# **Chapter 1: INTRODUCTION**

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# 1.1 OBJECTIVE AND DOCUMENT ORGANIZATION

The U.S. Environmental Protection Agency's ("U.S. EPA" or "the Agency") Office of Solid Waste (OSW) has developed an approach for conducting multi-pathway, site-specific human health risk assessments on Resource Conservation and Recovery Act (RCRA) hazardous waste combustors. The approach, also known as the Human Health Risk Assessment Protocol ("HHRAP" or "protocol") can be used where the permitting authority determines such risk assessments are necessary. The HHRAP replaces an earlier Peer Review Draft published in July 1998.

**PLEASE NOTE**: for the purposes of this guidance, "we" refers to the U.S. EPA OSW.

The HHRAP is written for the benefit of a varied audience, including risk assessors, regulators, risk managers, and community relations personnel. However, the "you" to which we speak is the performer of a risk assessment: the person (or persons) who will actually put the recommended methods into practice.

Our primary objective in developing the protocol was to offer a user-friendly approach to performing sitespecific combustion risk assessments. We wanted to develop a guidance document that would:

• be useful to a diverse group of users: risk assessors, permit writers, risk managers, and community relations personnel;

- provide a logical method for doing risk assessments of facilities that burn hazardous waste;
- completely explain the reason for each recommended procedure and parameter value;
- provide a comprehensive enough collection of default input parameters to conduct a risk assessment. The collection would also be flexible enough to accommodate regional or site-specific information; and finally
- make sufficient tools available to produce transparent, defensible, and realistic results. When
  coupled with an ecological assessment (U.S. EPA 1999a), these tools would provide critical
  information often needed by risk managers when faced with the decision of permitting a
  hazardous waste combustion facility.

The HHRAP brings together information from other risk assessment guidance and method documents prepared by U.S. EPA and state environmental agencies. It also contains the latest advancements in risk assessment science, as well as experience EPA has gained through conducting and reviewing combustion risk assessments. This version of the protocol also addresses the comments put forward by the public and external scientific peer reviewers regarding earlier drafts of the HHRAP.

The first volume of the HHRAP contains the main body of the document, providing a detailed explanation of a risk assessment approach that we recommend you consider when conducting a risk assessment. The second volume contains the appendices, including:

Appendix A: a collection of chemical-specific information which might be of interest -

- A-1 a compilation (from various EPA sources) of compounds of potential interest;
- A-2 Compound-specific parameter value information. Details the sources of, or
  equations used to calculate, parameter values used in fate & transport-,
  biotransfer-, exposure-, and toxicity-related equations. Parameter values
  themselves are found in a companion database to the HHRAP, which is also
  available for download.

**Appendix B:** Equations and recommended default variable values for estimating media concentrations; and

**Appendix C:** Equations and recommended default variable values for estimating potential cancer risk and non-cancer health effects.

**Please Note**: Although these guidelines address many types of situations encountered in the field, they cannot encompass every potential situation. You should ensure that the recommendations in this guidance are appropriate for the facility, based on site-specific information and/or circumstances.

This protocol is a "snapshot" of current risk assessment science, and we encourage you to evaluate updates and alternatives to the recommended parameters (e.g., toxicological benchmarks; exposure factors) when they become available. If you use alternative values, however, keep in mind how changes in one parameter may affect other parameter values and/or calculations. We may revise the protocol in the future if any of the following become available:

- new research in risk assessment science and/or the combustion field;
- new information gathered while conducting site-specific risk assessments; and
- new initiatives introduced by the Agency.

These types of changes are inevitable in this evolving and highly technical field.

