

STATE OF COLORADO

COLORADO DEPARTMENT OF HEALTH

Dedicated to protecting and improving the health and environment of the people of Colorado

4300 Cherry Creek Dr. S. Laboratory Building
Denver, Colorado 80222-1530 4210 E. 11th Avenue
Phone (303) 692-2000 Denver, Colorado 80220-3716
(303) 691-4700



Roy Romer
Governor

Patricia A. Nolan, MD, MPH
Executive Director

INTERIM FINAL POLICY AND GUIDANCE ON RISK ASSESSMENTS FOR CORRECTIVE ACTION AT RCRA FACILITIES

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GLOSSARY

Background Levels - defined as the arithmetic mean plus two standard deviations for the data set consisting of samples from unaffected or upgradient areas of the facility.

CDH - Colorado Department of Health

CHWA - Colorado Hazardous Waste Act

CHWR - Colorado Hazardous Waste Regulations

CMS - Corrective Measures Study: A study, undertaken by the facility, to evaluate appropriate remedial alternatives available for the SWMU or release site, given the physical characteristics and chemical constituents present at the site. The CMS includes, at a minimum, an evaluation of the protectiveness, short and long term effectiveness and reliability, implementability, cost, and community acceptance associated with each remedial alternative.

Detection limits - an appropriate detection limit must be used in the analytical program. These detection limits can be found in SW 846, 2nd Edition (available from the Division). Appropriate detection limits include the "estimated quantitation limits" specified in the method description, unless other limits are agreed upon by the Division. In the case of multiple potentially appropriate detection limits, consult the Division.

Soil - as used in this document, "soil" includes surface soils, subsurface soils to a depth of 12 feet (basement foundation excavation depth), and sediments. Sediments are soils associated with, and possibly deposited or reworked by, water; e.g. stream or lake sediments. Contaminated subsurface soils deeper than 12 feet need not be considered in the risk assessment, but will be considered in any subsequent corrective action.

SWMU - Solid Waste Management Unit - Any discernible unit at which solid wastes have been placed at any time, irrespective of whether the unit was intended for the management of solid or hazardous waste.

The Division - the Hazardous Materials and Waste Management Division of CDH

CORRECTIVE ACTION RISK ASSESSMENTS

1.0 STATEMENT OF POLICY AND PURPOSE

This document presents the interim final policy of the Colorado Department of Health, Hazardous Materials and Waste Management Division (the Division), regarding risk assessment methodology and the use thereof in making corrective action decisions at hazardous waste treatment, storage, or disposal (TSD) facilities and hazardous waste generator facilities regulated by the Colorado Hazardous Waste Act (CHWA) and its implementing regulations (CHWR). Corrective action may be required for permitted TSD facilities (CHWR, Section 264.101) and at interim status TSD facilities seeking permits (CHWR, Section 265.5), or at generator facilities where a release of hazardous constituents to the environment has occurred.

Protection of human health and the environment is required in each of the above regulatory citations as the standard for corrective action performance. To ensure this protection, the Division requires application of the following three-screen approach for evaluating the need for corrective action at any Solid Waste Management Unit (SWMU) or release site on a facility.

Screen 1 - The first screen applied to SWMUs or release sites is a comparison to background and/or detection limits. A SWMU or release site would move to the second and third screen if any medium affected by a release contains an analytically determined concentration of contaminant¹ that:

- a) exceeds detection limits (see glossary) for organic compounds except those that are naturally occurring, and/or
- b) exceeds background levels (see glossary) for inorganic and naturally occurring organic compounds.

SWMUs or release sites that meet the levels prescribed in criteria a) and b) are considered "clean" and further action would not be necessary.

Methods to compare contaminant levels in a SWMU or release site to background/detection limit levels (criteria a) and b)) are beyond the scope of this policy (more information on criteria a) and b) is available from the Division). Briefly, however, appropriate detection limits must be used for criterion a) and use of appropriate statistical methods is important for criterion b). In addition, for criterion b), an evaluation of the site-specific data set should be conducted. This evaluation should include a spatial and temporal

¹ For the purposes of this policy, the concentration of contaminants is the total concentration and not the TCLP concentration.

analysis of indicated contamination along with an evaluation of the number of "detects" for each contaminant at the site, data outliers, and data quality.

