Rule 3745-300-08 and 3745-300-09
Generic Numerical Standards and Risk Assessment
Introduction

Today I will be discussing how generic and property specific cleanup standards are derived for environmental media under the Voluntary Action Program, the exposure pathways that are addressed in the development of generic standards, and how to apply clean-up standards in a No Further Action Letter.

The Voluntary Action Program rules include procedures to derive applicable standards for environmental media at volunteer properties. Generic numeric clean-up standards for human direct contact with soil and potable use ground water are listed in Rule 08. Rule 08 also discusses generic standards, but does not list specific numerical standards for sediments, surface water, and soil standards from soil to groundwater. Rule 09 lists the procedures for deriving standards on a property-specific basis.

Discussions earlier today focused on Phase I and Phase II property assessments. Rules 3745-300-06 and -07 detail the procedures by which the CP/Volunteer presents the release history of the property and assessment of these releases. The Phase II property assessment includes assessment of existing and potentially complete exposure pathways, and selection of chemicals of concern (COCs). The Phase II also evaluates the concentration at a potential point of contact to a receptor, also known as the "exposure point concentration". In order to determine whether concentrations of COCs at a property are protective of human health and the environment, the concentration of COCs at the exposure point must meet an applicable standard. The standards for soil, groundwater, sediments and surface water are listed and/or discussed within Rules 08 and 09.

Generic numerical standards for human exposures are, with some exceptions, developed in accordance with US EPA's Risk Assessment Guidance for Superfund, also known as RAGS. These same principles

are used when deriving an applicable standard for human health within a property-specific risk assessment. The complete methodology for their development is found in the "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures" (August 2008). Other useful documents used in the development of the standards is U.S. EPA's Soil Screening Guidance, User's Guide and Technical Background Document (May 1996) and USEPA's Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (December 2002).

Generic standards for direct contact with soils consider the following exposure routes to humans:

- Incidental ingestion of contaminated soil
- Inhalation of contaminated soil particulates
- Inhalation of volatile COCs from soil to outdoor air
- Dermal contact with non-volatile COCs in soil

Here are two examples of soil issues on properties. The first set of photographs is from New Boston Coke in southern Ohio.

This was one of the first projects to be granted a Covenant not to Sue and involved a rather extensive PCB clean-up along with other COCs in soil.

The second set of photos is from Alsco Aluminum in Gnaddenhuten, Ohio.

This was a former NPL site and has been redeveloped for recreational land use.

Sometimes generic numerical standards cannot be solely utilized in the demonstration of applicable standards at all properties. If the complete or potentially complete exposure pathways at a property are not included in the development of the generic standard, a property-specific risk assessment must be conducted in accordance with Rule 09.

The generic numerical standards for human exposures to soils are developed for specific exposure scenarios, namely residential, commercial/industrial, and construction scenarios. If exposure scenarios are different at a VAP property – for example, a proposed recreational land use, generic numerical standards may not be appropriate. In such

cases, clean-up standards must be derived through a property-specific risk assessment.

The generic standards listed in Rule 08 also do not apply to chemicals of concern at a property that are not listed in the generic standards tables, if there are complete exposure pathways not listed in the development of the standards (for example, volatization of VOCs from soil or groundwater to indoor air), exposure pathways to important terrestrial ecological resources or if generic standards are exceeded for sediment or surface water at a property. All of these scenarios require a property-specific risk assessment in accordance with rule 09, unless a remedy is applied.

Before I discuss the standards listed in various tables in Rule 08, I'd like to explain how the VAP applies standards for petroleum releases. For residential and commercial properties, the generic numeric standards for petroleum in soil and ground water are those developed by the Department of Commerce, Bureau of Underground Storage Tank Regulations, also known as BUSTR. These standards, which are mandated by statute, apply regardless of whether the release is BUSTR regulated, i.e. for any release of petroleum, regardless of the source. For instance, if a petroleum release occurs from an aboveground storage tank, the clean-up standards are those developed by BUSTR. Remember, for BUSTR-regulated releases, the property is not VAP–eligible until a no further action letter is obtained for the release by BUSTR.

Please note that even if a petroleum UST was permanently closed prior to 1988, the site may still be subject to BUSTR closure requirements, and thus may not be eligible for the VAP until BUSTR requirements are met. Please see the VAP Technical Guidance Compendium for further information.