# 1.2 BACKGROUND<sup>1</sup>

Hazardous waste combustors are required to meet RCRA national performance standards and obtain a permit under 40 CFR Part 264, Subpart O; Part 266, Subpart H; and Part 270.<sup>2</sup> In addition, Section 3005(c)(3) of RCRA [codified at 270.32(b)(2)] requires that each permit contain the terms and conditions that the permitting authority considers necessary to protect human health and the environment. This is commonly referred to as the "omnibus authority." The omnibus authority gives the Agency both

<sup>&</sup>lt;sup>1</sup> This section summarizes the historical context of regulatory authority and associated policy regarding hazardous waste combustion site-specific risk assessment under the RCRA program. This discussion is not intended to update, revise or articulate new guidance or policy. Nor is it intended to update, revise or provide any new interpretations of any statutory or regulatory authority, including those relevant to the RCRA 3005(c)(3) "omnibus authority". In addition, it is not intended to reopen for consideration any statutory or regulatory interpretations of other related guidance documents, or the MACT rule (64 FR 52828).

<sup>&</sup>lt;sup>2</sup> When combustion sources demonstrate compliance with the Part 63, Subpart EEE MACT standards, they may request that certain RCRA permit conditions (e.g., those based on the national performance standards) be removed from their RCRA permit, because they are no longer applicable, through a class 1 permit modification request with prior agency approval. In some cases, RCRA performance standards may be retained in the RCRA permit if they are more stringent than the relevant MACT standard.

the authority and the responsibility to set up site-specific RCRA permit conditions as necessary to "be protective of human health and the environment." These permit conditions are intended to supplement, not replace those conditions that are already required under the national performance standards [See Federal Register 1999 (MACT Rule)].

The RCRA national performance standards for incinerators were published in 1981 (40 CFR Part 264, Subpart O) and for boilers and industrial furnaces in 1991 (40 CFR Part 266, Subpart H). Since then, however, new information on indirect exposure pathways and non-dioxin products of incomplete combustion (PICs) suggests that these standards may not fully address all potentially significant risks.

For example the RCRA national standards were based on estimates of risk only from *direct* exposure to (i.e. inhaling) stack emissions. New information suggests risks from *indirect* exposures (e.g. ingesting contaminated soil, food, or water) are also important (Federal Register 1999). Bioaccumulation tends to concentrate some chemicals as they migrate through the environment. These higher concentrations can lead to exposures and risks of concern. For example, Fradkin et al. (1988) linked elevated levels of chemical pollutants in soils, lake sediments, and cow's milk to atmospheric transport and deposition of pollutants from combustion sources. Also, the *1994 Draft Health Reassessment of Dioxin-Like Compounds* (U.S. EPA 1994a), and the 1997 *Mercury Study Report to Congress* (U.S. EPA 1997c), indicate that indirect exposure pathways can lead to significant risks.

Indirect exposure pathways weren't directly taken into account by the 1981 and 1991 hazardous waste combustion standards. The regulations also didn't take into account the uncertainty surrounding the types and quantities of non-dioxin products of incomplete combustion (non-dioxin PICs) or any potential risks posed by these compounds.

To address these concerns, the Agency issued the *Hazardous Waste Minimization and Combustion Strategy* in 1994. This strategy recommended conducting a site-specific risk assessment for each combustion facility seeking a RCRA permit. Permitting authorities could use the results of an assessment to determine, on a case-by-case basis, if a combustor operating in accordance with the performance

standards is protective of human health and the environment. If the permitting authority finds that the combustor operating in accordance with the performance standards is not protective of human health and the environment, the permitting authority would invoke the "omnibus authority" and either add additional conditions to the RCRA permit, or deny the RCRA permit. The permitting authority must explain the reasons for any additional permit conditions in the administrative record of the facility (Federal Register 1999).

In 1999 the Agency updated its earlier site-specific risk assessment recommendation, to account for the Phase 1 Maximum Achievable Control Technology (MACT) standards for hazardous waste incinerators, cement kilns, and lightweight aggregate kilns (see 64 FR 52828). While the Phase 1 MACT standards provide additional protection, we recognize that there may continue to be circumstances for which site-specific risk assessments are appropriate. For example, a site-specific risk assessment might be appropriate if there is reason to believe that operating in accordance with Phase 1 MACT standards alone may not be protective of human health and the environment. So, in the MACT standards rulemaking, we recommend that the permitting authority evaluate the need for a site-specific risk assessment on a case-by-case basis. For hazardous waste combustors not subject to the Phase 1 MACT standards, such as boilers and industrial furnaces, we continue to recommend that site-specific risk assessments generally be conducted as part of the RCRA permitting process (see Federal Register 1999).