Screen 2 - The second screen applied to a SWMU or release site is a risk evaluation. Screen 2 only applies when detection limits and/or background, as described in criteria a) and b) above, are exceeded and the medium is not a characteristic hazardous waste. A Corrective Measures Study (CMS), or equivalent, to identify appropriate corrective actions will be required if concentrations of contaminants in the SWMU or release site:

- c) present a risk to human health greater than 1×10^{-6} , using a risk analysis procedure approved by the Division Director, for carcinogenic compounds, and/or
- d) present a Hazard Quotient greater than 1.0 for non-carcinogenic compounds,

Even SWMUs or release sites that do not exceed the risk levels prescribed in criteria c) and d) must move on to Screen 3.

Screen 3 - The third screen applied to a SWMU or release site is comparison of contaminant levels to ground water protection criteria. It is possible that soil contamination at a site is above background, but below risk thresholds, and could still leach unacceptable levels of contaminants to ground water. In this case, a CMS, or equivalent, will be required to identify appropriate mitigation alternatives.

Section 1.1: The remainder of this guidance and policy presents the methodology for evaluating SWMUs and release sites against criteria c) and d) presented in Screen 2.

It is important to note the difference between Risk Assessment, Risk Management, and Corrective Action. Risk assessment only evaluates the risk that contamination poses at SWMUs or release sites. Risk management through a CMS, in turn, evaluates the management options (corrective actions) for sites with excessive risk. Risk Management corrective actions fall into two general categories: management of the risk through appropriate controls (institutional, source, etc.); or management of the risk via cleanup and/or removal of the media exceeding the unacceptable risk levels. The appropriate risk management technique for a given site will be determined after the CMS, or equivalent.

It should also be noted that corrective action is not dependent on or triggered only by risk to human health. As presented above, environmental protection and protection of ground water resources (from migration or leaching of contaminants) could also be the basis for a corrective action.

The risk assessment methodology presented herein is generally

consistent with the methodology presented in Risk Assessment Guidance for Superfund or RAGS (EPA, 1989a). However, the Division has determined that an abbreviated version of the RAGS methodology is sufficient to meet our decision making needs. The remainder of this policy explains how a facility can perform a risk assessment to evaluate the risk levels described in criteria c) and d). This methodology has been approved by the Division Director.

In addition to the policy, this document also provides guidance on the implementation of the policy. The policy and guidance are intended for use by Division staff and the staff of facilities that will be making corrective action decisions.

2.0 RISK ASSESSMENT METHODOLOGY

After data is collected from a site to assess the nature and extent of contamination through implementation of a RCRA Facility Investigation (RFI) Workplan or other sampling plan approved by the Division, the facility may assess where contamination exists that exceeds the detection limits or background levels as indicated in criteria a) and b), or may begin a risk assessment. If possible, the facility should consider whether cleanup of contaminated areas to criteria a) and b) standards is feasible, desirable, or warranted. If cleanup to criteria a) and b) levels will be conducted, no risk assessment is necessary. If not, the risk assessment to delineate areas of contamination that exceed risk levels described in criteria c) and d) can begin.

The risk assessment is subdivided into three main tasks, as follows:

- 1) Exposure Assessment
- 2) Toxicity Assessment
- 3) Risk Characterization

The following sections describe each of these subdivisions of the risk assessment in detail.

3.0 EXPOSURE ASSESSMENT

Generally the exposure assessment consists of three steps: 1) characterization of the exposure setting, 2) identification of the exposure pathways, and 3) quantification of exposure. For corrective action, as is described in Section 3.1, the exposure setting and exposure pathways both must evaluate direct exposure to all contaminated media within, or affected by, a contaminant release. Quantification of exposure is covered in Section 3.2.

