

## § 11.62

(3) The authorized official shall follow the guidance provided in the pathway section, §11.63 of this part, to determine the route through which the oil or hazardous substance is or was transported from the source of the discharge or release to the injured resource.

(4) If more than one resource, as defined in §11.14(z) of this part, has potentially been injured, an injury determination for each resource shall be made in accordance with the guidance provided in each section of the Injury Determination phase.

(d) *Selection of methodologies.* (1) One of the methodologies provided in §11.64 of this part for the potentially injured resource, or one that meets the acceptance criteria provided for that resource, shall be used to establish injury.

(2) Selection of the methodologies for the Injury Determination phase shall be based upon cost-effectiveness as that phrase is used in this part.

(e) *Completion of Injury Determination phase.* (1) Upon completion of the Injury Determination phase, the Assessment Plan shall be reviewed in accordance with the requirements of §11.32(f) of this part.

(2) When the authorized official has determined that one or more of the natural resources has been injured as a result of the discharge or release, the authorized official may proceed to the Quantification and the Damage Determination phases.

(3) When the authorized official has determined that an injury has not occurred to at least one of the natural resources or that an injury has occurred but that the injury cannot be linked to the discharge or release, the authorized official shall not pursue further assessment under this part.

### **§ 11.62 Injury determination phase— injury definition.**

(a) The authorized official shall determine that an injury has occurred to natural resources based upon the definitions provided in this section for surface water, ground water, air, geologic, and biological resources. The authorized official shall test for injury using the methodologies and guidance provided in §11.64 of this part. The test re-

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sults of the methodologies must meet the acceptance criteria provided in this section to make a determination of injury.

(b) *Surface water resources.* (1) An injury to a surface water resource has resulted from the discharge of oil or release of a hazardous substance if one or more of the following changes in the physical or chemical quality of the resource is measured:

(i) Concentrations and duration of substances in excess of drinking water standards as established by sections 1411–1416 of 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;

(ii) Concentrations and duration of substances in excess of water quality criteria established by section 1401(1)(D) of SDWA, or by other Federal or State laws or regulations that establish such criteria for public water supplies, in surface water that before the discharge or release met the criteria and is a committed use, as the phrase is used in this part, as a public water supply;

(iii) 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 that phrase is used in this part, as a habitat for aquatic life, water supply, or recreation. The most stringent criterion shall apply when surface water is used for more than one of these purposes;

(iv) Concentrations of substances on bed, bank, or shoreline sediments sufficient to cause the sediment to exhibit characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act, 42 U.S.C. 6921; or

(v) Concentrations and duration of substances sufficient to have caused injury as defined in paragraphs (c), (d), (e), or (f) of this section to ground water, air, geologic, or biological resources, when exposed to surface water, suspended sediments, or bed, bank, or shoreline sediments.

(2)(i) The acceptance criterion for injury to the surface water resource is the measurement of concentrations of oil or a hazardous substance in two samples from the resource. The samples must be one of the following types, except as specified in paragraph (b)(3) of this section:

(A) Two water samples from different locations, separated by a straight-line distance of not less than 100 feet; or

(B) Two bed, bank, or shoreline sediment samples from different locations separated by a straight-line distance of not less than 100 feet; or

(C) One water sample and one bed, bank, or shoreline sediment sample; or

(D) Two water samples from the same location collected at different times.

(ii) In those instances when injury is determined and no oil or hazardous substances are detected in samples from the surface water resource, it must be demonstrated that the substance causing injury occurs or has occurred in the surface water resource as a result of physical, chemical, or biological reactions initiated by the discharge of oil or release of a hazardous substance.

(3) If the maximum straight-line distance of the surface water resource is less than 100 feet, then the samples required in paragraph (b)(2)(i) (A) and (B) of this section should be separated by one-half the maximum straight-line distance of the surface water resource.

