PNNL-25791

Hanford Tank Farm Occupational Exposure and Risk Assessment Plan

Health Process Project

September 2016

C Timchalk
X-Y Yu

Prepared for the U.S. Department of Energy
under Contract DE-AC05-76RL01830

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Pacific Northwest National Laboratory
Richland, Washington 99352

Summary

The overall objective of the Hanford Tank Farm Occupational Exposure and Risk Assessment Plan (hereafter referred to as the "Assessment Plan") is to provide the Tank Operations Contractor (TOC), Washington River Protection Solutions (WRPS), and the U.S. Department of Energy (DOE) with a plan for developing a transparent, peer-reviewed process for assessing potential health risks associated with worker exposures to chemical emissions from the Hanford tank farms. When fully implemented, the recommendations from the Assessment Plan will facilitate future risk management decisions that are grounded in state-of-the-science measurement, simulation, and assessment practices. This Assessment Plan is based upon recommendations provided by the independent Tank Vapor Assessment Team (TVAT) that focused on dose-response and risk characterization. The assessment approach will interface with other ongoing activities focused on site characterization, exposure assessment, risk management and communication. The plan will establish a transparent framework for prioritization of tank farm chemical waste constituents of concern and establish a process for proposing new Occupational Exposure Limits (OELs) for both transient acute and chronic exposures to workers at the Hanford Tank Farms.

A critical element of this Assessment Plan is the recommendation that TOC establish a standing Hanford Tank Farm Occupational Exposure and Risk Assessment Advisory Team (hereafter referred to as the "Assessment Team") that is made up of a diverse group of members from TOC (or other Hanford contractors), Pacific Northwest National Laboratory, DOE, and local/regional academic and medical institutions that have the necessary scientific backgrounds to interpret and use existing and new information associated with the Hanford tank farm emissions (e.g., chemistry, toxicology, risk assessment, industrial hygiene, occupational medicine, health physics, exposure and dosimetry modeling, etc.). The Assessment Team will be responsible for prioritizing emission constituents by categories of concern, recommending OELs for emission constituents with known toxicity profiles, or, where unknown, defining a strategy for addressing critical knowledge gaps. The Assessment Team will serve as a central resource for TOC that will be responsible for the integration of all information about tank farm emissions, exposure guidelines, and critical data or research needs that enable risk management decisions and stakeholder communication.

To ensure transparency and that the assessment processes incorporate the latest information and best practices, we further recommend that an External Advisory Committee (EAC) be established to review all processes and recommendations for OELs and research recommendations prior to their implementation. Members of the EAC should include well-established, nationally or internationally recognized scientists, risk assessors, and stakeholders who can serve multi-year appointments to maintain continuity and "corporate memory."

The Assessment Team will require administrative support to facilitate scheduling, meetings, record-keeping, budgets, and reporting requirements. Information Technology technical support will also be needed to develop and maintain a Hanford database of constituent analyses, exposure measurements, industrial hygiene surveys, and key scientific literature and exposure guidelines through either commercially available or in-house–developed software. This database should have a user-friendly, secure interface that is accessible to registered contributors and users of the data and information.

Once the overall Assessment Plan has been reviewed, evaluated, and refined, a detailed implementation plan should be developed to establish the Assessment Team, EAC, and Hanford tank farm database and associated budgets, timelines, and milestones. The proposed overarching strategy with specific functional components is illustrated in Figure S.1. The strategy should exploit both measurement science and computational modeling technologies to inform the risk assessment process. The resulting risk assessments will be transparent and effectively communicated between all key stakeholders.