As part of the September 2005 rule finalizing MACT standards for hazardous waste-burning incinerators, cement kilns, lightweight aggregate kilns, boilers, and industrial furnaces, we maintain virtually the same the site-specific risk assessment policy recommendation as conveyed in the 1999 final rule preamble (see previous paragraph)<sup>3</sup>. That policy, which establishes that the need for an SSRA should be determined on a case-by-case basis, now applies equally to both Phase 1 and Phase 2 sources.

<sup>&</sup>lt;sup>3</sup> The standards for Phase 1 sources (incinerators, cement kilns, and lightweight aggregate kilns) are referred to as Replacement Standards. The Replacement Standards replace the February 13, 2002 Interim Standards that were developed in response to a court decision to vacate challenged portions of the 1999 Phase 1 MACT final standards. Thus, the 2005 final rule establishes MACT standards for both Phase 1 and Phase 2 (boilers and industrial furnaces) sources.

In addition, the 2005 final rule codifies additional regulatory language that provides the authority for SSRAs. Although a comparative risk analysis conducted for the 2005 final rule concluded that the MACT standards for both Phase 1 and Phase 2 sources are generally protective, there may be instances where we cannot be assured that emissions from each source will be protective of human health and the environment. Because we believe that SSRAs are likely to continue to be necessary at some facilities (i.e., mainly those that have not previously conducted an SSRA), we have codified language in \$\\$270.10(1) and 270.32(b)(3) that explicitly provides for the permit authority to require SSRAs on a case-by-case basis and add conditions to RCRA permits based on SSRA results, respectively. The language also reminds permit authorities that the determination that the MACT standards may not be sufficiently protective is to be based only on factors relevant to the potential risk from the hazardous waste combustion unit at the site. Additionally, guiding factors have been identified for permitting authorities to consider in determining whether the MACT will be sufficiently protective at an individual site. In summary, the 2005 final rule only modifies the statutory authority under which we implement the SSRA policy, while maintaining the same SSRA policy from a substantive standpoint.

#### 1.3 USING THIS DOCUMENT

This document contains our generally recommended approach for conducting multi-pathway, site-specific human health risk assessments of RCRA hazardous waste combustors. This document <u>does not</u> provide recommendations on how to:

# • Determine if a site-specific risk assessment should be performed;

You can find U.S. EPA's most recent recommendations for when, or if, a site-specific risk assessment should be performed, in documentation of the MACT rule, published on September 30, 1999 (Federal Register 1999).

# • Conduct stack emissions testing for a site-specific assessment;

A separate guidance document entitled *Risk Burn Guidance for Hazardous Waste Combustion Facilities* EPA 530-R-01-001, July 2001 (U.S. EPA 2001c) contains approaches for collecting emissions data to support site-specific risk assessments. This document is on the U.S. EPA OSW website at: <a href="http://www.epa.gov/epaoswer/hazwaste/combust/pdf">http://www.epa.gov/epaoswer/hazwaste/combust/pdf</a>s/burn.pdf.

• Develop a site-specific ecological risk assessment;

We'd previously published our recommendations for conducting screening level ecological combustion risk assessments in a separate, companion document to the HHRAP. This companion document, the *Screening Level Ecological Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (SLERAP) Peer Review Draft (U.S. EPA 1999a), is currently undergoing substantial revision. Until revisions are complete, we can't recommend using the SLERAP.

• Use risk assessment results in risk management decisions, such as setting RCRA permit conditions.