(c) *Ground water resources.* (1) An injury to the ground water resource has resulted from the discharge of oil or release of a hazardous substance if one or more of the following changes in the physical or chemical quality of the resource is measured:

(i) Concentrations of substances in excess of drinking water standards, established by sections 1411–1416 of the SDWA, or by other Federal or State laws or regulations that establish such standards for drinking water, in ground water that was potable before the discharge or release;

(ii) Concentrations of substances in excess of water quality criteria, established by section 1401(1)(d) of the SDWA, or by other Federal or State laws or regulations that establish such criteria for public water supplies, in ground water that before the discharge

or release met the criteria and is a committed use, as the phrase is used in this part, as a public water supply;

(iii) Concentrations 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 for domestic water supplies, in ground water that before the discharge or release met the criteria and is a committed use as that phrase is used in this part, as a domestic water supply; or

(iv) Concentrations of substances sufficient to have caused injury as defined in paragraphs (b), (d), (e), or (f) of this section to surface water, air, geologic, or biological resources, when exposed to ground water.

(2) The acceptance criterion for injury to ground water resources is the measurement of concentrations of oil or hazardous substance in two ground water samples. The water samples must be from the same geohydrologic unit and must be obtained from one of the following pairs of sources, except as specified in paragraph (c)(3) of this section:

(i) Two properly constructed wells separated by a straight-line distance of not less than 100 feet; or

(ii) A properly constructed well and a natural spring or seep separated by a straight-line distance of not less than 100 feet; or

(iii) Two natural springs or seeps separated by a straight-line distance of not less than 100 feet.

(3) If the maximum straight-line distance of the ground water resource is less than 100 feet, the samples required in paragraph (c)(2) of this section should be separated by one-half of the maximum straight-line distance of the ground water resource.

(4) In those instances when injury is determined and no oil or hazardous substance is detected in samples from the ground water resource, it must be demonstrated that the substance causing injury occurs or has occurred in the ground water resource as a result of physical, chemical, or biological reactions initiated by the discharge of oil or release of hazardous substances.

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(d) *Air resources.* An injury to the air resource has resulted from the discharge of oil or release of a hazardous substance if one or more of the following changes in the physical or chemical quality of the resource is measured:

(1) Concentrations of emissions in excess of standards for hazardous air pollutants established by section 112 of the Clean Air Act, 42 U.S.C. 7412, or by other Federal or State air standards established for the protection of public welfare or natural resources; or

(2) Concentrations and duration of emissions sufficient to have caused injury as defined in paragraphs (b), (c), (e), or (f) of this section to surface water, ground water, geologic, or biological resources when exposed to the emissions.

(e) *Geologic resources.* An injury to the geologic resource has resulted from the discharge of oil or release of a hazardous substance if one or more of the following changes in the physical or chemical quality of the resource is measured:

(1) Concentrations of substances sufficient for the materials in the geologic resource to exhibit characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act, 42 U.S.C. 6921;

(2) Concentrations of substances sufficient to raise the negative logarithm of the hydrogen ion concentration of the soil (pH) to above 8.5 (above 7.5 in humid areas) or to reduce it below 4.0;

(3) Concentrations of substances sufficient to yield a salt saturation value greater than 2 millimhos per centimeter in the soil or a sodium adsorption ratio of more than 0.176;

(4) Concentrations of substances sufficient to decrease the water holding capacity such that plant, microbial, or invertebrate populations are affected;

(5) Concentrations of substances sufficient to impede soil microbial respiration to an extent that plant and microbial growth have been inhibited;

(6) Concentrations in the soil of substances sufficient to inhibit carbon mineralization resulting from a reduction in soil microbial populations;

(7) Concentrations of substances sufficient to restrict the ability to access, develop, or use mineral resources with-

in or beneath the geologic resource exposed to the oil or hazardous substance;

(8) Concentrations of substances sufficient to have caused injury to ground water, as defined in paragraph (c) of this section, from physical or chemical changes in gases or water from the unsaturated zone;

(9) Concentrations in the soil of substances sufficient to cause a toxic response to soil invertebrates;

(10) Concentrations in the soil of substances sufficient to cause a phytotoxic response such as retardation of plant growth; or

(11) Concentrations of substances sufficient to have caused injury as defined in paragraphs (b), (c), (d), or (f), of this section to surface water, ground water, air, or biological resources when exposed to the substances.

(f) *Biological resources.* (1) An injury to a biological resource has resulted from the discharge of oil or release of a hazardous substance if concentration of the substance is sufficient to:

(i) 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; or

(ii) 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; or

(iii) Exceed levels for which an appropriate State health agency has issued directives to limit or ban consumption of such organism.

