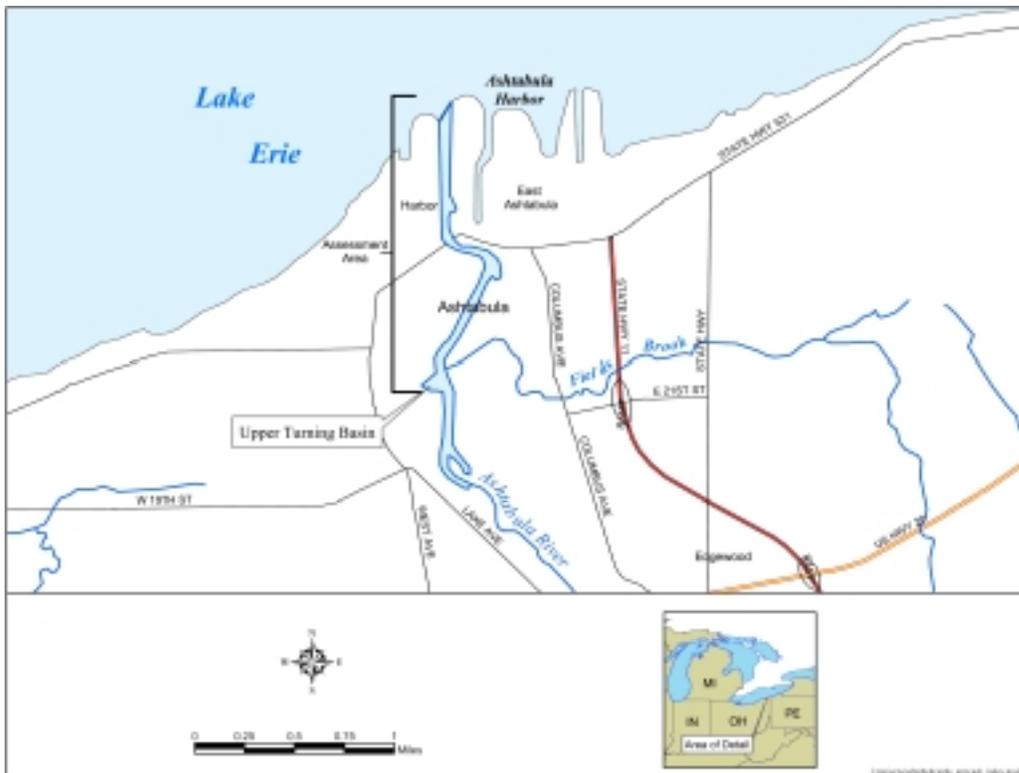


Figure 1. Geographic scope of the assessment area for the Ashtabula River and Harbor NRDA.

The assessment area of the Ashtabula River and Harbor is approximately 511 acres. Habitats in the assessment area include submergent wetlands, lotic (river) habitat, and lentic (lake) habitat.

2.3 Hazardous Substances Released

Hazardous substances released into the assessment area include, but are not limited to, polychlorinated biphenyls (PCBs), hexachlorobenzene, hexachlorobutadiene, and other compounds listed in Table 1. The compounds listed in Table 1 are hazardous substances as defined by 40 CFR § 302.4, pursuant to section 102(a) of CERCLA and section 311(b)(2) of the CWA. The trustees may consider other hazardous substances released by PRPs, based on the initial results of the assessment.

Table 1. Hazardous substances detected in the Ashtabula River and Harbor.

PCBs	Dichloroethane	Benzo(a)pyrene
Hexachlorobenzene	Trichloropropene	Benzo(b)fluoranthene
Pentachlorobenzene	Pentachloropropene	Benzo(g,h,i)perylene
Tetrachlorobenzene	Pentachloroanisole	Benzo(k)fluoranthene
Trichlorobenzene	Hexachloronorborene	Chrysene
Dichlorobenzene	Acetone	Di-n-butyl phthalate
Chlorobenzene	Methylene chloride	Fluoranthene
Hexachlorocyclopentadiene	Vinyl acetate	Fluorene
Dichlorobenzaldehyde	Toluene	Indeno(1,2,3-cd)pyrene
Tetrachlorobutadiene	DDT and metabolites	Naphthalene
Pentachlorobutadiene	Heptachlor	Heptachlorostryene
Hexachlorobutadiene	Lindane	Hexachlorostryene
Hexachloroethane	Dieldrin	Octachlorostryene
Hexachlorobutene	HxCDD	Phenanthrene
Pentyl furan	PeCDF	Pyrene
Tetrachloroethane	TCDF	Cadmium
Trichloroethane	Anthracene	Mercury
Trichloroethene	Benzo(a)anthracene	Copper

2.4 Sources of Releases

Based on a review of the readily available information, the trustees have tentatively concluded that hazardous substances were originally discharged or released to Fields Brook and its watershed during decades of manufacturing activity. Hazardous substances have migrated downstream from Fields Brook to the Ashtabula River, Ashtabula Harbor, and Lake Erie, contaminating bottom sediments, water, fish, and wildlife. Fish and wildlife have been and continue to be exposed to hazardous substances through direct contact with contaminated sediments and water, as well as food chain bioaccumulation. Desorption from and resuspension

of previously contaminated sediments continue to expose surface waters and fish and wildlife to hazardous substances.

2.5 Description of Natural Resources and the Services They Provide

The Ashtabula River, Ashtabula Harbor, and adjacent Lake Erie contain a variety of habitats and a diverse assemblage of fish and wildlife species, which have been exposed to or injured by hazardous substances released by PRPs (Figure 2). The Ashtabula Harbor is located on both the Atlantic and the Mississippi flyways, and over 3 million ducks and geese use this corridor (Figure 3). Many migratory bird species nest on the outer breakwalls and wetlands near the river. Migratory bird species include, but are not limited to, the osprey (*Pandion haliaetus*), wood duck (*Aix sponsa*), Canada goose (*Branta canadensis*), common merganser (*Mergus merganser*), great blue heron (*Ardea herodias*), cliff swallow (*Hirundo pyrrhonta*), tree swallow (*Tachycineta bicolor*), Caspian tern (*Sterna caspia*), Forster's tern (*Sterna forsteri*), common tern (*Sterna hirundo*), mallard (*Anas platyrhynchos*), black duck (*Anas rubripes*), lesser scaup (*Aythya affinis*), and kingfisher (*Ceryle alcyon*). Numerous additional species of migratory neotropical songbirds inhabit the area seasonally.

The Ashtabula River, Ashtabula Harbor and adjacent Lake Erie provide habitat, sustenance, spawning areas and other ecological services for numerous species of fish. These include, but are not limited to, yellow perch (*Perca flavescens*), white bass (*Morone chrysops*), pumpkinseed (*Lepomis gibbosus*), white crappie (*Pomoxis annularis*), goldfish (*Carassius auratus*), emerald shiner (*Notropis atherinoides*), gizzard shad (*Dorosoma cepedianum*), carp (*Cyprinus carpio*), brown bullhead (*Ictalurus nebulosus*), alewife (*Alosa pseudoharangus*), smallmouth bass (*Micropterus dolomieu*), rainbow smelt (*Osmerus mordax*), johnny darter (*Etheostoma nigrum*), walleye (*Stizostedion vitreum*), rainbow trout (*Oncorhynchus mykiss*), spottail shiner (*Notropis hudsonius*), log perch (*Percina caprodes*), freshwater drum (*Aplodinotus grunniens*), lake sturgeon (*Acipenser fulvescens*), and white sucker (*Catostomus commersoni*). Rainbow trout and rainbow smelt are anadromous fish species. Yellow perch, walleye, and lake sturgeon are nationally significant fish stocks. Three fish species of "Special Concern" in Ohio have been listed in the Ashtabula River lacustrine. These are the Great Lakes muskellunge (*Esox masquinongy*), blacknose shiner (*Notropis heterolepis*), and lake sturgeon (*Acipenser fulvescens*). Mammalian species, including beaver (*Castor canadensis*), muskrat (*Ondatra zibethicus*), raccoon (*Procyon lotor*), deer (*Odocoileus virginianus*), and mink (*Mustela vison*), also occur in the area.

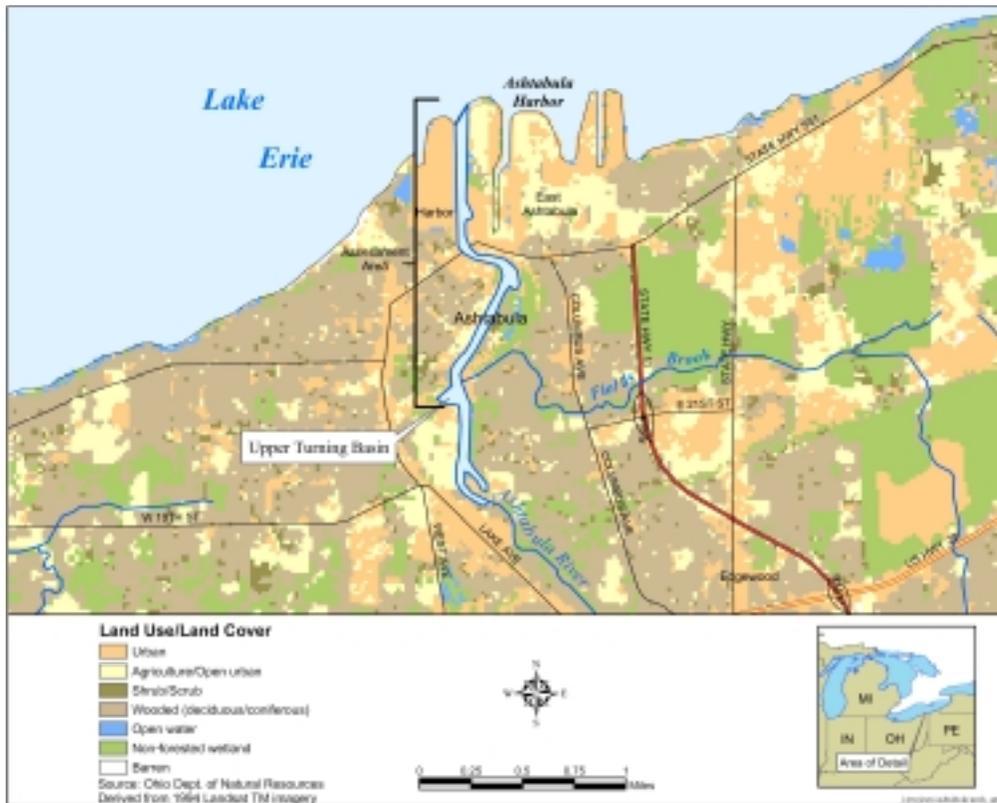


Figure 2. Land use/land cover in the vicinity of the assessment area of the Ashtabula River and Harbor NRDA.