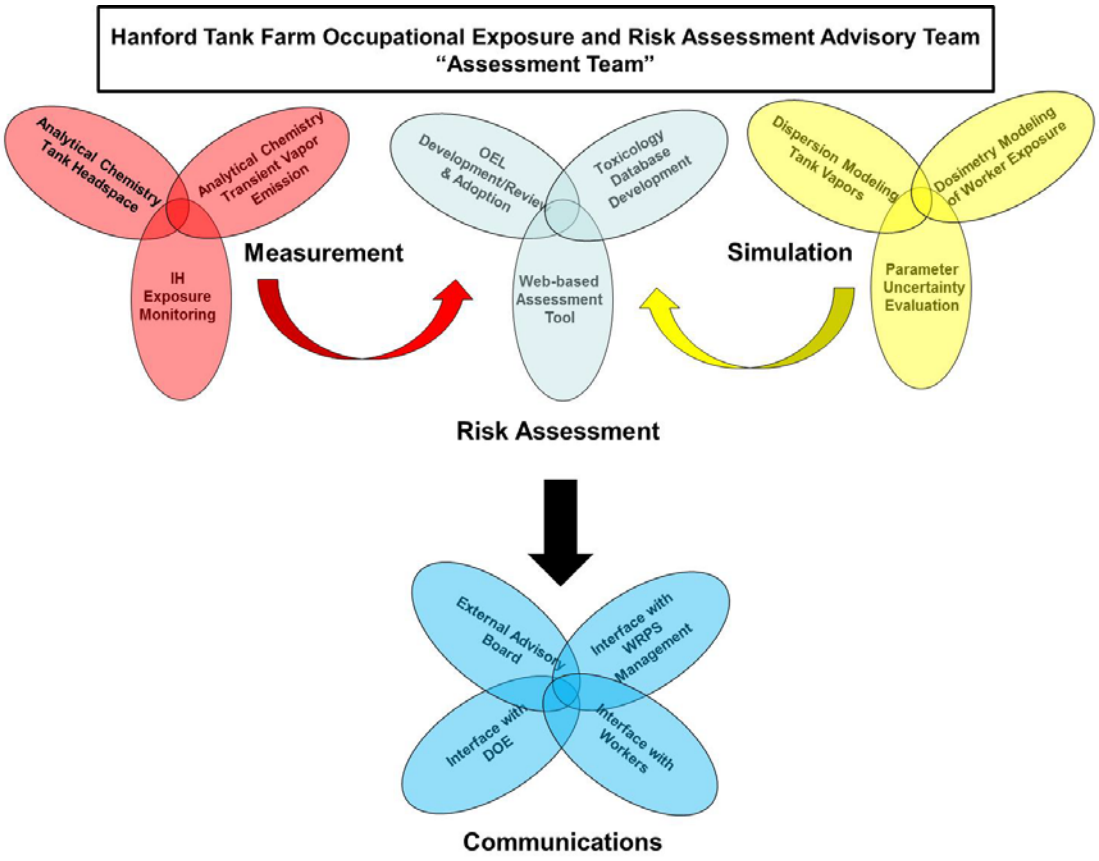

Figure S.1. Functional Components of the Assessment Team

Acronyms and Abbreviations

AEGL	(EPA) Acute Exposure Guideline Levels
ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygienist Association
AOEL	Acceptable Occupational Exposure Limit. OELs developed for Hanford tank farm chemicals without existing regulatory guidelines.
ANSI	American National Standards Institute
ATSDR	Agency for Toxic Substances and Disease Registry
BMD	benchmark dose
BMDL	BMD Limit
CAS	Chemical Abstracts Service
CFD	computational fluid dynamics
CMM	Chemical Mixture Methodology
COPC	chemical of potential concern
DOE	U.S. Department of Energy
DR	dose-response
EAC	External Advisory Committee
ED10	effective dose10
EPA	U.S. Environmental Protection Agency (references to particular U.S. state or foreign country EPAs are so noted)
ERPGs	Emergency Response Planning Guidelines
HCN	Health Code Number (or Health Council of the Netherlands)
hr	hour(s)
HSDB®	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
IH	industrial hygiene
IT	information technology
kg	kilogram(s)
LC_{50}	Lethal Concentration for 50% of test population
LD_{50}	Lethal Dose for 50% of test population
LC_{LO}	Lethal Concentration Low; the lowest concentration at which death occurred
LOEL	lowest observed effect level
MF	modifying factor

mg	milligram(s)
min	minute(s)
MOA	mode of action
NAS	National Academy of Science
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NOELs	no-observed-effect levels
NTP	National Toxicology Program
OECD	Organization for Economic Cooperation and Development
OEL(s)	Occupational Exposure Limit(s)
OEL-C	Occupational Exposure Limit-Ceiling
OR	overarching recommendation
OSHA	Occupational Safety and Health Administration
PAC	Protective Action Criteria
PBPK	Physiologically Based Pharmacokinetics
PEL	Permissible Exposure Limit
POD	Point of Departure
ppm	parts per million
ppmV	parts per million volume
PNNL	Pacific Northwest National Laboratory
QSAR	Quantitative Structure-Activity Relationship
RCH	risk characterization
REL	Recommended Exposure Limit
RfC	Reference Concentration
RTECS®	Registry of Toxic Effects of Chemical Substances
SAR	Structure-Activity Relationship
SCAPA	DOE Subcommittee on Consequence Assessment and Protective Actions
SEAL	Submarine Escape Actin Levels
SMAC	Spacecraft Maximum Allowable Concentration
SRNL	Savanah River National Laboratory
TCD	Tank Characterization Database
TEEL	Temporary Emergency Exposure Limit
TLV	Threshold Limit Value (ACGIH-specific)
TVAT	Tank Vapor Assessment Team
TWA	time-weighted average
TOC	Tank Operations Contractor