Because this protocol is a technical risk *assessment* tool, it does not discuss risk *management* issues, such as how risk managers are to use the provided information (including uncertainty information), the potential for cumulative risks, or target risk levels. U.S. EPA's generally recommended risk and hazard targets can be found in *Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities* (U.S. EPA 1994f). Additionally, EPA Region 6's region-specific risk target recommendations, *Region 6 Risk Management Addendum* (U.S. EPA 1998b), are available on their website at: <a href="https://www.epa.gov/earth1r6/6pd/rcra">www.epa.gov/earth1r6/6pd/rcra</a> c/protocol/r6add.pdf.

**Please Note:** the ultimate decision for how to incorporate risk assessment estimates in risk management decisions rests with the permitting authority.

For your convenience, the HHRAP many of the recommendations found in the above-referenced documents. However, unless we say so explicitly, the HHRAP does not intend to update, revise, or replace any of the information contained in the above-referenced documents.

The HHRAP *does* update and replace the following guidance documents:

- U.S. EPA, Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes, April 15, 1994 Draft and the October 4, 1994 Errata;
- U.S. EPA, Protocol For Screening Level Human Health Risk Assessment at Hazardous Waste Combustion Facilities Volumes 1 & 2, Internal Review Draft, EPA-R6-096-002 February 28, 1997;
- U.S. EPA, *Human Health Risk Assessment Protocol*, Draft Interim Final, April 1998 (CD-Rom version);

• U.S. EPA, *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities - Volume 1-3*, Peer Review Draft, EPA 530-D-98-001A, B & C, July 1998 and the August 2, 1999, Errata.

We anticipate that risk assessments will be completed for new and interim-status facilities, where necessary, when they apply for their RCRA permit. The process we recommend evaluates risks to receptors posed by potential emissions from RCRA-regulated units. We encourage you to use existing and site-specific information throughout the risk assessment process in order to properly evaluate actual regulated operations for any particular combustor. We generally recommend conservative default assumptions only when they will provide confidence that ensuing permit limits will be health protective.

Throughout the HHRAP we offer parameter values for you to consider. These values are based on a number of elements, such as the best science available and professional judgement. Since this is a national level guidance, the recommended values typically reflect national average conditions. The values will be more appropriate for some sites, and less so for others. For example, the type of waterbody near a facility (i.e. lake, river, wetland) may affect the methylation rate of mercury in the waterbody, or the type of fish consumed may affect percent lipid content used in the assessment. So, a value that is reasonable for one facility may be over (or under) protective at a different facility.

In all cases, though, we give the reason for the suggested value. We encourage you to consider our reasoning, in deciding if a more representative estimate of a site-specific value (or range of values) is available and appropriate. If you use values other than those we recommend, you should explore how, or if, those changes may affect other parameter values and calculations used in the assessment. As with values recommended in this guidance, using values other than those recommended here should always be clearly identified and discussed in the risk plan and/or risk assessment (as appropriate). This will ensure clarity and transparency of the final risk assessment results.

You would need considerable time, effort, and funding to investigate the representativeness of all the values (or ranges of values) available in the HHRAP. As a result, you might choose to use only readily available site-specific information in an initial assessment. You could then use the results of that

assessment to determine where (or if) more site-specific risk information should be collected (see Figure 1-1). This allows you to use resources most efficiently and effectively, by focusing resources on areas that are considered "risk drivers", rather than areas that do not appreciably affect the risk outcome. For example, if the assessment shows that the primary pollutant and exposure pathway is mercury in fish, then you could target site-specific data gathering efforts on values related to mercury emissions, surface water concentrations and/or fish consumption. You would not have to spend resources collecting site-specific information that may not affect the final results of the assessment (for example, Manganese exposure through ingestion of produce).