For any petroleum release at residential or commercial properties, the generic standards are BUSTRs Tier I action levels. For a petroleum-only release within an identified area, the BUSTR generic standards are limited to 13 COCs. At commercial or residential properties applying generic standards, it is not necessary to derive or apply standards for additional COCs. Additionally, all pathways addressed through the

application of BUSTR generic standards are satisfactory for VAP purposes.

BUSTR applies the distillate-specific soil saturation limits for free product. Free product in groundwater is defined as a separate liquid hydrocarbon phase that has a measurable thickness of greater than one one-hundredth of a foot. When applying BUSTR petroleum standards for voluntary actions, all free product must be removed to the maximum extent practicable. Properties with free product exceed unrestricted potable standards for ground water. Response requirements found in VAP Rule -10 apply even if there are no dissolved constituents exceeding UPUS.

Rule -08 contains six different tables for generic direct contact soil standards.

Table I lists generic direct contact standards for residential land use. These standards also apply for any property where land use is unrestricted. At residential properties, exposure point for direct contact is assumed from the surface to 10 feet below surface. In other words, unrestricted land use must meet residential standards up to a 10 foot point of compliance. Residential standards are considered protective for, and may be applied to, all land use categories, without restriction.

Table II lists values for commercial/industrial land use. For commercial and industrial properties, direct contact is assumed from the surface to two feet below the surface. The application of commercial/industrial direct contact soil standards requires an environmental covenant which allows for the long-term enforcement of land use controls, also known as an institutional controls, or activity and use limitations, as a remedy.

Direct contact soil standards for construction/excavation activities are listed in Table III. For this category, the point of compliance is the anticipated depth of activity.

Table IV lists the applicable direct contact standard for lead in soils. The lead standard is isolated from the other COCs because it is calculated with a risk model unlike the one used for Tables I-III. Because the method to calculate the standard differs from the others, the

lead standard is not subject to multiple chemical adjustment with the other COCs.

The procedures and rationale used to generate the generic numerical direct contact standards are found in the "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures". The support document details contaminant transport and intake equations, chemical and physical parameters, calculation methodologies for clean up standards for cancer and non-cancer endpoints, soil saturation, the derivation of TPH limits, and the rationale for the lead soil standard. The support document also provides rationale for the exposure factors used and is updated with the revision of the generic standards and the rule every five years.

Default point values are listed in the support document for exposure assumptions used in the development of the generic standards. Property-specific data used in the identification of receptor populations, the identification of exposure pathways, or the quantification of chemical-specific intake is allowed. However, property-specific data must be collected in accordance with Rule -07(E). Property-specific information used to define any parameter which requires the prediction of human use and activity patterns of the receptor populations must be representative of the reasonably anticipated land use and the actual property characteristics, and must be included in an institutional or engineering control.

Default exposure values are given for the following:

- **Exposure Duration, Exposure Frequency, Body Weight**
- **Soil Ingestion Rate**
- **Fraction Contaminated Soil**
- **Surface Area of exposed skin**
- **Soil to Skin Adherence Factor**
- **Inhalation Rate and Inhalation Exposure Time** - because the toxicity used for inhalation is concentration-based and not dose-based, inhalation rates and exposure times are no longer used in the development of generic soil standards. However, development of the ground water standards considers a showering scenario. For

those standards, the inhalation toxicity factors are transformed from a concentration term to a dosing term.
Because RAGS F was published after the standards were set in rule, the support document will be amended to allow the use of RAGS F when calculating inhalation exposures. This includes modifying the exposure for an 8 hour workday in a commercial/industrial setting.

Determining the ability and extent of contaminant transport from soils is modeled within the equations using standardized modeling assumptions for soil and climatic parameters.
For example:

- Fraction vegetative cover
- Soil porosity
- Soil bulk density
- Fraction organic matter
- Wind speed
- Diffusion height…etc.

These are used primarily to quantify the amount of contaminant that can become airborne either through particulate emission or volatilization. These, combined with COC specific physical and chemical properties, are used to approximate mass quantities available for intake pathway quantification.

Chemical specific values used to generate risk-derived standards include physical properties such as molecular weight, Henry's law constant, octanol - water coefficient, solubility, air and water diffusivities, and melting point. The Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures lists the source hierarchy for physical, chemical and toxicology information.
Toxicity assessment is generally accomplished in two steps:

1. Hazard identification – the process of determining whether exposure causes an increase of an adverse health effect and whether this adverse health effect is likely to occur in humans; and

2. Dose-response evaluation – a quantitative evaluation of dose and response. From this quantitative dose-response relationship, toxicity factors are derived that can be used to estimate the potential for adverse effects upon human exposure.