TOXNET®	The Toxicology Data Network
TWINS	Tank Waste Information Network System
UF	Uncertainty Factor
WEEL	Workplace Environmental Exposure Limit
WRPS	Washington River Protection Solutions

Contents

1.0 Introduction

The Savannah River National Laboratory (SRNL), at the request of Washington River Protection Solutions (WRPS), assembled a panel of nationally recognized experts to assess worker exposure and potential health issues associated with Hanford waste tank vapors. Experts in the fields of occupational and environmental health, environmental engineering and science, toxicology, health physics and industrial hygiene conducted the scientific and technical assessment. This expert panel—known as the Tank Vapor Assessment Team (TVAT)—issued its final report entitled, "Hanford Tank Vapor Assessment Report," in October 2014 (SRNL 2014). The TVAT report included 10 overarching recommendations (ORs) reflecting the scope of the issues identified across all technical assessment areas and more than 40 specific recommendations for improvements (for details see SRNL 2014). This Assessment Plan is focused on the specific recommendations associated with dose-response (DR) in the TVAT report and risk characterization (RCH) for both current and future tank vapor chemicals of potential concern (COPCs). The specific recommendations, as they were designated in the TVAT report, include the following:

> **DR-1.** Conduct an additional review and re-prioritization of COPCs under tank-disturbing conditions to provide adequate emission characterization, OEL [Occupational Exposure Limit] development, and worker exposure surveillance.
>
> **DR-2.** Conduct a rigorous review of the COPC list to ensure it is current, and develop a process to document the mechanisms used to ensure COPC updates and the basis for changes in the COPC list over time.
>
> **DR-3.** Conduct additional evaluations of COPC toxicological studies to provide insight into the sensory and pathophysiological irritation response, including the role of mixture interactions and the potential need for additional toxicological evaluation.
>
> **DR-4.** Perform a comprehensive evaluation of acute odor thresholds and toxicity effect levels for all COPCs to facilitate the establishment of action levels based upon the relationship between odor and toxicity thresholds.
>
> **DR-5.** Continue to evaluate COPC OEL's within the context of observed symptomatology, verses 10% of the irritation thresholds and develop a "new" acute OEL list.
>
> **DR-7.** Evaluate tank vapor mixture toxicological interactions at concentrations associated with transient plume exposures to modify OELs to accommodate mixture effects.
>
> **DR-9.** Develop a research strategy roadmap in partnership with DOE, National Laboratories, and University faculty subject matter experts to address critical questions regarding tank vapor emissions and exposures.
>
> **RCH-1.** Identify an Occupational Exposure Limit-Ceiling (OEL-C) for each constituent in Hanford tank head space(s).
>
> **RCH-2.** Classify and conduct toxicological testing on a reasonable number of distinct types of Hanford tank headspace vapors (e.g., potential classes of tank vapor types such as ammonia rich, ammonia poor, nitrosamine rich, etc.).

RCH-3. Use the OEL-C from analysis or subsequent toxicological testing to characterize the hazard index and risk from the tank vapor mixtures, and control to 10% of the value.

RCH-4b (Acute). Transient vapor/gas exposures concentrations (i.e., high dose rate) are substantially greater than what is currently measured as a TWA [time-weighted average]; alternative strategies for evaluating transient plume like vapor exposures is recommended and adherence to excursion limit principles must be implemented (3 times OEL) in the absence of appropriate OEL-C values.

Although the Assessment Plan focuses on implementation of specific recommendations associated with DR and RCH, the overarching goal is to interface with key ongoing activities noted in the TVAT report that deal with site characterization, exposure assessment, risk management and stakeholder communications (see Figure S.1). The ORs, as designated in the TVAT report, include the following:

OR3. Establish a program to sample proactively the headspace of tanks to validate and enhance chemical characterization.

OR4. Accelerate development and implementation of a revised IH [industrial hygiene] exposure assessment strategy that is protective of worker health and establishes stakeholder confidence in the results for acute as well as chronic exposures.

OR5. Modify the medical case evaluation process and reporting procedures to recognize the appropriate uses and limitations of the available monitoring data and other potential exposure information when evaluations are made regarding tank chemical vapor exposures.

OR6. To reduce the impacts of bolus exposures, utilize real-time personal detection and protective equipment technologies specifically designed to protect individual employees.

OR7. Accelerate implementation of tailored engineering technologies to detect and control vapor emissions and exposures experienced in the Hanford tank farms ("tank farm of the future").