You can also use the HHRAP as a screening tool. For example, a facility with a highly variable waste stream might choose to provide the permitting authority with historical data and assume that all compounds will be retained in the risk analysis. Or you might choose to use more conservative assumptions throughout, to make the assessment fit a more classic "screening level" approach. For example, you could choose *not* to initially investigate the actual land use surrounding a facility, but instead locate all the selected receptors at the area of greatest contaminant deposition. If estimates don't exceed the selected risk target, additional iterations of the assessment may not be necessary. Regardless, every risk assessment is limited by the quantity and quality of:

- Site-specific environmental data;
- Emission rate information; and
- Other assumptions made during the risk estimation process (e.g., fate and transport variables, exposure assumptions, and receptor characteristics).

These limitations and uncertainties are described extensively throughout the main document and the appendices, and are summarized in Chapter 8. You should generally make every effort to reduce limitations and uncertainties in the risk assessment process, since they can affect the confidence in the risk assessment results.

# FIGURE 1-1 HUMAN HEALTH RISK ASSESSMENT PROCESS

#### **Facility Characterization** - Compiling Basic Facility Information (Section 2.1) - Identifying Emission Sources & Estimating Emission Rates (Section 2.2) - Identifying Compounds of Potential Concern (COPC) (Section 2.3) - Estimating COPC Concentrations for Non-Detects (Section 2.4) - Evaluating Contamination in Blanks (Section 2.5) **Exposure Scenario Selection** Air Dispersion and Deposition Modeling - Exposure Setting Characterization (Section 4.1) - Partitioning Emissions (Section 3.2) - Recommended Exposure Scenarios (Section 4.2) - Site-Specific Characteristics Required for Air Modeling (Section 3.3 - Selecting Exposure Scenario Locations (Section 4.3) - Meteorological Preprocessor Data Needs (Section 3.5) - ISCST3 Model Input Files (Sections 3.6) - ISCST3 Model Execution (Section 3.7) - Using Model Output (Section 3.8) - Modeling Fugitive Emissions (Section 3.9) - Modeling Acute Risk (Section 3.10) **Estimating Media Concentrations** - Calculating Air Concentrations in Air for Direct Inhalation (Section 5.1) - Calculating Concentrations in Soil (Section 5.2) - Calculating Concentrations in Produce (Section 5.3) - Calculating Concentrations in Meats, Milk, and Eggs (Sections 5.4 through 5.6) - Calculating Concentrations in Drinking Water and Fish (Section 5.7) **Quantifying Exposure** - Inhalation Exposure Pathways (Section 6.1) - Ingestion Exposure Pathways (Section 6.2) - Dermal Exposure Pathways (Section 6.3) - Exposure Frequency (Section 6.4) - Exposure Duration (Section 6.5) Averaging Time (Section 6.6) Characterizing Risk and Hazard - Quantitatively Estimating Cancer Risk (Section 7.1) - Quantitatively Estimating Noncancer Hazard (Section 7.2) - Target Levels (Section 7.3) - Estimating Acute Exposure from Direct Inhalation (Section 7.4) **Interpreting Uncertainty** - Understanding Uncertainty and Limitations of the Human Health Risk Assessment Process (Section 8.1) - Identifying Types of Uncertainty (Section 8.2) Determining Qualitative Uncertainty (Section 8.3) - Determining Quantitative Uncertainty (Section 8.4) - Discussing Human Health Risk Assessment Uncertainty (Section 8.5) Risk Assessment Risk Management Use Additional Collect Additional Site-Specific Information Site-Specific Information To Reevaluate Risk NO NO Risk

Develop Protective Operating Permit

U.S. EPA Region 6 Multimedia Planning and Permitting Division Center for Combustion Science and Engineering

Deny Permit

Acceptable?

Issue Permit

YES

The EPA Information Quality Guidelines (U.S. EPA 2002c) recommend ensuring the objectivity of information found in risk assessments by applying, to the extent practicable and consistent with Agency statutes and existing legislative regulations, the following adaptation of the quality principles found in the Safe Drinking Water Act (SDWA) Amendments of 1996:

- (A) The substance of the information is accurate, reliable and unbiased. This involves the use of:
  - (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and
  - (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).
- (B) The presentation of information on human health, safety, consistent with the purpose of the information, is comprehensive, informative, and understandable. In a document made available to the public, EPA specifies:
  - (i) each population addressed by any estimate of applicable human health risk;
  - (ii) the expected risk for the specific populations affected;
  - (iii) each appropriate upper-bound or lower-bound estimate of risk;
  - (iv) each significant uncertainty identified in the process of the assessment of risk; and
  - (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.