Public human use services that may be affected by hazardous substances releases include, but are not limited to, sport fishing, hunting, bird watching, navigation, boating, tourism, as well as use, enjoyment, and passive uses of natural areas, parks, forests, waterways, and a healthy ecosystem.

2.6 Confirmation of Exposure

A natural resource has been “exposed” to a hazardous substance if all or part of a natural resource is, or has been, in physical contact with a hazardous substance or with media containing a hazardous substance [43 CFR § 11.14(q)]. The Assessment Plan should confirm that at least one of the natural resources identified as potentially injured in the PAS has in fact been exposed to the released substance [43 CFR § 11.37(a)]. Whenever possible, exposure should be confirmed by using existing data from previous studies of the assessment area [43 CFR

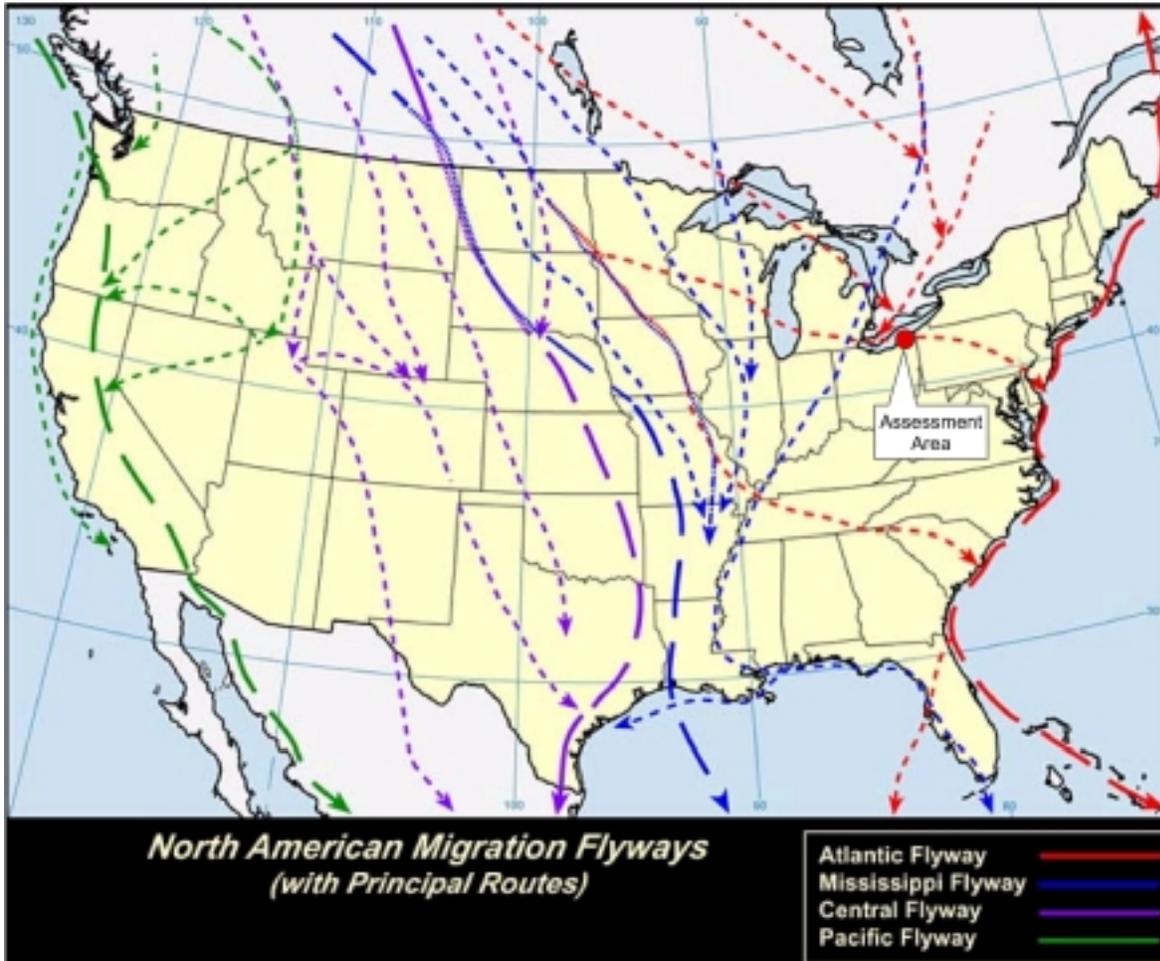


Figure 3. Migratory flyways in North America.

Source: Birdnature, 2002.

§ 11.37(b)(1)]. The following sections provide confirmation of exposure for a number of potentially injured natural resources identified in the PAS. However, the following discussion does not necessarily review all existing information that could confirm exposure of natural resources to hazardous substances in the assessment area.

2.6.1 Surface water and sediments

The DOI regulations define “surface water resources” to include sediments suspended in water or laying on the bank or bed, and shoreline sediments in or transported through marine areas [43 CFR § 11.14]. Fields Brook, the suspected hazardous substance pathway from the PRP facilities to the Ashtabula River, enters the Ashtabula River at the Upper Turning Basin. Table 2 summarizes data that clearly demonstrate that sediments downstream of Fields Brook have been exposed to hazardous substances.

Table 2. Concentration ranges for selected hazardous substances in sediments from the Ashtabula River and Harbor (mg/kg dry weight).

Location	PCBs	HCB	HCBD	Phenanthrene	Pyrene	Flouranthene	C-PNAs
Above Upper Turning Basin	nd – 11.2	nd – 1.0	nd	nd – 10	nd – 1	nd – 10	nd – 1.6
Upper Turning Basin to 5th St. Bridge	0.77 – 660	nd – 45000	nd – 500	nd – 100	nd – 75	nd – 50	nd – 125
5th St. Bridge — Mouth	nd – 3.9	ns	ns	ns	ns	ns	nd – 13
Harbor	nd – 0.21	ns	ns	ns	ns	ns	ns

nd = not detected.

ns = not sampled.

PCBs = polychlorinated biphenyls.

HCB = hexachlorobenzene.

HCBD = hexachlorobutadiene.

C-PNAs = carcinogenic polynuclear aromatics.

Source: Woodward Clyde, 1993.

2.6.2 Biota

Hazardous substances have been detected in fish and avian species in the Ashtabula River and Harbor downstream of Fields Brook by state and federal agencies and several individual investigators. Table 3 contains fish tissue residue data reported by various agencies and authors between 1981 and 1994.

Since 1983, elevated concentrations of PCBs and other hazardous substances have resulted in the issuance and posting of sport fish consumption advisories for the Ashtabula River by the Ohio Department of Health. The Ohio Department of Health issues sport fish consumption advisories when PCB concentrations exceed 0.05 mg/kg. Fish tissue PCB concentrations have exceeded 0.05 mg/kg between 1981 and the present.

Table 3. Concentrations of selected hazardous substances in Ashtabula River fish tissue (mg/kg wet weight).

Location	Year	Species	Sample type	PCB	HCB	PeCB	HCBD	PCBD	Reference
Upstream of Fields Brook	1981	white sucker	whole	0.68					1
	1981	white sucker	whole	1.2					1
	1981	brown bullhead	whole	2.8					1
	1990	carp	whole	0.25					3
	1990	small/large mouth bass	whole	0.13					3
Downstream of Fields Brook	1990	carp	whole	0.81					3
	1990	small/large mouth bass	whole	0.2					3
	1990	small/large mouth bass	whole	0.09					3
	1990	carp	whole	1.3					3
	1994	largemouth bass	fillet	74.5					2
	1994	golden redhorse	fillet	0.06					2
	1994	drum	fillet	0.15					2
	1994	carp	fillet	1.05					2
	1981	northern pike	whole	6.6	2.19	3.8	2.8	4.8	1
	1981	blue gill	whole	10.7	3.47	3.1			1
	1981	yellow bullhead	whole	1.7	0.31				1
	1994	brown bullhead	fillet	0.16					2
	1994	largemouth bass	fillet	0.42					2
	1994	carp	fillet	3.6					2
1994	largemouth bass	fillet	1.2					2	

PCB = polychlorinated biphenyls.

HCB = hexachlorobenzene.

PeCB = pentachlorobenzene.

HCBD = hexachlorobutadiene.

PCBD = pentachlorobutadiene.

1. DeVault, 1984; 1985.

2. OH EPA, unpublished data.

3. Woodward Clyde, 1993.

Elevated PCB concentrations were also observed in herring gull eggs collected on the breakwall separating the Ashtabula Harbor from Lake Erie (Table 4).

Table 4. PCB concentrations (mg/kg fresh weight) in herring gull eggs from the east breakwall, Ashtabula Harbor in 1991.

PCB	Egg #1	Egg #2	Egg #3	Egg #4	Egg #5	Egg #6	Egg #7	Mean
Aroclor 1254	5.2	6.7	11.4	9.1	5.4	6.6	8.3	7.5
Aroclor 1260	10.3	11.3	24.6	14.1	7.5	14.1	14.1	13.7
Total PCB	15.5	18.0	36.0	23.2	12.9	20.7	22.4	21.2

Source: U.S. Fish and Wildlife Service, unpublished data.