OR9. Effectively communicate vapor exposure issues and actions proactively with all stakeholders.

To successfully implement the specific DR and RCH recommendations and achieve integration with other key activities recommended in the TVAT report, this Assessment Plan recommends that a Hanford Tank Farm Occupational Exposure and Risk Assessment Advisory Team be established along with an External Advisory Committee (EAC) that will serve as a central resource to TOC and DOE (see Sections 4 and 5 and the Appendix for details).

2.0 Key Elements of the Assessment

The assessment involved processes for prioritizing constituents of concern and for proposing exposure limits.

2.1 Process for Prioritizing Constituents of Concern

Because of the large number of chemicals (>1800) present or predicted to be present in the Hanford tank headspaces (Burgeson et al. 2004), a process must be established to prioritize assessments of (COPCs) that could be present in the worker's breathing zone. In 2004, Pacific Northwest National Laboratory (PNNL) established such a process by grouping chemicals present or potentially present in tank headspace into categories of toxicological concern for occupational inhalation exposure based upon previously established occupational and chronic allowable exposure levels (Burgeson et al. 2004). Upon reviewing this approach, the TVAT report authors noted a number of limitations that warranted modification of the process. First, health impacts from radiolytically generated free radicals need to be considered within the COPC prioritization strategy. Some of these radicals may be highly transient in nature (i.e., difficult to measure), but capable of producing significant respiratory system irritation following acute inhalation exposure. Secondly, exposure to aerosols has not been previously considered, and needs to likewise be a component of the current evaluation and prioritization strategy. Finally, to help facilitate differentiation between odor and respiratory irritation effects, the dosimetric relationship between odor and irritant thresholds needs to be determined and included in the evaluation process.

For the majority of chemicals originally identified in tank headspaces that had no acceptable occupational exposure data or OELs, PNNL developed a process for identifying the chemicals that would be further assessed for potential health risk to tank farm workers (Poet et al. 2006). The process involved establishing headspace chemical concentration screening values using available industrial hygiene and toxicological data. The screening values were defined as the chemical concentrations being an order of magnitude below concentrations that may cause adverse health effects in workers (40 hours/week occupational exposure). The screening values were then compared to the maximum reported headspace concentrations; any concentrations that exceeded the screening value were further evaluated. The report by Poet et al. (2006) assigned screening values to 606 chemicals, of which 72 were determined to be in the tank headspace at or above these values.

Each of these methods used in the past to prioritize COPCs from tank farm headspace measurements should be exploited as starting points for future assessments. However, additional information that addresses the potential transient nature of occupational exposures needs to be developed and supplemented with additional approaches such as

- computational modeling of headspace emissions under static and tank-disturbing conditions;
- fate and transport of emissions within the tank farm local environment;
- quantitative structure-activity determinations for identifying potentially toxic constituents;
- computational models for predicting constituent uptake in the body; and
- establishment of screening procedures for evaluating hazardous properties of headspace mixtures (e.g., based upon common modes of action such as irritation, cytotoxicity, inflammation, mutagenicity, etc.) as new data become available.

Furthermore, a process must be developed to ensure COPCs are regularly updated and the reasons for any changes are documented as new information becomes available. Additional details are provided in the Appendix.

2.2 Process for Proposing Exposure Limits

Prior approaches for developing OELs for the Hanford tank farms focused upon worker exposures that may cause adverse health effects over a normal workday or workweek (Poet and Timchalk 2006). The strategy for screening COPCs and assigning AOELs is described in detail in the Appendix (A.2 and A.3). In addition, as recommended in the TVAT report (SRNL 2015), new procedures must be established for setting short-term guidelines for episodic exposures (see the Appendix for details).

The need for the establishment of short-term guidelines is based upon the following TVAT assertion:

> *The TVAT developed a hypothesis that vapors coming out of tanks in high concentration (bolus) plumes sporadically intersected with the breathing zones of workers, resulting in brief but intense exposures to some workers. The TVAT then sought additional data and information to support or refute the hypothesis. The hypothesis was substantiated by computer modeling, which indicated that under certain weather conditions, concentrations approaching 80% of the head space concentration could exist 10 feet downwind from the release point and potentially in workers' breathing zones. To affirm further the likelihood of a causal linkage between tank vapor exposure and the adverse health effects reported by tank farm workers, the TVAT applied the principles of Hill's Criteria of Causation. Established by English epidemiologist Sir Austin Bradford Hill in 1965, Hill's Criteria of Causation comprise a group of minimal conditions necessary to provide adequate evidence of a causal relationship between an incident and a consequence. Based on the body of data and information the team has examined, analysis of the Hill's criteria strongly suggests a causal link between chemical vapor releases and subsequent health effects, particularly upper respiratory irritation, experienced by tank farm workers.*