(2) The method for determining injury to a biological resource, as defined in paragraph (f)(1)(i) of this section, shall be chosen based upon the capability of the method to demonstrate a measurable biological response. An injury can be demonstrated if the authorized official determines that the biological response under consideration can satisfy all of the following acceptance criteria:

(i) The biological response is often the result of exposure to oil or hazardous substances. This criterion excludes biological responses that are

caused predominately by other environmental factors such as disturbance, nutrition, trauma, or weather. The biological response must be a commonly documented response resulting from exposure to oil or hazardous substances.

(ii) Exposure to oil or hazardous substances is known to cause this biological response in free-ranging organisms. This criterion identifies biological responses that have been documented to occur in a natural ecosystem as a result of exposure to oil or hazardous substances. The documentation must include the correlation of the degree of the biological response to the observed exposure concentration of oil or hazardous substances.

(iii) Exposure to oil or hazardous substances is known to cause this biological response in controlled experiments. This criterion provides a quantitative confirmation of a biological response occurring under environmentally realistic exposure levels that may be linked to oil or hazardous substance exposure that has been observed in a natural ecosystem. Biological responses that have been documented only in controlled experimental conditions are insufficient to establish correlation with exposure occurring in a natural ecosystem.

(iv) The biological response measurement is practical to perform and produces scientifically valid results. The biological response measurement must be sufficiently routine such that it is practical to perform the biological response measurement and to obtain scientifically valid results. To meet this criterion, the biological response measurement must be adequately documented in scientific literature, must produce reproducible and verifiable results, and must have well defined and accepted statistical criteria for interpreting as well as rejecting results.

(3) Unless otherwise provided for in this section, the injury determination must be based upon the establishment of a statistically significant difference in the biological response between samples from populations in the assessment area and in the control area. The determination as to what constitutes a statistically significant difference must be consistent with the quality as-

urance provisions of the Assessment Plan. The selection of the control area shall be consistent with the guidance provided in § 11.72 of this part.

(4) The biological responses listed in this paragraph have been evaluated and found to satisfy the acceptance criteria provided in paragraph (f)(2) of this section. The authorized official may, when appropriate, select from this list to determine injury to fish and wildlife resources or may designate another response as the determiner of injury provided that the designated response can satisfy the acceptance criteria provided in paragraph (f)(2) of this section. The biological responses are listed by the categories of injury for which they may be applied.

(i) *Category of injury—death.* Five biological responses for determining when death is a result of exposure to the discharge of oil or release of a hazardous substance have met the acceptance criteria.

(A) *Brain cholinesterase (ChE) enzyme activity.* Injury has occurred when brain ChE activity in a sample from the population has been inhibited by at least 50 percent compared to the mean for normal brain ChE activity of the wildlife species. These enzymes are in the nervous system of vertebrate organisms and the rate of ChE activity is associated with the regulation of nerve impulse transmission. This biological response may be used to confirm injury when anti-ChE substances, such as organophosphorus and carbamate pesticides, are suspected to have resulted in death to bird and mammal species.

(B) *Fish kill investigations.* Injury has occurred when a significant increase in the frequency or numbers of dead or dying fish can be measured in accordance with the procedures for counting dead or dying fish contained in Part II (Fish-Kill Counting Guidelines) of "Monetary Values of Freshwater Fish and Fish-Kill Counting Guidelines," American Fisheries Society Special Publication Number 13, 1982 (incorporated by reference, see § 11.18).

(C) *Wildlife kill investigations.* Injury has occurred when a significant increase in the frequency or number of dead or dying birds or mammal species

can be measured in a population sample from the assessment area as compared to a population sample from a control area. Wildlife kill investigations may be used when acute mortality has occurred to multiple wildlife species, or when detectable quantities of oil or hazardous substances have adhered to, bound to, or otherwise covered surface tissue, or had been ingested or inhaled by dead or dying bird or mammal species.

(D) *In situ bioassay.* Injury has occurred when a statistically significant difference can be measured in the total mortality and/or mortality rates between population samples exposed in situ to a discharge of oil or a release of hazardous substance and those in a control site. In situ caged or confined bioassay may be used to confirm injury when oil or hazardous substances are suspected to have caused death to fish species.