How risk results are viewed by the risk manager and other stakeholders is complex and can involve other factors besides those included in this document (e.g. public concern). Consequently, interpreting risk assessment results warrants careful consideration. Risk management decisions are beyond the scope of the HHRAP, and we don't provide any guidance on interpreting risk results. It should be noted, though, that identifying potentially unacceptable risks does not necessarily signify the end of the risk assessment process. You can view risk assessments as an iterative process<sup>4</sup>, with a number of available options once risk estimates are produced. The iterative nature of the risk assessment/risk management interface is graphically represented in Figure 1-1, and the various available options are briefly described below:

<sup>&</sup>lt;sup>4</sup>As stated in the U.S. EPA (2002c) "Risk assessments may be performed iteratively, with the first iteration employing protective (conservative) assumptions to identify possible risks. Only if potential risks are identified in a screening level assessment is it necessary to pursue a more refined, data-intensive risk assessment. The screening level assessments may not result in "central estimates" of risk or upper and lower-bounds of risks. Nevertheless, such assessments may be useful in making regulatory decisions..."

- **Example 1**: If the initial risk estimates (coupled with any other related factors) indicate that risks are not expected to pose a concern to human health or the environment, the risk manager and/or permit writer will likely end the site-specific risk assessment process and the facility will likely receive a permit.
- **Example 2**: If the initial risk estimates (coupled with any other related factors) indicate that the risks are at or above a level that may pose a risk to human health or the environment, then additional information might be added to the risk assessment (e.g. site-specific information that's more representative of the actual exposure settings). Additional iterations of the risk assessment could then be performed. This iterative process enables you to determine if the risks identified in the earlier assessment accurately represent the situation at a given combustion facility.
- **Example 3**: If the initial risk estimates (coupled with any other related factors) or subsequent iterations (as detailed in Example 2 above), indicate potentially unacceptable risk, risk managers and/or permit writers might use the results of the risk assessment to propose revised or additional permit conditions (such as waste feed limits and/or process operating conditions) to lower the potential risk to acceptable levels. Another risk assessment could verify that the proposed permit conditions will enable the combustor to operate in a manner that's protective of human health and the environment.

In some situations, target risk levels might be selected and back-calculations conducted to determine what emission and/or waste feed rate would allow the facility to operate in a protective manor. In any case, the acceptable waste feed rate and other appropriate conditions could be incorporated into the RCRA permit.

**Example 4**: If the initial risk estimates or subsequent iterations (coupled with any other related factors) indicate potentially unacceptable risk, risk managers and/or permit writers might also choose, where appropriate, to deny the permit.

The HHRAP may also be useful when a facility or regulatory agency decides to perform a pre-trial burn risk assessment. A pre-trial burn risk assessment can evaluate pre-existing permit limits (e.g. regulatory limits such as MACT or BIF) to determine if more extensive or refined risk-based testing is necessary as part of the trial burn testing program. Also, the pre-trial burn risk assessment can test the parameters used in the initial trial burn sampling and analysis plan. Testing trial burn parameters minimizes trial burn contributions to risk assessment uncertainty, and avoids the expense of multiple trial burn iterations. For example, if the initial detection or quantitation limit for a specific compound (such as a dioxin, furan, or bioaccumulative metal) is too high during trial burn sampling and analysis, then the final risk estimate may be artificially inflated, especially for indirect exposure pathways. If trial burn sampling and analysis

uses a *lower* detection or quantitation limit, the compound might be found not to add appreciably to the risk results. The pre-trial burn risk assessment can also determine whether modifications to the sampling collection (such as increased sample volumes) are needed to achieve lower detection or quantitation limits. Please see Chapter 2 for more detailed information on how risk assessments relate to trial burns.