Specific toxicity factors applied to individual chemicals of concern include:

- **slope factors**, expressed as risk per mg/kg per day for carcinogen evaluation,
- **reference doses**, in mg/kg per day for non-cancer evaluation,
- **inhalation unit risk** – expressed as risk per mg/m^3 for carcinogen evaluation
- **reference concentration** – in mg/m^3 for non-cancer evaluation
- **chemical – specific absorption factors** – used to adjust an administered dose toxicity value for an absorbed dose intake equation, or adjust an absorbed dose toxicity value for an administered dose intake. For example, the dermal intake equation is calculated as an absorbed dose intake. Any toxicity value not derived from absorbed dose data must be adjusted by an absorption factor.

Fortunately, US EPA has performed the toxicity assessment step for numerous chemicals and has made available the resulting toxicity information and toxicity values. These values are published only after extensive peer review. Toxicity values are chosen for generic standards development and/or deriving a standard through a property-specific risk assessment through the following information hierarchy.

– **U.S. EPA's Integrated Risk Information System, also known as IRIS –** These values undergo extensive peer review prior to publication. For COCs not listed in IRIS, Ohio EPA uses the following sources:
  - **National Center for Environmental Assessment – US EPA provisional peer reviewed toxicity values (PPRTVs).** This information is not publicly available.

- **Agency for Toxic Substance and Disease Registry, also known as ATSDR**– This information requires some knowledge to decipher. However, it is a good source of narrative information about health effects from exposure to various hazardous substances.
- **U.S. EPA criteria documents**. Occasionally, Ohio EPA will refer to documents that rely on other sources, such as US EPA Regional Screening Levels or toxicity data derived by other states.

Non-cancer toxicity values are derived for the route of entry as defined by the critical study. For example, feeding a rat a dose of a chemical that produces a critical effect is called the oral reference dose. Inhalation reference concentrations are developed by subjecting test animals to inhalation hazards. A route to route extrapolation refers to the application of a toxicity value derived by one route of entry to a different route of entry.

In the development of the generic standards, an extrapolation of oral toxicity to dermal is done for certain chemicals of concern. In general, these include:

- COCs that are not volatile
- COCs that have a chemical-specific or class-based dermal absorption factor
- Of these, an evaluation of the appropriateness of the route-to-route evaluation is done based on mechanism of action.

Extrapolation of oral toxicity to the inhalation pathway is *not* used to estimate criteria for the inhalation pathway for any COC in the development of the generic standards.

For a property-specific risk assessment, route extrapolation from oral to inhalation is done when the pathway which represents the only complete or most significant pathway would otherwise have no toxicity criterion, and the extrapolation is appropriate, based on mechanism of action. An example of this would be the assessment of the risk or hazard posed by the vapor intrusion pathway.

How are the standards generated? The exposure assumptions, toxicity factors, and physical parameters are all used as inputs to equations to determine an acceptable target concentration. Exposure factor values are recommended by U.S.EPA or are derived from primary sources by Ohio EPA.

For generic standards, we currently use a Monte Carlo simulation using Crystal Ball software for probabilistic development of the standards. This process involves performing iterative calculations where input terms are drawn from probability distributions of each exposure factor. Distributions vary, but examples include normal, triangular, or custom distributions.

Body weight is iteratively selected from a normal distribution. Adult values range from 32 Kg to 117 Kg with a mean of 71 Kg.

The fraction of soil at a property considered to be contaminated is distributed uniformly from 0.01 to 1.0

Exposure duration is the number of years a person is at the property. For residential adults, this is a custom distribution based on the U.S. Census 2000 Supplementary Survey Summary Tables for residency occupancy period data for Ohio.

By solving the equations iteratively, the generic standards are developed from populations of chemical concentrations which meet the appropriate cancer or non-cancer risk level under a wide range of possible exposures. For the cancer endpoint, the target risk is excess lifetime cancer risk of 1E-05. In other words, the excess risk of developing cancer from site-wide exposures during a lifetime is 1 in 100,000. For non-carcinogenic chemicals, the target Hazard Index is 1. Values chosen for the standards are selected from the resulting distributions at the 90% level. This can also be described as 10% of the derived chemical concentration population exceeds the target risk levels.