3. Assessment Approach

This section outlines the general approach that the trustees initially intend to follow in assessing natural resource damages for the Ashtabula assessment area. The next section proposes initial assessment activities that may begin this field season, including a preliminary evaluation of injuries and restoration to more fully organize and analyze existing data and information. Based on the preliminary evaluation, the general approach presented in this section and the assessment activities described in the next section may be modified. If so, Assessment Plan addenda will be issued for public comment.

3.1 Hazardous Substance Pathways and Injuries to Natural Resources

3.1.1 Introduction

It is likely that surface water resources and biological resources have been and continue to be injured as a result of exposure to hazardous substances. The purpose of the injury assessment phase is to determine whether natural resources have been injured and whether the injury was the result of the release of hazardous substances [43 CFR § 11.61], to quantify the degree and extent (spatial and temporal) of injury [43 CFR § 11.71], and to identify the environmental pathways through which injured resources have been exposed to hazardous substances [43 CFR § 11.63].

DOI regulations define “injury” as a measurable adverse change, either long or short term, in the chemical or physical quality or the viability of a natural resource resulting either directly or indirectly from exposure to a release of a hazardous substance, or exposure to a product of reactions resulting from the release of a hazardous substance [43 CFR § 11.14 (v)]. The trustees will use existing literature and data, where available, to determine and quantify injuries. Where

these data are insufficient, additional studies needed to determine and quantify injuries may be identified at a later date.

3.1.2 Injury assessment process

The “injury determination” phase of the assessment includes the following steps:

- ▶ **Injury definition.** In the injury definition phase, injuries that meet the definitions of injury in 43 CFR § 11.62 are determined, as well as other relevant injury categories.
- ▶ **Pathway determination.** In the pathway determination phase, exposure pathways for transport of hazardous substances to injured natural resources are identified [43 CFR § 11.63]. DOI regulations note that pathway determination may be accomplished by the “demonstration of sufficient concentrations in the pathway for it to have carried the substance to the injured resources” [51 FR 27684].

The final phase consists of “injury quantification:”

- ▶ **Injury quantification.** The effects of the releases of hazardous substances are quantified in terms of changes from “baseline conditions” [43 CFR § 11.70 (a)]. Specific steps in the quantification phase include measuring the extent of injury relative to baseline conditions and quantifying the spatial and temporal extent of injury [43 CFR § 11.71 (b)]. Baseline conditions are the conditions that “would have existed at the assessment area had the . . . release of the hazardous substance . . . not occurred” [43 CFR § 11.14 (e)] and are the conditions to which injured natural resources should be restored [43 CFR § 11.14 (II)].

3.1.3 Surface water

Relevant definitions of injury to surface water resources that may be evaluated by the trustees include the following:

- ▶ Concentrations and duration of substances in excess of applicable water quality criteria established by Section 304(a)(1) of the CWA, or by other federal or state laws or regulations that establish such criteria, in surface water that before the discharge or release met the criteria and is a committed use as habitat for aquatic life, water supply, or recreation. The most stringent criterion applies when surface water is used for more than one of these purposes [43 CFR § 11.62 (b)(1)(iii)].

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- ▶ Concentrations and duration of substances in excess of drinking water standards as established by Sections 1411-1416 of the Safe Drinking Water Act (SDWA), or by other federal or state laws or regulations that establish such standards for drinking water, in surface water that was potable before the discharge or release [43 CFR § 11.62 (b)(1)(i)].
 - ▶ Concentrations and duration of substances sufficient to have caused injury to biological resources when exposed to surface water or suspended sediments [43 CFR § 11.62 (b)(1)(v)].

3.1.4 Sediments

Relevant definitions of injury to sediments that may be evaluated by the trustees include the following:

- ▶ Concentrations of hazardous substances sufficient to cause injury to biological or surface water resources that are exposed to sediments [43 CFR § 11.62(b)(1)(v)].
- ▶ Concentrations of hazardous substances sufficient to exceed the Toxic Substances Control Act (TSCA) regulations for hazardous chemical disposal [40 CFR § 761.60(a)(5)].²

3.1.5 Aquatic biota resources

Relevant biological injuries defined by DOI regulations [43 CFR § 11.62 (f)(1)] include the following:

- ▶ Concentrations of a hazardous substance sufficient to exceed action or tolerance levels established under section 402 of the Food, Drug and Cosmetic Act, 21 U.S.C. 342, in edible portions of organisms [43 CFR § 11.62 (f)(1)(ii)].

2. This definition of injury is not included in the DOI NRDA regulations. However, the DOI regulations indicate that sediments are injured when hazardous substance concentrations are sufficient to cause the sediment to exhibit characteristics identified or listed pursuant to Section 3001 of the Solid Waste Disposal Act (SWDA) 42 U.S.C. 6921 [43 CFR 11.62(b)(1)(iv)]. To the extent that regulations promulgated under TSCA require that sediments containing PCBs at concentrations greater than 50 mg/kg be either incinerated or disposed of in a U.S. EPA-approved chemical waste landfill, they are conceptually similar to the effect of listing under the SWDA. Moreover, the response costs incurred as a result of the TSCA guidelines (dredging restrictions, restrictions on sediment disposal) are a measure of damages.

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- ▶ Concentrations of a hazardous substance sufficient to exceed levels for which an appropriate state health agency has issued directives to limit or ban consumption of such organism [43 CFR § 11.62 (f)(1)(iii)].
 - ▶ Concentrations of a hazardous substance sufficient to cause the biological resource or its offspring to have undergone at least one of the following adverse changes in viability: death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction), or physical deformations [43 CFR § 11.62 (f)(1)(i)].

3.1.6 Terrestrial biota resources

Relevant biological injuries defined by DOI regulations include the following:

- ▶ Concentrations of a hazardous substance sufficient to exceed action or tolerance levels established under Section 402 of the Food, Drug and Cosmetic Act, 21 U.S.C. 342, in edible portions of organisms [43 CFR § 11.62 (f)(1)(ii)].
- ▶ Concentrations of a hazardous substance sufficient to exceed levels for which an appropriate state health agency has issued directives to limit or ban consumption of such organism [43 CFR § 11.62 (f)(1)(iii)].
- ▶ Concentrations of a hazardous substance sufficient to cause the biological resource or its offspring to have undergone at least one of the following adverse changes in viability: death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction), or physical deformations [43 CFR § 11.62 (f)(1)(i)].

3.2 Quantification of Injuries, Damages, and Restoration

3.2.1 Definition of key terms and concepts

This subsection provides perspective on the restoration planning and damage determination process by defining and discussing key terms and concepts.

First, as described in the NRDA regulations promulgated by the DOI, a damage determination is intended to “establish the amount of money to be sought in compensation for injuries to natural resources resulting from a . . . release of a hazardous substance” [43 CFR § 11.80 (b)]. The measure of damages is defined as *restoration costs* plus, at the discretion of the trustees, *compensable values for interim losses* [43 CFR § 11.80 (b)].

Restoration refers to actions undertaken to return an injured resource to its baseline condition as measured by the services provided by that resource [43 CFR § 11.14 (ll)]. Restoration includes rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources or services. *Baseline* refers to the conditions that would have existed in the assessment area had the release of hazardous substances not occurred [43 CFR § 11.14 (e)] and *services* are defined as the “physical and biological functions performed by the resource, including the human uses of those functions” [43 CFR § 11.14 (nn)]. Restoration can be accomplished by restoring or rehabilitating resources or by replacing or acquiring the equivalent of the injured natural resources and their service flows. Restoration should be distinguished from *remediation* or *response actions* undertaken pursuant to CERCLA or to the NCP.

Compensable values include “the value of lost public use of the services provided by the injured resources plus lost nonuse values such as existence and bequest values” [43 CFR § 11.83 (c)(1)]. Under CERCLA, the compensable values for interim services lost to the public (“interim losses”) accrue from the time of discharge or release or 1980, whichever is later, until restoration is complete [see 43 CFR § 11.80 (b)].

3.2.2 Overview of the restoration and compensation determination process

The objective of the restoration planning phase is to develop a “reasonable number of possible alternatives for the restoration, rehabilitation, replacement, and/or acquisition of the equivalent of the injured natural resources,” as measured by the services those resources provide [43 CFR § 11.82 (a)]. The trustees then evaluate these alternatives, and a preferred alternative is selected (an alternative can consist of single actions or combinations of actions [43 CFR § 11.82 (b)(1)]). The costs to perform the preferred alternative become the restoration cost component of total damages.

The NRDA regulations indicate that a Restoration and Compensation Determination Plan (RCDP) shall be prepared that lists a reasonable number of alternatives for restoration, rehabilitation, replacement, or acquisition of equivalent resources and the related services lost to the public associated with each; selects one of the alternatives; gives the rationale for selecting that alternative; and identifies methods to be used to determine the cost of the selected alternative and the compensable value of services lost to the public [43 CFR § 11.81 (a)(1)]. However, if information is not available to select an alternative, an initial RCDP may be prepared to keep the public informed and to help inform restoration planning and damage determination [59 FR 14280].

After identifying, screening, and selecting restoration alternatives, the trustees anticipate preparing an RCDP that evaluates the restoration alternatives and selects one. Based on that RCDP, the trustees will calculate the costs of implementing the selected alternative and will

calculate compensable values. These elements (together with the trustees' assessment costs) will comprise the claim for natural resource damages. Following recovery of damages, the trustees anticipate preparing a final restoration plan that describes the use of the recovered damages.

3.2.3 Restoration planning and scaling

The trustees anticipate developing a range of alternatives [43 CFR § 11.82 (c)] that will include selected restoration projects designed to restore or replace injured resources, as measured by their services. One alternative that will be considered is no action, or natural recovery.

Restoration projects will be aimed at performing activities that restore, enhance, replace, or acquire similar resources and services to those lost. These potential projects will be evaluated and ranked using criteria developed by the trustees for the Ashtabula NRDA. These criteria will be based on factors identified in the DOI NRDA regulations [43 CFR § 11.82 (d)].

Once projects have been identified and preferred alternatives have been selected, restoration projects will be "scaled." *Scaling* is the process of determining the appropriate size of a restoration project.