(E) *Laboratory toxicity testing.* Injury has occurred when a statistically significant difference can be measured in the total mortality and/or mortality rates between population samples of the test organisms placed in exposure chambers containing concentrations of oil or hazardous substances and those in a control chamber. Published standardized laboratory fish toxicity testing methodologies for acute flow-through, acute static, partial-chronic (early life stage), and chronic (life cycle) toxicity tests may be used to confirm injury. The oil or hazardous substance used in the test must be the exact substance or a substance that is reasonably comparable to that suspected to have caused death to the natural population of fish.

(ii) *Category of injury—disease.* One biological response for determining when disease is a result of exposure to the discharge of oil or release of a hazardous substance has met the acceptance criteria.

(A) *Fin erosion.* Injury has occurred when a statistically significant difference can be measured in the frequency of occurrence of fin erosion (also referred to as fin rot) in a population sample from the assessment area as compared to a sample from the control area. Fin erosion shall be confirmed by appropriate histological pro-

cedures. Fin erosion may be used when oil or hazardous substances are suspected to have caused the disease.

(iii) *Category of injury—behavioral abnormalities.* Two biological responses for determining when behavioral abnormalities are a result of the exposure to the discharge of oil or release of a hazardous substance have met the acceptance criteria.

(A) *Clinical behavioral signs of toxicity.* Injury has occurred when a statistically significant difference can be measured in the frequency of occurrence of clinical behavioral signs of toxicity in a population sample from the assessment area as compared to a sample from the control area. Clinical behavioral signs of toxicity are characteristic behavioral symptoms expressed by an organism in response to exposure to an oil or hazardous substance. The clinical behavioral signs of toxicity used shall be those that have been documented in published literature.

(B) *Avoidance.* Injury has occurred when a statistically significant difference can be measured in the frequency of avoidance behavior in population samples of fish placed in testing chambers with equal access to water containing oil or a hazardous substance and the control water. The oil or hazardous substance used in the test must be the exact substance or a substance that is reasonably comparable to that suspected to have caused avoidance to the natural populations of fish. This biological response may be used to confirm injury when oil or hazardous substances are suspected to have resulted in avoidance behavior in fish species.

(iv) *Category of injury—cancer.* One biological response for determining when cancer is a result of exposure to the discharge of oil or release of a hazardous substance has met the acceptance criteria.

(A) *Fish neoplasm.* Injury has occurred when a statistically significant difference can be measured in the frequency of occurrence of the fish neoplasia when comparing population samples from the assessment area and a control area. Neoplasms are characterized by relatively autonomous growth of abnormal cells that by proliferation infiltrate, press upon, or invade

healthy tissue thereby causing destruction of cells, interference with physiological functions, or death of the organism. The following type of fish neoplasia may be used to determine injury: liver neoplasia and skin neoplasia. The neoplasms shall be confirmed by histological procedures and such confirmation procedures may also include special staining techniques for specific tissue components, ultra-structural examination using electron microscopy to identify cell origin, and to rule out or confirm viral, protozoan, or other causal agents. Fish neoplasms may be used to determine injury when oil or hazardous substances are suspected to have been the causal agent.

(v) *Category of injury—physiological malfunctions.* Five biological responses for determining when physiological malfunctions are a result of exposure to the discharge of oil or release of a hazardous substance have met the acceptance criteria.

(A) *Eggshell thinning.* Injury has occurred when eggshell thicknesses for samples for a population of a given species at the assessment area are thinner than those for samples from a population at a control area, or are at least 15 percent thinner than eggshells collected before 1946 from the same geographic area and stored in a museum. This biological response is a measure of avian eggshell thickness resulting from the adult bird having assimilated the oil or hazardous substance. This biological response may be used when the organochlorine pesticide DDT or its metabolites are suspected to have caused such physiological malfunction injury.

(B) *Reduced avian reproduction.* Injury has occurred when a statistically significant difference can be measured in the mean number of young fledged per active nest when comparing samples from populations in the assessment area and a control area. The fledging success (the number of healthy young leaving the nest) shall be used as the measurement of injury. Factors that may contribute to this measurement include egg fertility, hatching success, and survival of young. This biological response may be used when oil or hazardous substances are suspected to

have reduced the nesting success of avian species.