The ability to accurately predict risk from free phase chemicals is not addressed by our direct contact risk equations. The equation used to calculate soil saturation is shown here. Standard defaults or property-specific data can be used in the calculation of soil saturation values. Saturation values also are not calculated for COCs that are solid at soil

temperature - whose melting point is > 17 degrees Centigrade. For petroleum COCs, soil saturation is defined by BUSTR for generic petroleum standards. For a VAP PSRA, the TPH values in rule -09 define saturation.

An applicable direct contact soil standard, both generic and derived through a property-specific risk assessment, is the lowest of the cancer value, non-cancer value, or soil saturation value. However, the target risk goal of 1.0 E-05 and Hazard Index of 1 is based on assumption of only one chemical of concern at a property. When multiple COCs exist, the applicable standard must be adjusted to account for the incremental risk and hazard posed by each COC. I'll walk through the exercise of a multiple chemical adjustment of a standard in a few minutes.

For ground water, the generic standards for human exposure address only the unrestricted potable use pathway. There are two tables of generic unrestricted potable use standards (UPUS):

- Table V list standards adopted from US EPA, known as Maximum Contaminant Levels (MCLs), or other regulatory established criteria. MCLs, by definition, are the highest level of a contaminant that is allowed in drinking water at public water intakes. Maximum Contaminant Level Goals (MCLGs) are the level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety and are non-enforceable public health goals. MCLs are set as close to MCLGs as feasible using the best available treatment technology and taking cost into consideration. MCLs are enforceable standards. Because MCLs are not based solely on risk to the receptor, they are not subject to a multiple chemical adjustment.
- Table VI lists unrestricted potable use standards that are derived through risk equations. Assumed exposure includes ingestion, using a point value of 2.0 liters per day, and dermal and inhalation exposures during bathing. Exposure times are similar to those used for soil direct contact. Ground water standards from Table VI are subject to multiple chemical adjustment.

For surface water, the generic numerical standards are the Outside the Mixing Zone Average (known as the OMZA) chemical criteria pursuant to Chapter 3745-1 of the Ohio Administrative Code. The OMZA for human health and aquatic life are compared against a 30 day average value from the following locations:

1. ground water monitoring wells at the property boundary or immediately adjacent to the surface water, if the ground water daylights to surface water on an adjoining property;
2. surface water on the property;
3. surface water at off-property locations, at the point of immediate discharge of contaminated ground water.

Single ambient samples are not to exceed the Outside the Mixing Zone Maximum (OMZM). If chemical constituents exceed the OMZA or OMZM, then surface water must be further assessed in a property-specific risk assessment, or a remedy conducted.

All regulated point source discharges to surface waters must comply with all permit requirements. The release of liability with a Covenant Not to Sue does not extend to permit violations. Similarly, complete exposure pathways of a permitted storm water discharge or any other permitted source, need not be analyzed in an NFA Letter. Permit requirements are assumed to address regulated pathways. As a practical application, any settling pond or retention basin does not constitute an important ecological resource if it is up-gradient of a permitted outfall.

Sediments must be evaluated at a property when complete exposure pathways to sediments exist on the property or contaminated sediments are migrating from the property to adjacent property. In other words, past releases to sediments that are now off-property or downstream are not required if contaminated sediments are not on the property when the NFA is issued. An exception is made for properties immediately adjacent for complete pathways other than sediment to sediment, for example, ground water to sediments. Sediment assessment includes risks to both human health and important ecological resources.

Sediments are sampled according to Ohio EPA, “Sediment Sampling Guide and Methodology”

Show sediment collection videos

This typically requires sediment collection from areas that contain finer grained materials. Composite samples from one area are acceptable. For exposure point concentration, you can use either the maximum concentration or 95% UCL.

For human health evaluation, a complete pathway from sediments to humans is considered complete only if COCs are persistent, bioaccumulative, and toxic in sediment and surface water <u>and</u> the surface water body can produce a consistent supply of edible-sized fish. Complete pathways to humans can also be presumed if the surface water containing sediments supports wading, fishing, swimming, boating.

The generic direct contact soil standards for residential land use can be used as generic sediment standards for human health. However, because these standards consider only direct contact, a property-specific risk assessment must be conducted if the COCs in sediment are persistent, bioaccumulative and toxic.