Projects that restore or rehabilitate injured resources are scaled so that they provide the same quantity of services lost. This approach is known as *service-to-service* scaling. Projects that involve replacing or acquiring equivalent resources, as measured by their services, can be scaled the same way if the equivalent resources provide the same type and quality of services. However, sometimes it makes sense to consider replacement or acquisition of natural resources that provide services of a similar but not identical type or quality to those lost. For example, projects that restore the same or similar services as those still impaired may be technically infeasible or prohibitively expensive. When a replacement or acquisition project provides services that are similar to, but not the same as, those lost, a different scaling mechanism is needed to determine when the project has produced "equivalent" resources as measured by the services, such as *value-to-value* scaling.

Thus, for any replacement or acquisition of natural resources that provide services different in type or quality from those lost, the trustees may scale projects so they provide services with an economic value equal to the economic value of the services lost. Value-to-value scaling for such projects supports the selection and scaling of restoration of human use services. Combined with selections and scaling of restoration of ecological services using non-value-based ecological equivalency methods, this can ensure that any replacement or acquisition projects considered provide *equivalent* resources, as required by the DOI NRDA regulations.

3.2.4 Compensable values

The trustees may also include in the calculation of damages “the compensable value of all or a portion of the services lost to the public for the time period from the discharge or release until the attainment of the restoration, rehabilitation, replacement, and/or acquisition of the equivalent of the resources and their services to baseline” [43 C.F.R. 11.80(b)]. Compensable values include “the value of lost public use of the services provided by the injured resources, plus lost *nonuse* values such as *existence* and *bequest values*” [43 C.F.R. 11.83(c)(1)].

Cost estimating and valuation methods will be consistent with the guidance provided in the DOI regulations. The trustees intend to complete a final determination of compensable value for the assessment area in an RCDP, as described in the DOI regulations.

3.2.5 Initial focus

The trustees will initially explore the possibility of quantifying the following categories of injuries, service losses, damages, and restoration:

- ▶ the loss or impairment of surface water, sediments, and bank soils as habitat for biological resources
- ▶ the loss or impairment of recreational fishing and boating opportunities representing the lost human uses of injured biological resources.

4. Assessment Tasks

Injury determination and quantification assessment studies

To bring the public into the assessment process as quickly as possible, this Assessment Plan has been developed in advance of specific study formulation and detailed sampling plans. Specific assessment activities not provided in this Assessment Plan will be documented in addenda or work plans that will be made available for public review as they are developed. Assessment activities described in addenda or work plans will not begin before the end of a 30-day public comment period. Exceptions to this will be considered case by case. Beginning work before the end of the 30-day review will generally be considered only if the trustees determine that the opportunity to collect important data may be lost if prompt action is not taken.

The trustees' initial approach to injury determination will be to document the impact of hazardous substances on selected resources that represent key elements of the assessment area ecosystem. Specifically, the trustees intend to examine:

- ▶ **Surface water.** Surface water is the immediate receptor of hazardous substances from point and nonpoint sources, and a medium in which biological resources are potentially exposed through direct contact and by propagation through the food chain.
- ▶ **Sediments.** Sediments are the medium in which many contaminants discharged or released to surface water come to be located, thus becoming a secondary source of contamination that results in the propagation of contaminants through the food chain.
- ▶ **Benthic invertebrates.** Benthic invertebrates are particularly susceptible to injury as a result of direct contact with contaminated sediments. Disruption or impairment of the invertebrate community may result in the impairment of higher level organisms that depend on invertebrates for food (e.g., fish, birds). Invertebrates may also serve as a pathway by which higher level organisms are exposed to hazardous substances.
- ▶ **Fish.** Fish are important biological resources because of their position in the food chain and their relationship to human uses of the environment. Fish may also provide an exposure pathway to piscivorous birds and mammals.
- ▶ **Birds.** Birds represent higher level biological resources that are susceptible to injury through direct contact with or ingestion of hazardous substances.

This section describes initial tasks that the trustees may pursue during the 2003 field season. The trustees may modify the assessment approach and activities based on the initial results of activities described in this plan. Modification of assessment approaches and activities will be documented as addenda to this Assessment Plan and study work plans, which will be released for review by the public.

4.1 Preliminary Evaluation of Injuries and Damages

The first task that the trustees will pursue is a *Preliminary Evaluation of Injuries and Damages*. Because there are so many relevant site-specific data, analyses, and previous actions relevant to the assessment area, the trustees believe that completion of many elements of a Type B assessment may be possible without collecting new data or undertaking new analyses. However, existing information must be organized and scrutinized for its applicability and relevance to the NRDA process. This evaluation will inform trustee decisions about what additional new data may still be needed and available at reasonable assessment costs. The results of this evaluation

may also lead the trustees to modify assessment approaches and activities to complete the NRDA. Modifications will be described in addenda and study plans that will be released for public review. The trustees intend to review existing information about the following.

4.1.1 Evaluate potential reference sites

Reference sites that represent the physical, chemical, and biological conditions in the assessment area absent the hazardous substance release can be used as part of the characterization of baseline conditions [43 CFR § 11.72(d)] The trustees will further evaluate the suitability of selected areas, including Conneaut Creek and Harbor, as reference sites for Ashtabula River and Harbor.³ Ohio EPA's Qualitative Habitat Evaluation Index (QHEI) scores and metrics for the Ashtabula River, Conneaut Creek, and other Lake Erie tributaries will be compiled and compared to evaluate the comparability of physical habitat between the assessment area and potential reference sites. Similarly, water quality data for constituents such as suspended solids, nutrients, temperature, and dissolved oxygen will be compiled and compared between the sites. This information will be used, in part, to identify areas that can serve as appropriate reference sites for the assessment area.

4.1.2 Evaluate surface water with respect to applicable water quality criteria and standards

This evaluation will assess injury to surface water (water column) resources and establish whether surface water is a link in the exposure pathway to other potentially injured resources. Surface water injury has resulted if the trustees can measure concentrations in excess of applicable water quality criteria established by section 304(a)(1) of the CWA, or by other federal or state laws or regulations that establish such criteria or standards, in surface water that before the discharge or release met the criteria and is a committed use as a habitat for aquatic life, water supply, or recreation [43 CFR § 11.62(b)(1)(iii)]. One acceptance criterion for injury to surface water is the measurement of concentrations of a hazardous substance in two samples from different locations separated by a straight-line distance of not less than 100 feet [43 CFR § 11.62(b)(2)(i)(A)].

The trustees collected water samples from seven locations in the Ashtabula River and Harbor in June and August 2001. These samples were collected in accordance with the 100 ft separation requirement described above and will be analyzed for PCBs and hexachlorobenzene. Samples were collected both upstream and downstream of the confluence with Fields Brook. These

3. The Ohio EPA has designated Conneaut Creek as a potential reference site for the Ashtabula River and Harbor because they are similar in many important aspects other than hazardous substance concentrations.

samples were collected before the completion of this Assessment Plan because it was necessary to collect samples before completion of remedial actions under way on Fields Brook, the source of hazardous substances to the Ashtabula River and Harbor. In evaluating these and any other existing data, the trustees will provide documentation that samples satisfy regulatory criteria. The trustees will also provide documentation showing that existing data are the result of sample collection and analysis that was conducted using generally accepted methods [43 CFR § 11.64(b)(2) and (4)].

4.1.3 Evaluate the nature and extent of sediment contamination

This evaluation will assess contaminant concentrations in the sediments of the Ashtabula River and Harbor and associated wetlands, establish whether sediment is a link in the pathway between contaminant sources and biological resources, and provide the data necessary for the eventual formulation of an appropriate restoration plan. An injury to a surface water and sediment resource has resulted from the discharge of oil or release of a hazardous substance if the trustees can measure concentrations of substances in suspended, bed, bank, or shoreline sediments sufficient to have caused injury to biological resources [43 CFR § 11.62(b)(1)(v)]. Similarly, geologic resources (e.g., wetland soils) are injured if they contain concentrations of substances sufficient to cause injury to other resources (e.g., surface water, groundwater, biological). The acceptance criterion for injury to the sediment portion of surface water resources is the measurement of concentrations of a hazardous substance in two samples from different locations separated by a straight-line distance of not less than 100 feet [43 CFR § 11.62(b)(2)(i)(B)]. In evaluating existing data and collecting new data, the trustees will provide documentation showing that this criterion has been satisfied. The trustees will also provide documentation showing that existing data and any new data that are collected under this assessment are the result of sample collection and analysis conducted using generally accepted methods [43 CFR § 11.64(b)(2) and (4)].

Sediments in the assessment area have been sampled and analyzed on numerous occasions over the past 20 years. In light of this wealth of potentially useful data, a primary trustee goal is to identify any significant data gaps. To accomplish this goal, the trustees propose to undertake a phased approach. The trustees will obtain and review existing sediment data sets collected by government agencies, university researchers, and contractors to determine their conformance with the regulatory guidelines. Data that meet the quality standards necessary to document sediment chemistry then will be included in the NRDA. After identifying data gaps, the trustees will also identify additional sampling that may be necessary or useful at reasonable assessment costs.

4.1.4 Evaluate the nature and extent of contamination of the benthic invertebrate population

This evaluation will attempt to demonstrate whether the benthic invertebrate community is a pathway of exposure to other potentially injured natural resources. DOI regulations allow the use of chemical analysis of either free ranging organisms or in situ indicator species in establishing pathways for biological resources. The trustees will attempt to use free ranging benthic invertebrate species. In addition, this evaluation will determine whether benthic invertebrate samples should be collected from the Ashtabula River and Harbor and appropriate reference areas using standard collection methods. If so, a sampling and analysis plan will specify what samples will be collected and how they will be analyzed.

4.1.5 Evaluate the nature and extent of fish tissue contamination

This evaluation will seek to document present and historical concentrations of hazardous substances in fish from the Ashtabula River and Harbor and establish whether there is a link in the pathway from surface water (and sediments) to higher trophic level fish, avian, and mammalian species. DOI regulations allow the use of chemical analysis of either free ranging organisms or in situ indicator species in establishing pathways for biological resources. The trustees will attempt to use free ranging fish species.