# 1.4 PRIMARY REFERENCE DOCUMENTS

One of the main benefits of the HHRAP is that it assembles in one place more than a decade of research and experience regarding practices for conducting risk assessments of hazardous waste combustion facilities. This section describes, in chronological order, the *primary* guidance documents we used to prepare the HHRAP. Many other important reference materials were also needed to produce a document of this magnitude. We have listed *all* reference materials used in preparing this document in the Reference chapter.

Some of the documents we used were themselves developed over a period of several years, including revisions. In some cases, revisions to the original document address only specific issues rather than a complete revision of the original document. The following discussion lists and briefly describes each document. Overall, the guidance documents listed below reflect a continual refining and enhancing of the risk assessment method.

The following was the first U.S. EPA guidance document for conducting risk assessments at combustion units:

**U.S. EPA. 1990e.** *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions, Interim Final.* Environmental Criteria and Assessment Office. ORD. EPA-600-90-003. January.

Referred to as the "IEM" document, EPA (1990e) outlines and explains a set of general procedures for conducting risk assessments that includes both the direct inhalation pathway and indirect food chain pathways. The IEM document was subsequently supplemented by the following:

**U.S. EPA. 1993f.** Addendum to the Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions, Review Draft. Office of Health and Environmental Assessment. ORD. EPA-600-AP-93-003. November 10.

Referred to as the "Addendum", EPA (1993f) outlines recommended revisions and added new exposure pathways to the previous U.S. EPA guidance (1990e), and has been used by the risk assessment community since its release.

In 1994, we issued several additional hazardous waste combustion risk assessment documents, including:

**U.S. EPA. 1994f.** *Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities.* OSWER. EPA-530-R-94-021. April.

This document (1994f) is made up of a series of four attachments, all issued around the same time frame (April/May 1994) as separate documents:

**U.S. EPA. 1994g**. Draft Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes. Attachment C, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities. April 15.

**U.S. EPA. 1994h**. Table 1, "Chemicals Recommended for Identification," and Table 2, "Chemicals for Potential Identification." *Attachment A, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities*. April 15.

**U.S. EPA. 1994i.** Draft Revision, Implementation Guidance for Conducting Indirect Exposure Analysis at RCRA Combustion Units. Attachment, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities. April 22.

**U.S. EPA. 1994j**. Draft Guidance on Trial Burns. Attachment B, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities. May 2

Combined, these four documents present a generally recommended procedure for sampling the combustor emissions, identifying the compounds of concern, conducting both a direct and indirect risk assessment, and implementing the results of the risk assessment for hazardous waste combustion facilities. We used the methodologies identified in both the ORD "IEM" and "Addendum" documents as the foundation of

our hazardous waste combustion risk assessment methodology. The "IEM" and the "Addendum" were broader in scope than our document. We used many, but not all, of the methods, models and exposure scenarios that are described in the two ORD documents. Because the ORD documents contain much of the background information necessary to complete a risk assessment, that information was not repeated in our guidance documents. Shortly after the release of our documents, the trial burn portion and the risk assessment portion were further revised with the following releases:

**U.S. EPA. 1994n**. *Draft Revision of Guidance on Trial Burns*. *Attachment B, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities*. OSWER. June 2.

**U.S. EPA. 1994p**. Errata, Draft Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes. Attachment C, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities. October 4.

As a follow-up to these documents, we prepared another draft guidance. The following was released for internal review, but never formally or officially released as a program-supported document:

**U.S. EPA. 1994r**. Revised Draft Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes. Attachment C, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities. Office of Emergency and Remedial Response. OSW. December 14.