Generic numerical standards for sediments to important ecological resources are found in Rule 08(H). The volunteer can sample sediments directly and compare concentrations to the Ohio-specific sediment reference values or SRVs found in Ohio EPA’s “Guidance for Conducting Ecological Risk Assessments”.

If there are COCs for which there are no SRVs, then the volunteer must compare the COC concentration to the consensus-based threshold effects concentration values in MacDonals, et. al.”Development and Evaluation of Consensus-based Sediment Quality Guidelines for Freshwater Ecosystems” or U.S. EPA, Region 5 ecological screening levels.

COCs must meet the benchmark values discussed. However, COCs that are persistent, bioaccumulative, and toxic must be evaluated through a property specific risk assessment even if they meet the stated benchmarks, unless the benchmarks consider bioaccumulative effects.

If sediment values are not compared to the stated hierarchy of values, or if concentrations of COCs exceed those values, then sediments must be evaluated by conducting either bioassays or biocriteria surveys in accordance with the property specific risk assessment rule. In lieu of further assessment, a remedy may be performed.

For all COCs listed in Tables I, II, III and VI, an adjustment must be made to the applicable standard if more than one chemical is found at a property. Adjusting the standards for the presence of multiple chemicals is not appropriate for Lead or groundwater MCLs because those standards take into consideration factors other than risk to receptor. When using generic standards, a multiple chemical adjustment for soil and ground water is calculated separately. When conducting a property-specific risk assessment, the incremental risk from each COC, media and pathway must be summed to develop an estimation of total risk.

The reason the generic standards tables are in three columns is to provide the value for cancer and non cancer effects and soil saturation. For a multiple chemical adjustment, the cancer and non cancer values are considered separately. Soil saturation is not subject to multiple chemical adjustment. For standards that default to soil saturation, perform an MCA on the listed cancer and non cancer values.

Divide the exposure point concentration at the site by the single chemical standard value to obtain a ratio for each COC. If the sum of the ratios is less than one, then collectively the concentration of COCs at the property meet the risk goal – 1E-5 for cancer and an HI of 1 for non-cancer. Further separation of the non-cancer multiple chemical adjustment can be performed by categorizing COCs according to which target organ was identified in the critical study.

Another way to adjust for multiple chemicals is to divide the standard for each COC by number of COCs. The adjusted value can then be compared to the single chemical value, and each ratio summed. If the summed ratios are less than 1, the applicable standards are met. If summed ratios exceed one, the applicable standards are not met.

If the applicable standards are not met, a remedy is necessary. However, it is possible to further adjust the standards if remedial activities lower the exposure point concentration for a particular COC. Remember, the goal is for all COCs in each media to reach a concentration such that the risk goals for the property are met for all COCs and exposure pathways.

The following two slides illustrate a basic multiple chemical adjustment. Suppose a property has these four COCs in soils. For this example, soil saturation limits are higher than either the cancer or non cancer standard value so the soil saturation values are not shown in the example.

Using the site concentration values divided by the standard, a ratio can be calculated. If the ratios are less than one, the standard does not have to be adjusted for the presence of multiple chemicals. If the ratio exceeds 1, then the standard must be adjusted. In this case, the cancer ratio exceeds one, and thus a remedy is necessary.

An MCA can also be calculated by dividing the standard by the number of COCs and determining if site COC concentration exceeds the multiple chemically adjusted value. If there is a cushion of risk available in concentration of other COCs compared to the standard, the multiple chemically adjusted standard can be further adjusted. The goal is to meet a 1E-05 risk goal or hazard index of 1.

The certified professional must verify that the standards derived through cumulative adjustment of multiple chemicals are not below the CLs reporting limits. This can seem like a Catch–22 because the applicable standards may not be fully known without analytical results, yet the CP must inform the lab of expected reporting limits to meet an applicable standard. Sometimes multiple rounds of sampling at a property are required in order to sufficiently demonstrate that COCs in media at a property meet an applicable standard. As a conservative measure, a fractional estimate can be used to approximate the multiple chemically adjusted standard. Each potential COC single chemical non-cancer and cancer value can be divided by the total number of suspected COCs.