State and federal agencies, and individual investigators, have collected substantial fish tissue data from the Ashtabula River and Harbor. These data will be compiled and evaluated for adherence with accepted quality assurance and quality control practices and the acceptance criteria for demonstrating injury to biological resources. Qualified data will be used to attempt to establish current and historical concentrations of contaminants in fish. In addition, this evaluation will determine whether additional data should be collected from the Ashtabula River and Harbor and appropriate reference areas to fill data gaps. If so, a sampling and analysis plan will specify what samples will be collected and how they will be analyzed.

4.1.6 Evaluate the potential impacts of hazardous substances on avian and mammalian populations in the Ashtabula River and Harbor

This evaluation will assess exposure and potential injury to birds and mammals in the assessment area, and the disruption of the assessment area ecosystem caused by the presence of hazardous substances. An injury to birds or mammals has occurred if concentrations of released hazardous substances are sufficient to cause the birds or their offspring to have undergone at least one of the following adverse changes in viability: death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction), or physical deformations [43 CFR § 11. 62(f)(1)(i)]. In addition, this evaluation will determine

whether additional data should be collected from the Ashtabula River and Harbor and appropriate reference areas to fill data gaps. If so, a sampling and analysis plan will specify what samples will be collected and how they will be analyzed.

4.1.7 Evaluate potential restoration opportunities

This evaluation will explore existing site-specific environmental restoration activities, plans, and opportunities in and near the assessment area. Potential restoration planning criteria will also be explored, and potential restoration activities will be categorized. The trustees will use this information to help develop an RCDP (or initial RCDP) for public review.

4.1.8 Evaluate potential scaling techniques

This evaluation will explore scaling techniques that may be suitable for injury, restoration, or damages scaling at the site for determining necessary baseline restoration or compensable values. The potential applicability of habitat equivalency analysis, resource equivalency analysis, habitat-based replacement costs, benefits transfer, market analysis, fishing and recreational valuation, total valuation, and total equivalency may all be considered. The trustees will use this information to help develop an RCDP (or initial RCDP) for public review.

4.2 Collect New Data to Measure Additional Impacts of Contaminants on Biota

Although the preliminary evaluation of injuries and damages will help inform trustee decisions about what additional data are needed or useful at reasonable assessment costs, the trustees believe that there may be significant opportunities to collect valuable data relevant to injuries to aquatic organisms this field season. Therefore, this plan includes several data collection activities that may begin before the preliminary evaluation is completed.

4.2.1 Study the impact of sediment contamination on invertebrate communities

If conducted, this study will determine whether there are injuries to sediments by demonstrating that sediments are injurious to the invertebrate community. An injury to a sediment resource has resulted if the trustees can measure concentrations of substances in suspended, bed, bank, or shoreline sediments sufficient to have caused injury to biological resources. In general, an injury to a biological resource has occurred if concentrations of hazardous substances are sufficient to cause the invertebrates or their offspring to have undergone at least one of the following adverse

changes in viability: death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction), or physical deformations [43 CFR § 11.62(f)(1)(i)]. The DOI regulations describe four acceptance criteria for demonstrating injuries to biological resources in general:

- ▶ The biological response (i.e., the injury) is often the result of exposure to hazardous substances [43 CFR § 11.62(f)(2)(i)].
- ▶ Exposure to oil or hazardous substances is known to cause this biological response in free ranging organisms [43 CFR § 11.62(f)(2)(ii)].
- ▶ Exposure to oil or hazardous substances is known to cause this biological response in controlled experiments [43 CFR § 11.62(f)(2)(iii)].
- ▶ The biological response measurement is practical to perform and produces scientifically valid results [43 CFR § 11.62(f)(2)(iv)].

As part of the sediment characterization effort, the trustees will collect samples to test the toxicity of the sediments to invertebrate species. Selected species will be exposed to both Ashtabula River and Harbor sediments and suitable uncontaminated sediments. Laboratory toxicity testing is an accepted way to measure death as a biological response to hazardous substances. Injury is documented if the trustees measure a statistically significant difference in total mortality or mortality rates between population samples in exposure chambers and population samples in control chambers [43 CFR § 11.62(f)(4)(i) (E)].

4.2.2 Study the incidence of cancer in wild fish populations in the Ashtabula River and Harbor

If conducted, this study will document the prevalence of neoplasms in wild fish populations in the Ashtabula River and Harbor relative to an uncontaminated control area. An injury to fish has occurred if a statistically significant difference can be measured in the frequency of occurrence of fish neoplasia compared to a control area. Liver and/or skin neoplasia may be used to determine injury.

Neoplasms may be confirmed by histological procedures, including special staining techniques for specific tissue components and ultrastructural examination using electron microscopy to identify cell origin and to rule out or confirm viral, protozoan, or other causal agents.

The trustees may determine the prevalence of neoplasia in fish from the Ashtabula River and Harbor relative to an appropriate reference area. Samples may be collected from locations in the Ashtabula River and Harbor and from a reference area. Samples may be processed according to

DOI regulations and the incidence of skin and liver neoplasia compared between the two geographic areas. Preserved samples and slides from samples collected in the 1980s and early 1990s may also be examined to determine trends in neoplasia in the Ashtabula River and Harbor.

4.2.3 Study the incidence of fin erosion in wild fish populations in the Ashtabula River and Harbor

If conducted, this study will document the prevalence of fin erosion in wild fish populations in the Ashtabula River and Harbor relative to an uncontaminated control area. An injury to fish has occurred if a statistically significant difference can be measured between the frequency of occurrence of fin erosion in the Ashtabula River and Harbor and the frequency in samples from a reference area.

Ohio EPA has collected data on fin erosion in fish from the Ashtabula River and Harbor as well as potential reference locations since the late 1980s. These data will be compiled and evaluated for adherence with accepted quality assurance and quality control practices and the acceptance criteria for demonstrating injury to biological resources. Acceptable data may be used to establish the current and historical prevalence of fin erosion. Additional data may be collected as necessary to fill data gaps.

4.3 Procedures for Sharing Data

The DOI NRDA regulations state that an assessment plan includes:

procedures and schedules for sharing data, split samples, and results of analyses, when requested, with any identified potentially responsible parties and other natural resource trustees [43 C.F.R. 11.31(a)(4)].

To facilitate the data-sharing process, PRPs and other state or federal agencies will be provided with an opportunity, as deemed appropriate, to obtain a copy of the databases used in the assessment. If PRPs or state or federal agencies wish to receive such data, a written request identifying the data desired should be sent to either:

David DeVault
U.S. Fish and Wildlife Service, Region 3
B.H.W. Federal Building, 1 Federal Drive
Ft. Snelling, MN 55111-4096

or

Sheila Abraham
Ohio Environmental Protection Agency
North East District Office
2110 East Aurora Road
Twinsburg, OH 44087

The trustees will provide the data to the PRPs and any other interested parties once the data have been validated and are available.

5. Quality Assurance Project Plan

5.1 Introduction

This Quality Assurance Project Plan (QAPP) has been developed to support studies that may be performed as part of the Ashtabula NRDA. The NRDA regulations [43 CFR § 11.31] require a QAPP that specifies procedures to ensure data quality and reliability. This QAPP is intended to provide quality assurance/quality control (QA/QC) procedures, guidance, and targets for use in future studies conducted for the NRDA. It is not intended to provide a rigid set of predetermined steps with which all studies must conform or against which data quality is measured, nor is it intended that existing data available for use in the NRDA must adhere to each of the elements presented in this QAPP. Ultimately, the quality and usability of data are based on methods employed in conducting studies, the expertise of study investigators, and the intended uses of the data. The QAPP has been designed to be consistent with the NCP and EPA's Guidelines and Specifications for Preparing Quality Assurance Project Plans (EPA, 1998).

The elements outlined in this plan are designed to:

- ▶ provide procedures and criteria for maintaining and documenting custody and traceability of environmental samples
- ▶ provide procedures and outline QA/QC practices for sampling, collecting, and transporting samples
- ▶ outline data quality objectives (DQOs) and data quality indicators
- ▶ provide a consistent and documented set of QA/QC procedures for preparing and analyzing samples
- ▶ help ensure that data are sufficiently complete, comparable, representative, unbiased, and precise so as to be suitable for their intended uses.

Before the implementation of NRDA studies, Standard Operating Procedures (SOPs) providing descriptions of procedures typically will be developed. These SOPs will be appended to this QAPP, as developed, to provide an ongoing record of methods and procedures employed in the assessment. SOPs will be developed and updated as methods and procedures are reviewed and accepted for use.

5.2 Project Organization and Responsibility

Definition of project organization, roles, and responsibilities helps ensure that individuals are aware of specific areas of responsibility that contribute to data quality. However, fixed organizational roles and responsibilities are not necessary and may vary by study or task. An example of project quality assurance organization, including positions with responsibility for supervising or implementing quality assurance activities, is shown in Figure 4. Key positions and lines of communication and coordination are indicated. Descriptions of specific quality assurance responsibilities of key project staff are included below. Only the project positions related directly to QA/QC are described; other positions may be described in associated project plans. Specific individuals and laboratories selected to work on this investigation will be summarized and appended to this QAPP or included in study-specific SOPs when they are established.