3.1: Exposure Setting and Pathways: At any facility, for corrective action purposes, the risk associated with Section 1.0 criteria c) and

d) must be determined:

- 1) assuming certain residential exposure pathways are or will become complete using a residential exposure scenario,
- 2) using the primary "direct-exposure"² pathways in the residential exposure scenario,
- 3) considering children as a sensitive subpopulation for the first six years of the exposure,
- 4) assuming no dilution or attenuation of contamination to the receptor, and
- 5) on a SWMU- or release-specific basis.

These items are discussed further in the following sections.

3.1.1 Residential Exposure: For a corrective action site to be completely released from regulatory control, it is necessary to clean the site to a level that supports unrestricted use. To support unrestricted use, the Division requires on-site residential exposure as the bounding scenario. It is assumed that if the site is cleaned to levels that do not present an unacceptable risk to on-site residents, then it will not present unacceptable risks for any other human use. Therefore, the Division assumes a residential receptor at or within a SWMU or release site and requires that the risk to that receptor be evaluated assuming ingestion, inhalation, and dermal exposure.

Long term future use of any site is difficult to predict. Therefore, even sites that are currently within a large industrial complex must consider the future on-site residential exposure scenario. In these cases, appropriate current and future worker exposure scenarios may also be considered. If the site can be cleaned to a level that does not present unacceptable risk to current and future workers, even though it is not clean enough to support unrestricted use, further cleanup of some portions of the facility may be deferred to a time when use changes. Depending on the types and amounts of contamination, however, monitoring and stabilization of the site are usually necessary during this cleanup deferral period to assure that contamination does not continue to worsen or spread.

3.1.2 Dermal Exposure: Within the residential and worker exposure scenarios described above, the hypothetical resident or worker is placed on or within the SWMU boundary or any additional area affected by a release. Inhalation, ingestion, and dermal contact are the routes of exposure considered for each contaminant.

² "Direct exposure" in this policy shall mean placing a receptor (current/future resident or industrial worker) on or in the source - i.e., the SWMU or release site.

The list of direct exposure pathways that need to be evaluated is limited to the following:

- a) ingestion of soil (see glossary),
- b) dermal contact with soil,
- c) inhalation of soil particles
- d) ingestion of homegrown fruits and vegetables, and
- e) inhalation of indoor air VOCs.

Water-related pathways have not been included. The reason for this is presented in Section 3.1.2.1. In addition, pathway d) should not be applied to workers at facilities, or portions thereof. Details, including intake calculation equations and exposure parameters for each of these pathways, are provided in Appendix A, Tables A-1 through A-9.

3.1.2.1: Water Pathways: For releases of contaminants that consist of, or include, contaminated surface or ground water that exceeds State and/or Federal water quality standards, the Division applies the standards in lieu of an evaluation of the water pathways in the risk assessment. In these cases, the contamination in the water above the standard would require corrective action. The Division applies, for each chemical, the most stringent of the following water quality standards:

- a) protective Colorado water quality standards as set by the Colorado Water Quality Control Commission including, but not limited to:
 - domestic use water supply standards
 - agricultural water supply standards
- b) Safe Drinking Water Act standards
- c) Clean Water Act standards

Cases where no water quality standards exist for specific contaminants will be handled on a case-by-case and site-specific basis by the Division.

3.1.2.2: Soil Pathways: For each area of soil contamination, only certain direct exposure pathways are required to be evaluated and are listed above in Section 3.1.2.

It should be noted again that the ultimate corrective action for soil contamination at a facility must take into account not only direct exposure, but also potential future migration to, and protection of, ground water (i.e. leachability, migration) and other environmental receptors.

3.1.3: Sensitive Subpopulations: The Division requires that, for each pathway considered, exposure parameters for children (age 0 to 6), as a common sensitive subpopulation, be included in the evaluation. Children are a very common subpopulation with unique toxicological and dose-response parameters. The appropriate exposure parameters for children have been included in Appendix A.

Other sensitive populations unique to the site in question may also need evaluation. This will be determined on a facility-specific basis at the discretion of the Division.