In addition to evaluating direct exposure to contaminated media, rule -08 requires that the volunteer develop soil standards for leaching of chemicals of concern from soil to ground water. Soil standards for leaching are the concentrations determined to meet unrestricted potable use standards for ground water when ground water meets UPUS, or for any other pathway that must be met for the ground water response requirements when the ground water exceeds UPUS. Such pathways may include meeting COCs at the property boundary, or vapor intrusion to indoor air.

A property-specific risk assessment is based on the same principles as those used to generate the generic numeric standards. A property-specific risk assessment can be either elective or mandatory. A volunteer can elect to use property-specific information as inputs to the algorithm generating the standard, subject to reasonableness for the property.

Mandatory application of a property-specific risk assessment applies under the following scenarios:

- When the exposure pathways for the intended land use aren't included in the development of the generic standard – for example, volatilization of COCs to indoor air, or when an exposure scenario exists other than residential, commercial/industrial land use;
- If a COC at the property does not have a generic standard in Rule 08
- If concentrations of COCs in surface water or sediment exceed applicable standards in accordance with Rule -08;
- If complete exposure pathways to important ecological resources other than sediment or surface water exist (such as terrestrial receptors); or
- If the COCs at the property are persistent, bioaccumulative, and toxic, and the generic standards do not consider these effects.

The risk goals that must be met within a property-specific risk assessment are the same as those when using generic numerical standards, with one exception:

For COCs with carcinogenic effects, the total site-wide risk cannot exceed 1E-05 for commercial and residential properties. For industrial

properties, a volunteer may use an excess lifetime cancer risk goal of 1E-04, provided that the risk to off-property receptors is 1E-05.

When assessing petroleum releases within a property specific risk assessment, the COCs that must be evaluated are dependent on the petroleum fraction of the released product. Applicable standards consist of meeting TPH soil saturation concentrations listed in Table I for the appropriate COCs typically associated with the corresponding petroleum fraction. It may be appropriate to evaluate additional petroleum constituents or typical impurities.

A property-specific risk assessment consists of 4 parts:

1. Selection of COCs
2. Exposure Assessment
3. Toxicity Assessment, and
4. Risk characterization, which includes summation incremental risk from multiple COCs and pathways and uncertainty analysis.

All COCs must be evaluated within a risk assessment except for those concentrations determined to be below background (in fact, background values are not considered as part of an applicable standard, and therefore, are not subject to a multiple chemical adjustment), and COC concentrations determined to be de minimus. Additionally, COCs at a property that are considered to be essential human nutrients, as long as they are present near naturally occurring levels, may be toxic only at high concentrations. COCs that are determined to contribute less than one percent of the estimate risk or hazard can also be eliminated from further evaluation.

Exposure assessment in a property-specific risk assessment is no different than the process used for derivation of the applicable standards. Components include identification of receptors, evaluation of complete or potentially complete pathways, and quantification of intake for the current or intended exposure scenario.

The toxicity assessment is the same as the assessment used in the development of the generic values. The hierarchy followed is first IRIS, then NCEA or ATSDR.

A common pathway addressed at VAP sites that is not part of the generic numerical standards is vapor intrusion of volatile chemicals from soil and/or groundwater to indoor air. There are several tools that can be used to evaluate this pathway, including U.S. EPA Vapor Intrusion Guidance, Guidance from the Interstate Technology & Regulatory Council, and the Johnson and Ettinger Model. Ohio EPA, Division of Emergency and Remedial Response is developing program-specific guidance for this pathway.

Contact a technical staff member in Central Office for the latest updates.

In a property-specific risk assessment, the total risk to the receptor must be characterized. This includes not only a multiple chemical adjustment of an applicable standard for each media, but also includes calculation of the incremental risk from each exposure pathway. Thus, an estimation of the site-wide risk to the receptor is calculated.

Cumulative risk from all pathways can be represented as either a ratio or incremental risk. A ratio of 1.0 indicates a total risk goal of 1E-05 and/or a Hazard Index of 1. Incremental risk and hazard must be summed for each COC and media across all complete or potentially complete exposure pathways.

A property-specific risk assessment is also required when complete exposure pathways to important ecological resources, excluding sediment and surface water, exist from COCs on the property. For the most part, this includes terrestrial habitats that support rare, endangered or threatened species, and wildlife populations and their important nesting areas and food resources. Estimation of habitat quality is necessary to determine if significant wildlife populations or food resources exist. For example, an industrialized property may have limited green space around buildings, roadways, etc. There may be a limited number of trees or nesting sites . This type of habitat would generally not be considered as an important ecological resource.