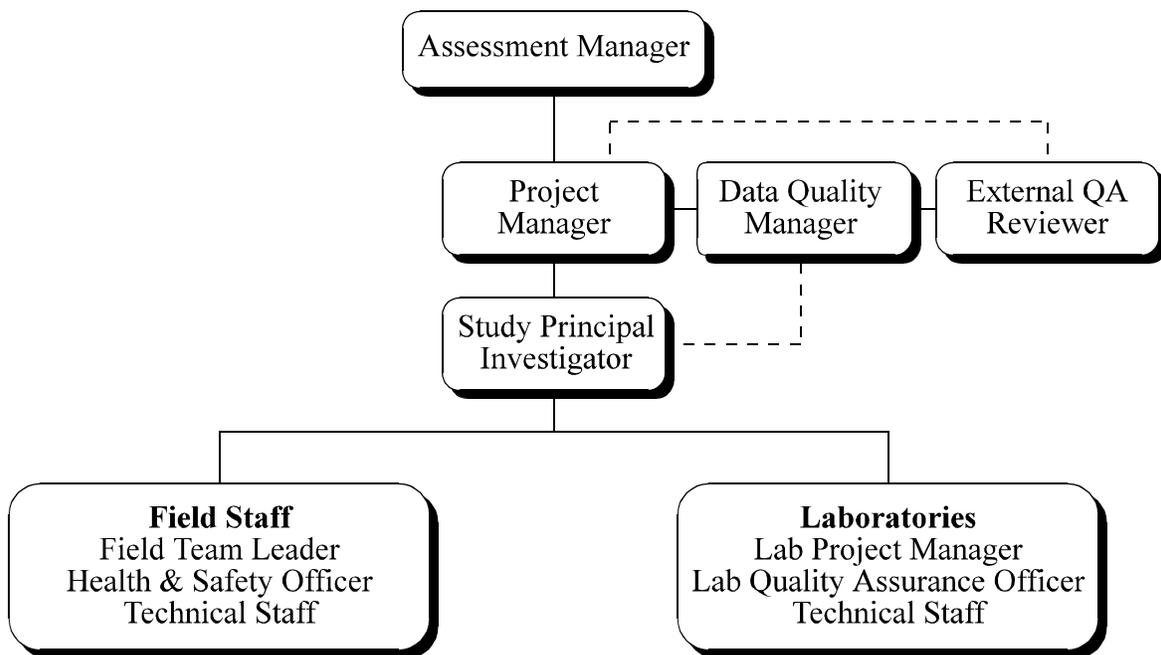


Figure 4. Project organization.

5.2.1 Assessment Manager and Project Manager

The Assessment Manager (AM) is responsible for all technical, financial, and administrative aspects of the project. The Project Manager (PM) supports the AM and is responsible for producing quality data and work products for this project within allotted schedules and budgets. Duties include executing all phases of the project and efficiently applying the full resources of the project team in accordance with the project plans. Specific QA-related duties of the AM and the PM can include:

- ▶ coordinating the development of a project scope, project plans, and data quality objectives
- ▶ ensuring that written instructions in the form of SOPs or associated project plans are available for activities that affect data quality
- ▶ monitoring investigative tasks for their compliance with plans, written procedures, and QC criteria
- ▶ monitoring the performance of subcontractors in regard to technical performance and specifications, administrative requirements, and budgetary controls
- ▶ participating in performance or systems audits and monitoring the implementation of corrective actions
- ▶ reviewing, evaluating, and interpreting data collected as part of this investigation
- ▶ supervising the preparation of project documents, deliverables, and reports
- ▶ verifying that all key conclusions, recommendations, and project documents are subjected to independent technical review, as scheduled in the project plans.

5.2.2 Data Quality Manager

A Data Quality Manager can be assigned to be responsible for overall implementation of the QAPP. Duties include conducting activities to ensure compliance with the QAPP, reviewing final QA reports, preparing and submitting QA project reports to the AM and PM, providing technical QA assistance, conducting and approving corrective actions, training field staff in QA procedures, and conducting audits, as necessary. Specific tasks may include:

-
- ▶ assisting the project team with the development of data quality objectives
 - ▶ managing the preparation of and reviewing data validation reports
 - ▶ submitting QA reports and corrective actions to the PM
 - ▶ ensuring that data quality, data validation, and QA information are complete and are reported in the required deliverable format
 - ▶ communicating and documenting corrective actions
 - ▶ maintaining a copy of the QAPP
 - ▶ supervising laboratory audits and surveillance
 - ▶ ensuring that written instructions in the SOPs and associated project plans are available for activities that affect data quality
 - ▶ monitoring investigative tasks for their compliance with plans, written procedures, and QC criteria
 - ▶ monitoring the performance of subcontractors in regard to technical performance and specifications, administrative requirements, and budgetary controls
 - ▶ reviewing, evaluating, and interpreting data collected as part of this investigation.

5.2.3 External QA Reviewer

External QA Reviewers can review QA documentation and procedures, perform data validation, and perform field and laboratory audits if needed.

5.2.4 Principal Investigator

Study-specific Principal Investigators (PIs) ensure that QA guidance and requirements are followed. The PI or the designee note significant deviations from the QAPP for the study. Significant deviations are recorded and promptly reported to the PM and Data Quality Manager. In addition, the PI typically is responsible for reviewing and interpreting study data and preparing reports.

5.2.5 Field Team Leader

The Field Team Leader (FTL) supervises day-to-day field investigations, including sample collection, field observations, and field measurements. The FTL generally is responsible for all field QA procedures defined in the QAPP, and in associated project plans and SOPs. Specific responsibilities may include:

- ▶ implementing the field investigation in accordance with project plans
- ▶ supervising field staff and subcontractors to monitor that appropriate sampling, testing, measurement, and recordkeeping procedures are followed
- ▶ ensuring the proper use of SOPs associated with data collection and equipment operation
- ▶ monitoring the collection, transport, handling, and custody of all field samples, including field QA/QC samples
- ▶ coordinating the transfer of field data, including field sampling records, chain-of-custody records, and field logbooks
- ▶ informing the PI and Data Quality Manager when problems occur, and communicating and documenting any corrective actions that are taken.

5.2.6 Laboratory Project Manager

A Laboratory Project Manager can be responsible for monitoring and documenting the quality of laboratory work. Duties may include:

- ▶ ensuring that the staff and resources produce quality results in a timely manner are committed to the project
- ▶ ensuring that the staff are adequately trained in the procedures that they are using so that they are capable of producing high quality results and detecting situations that are not within the QA limits of the project
- ▶ ensuring that the stated analytical methods and laboratory procedures are followed and that the laboratory's compliance is documented
- ▶ maintaining a laboratory QA manual and documenting that its procedures are followed
- ▶ ensuring that laboratory reports are complete and reported in the required deliverable format

- ▶ communicating, managing, and documenting all corrective actions initiated at the laboratory
- ▶ notifying the Data Quality Manager, within one working day of discovery at the laboratory, of any situations that could result in qualification of analytical data.

5.2.7 Technical staff

Project technical staff represent a variety of technical disciplines and expertise. Technical staff should have adequate education, training, and specific experience to perform individual tasks, as assigned. They are required to read and understand any documents describing the technical procedures and plans that they are responsible for implementing.

5.3 Quality Assurance Objectives for Measurement Data

5.3.1 Overview

The overall QA objective is to help ensure that the data collected are of known and acceptable quality for their intended uses. QA objectives are qualitative and quantitative statements that aid in specifying the overall quality of data required to support various data uses. These objectives often are expressed in terms of accuracy, precision, completeness, comparability, representativeness, and sensitivity. Laboratories involved with the analysis of samples collected in support of this NRDA will make use of various QC samples such as standard reference materials (SRMs), matrix spikes, and replicates to assess adherence to the QA objectives discussed in the following sections and in specific laboratory QA/QC plans. Field and laboratory QC targets for chemical analyses, frequency, applicable matrices, and acceptance criteria are listed in Table 5.

Table 5. Laboratory and field quality control sample targets for chemical analyses.

QC element	Target frequency	Applicable matrices	Target acceptance criteria
Method blank	1 in 20 samples	S, SW, T	Method dependent
Laboratory duplicate	1 in 20 samples	S, SW, T	Method dependent
Matrix spike	1 in 20 samples	S, SW, T	Method dependent
Standard reference material	1 in 20 samples	S, SW, T	Method dependent
Equipment blank	1 in 20 samples	SW	Study dependent
Field duplicate	1 in 20 samples	S, SW, T	Study dependent
Surrogates	All samples for organics analysis	S, SW, T	Method dependent
Laboratory control sample	1 in 20 samples	S, SW, T	Method dependent

S = sediment; SW = surface water; T = tissue.

Because numeric QC criteria are specific to a study, method, or laboratory, criteria are not included in this QAPP. When appropriate, criteria can be established when study and method procedures are approved; such criteria will be appended to this QAPP or included in study-specific SOPs. Criteria will be determined based on factors that may include:

- ▶ specific analytical methods and accepted industry standards of practice
- ▶ matrix-specific control limits for acceptable sample recovery, accuracy, or precision
- ▶ historical laboratory performance of selected analytical methods
- ▶ intended uses of the data.

Where statistically generated or accepted industry standards of practice are not available, QC criteria may be defined by the Data Quality Manager working with the Laboratory QA Officer and PIs.

5.3.2 Quality control metrics

Accuracy

Accuracy is a quantitative measure of how close a measured value lies to the actual or “known” value. Sampling accuracy is partially evaluated by analyzing field QC samples such as field blanks, trip blanks, and rinsates (or equipment blanks). In these cases, the “true” concentration is assumed to be not detectable, and any detected analytes may indicate a positive bias in associated environmental sample data.

Laboratory accuracy is assessed using sample (matrix) spikes and other QC samples. For example, a sample (or blank) may be spiked with an inorganic compound of known concentration and the average percent recovery (%R) calculated as a measurement of accuracy. A second procedure is to analyze a standard (e.g., SRMs or other certified reference materials) and calculate the %R for that known standard. As an additional, independent check on laboratory accuracy, blind SRMs submitted as field samples may be used.

Accuracy criteria are established statistically from historical performance data, and often are based on confidence intervals set about the mean. Where historical data are not adequate for statistical calculations, criteria may be set by the Laboratory Project Manager, Data Quality Manager, and PIs. Accuracy criteria will be appended to this QAPP or included in study-specific SOPs, when established. Accuracy may be assessed during the data validation or data quality assessment stage of these investigations.

Precision

Precision is a measure of the reproducibility of analytical results under a given set of conditions. The overall precision of a set of measurements is determined by both sampling and laboratory variables. Reproducibility is affected by sample collection procedures, matrix variations, the extraction procedure, and the analytical method.