(C) *Cholinesterase (ChE) enzyme inhibition.* Injury has occurred when brain ChE activity in a sample from the population at the assessment area shows a statistically significant inhibition when compared to the mean activity level in samples from populations in a control area. These enzymes are in the nervous systems of vertebrate organisms and the rate of ChE activity is associated with the regulation of nerve impulse transmission. This biological response may be used as a demonstration of physiological malfunction injury to birds, mammals, and reptiles when anti-ChE substances, such as organophosphorus and carbamate pesticides, have been discharged or released.

(D) *Delta-aminolevulinic acid dehydratase (ALAD) inhibition.* Injury has occurred when the activity level of whole blood ALAD in a sample from the population of a given species at an assessment area is significantly less than mean values for a population at a control area, and ALAD depression of at least 50 percent can be measured. The ALAD enzyme is associated with the formation of hemoglobin in blood and in chemical detoxification processes in the liver. This biological response is a measure of the rate of ALAD activity. This biological response may be used to determine injury to bird and mammal species that have been exposed to lead.

(E) *Reduced fish reproduction.* Injury has occurred when a statistically significant difference in reproduction success between the control organisms and the test organisms can be measured based on the use of published standardized laboratory toxicity testing methodologies. This biological response may be used when the oil or hazardous substance is suspected to have caused a reduction in the reproductive success of fish species. Laboratory partial-chronic and laboratory chronic toxicity tests may be used. The oil or hazardous substance used in the test must be the exact substance or a substance that is reasonably comparable to that suspected to have caused reduced reproductive success in the natural population of fish.

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(vi) *Category of injury—physical deformation.* Four biological responses for determining when physical deformations are a result of exposure to the discharge of oil or release of a hazardous substance have met the injury acceptance criteria.

(A) *Overt external malformations.* Injury has occurred when a statistically significant difference can be measured in the frequency of overt external malformation, such as small or missing eyes, when comparing samples from populations of wildlife species from the assessment area and a control area. This biological response may be used as a demonstration of injury when such physical deformations are observed in wildlife species exposed to oil or hazardous substances.

(B) *Skeletal deformities.* Injury has occurred when a statistically significant difference can be measured in the frequency of skeletal deformities, such as defects in growth of bones, when comparing samples from populations of wildlife species from the assessment area and a control area. This biological response may be used as a demonstration of injury when such physical deformations are observed in wildlife species exposed to oil or hazardous substances.

(C) *Internal whole organ and soft tissue malformation.* Injury has occurred when a statistically significant difference can be measured in the frequency of malformations to brain, heart, liver, kidney, and other organs, as well as soft tissues of the gastrointestinal tract and vascular system, when comparing samples from populations of wildlife species in the assessment area and a control area. This biological response may be used as a demonstration of injury when such physical deformations are observed in wildlife species exposed to oil or hazardous substances.

(D) *Histopathological lesions.* Injury has occurred when a statistically significant difference can be measured in the frequency of tissue or cellular lesions when comparing samples from populations of wildlife species from the assessment area and a control area. This biological response may be used as a demonstration of injury when such physical deformations are observed in

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wildlife species exposed to oil or hazardous substances.

### § 11.63 Injury determination phase—pathway determination.

(a) *General.* (1) To determine the exposure pathways of the oil or hazardous substance, the following shall be considered:

(i) The chemical and physical characteristics of the discharged oil or released hazardous substance when transported by natural processes or while present in natural media;

(ii) The rate or mechanism of transport by natural processes of the discharged oil or released hazardous substance; and

(iii) Combinations of pathways that, when viewed together, may transport the discharged oil or released hazardous substance to the resource.

(2) The pathway may be determined by either demonstrating the presence of the oil or hazardous substance in sufficient concentrations in the pathway resource or by using a model that demonstrates that the conditions existed in the route and in the oil or hazardous substance such that the route served as the pathway.

(3) To the extent that the information needed to make this determination is not available, tests shall be conducted and necessary data shall be collected to meet the requirements of this section. Methods that may be used to conduct these additional tests and collect new information are described in § 11.64 of this part.

(b) *Surface water pathway.* (1) When the surface water resource is suspected as the pathway or a component of the pathway, the authorized official shall determine, using guidance provided in this paragraph, whether the surface water resource, either solely or in combination with other media, served as the exposure pathway for injury to the resource.

(2)(i) Using available information and such additional tests as necessary, it should be determined whether the surface water resource downstream or downcurrent of the source of discharge or release has been exposed to the oil or hazardous substance.

(ii) When the source of discharge or release is on an open water body, such