If sediments or surface water exceed generic standards discussed in Rule 08, or if the COCs in sediment and surface water were not compared to the COCs for which there are standards in Rule 08, then an

assessment of the biology is warranted. Site impacts are assessed to determine possible biology impacts for an aquatic life use designation. Determining which aquatic life use designation applies to a given water body is primarily based on the ability of the available habitat to support a given use. Two important factors are involved and include an assessment of the physical habitat and knowledge of what the habitat will biologically support. Ohio EPA sampled bodies of water throughout the entire state, and designated certain sites as "reference sites." These reference sites were then compared to the rest of the sites within the state, and use designations were then applied.

There are 5 different aquatic life use designations: exceptional warmwater habitat (EWH), warm water habitat (WWH), modified warm water habitat (MWH), coldwater habitat (CWH), seasonal salmonid habitat (SSH), which are assessed through biological assessment of fish and macroinvertebrates.

For limited resource water, or lakes, reservoirs, wetlands, or ponds, applicable standards are the absence of toxic effects for growth and mortality as measured through bioassays.

For surface waters with an aquatic life use designation of limited warm water habitat or with no aquatic life use designation, a volunteer must either conduct a use attainability analysis or apply biocriteria for warm water habitat.

Assessing biology for designated use attainability involves assessing habitat quality that support fish and macro invertebrates, sampling biota, and the application of specific metrics to determine if site impacts are affecting the use attainment.

In order to measure how site impacts affect use attainability, biological surveys must be conducted by a person certified by the VAP to conduct biocriteria. Ohio EPA provides training to become certified in biocriteria in Ohio. Separate certificates are issued for fish, macroinvertebrate, and habitat assessment. Alternatively, Ohio EPA can perform the bioassessment under paid technical assistance.

Biological surveys for streams designated as warm water habitat, exceptional warm water habitat, modified warm water

habitat and cold water habitat include the qualitative habitat evaluation index (QHEI), two fisheries metrics: the modified index of well being (MIWB) and the index of biotic integrity (IBI); and the invertebrate community index (ICI). The following slides will outline these surveys in more detail.

For LRW, or wetlands, lakes, ponds, or reservoirs, a sediment bioassay must be performed to determine if toxic effects are present to organisms found in sediment. Two species are used in the 10-day toxicity test: Chironomus tentans, a midge; and Hyalella azteca, an amphipod. The endpoints of the bioassay are mortality and growth. Mortality is calculated for both species, while growth is only calculated for C. tentans. To pass sediment bioassay, it must be shown that an absence of toxic effects exists in both organism groups. Therefore, mortality in test sediments must not differ significantly from the control groups, and growth of organisms in test sediments must not differ significantly form the control groups.

Applicable standards for sediments can be achieved either through a remedy, or through a demonstration that hazardous substances or petroleum on the property are not contributing to the failure of the on-property sediments to meet applicable standards. In other words, if sediments upstream are the culprit, applicable standard for sediments for eco receptors for the subject property can be considered to be met. The off-property "pass-through" demonstration only applies to ecological receptors. Regardless of source, on-property sediment exposures must be protective of human health.

When conducting a property-specific risk assessment, applicable standards consist of the following:

- **Concentration of COCs meeting human health risk goals**
- **Concentration of COCs meeting ecological risk goals**
- **Sediment standards**
- **Surface water standards**
- **Soil saturation values**

For each media, the applicable standard defaults to the lowest value of these standards, after adjusting for the presence of multiple chemicals and pathways.

Each NFA Letter that uses any portion of Rule 09 should include a property-specific risk assessment report. For minor risk issues, the risk report can be contained within the Phase II Assessment. The report should contain the following components, as applicable:

- Reason for PSRA
- List of institutional and/or engineering controls
- List of COCs not considered
- List of exposure pathways
- Derivation of exposure pathways
- Toxicity values
- Risk characterization
- Uncertainty analysis (if conducted)
- Ecological, sediment, surface water assessment
- Summary of compliance with applicable standards

It is important to include a separate report for risk analysis because of the method of review at Ohio EPA. Risk assessors are assigned to projects that have risk issues. When parts of a risk assessment are included as a portion of the Phase II report, it becomes difficult to review the risk portions separately. This adds to the length of time needed for all reviewers to reply to the CP with comments.