Field precision typically is evaluated using sample replicates, which are usually duplicate or triplicate samples. Sample replicates may be generated by homogenizing the sample, splitting the sample into several containers, and initiating a blind submittal to the laboratory with unique sample numbers. For a duplicate sample, precision of the measurement process (sampling and analysis) is expressed as:

$$\text{Relative Percent Difference (RPD)} = \frac{(\text{Duplicate Sample Result} - \text{Sample Result})}{(\text{Duplicate Sample Result} + \text{Sample Result})} \times 200.$$

For a triplicate analysis, precision of the sampling and analysis process is expressed as:

$$\text{Percent Relative Standard Deviation (\% RSD)} = \frac{\sigma_{n-1}}{\text{Mean}} \times 100,$$

where σ_{n-1} is the standard deviation of the three measurements.

Laboratory precision typically is evaluated using laboratory duplicates, matrix spike duplicates, or laboratory control sample or SRM duplicate sample analysis. Duplicates prepared in the laboratory are generated before sample digestion. Laboratory precision is also expressed as the relative percent difference (RPD) between a sample and its duplicate, or as the %RSD for three values.

Precision criteria are established statistically from historical performance data, and are usually based on the upper confidence interval set at two standard deviations above the mean. Where historical data are not adequate for statistical calculations, criteria may be set by the Laboratory Project Manager, Data Quality Manager, and PIs. Precision criteria will be appended to this QAPP or included in study-specific SOPs, when established.

Completeness

Completeness is defined as the percentage of measurement data that remain valid after discarding any invalid data during the field or laboratory QC review process. A completeness check may be performed following a data validation process. Analytical completeness goals may vary depending on study type, methods, and intended uses of the data.

Analytical data completeness will be calculated by analyte. The percent of valid data is 100 times the number of sample results not qualified as unusable (R), divided by the total number of samples analyzed. Data qualified as estimated (J) because of minor QC deviations (e.g., laboratory duplicate RPD exceeded) will be considered valid.

Comparability

Comparability is a qualitative parameter expressing the confidence with which one dataset can be compared to another. Comparability is facilitated by use of consistent sampling procedures, standardized analytical methods, and consistent reporting limits and units. Data comparability is evaluated using professional judgment.

Representativeness

Representativeness expresses the degree to which data accurately and precisely represent a defined or particular characteristic of a population, parameter variations at a sampling point, a processed condition, or an environmental condition. Representativeness is a qualitative parameter that is dependent on the proper design of the sampling program and proper laboratory protocol. Sampling designs for this investigation will be intended to provide data representative of sampled conditions. During development of sampling plans and SOPs, consideration will be given to existing analytical data, environmental setting, and potential industrial sources. Representativeness will be satisfied by ensuring that the sampling plan is followed.

Sensitivity

Detection limit targets for each analyte and matrix will be appended to this QAPP or included in study-specific SOPs as they are established.

5.4 Sampling Procedures

5.4.1 Sample collection

Samples are collected and handled in accordance with the procedures contained in SOPs or associated project plans. These documents typically describe sample collection, handling, and documentation procedures to be used during field activities. SOPs and work plans/protocols may cover the following topics, as appropriate:

- ▶ procedures for selecting sample locations and frequency of collection
- ▶ sample site selection, positioning, and navigation procedures

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- ▶ sampling equipment operation, decontamination, and maintenance
 - ▶ sample collection and processing, which includes sample collection order and homogenization procedures, sample containers, and volume required
 - ▶ field QC sample and frequency criteria
 - ▶ sample documentation, including chain-of-custody (COC) and field documentation forms and procedures
 - ▶ sample packaging, tracking, storage, and shipment procedures.

5.4.2 Sample containers, preservation, and holding times

Containers will be prepared using EPA specified or other professionally accepted cleaning procedures. Analysis statements for containers prepared by third-party vendors will be included in the project file. Since the investigations involved with this NRDA may involve samples not amenable to typical environmental sample containers (such as whole body tissue samples), multiple types of containers may be required. Sample containers may include aluminum foil and watertight plastic bags for tissue samples and whole body samples.

When appropriate, sample coolers will contain refrigerant in sufficient quantity to maintain samples at the required temperatures until receipt at the laboratories.

5.4.3 Sample identification and labeling procedures

Before transportation, samples will be properly identified with labels, tags, or markings. Identification and labeling typically include, but need not be limited to, the following information:

- ▶ project identification
- ▶ place of collection
- ▶ sample identification
- ▶ analysis request
- ▶ preservative
- ▶ date and time of collection
- ▶ name of sampler (initials)
- ▶ number of containers associated with the sample.

5.4.4 Field sampling forms

Field sampling forms should be described in the appropriate SOP or associated project plans. Forms typically must be completed in the field at the same time as the sample label. As with the sample label, much of the information can be preprinted, but date, time, sampler's initials, and other specific field observations should be completed at the time of sampling.

5.4.5 Sample storage and tracking

In the field, samples may be stored temporarily in coolers with wet or dry ice (as appropriate). Security should be maintained and documentation of proper storage should be provided in the project field notebook. Samples stored temporarily in coolers should be transported to a storage facility as soon as logistically possible. When possible, samples will be shipped directly to the appropriate laboratories from the field.

Before analysis, samples will be stored under appropriate conditions at the storage facility or laboratory (refrigerator or freezer). Security should be maintained at all times. A log book or inventory record typically is maintained for each sample storage facility refrigerator or freezer. The log books or inventory records are used to document sample movement in and out of the facility. In general, samples will be placed into a freezer and information regarding sample identification, matrix, and study will be recorded. Additional information in the record for each sample may include the date of the initial storage, subsequent removal/return events with associated dates, and initials of the person(s) handling the samples. Additional information may also include study name and special comments. If required, unused samples or extra samples will be archived in a secure location under appropriate holding conditions to ensure that sample integrity is maintained.

Documentation should allow for unambiguous tracking of the samples from the time of collection until shipment to the laboratory. The tracking system should include a record of all sample movement and provide identification and verification (initials) of the individuals responsible for the movement.

5.5 Sample Custody

COC procedures are adopted for samples throughout the field collection, handling, storage, and shipment process. Each sample will be assigned a unique identification label and have a separate entry on a COC record. A COC record should accompany every sample and every shipment to document sample possession from the time of collection through final disposal.

5.5.1 Definition of custody

A sample is defined as being in a person's custody if one of the following conditions applies:

- ▶ The sample is in the person's actual possession or view.
- ▶ The sample was in the person's possession and then was locked in a secure area with restricted access.
- ▶ The person placed the sample in a container and sealed the container with a custody seal in such a way that it cannot be opened without breaking the seal.

5.5.2 Procedures

The following information typically will be included on COC forms:

- ▶ place of collection
- ▶ laboratory name and address
- ▶ sample receipt information (total number of containers, whether COC seals are intact, whether sample containers are intact, and whether the samples are cold when received)
- ▶ signature block with sufficient room for "relinquished by" and "received by" signatures for at least three groups (field sampler, intermediate handler, and laboratory)
- ▶ sample information (field sample identifier, date, time, matrix, laboratory sample identifier, and number of containers for that sample identifier)
- ▶ name of the sampler
- ▶ airbill number of overnight carrier (if applicable)
- ▶ disposal information (to track sample from "cradle to grave")
- ▶ block for special instructions
- ▶ analysis request information.

The sample identification, date and time of collection, and request for analysis on the sample label should correspond to the entries on the COC form and in associated field log books or sampling forms.

The Data Quality Manager or designated representative is responsible for reviewing the completed COC forms. Any inconsistencies, inaccuracies, or incompleteness in the forms must be brought to the attention of the field staff completing the form. If the problem is significant, corrective action should be taken and documented. Depending on the problem, this may involve informing the laboratory that a sample ID or analysis request needs to be changed, or notifying the FTL that retraining of field staff in COC procedures is indicated. The corrective action and its outcome should be documented.

5.6 Analytical Procedures

Analytical methods will be consistent with, or equivalent to, EPA methods or some other commonly accepted or approved method, as approved by the Data Quality Manager. All laboratory equipment and instruments will be operated, maintained, calibrated, and standardized in accordance with EPA-accepted or manufacturer's practices.

Several methods or procedures may be used to measure analytes in different environmental media. For example, PCBs may be measured by quantification of Aroclors using Method 8081, quantification of total PCBs using Method 8081, or quantification of PCB congeners and coplanars using gas chromatography with electron capture detection (GC/ECD) and/or gas chromatography with mass spectrophotometry (GC/MS). Coplanar PCB congeners may be analyzed and reported with the PCB congener analysis. Preconcentration steps (e.g., carbon column cleanup) may be required to obtain adequate detection limits for these compounds. General QC considerations and targets for analyses are described below, along with considerations for biological testing.

Laboratory method detection limit (MDL) studies should be conducted for each matrix per analytical method, according to specifications described in 40 CFR Part 136 or other comparable professionally accepted standards. The MDL is a statistically derived, empirical value that may vary.

Laboratory QC samples, which include a method blank, replicate (matrix spike or duplicate) analyses, laboratory control sample, and SRM, will be performed at a target frequency of 1 per 20 samples per matrix per analytical batch. Method blanks should be free of contamination of target analytes at concentrations greater than or equal to the MDL, or associated sample concentrations should be greater than 10 times the method blank values. The matrix spike/matrix spike duplicate and laboratory control sample analyses should meet the specific accuracy and precision goals for each matrix and analytical method.

5.7 Calibration Procedures and Frequency

This section provides information on general calibration guidelines for laboratory and field methods.

5.7.1 Laboratory equipment

All equipment and instruments used for laboratory analyses will be operated and maintained according to the manufacturer's recommendations and criteria defined in the laboratory's SOPs. Operation, maintenance, and calibration should be performed by personnel properly trained in these procedures. Documentation of all routine and special maintenance and calibration should be recorded in appropriate log books and reference files.

Calibration curve requirements for all analytes and surrogate compounds should be met before sample analysis. Calibration verification standards, which should include the analytes that are expected to be in the samples and the surrogate compounds, should be analyzed at a specified frequency and should be within a percent difference or percent drift criterion.