In 1997, the state of North Carolina's Department of Environment, Health, and Natural Resources (DEHNR) developed the following guidance document for conducting risk assessments in their state:

**NC DEHNR. 1997**. North Carolina Protocol for Performing Indirect Exposure Risk Assessments for Hazardous Waste Combustion Units. January.

The NC DEHNR document reiterates U.S. EPA procedures (1994r), with the addition of a tiered approach that can help the regulatory agency or facility to choose approaches that reflect the investment they want to make in conducting risk assessments. For instance, a small, on-site unit with limited waste stream variability may find the first tier assessment (worst-case) in the North Carolina protocol appropriate, whereas a larger facility with a diverse waste feed mixture may decide to complete a Tier 2 or Tier 3 assessment, which are progressively more site-specific.

In 1998, the ORD revised, updated and combined the "IEM" and the "Addendum" documents into one document, entitled:

**U.S. EPA 1998**. *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions* (U.S. EPA 1998c).

This document is referred to as the "MPE" document. It includes information which was gained from cross-Agency review, EPA's Science Advisory Board (SAB) and the public on the "IEM" and the "Addendum" documents. It also includes information from the draft dioxin reassessment "Estimating Exposure to Dioxin-Like Compounds" (U.S. EPA 1994a) and the "Mercury Study Report to Congress" (December 1997). As with the MPE's predecessor documents, it is considered the foundation of our hazardous waste combustion risk assessment methodology and is frequently referenced in the HHRAP.

In 1999 we released a technical document that detailed the risk assessment conducted to support the hazardous waste combustion Maximum Achievable Control Technology (MACT) standards:

**RTI 1999**. The Background Information Document to the Risk Assessment Support to the Development of Technical Standards for Emissions from Combustion Units Burning Hazardous Wastes Final Report. EPA Contract Number 68-W6-0053.

To ensure consistency, we considered EPA(1999) throughout the development of the HHRAP.

Finally, in 2001 we updated and finalized the document entitled:

U.S. EPA 2001c. Risk Burn Guidance for Hazardous Waste Combustion Facilities, July.

Referred to as the "risk burn guidance," EPA(2001c) was prepared by U.S. EPA Region 4 and U.S. EPA OSW. It details recommendations regarding stack emissions tests which may be performed at hazardous waste combustion facilities to support site-specific risk assessments.

As previously stated, our primary objective in developing the HHRAP was to suggest a user-friendly approach to performing site-specific combustion risk assessments. The HHRAP achieves this goal by

offering a comprehensive set of tools. You will no longer need to search through a long list of guidance documents to find an appropriate method and/or value when conducting a site-specific risk assessment of a hazardous waste combustor. Instead, you have one self-contained document with the majority of all the available information needed to complete a risk assessment. With the HHRAP's extensive reference list, you also have the original source of a method and/or value. This simplifies the process of deciding if the reference is appropriate to use for your specific situation.

# 1.5 RISK NOMENCLATURE

Unless otherwise stated, the following definitions for risk-related terms are from the National Academy of Sciences 1983, *Risk Assessment in the Federal Government*, and used throughout this guidance:

Risk Assessment T	The scientific evaluation	n of potential hea	Ith impacts that ma	v result from
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exposure to a particular substance or mixture of substances under

specified conditions.

**Hazard** An impact to human health by chemicals of potential concern.

**Risk** An estimation of the probability that an adverse health impact may occur

as a result of exposure to chemicals in the amount and by the pathways

identified.

**Dose** The amount of a substance available for interaction with metabolic

processes or biologically significant receptors after crossing the

exchange boundary of an organism (U.S. EPA 1998c).

**Exposure** The condition of a chemical contacting the exchange boundary of an

organism (U.S. EPA 1998c).

**Indirect Exposure** Resulting from contact of human and ecological receptors with soil,

plants, or waterbodies on which emitted chemical has been deposited. For screening level purposes, indirect exposure includes ingestion of above ground fruits and vegetables, beef and milk, chicken and eggs,

freshwater fish and soil.

**Direct Exposure** Exposure via inhalation.