3.1.4: Dilution/Attenuation: Because use of the direct exposure route is required, no dilution or attenuation of the contaminant concentrations can be assumed. Arguments relying on fate and transport calculations will not be accepted in the exposure assessment (fate and transport are considered in the corrective action decision).

3.1.5: SWMU- or Release-Specific Risk Evaluation: The decision to take a corrective action will be made by the Division for each SWMU or release site individually. This is clear in CHWR, Sections 264.101 and 265.5. Therefore, the risk evaluation must also be completed for each SWMU or release site that contains contaminated soil (per section 3.1.2.1 and 3.1.2.2 above).

To the extent that contaminated sites are adjacent to one another, have similar contamination, and a probable similar remedy, the corrective action may be combined, but the risk evaluation cannot. If releases from different SWMUs or sites coalesce or overlies one another such that the risk in the area of dual contamination may be higher than when both SWMUs are considered separately, this additive risk must be considered. Alternatively, if a SWMU or release site is sufficiently large and has varying contaminant levels and/or contaminant suites, the site can be subdivided into separate risk evaluations at the discretion of the Division.

3.2: Exposure Quantification: In order to calculate risk, it is first necessary to determine contamination intake of the receptor. Intakes are calculated using standard equations (EPA, 1989a) that include parameters for exposure concentration, contact rate, exposure frequency, exposure duration, body weight, and exposure averaging time. These equations are pathway-specific and appear in Appendix A. For corrective action, direct exposure requires that the exposure concentrations used to calculate intake equal the maximum site contaminant concentrations.

Intakes are expressed in terms of the mass of contaminant in contact with the body (ingested, inhaled, or dermally exposed) per unit body weight per unit time (mg contaminant/kg body weight-unit time or mg/kg-day).

The values for the variable parameters in the equations have been standardized in Appendix A where possible. Some parameters have been assigned default values, but could be adjusted for site-specific conditions by either the facility or the Division. Variations from the default values must be approved by the Division.

The result of the Exposure Quantification is an estimated intake for each chemical in soil for each pathway. An example table shell for exposure quantification is presented in Table A-10 of Appendix A.

4.0 TOXICITY ASSESSMENT

The Toxicity Assessment consists of determining the toxicity values for both carcinogenic and non-carcinogenic effects of site contaminants. Because toxicity information may change rapidly and quickly become outdated or expanded, care must be taken to find the most recent information.

Generally, the two best sources are, in order of preference, the Integrated Risk Information System (IRIS) which is updated monthly and provides verified reference doses (RfDs) and slope factors, and the Health Effects Assessment Summary Tables (HEAST) which provides interim and verified values for RfDs and slope factors. HEAST information should be sought only for those chemicals not listed in IRIS.

Toxicity information may be found in many additional sources such as other EPA documents, the Agency for Toxic Substances and Disease Registry (ATSDR), medical/technical publications, etc. Before using information from references other than IRIS and HEAST, approval of the Division is required.

If toxicity information on a chemical is unavailable, the Division should be consulted. Generally this occurs because the chemical is not suspected of causing detrimental effects to humans, because the current data is being re-evaluated, or because there is insufficient data to develop RfD and slope factor values. The Division will handle these cases individually. Depending on the reason for unavailable toxicity information, the Division may accept a qualitative risk evaluation of the chemical.

If toxicity information is only available for some, but not all, of the routes of exposure being considered, the Division should be consulted. Route-to-route extrapolation may be recommended if appropriate, or the contaminant may be considered only in the pathways with information. Again, the Division will handle these cases individually and may accept a qualitative evaluation of the affected pathways.

The results of the Toxicity Assessment should be RfDs for all non-

carcinogenic constituents and slope factors for all carcinogenic constituents collected for each contaminant in each medium and each pathway. For example, if a site is contaminated with methylene chloride, an RfD and slope factor for methylene chloride should be determined for ingestion, dermal contact, and inhalation since methylene chloride is both a non-carcinogenic toxicant and a class B2 carcinogen.