5.7.2 Field equipment

All equipment and instruments used to collect field measurements will be operated, maintained, and calibrated according to the manufacturer's recommendations and criteria defined in individual SOPs. Operation, calibration, and maintenance should be performed by personnel properly trained in these procedures. Documentation of all routine and special maintenance and calibration should be recorded in appropriate log books or reference files. Field instruments that may be used include thermometers/temperature probes, scales, pH meters, dissolved oxygen meters, and global positioning system units.

5.8 Data Validation and Reporting

5.8.1 General approach

Data generated by the laboratory and during field measurements may undergo data review and validation by an External QA Reviewer. Laboratory data may be evaluated for compliance with data quality objectives, with functional guidelines for data validation, and with procedural requirements contained in this QAPP.

5.8.2 Data reporting

Laboratories should provide sufficient information to allow for independent validation of the sample identity and integrity, the laboratory measurement system, the resulting quantitative and qualitative raw data, and all information relating to standards and sample preparation.

5.8.3 Data review and validation of chemistry data

Data review is an internal laboratory process in which data are reviewed and evaluated by a laboratory supervisory or QA personnel. Data validation is an independent review process conducted by personnel not associated with data collection and generation activities. External and independent data validation may be performed for selected sample sets as determined by the PM and Data Quality Manager. Each data package chosen for review will be assessed to determine whether the required documentation is of known and documented quality. This includes evaluating whether:

- ▶ field COC or project catalog records are present, complete, signed, and dated
- ▶ the laboratory data report contains required deliverables to document procedures.

Two levels of data validation may be performed: full or cursory validation. Initial data packages received for each sample matrix may receive full validation. This consists of a review of the entire data package for compliance with documentation and quality control criteria for the following:

- ▶ analytical holding times
- ▶ data package completeness
- ▶ preparation and calibration blank contamination
- ▶ initial and continuing calibration verifications
- ▶ internal standards
- ▶ instrument tuning standards
- ▶ analytical accuracy (matrix spike recoveries and laboratory control sample recoveries)
- ▶ analytical precision (comparison of replicate sample results)
- ▶ reported detection limits and compound quantitation
- ▶ review of raw data and other aspects of instrument performance
- ▶ review of preparation and analysis bench sheets and run logs.

Cursory validation may be performed on a subset of the data packages at the discretion of the PM and Data Quality Manager. Cursory review includes the comparison of laboratory summarized QC and instrument performance standard results to the required control limits, including:

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- ▶ analytical holding times
 - ▶ data package completeness
 - ▶ preparation and calibration blank contamination
 - ▶ analytical accuracy (matrix spike recoveries and laboratory control sample recoveries)
 - ▶ analytical precision (comparison of replicate sample results).

The full or cursory validation will follow documented QC and review procedures as outlined in the guidelines for data validation (EPA, 1998) and documented in validation and method SOPs. Various qualifiers, comments, or narratives may be applied to data during the validation process. These qualifier codes may be assigned to individual data points to explain deviations from quality control criteria and will not replace qualifiers or footnotes provided by the laboratory. Data validation reports summarizing findings will be submitted to the Data Quality Manager for review and approval.

Laboratory data will be evaluated for compliance with data quality objectives. Data usability, from an analytical standpoint, may be evaluated during the data evaluation. The data users (the PI, PM, AM) will determine the ultimate usability of the data.

5.9 Performance and System Audits

A Data Quality Manager or designee will be responsible for coordinating and implementing any QA audits that may be performed. Checklists may be prepared that reflect the system or components being audited, with references to source of questions or items on the checklist. Records of all audits and corrective actions should be maintained in the project files.

5.9.1 Technical System Audits

Technical System Audits (TSAs) are qualitative evaluations of components of field and laboratory measurement systems, including QC procedures, technical personnel, and QA management. TSAs determine if the measurement systems are being used appropriately. TSAs are normally performed before or shortly after measurement systems are operational, and during the program on a regularly scheduled basis. TSAs involve a comparison of the activities described in the study plan and SOPs with those actually scheduled or performed. Coordination and implementation of any TSAs will be the responsibility of the Data Quality Manager or designee.

Analytical data generation (laboratory audit)

Laboratory audits may be performed to determine whether the laboratory is generating data according to all processes and procedures documented in the associated project plans, QAPP,

SOPs, and analytical methods. Laboratory audits can be performed by an External QA Reviewer, a Data Quality Manager, or their designee.

Field audits

Field audits may be performed to determine whether field operations and sample collection are being performed according to processes and procedures documented in the study plan, QAPP, and SOPs.

5.9.2 Performance evaluation audits

Performance evaluation audits are quantitative evaluations of the measurement systems of a program. Performance evaluation audits involve testing measurement systems with samples of known composition or behavior to evaluate precision and accuracy, typically through the analysis of standard reference materials. These may be conducted before selecting an analytical laboratory.

5.10 Preventative Maintenance Procedures and Schedules

Preventative maintenance typically is implemented on a scheduled basis to minimize equipment failure and poor performance. In addition to the scheduled calibration procedures described above, the following procedures may be followed.

- ▶ Thoroughly clean field equipment before returning to the office. The equipment generally should be stored clean and dry.
- ▶ Replaceable components such as pH electrodes and dissolved oxygen membranes should be inspected after and before each use, and replaced as needed to maintain acceptable performance.
- ▶ Equipment that is malfunctioning or out of calibration will be removed from operation until repaired or recalibrated.

5.11 Procedures Used to Assess Data Usability

Data usability ultimately is a function of study methods, investigator expertise and competence, and intended uses. QA/QC procedures are designed to help ensure data usability but, in themselves, neither assure data usability nor — if not implemented — indicate that data are not useable or valid. Data validity and usability will ultimately be determined by the PI, PM, and

AM using their best professional judgment. Independent data validation, consultations with Data Quality Managers, and review of project-wide databases for data compatibility and consistency can be used to support usability evaluations. The usability and validity of existing and historical data, which were not collected pursuant to the QAPP presented in this Assessment Plan, will be determined by the AM, PM, PIs, and trustee technical staff using their best professional judgment.

5.12 Corrective Actions

5.12.1 Definition

Corrective actions consist of the procedures and processes necessary to correct and/or document situations where data quality and/or QA procedures fall outside of acceptance criteria or targets. [These criteria/targets may be numeric goals such as those discussed in Section 10.3, or procedural requirements such as those presented throughout the QAPP and other project documents (e.g., SOPs)].

The goal of corrective action is to identify as early as possible a data quality problem and to eliminate or limit its impact on data quality. The corrective action information typically is provided to a Data Quality Manager for use in data assessment and long-term quality management. Corrective action typically involves the following steps:

1. discovering any nonconformance or deviations from data quality objectives or the plan
2. identifying the party with authority to correct the problem
3. planning and scheduling an appropriate corrective action
4. confirming that the corrective action produced the desired result
5. documenting the corrective action.

5.12.2 Discovery of nonconformance

The initial responsibility of identifying nonconformance with procedures and QC criteria lies with the field personnel and bench-level analysts. Performance and system audits are also designed to detect these problems. However, anyone who identifies a problem or potential problem should initiate the corrective action process by, at the least, notifying a PI or Data Quality Manager of his or her concern.

Deviations from QAPP or SOP procedures are sometimes required and appropriate because of field or sample conditions. Such deviations should be noted in field or laboratory logbooks and their effect on data quality evaluated by a PI and Data Quality Manager. Occasionally, procedural changes are made during an investigation because method improvements are

identified and implemented. Even though these procedural improvements are not initiated because of nonconformance, they are procedural deviations and typically should be documented.

5.12.3 Planning, scheduling, and implementing corrective action

Appropriate corrective actions for routine problems depend on the situation and may range from documentation of the problem to resampling and reanalysis to the development of new methods. When the corrective action is within the scope of these potential actions, the bench-level analyst or the field staff can identify the appropriate corrective action and implement it. Otherwise, the corrective action should be identified and selected by the PM, the FTL, the Laboratory Manager, or the Data Quality Manager.

5.12.4 Confirmation of the result

While a corrective action is being implemented, additional work dependent on the nonconforming data should not be performed. When the corrective action is complete, the situation should be evaluated to determine if the problem was corrected. If not, new corrective actions should be taken until no further action is warranted, either because the problem is now corrected or because no successful corrective action has been found.

5.12.5 Documentation and reporting

Corrective action documentation may consist of the following reports or forms:

- ▶ corrective action forms initiated by project staff that will be collected, evaluated, and filed by the Data Quality Manager
- ▶ corrective action log maintained by the Data Quality Manager to track the types of nonconformance problems encountered and to track successful completion of corrective actions
- ▶ corrective action plans, if needed, to address major nonconformance issues
- ▶ performance and systems audit reports, if such audits are performed
- ▶ corrective action narratives included as part of data reports from independent laboratories
- ▶ corrective action forms initiated by laboratory staff and summarized in the report narrative.

5.12.6 Laboratory-specific corrective action

The need for corrective action in the analytical laboratory may come from several sources: equipment malfunction, failure of internal QA/QC checks, method blank contamination, failure of performance or system audits, and noncompliance with QA requirements.

When measurement equipment or analytical methods fail QA/QC checks, the problem should immediately be brought to the attention of the appropriate laboratory supervisor in accordance with the laboratory's SOP or Quality Assurance Manual. If failure is due to equipment malfunction, the equipment should be repaired, the precision and accuracy should be reassessed, and the analysis rerun.

All incidents of QA failure and the corrective action tasks should be documented, and reports should be placed in the appropriate project file. Corrective action should also be taken promptly for deficiencies noted during spot checks of raw data. As soon as sufficient time has elapsed for a corrective action to be implemented, evidence of correction of deficiencies should be presented to a Data Quality Manager or PI.

Laboratory corrective actions may include, but are not limited to:

- ▶ reanalyzing the samples, if holding time criteria permit and sample volume is available
- ▶ resampling and analyzing
- ▶ evaluating and amending sampling analytical procedures
- ▶ accepting data and acknowledging the level of uncertainty.

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