5.0 RISK CHARACTERIZATION

The final step in the risk assessment process is Risk Characterization. This step combines the exposure and toxicity assessments into a risk calculation. The risk calculation is different for carcinogens and non-carcinogens.

Carcinogens: Carcinogenic risk is calculated by multiplying the contaminant intake in one pathway (from the exposure quantification in Section 3.2) by the slope factor for the contaminant in that pathway. This is done for each contaminant and pathway. These contaminant/pathway specific risks are summed together for a total SWMU- or release-specific risk. This is a three step process: 1) calculate the risk for each chemical in a given pathway, 2) sum all of the risks for all of the chemicals in that pathway, and 3) perform steps 1) and 2) for all pathways and sum all of the pathway risks into a total risk. The numerical result is the excess probability that an individual will develop cancer because of exposure to the site over a lifetime, given the exposure parameters used in the intake calculation and the contaminants at the site. As expressed in Section 1.0, criterion c), any SWMU or release site with a total risk greater than 1×10^{-6} (or 1 added cancer death per million exposed individuals) presents an unacceptable risk to human health and will require a Corrective Measures Study (CMS), or equivalent, to identify appropriate corrective actions to manage the risk.

When possible, organ-specific carcinogenic risk should be evaluated. If the level of risk from the SWMU or release site to any specific organ exceeds 1×10^{-6} , a CMS, or equivalent, will be required to identify appropriate corrective actions to manage the risk. (It should be noted that, when organ-specific risk is evaluated, while the risk to any one organ presented by a contaminated site may not exceed 1×10^{-6} , the total risk from the SWMU or release site could exceed 1×10^{-6} . Where total organ-specific risk does not exceed 1×10^{-6} , a CMS would not be required.)

Non-Carcinogens: Non-carcinogenic effects are expressed as a ratio of the contaminant intake in one pathway (from the Exposure quantification in Section 3.2) to the RfD for that pathway. This ratio is called the Hazard Quotient (HQ). HQs are determined for each contaminant and pathway and then summed together for a total SWMU- or release-specific HQ. This is a three step process: 1)

calculate the HQ for each chemical in a given pathway, 2) sum all of the HQs for all of the chemicals in that pathway, and 3) perform steps 1) and 2) for all pathways and sum all of the pathway HQs into a total HQ. As expressed in Section 1.0, criterion d), any SWMU or release site with a total HQ over 1.0 presents an unacceptable risk to human health and will require a CMS, or equivalent, to identify appropriate corrective actions to manage the risk. An HQ greater than 1.0 implies that the intake of the contaminant(s) at the site will be greater than the intake that is known to cause detrimental effects to humans.

When possible, organ-specific effects should be evaluated. If the hazard from a SWMU or release site to any organ exceeds 1.0, a CMS, or equivalent, will be required to identify appropriate corrective actions to manage the risk. (As with carcinogens, when organ-specific effects are evaluated, even though the HQ for any organ does exceed 1.0. Sites where organ specific HQ from the SWMU or release site could not require a CMS.)

Example tables for both risk and HQ calculation can be found in Appendix A (Tables A-11 through A-14). Case study examples of exposure quantification and risk characterization can be found in Appendix C. This risk assessment procedure lends itself to computer spreadsheet applications. The Division is pursuing these and will make them available at the earliest possible time.

***** Certain aspects of traditional risk assessments have been omitted from the methodology presented in this policy. This includes such items as uncertainty analysis, elimination of essential nutrients, and elimination of an evaluation of water contamination risk. This was done to simplify and standardize the risk determination and methodology as well as to alleviate financial burdens on facilities conducting risk assessments. Should any facility wish to incorporate portions of the risk assessment that are not included herein, they may do so. In particular, these additional risk assessment efforts may be warranted for facilities with risk levels only slightly above the limits presented in Section 5.0. Any such efforts will be considered by the Division, but should be in addition to compliance with the requirements of this policy.

Joan Sowinski 16 Nov. 1993
Joan Sowinski, Program Manager Date
Hazardous Waste Control Program