To accomplish this goal, initially exploiting the approaches established by the National Academy of Science (NAS) Subcommittee on Acute Exposure Guideline Levels (AEGLs) (NAS 2001) and DOE Protective Action Criteria (PACs) are recommended. . The AEGLs were developed for once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals. The AEGLs are threshold exposure limits ranging from 10 min to 8 hr (10 min, 30 min, 1, 4, and 8 hr) of exposure with three levels of toxic-effect severity defined by NAS (2001) as follows:

- **AEGL-1** is the airborne concentration (ppm or mg/m^3) of a substance above which it is expected the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
- **AEGL-2** is the airborne concentration (ppm or mg/ m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.
- **AEGL-3** is the airborne concentration (ppm or mg/ m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

The NAS process is currently the most comprehensive, peer-reviewed approach for recommending short-term exposure limits for acutely toxic chemicals. Therefore, it is a strong foundation for establishing recommended occupational exposure levels for tank farm occupational exposures with the acknowledgment that additional refinements might be required to address transient mixed chemical exposures in the tank farms. DOE developed PACs based on AEGLs and Emergency Response Planning Guidelines (ERPGs) (Rusch 1993; Rusch et al., 2000; Rusch et al., 2002), and Temporary Emergency

Exposure Limits (TEELs), in that priority, as the emergency exposure limits (DOE 2005, 2010, 2012). Similarly, successive PACs (i.e., PAC-1, -2, and -3) are benchmark values associated with increasingly severe acute health effects due to short-term (60 min) exposures (DOE 2008) (for details see: Appendix A.3).

It is important to emphasize that any initial recommendations for OELs, must be independently peer-reviewed. After revising the exposure guidelines based upon the external peer review the recommendations and supporting documentation will be submitted to TOC and DOE for final review and approval. It should also be emphasized that for many, if not most of the chemicals that have historically been measured in the headspaces of waste storage tanks at the Hanford tank farms, insufficient toxicological data are available for establishing short-term exposure guidelines under the NAS process. Consistent with the TVAT report recommendations, alternative strategies will need to be considered. These strategies should include, but not be limited to, establishing short-term excursion limits for chemicals with some limited data (Jayjock et al. 2000), recommending preliminary total organic/inorganic chemical exposure levels based upon known highly toxic constituents, recommending additional testing for prioritized COPCs or representative headspace mixtures, or developing computational exposure and dosimetry models based upon physical/chemical properties, Quantitative Structure-Activity Relationship (QSAR), etc. to establish preliminary exposure limits.

3.0 Hanford Tank Farm Occupational Exposure and Risk Assessment Advisory Team

Establishment of a standing Hanford Tank Farm Occupational Exposure and Risk Assessment Advisory Team (Assessment Team) is an essential component of the response to recommendations of the TVAT report (SRNL 2014). The Assessment Team will serve as a central resource for TOC and DOE and will be responsible for the integration of all information about tank farm emissions (including analytical data, simulations, and industrial hygiene surveys), establishment of exposure guidelines for constituents with known toxicities, prioritizing constituents for toxicity screening (individual components or mixtures), and recommending screening approaches that enable more effective risk management decisions and stakeholder communication.

Roles & Responsibilities of Assessment Team

- Establish Team Charter for organization, membership, record-keeping, decision processes, and communications.
- Prioritize constituents and mixtures for toxicity screening.
- Establish standard operating procedures and recommended exposure guidelines for constituents of concern.
- Develop and maintain an information database on tank farm analyses, exposure monitoring, and peer-reviewed literature.
- Organize and administer the External Advisory Committee.
- Serve as a central resource for Hanford/DOE risk management decisions and stakeholder communication.

The Assessment Team should include members who have expertise in multiple scientific disciplines, such as toxicology, occupational health, industrial hygiene, analytical chemistry, risk assessment, and exposure/dosimetry modeling. Core membership should be drawn from multiple organizations including TOC, PNNL, other Hanford contractors, DOE Office of River Protection, and local/regional medical and academic institutions as long as they have the appropriate expertise, availability, and ability to meet regularly onsite. To be successful, this must be a fully funded, not volunteer, activity with administrative and information technology (IT) technical support.

Ideally, members should serve a minimum of one 3-year term to establish and maintain operational continuity and core expertise on Hanford tank farm occupational exposures. A Chairman (preferably a TOC manager) and a Vice-Chairman, with administrative support, will lead the Assessment Team. Once established, the Assessment Team will develop a charter for operation, membership (core and ad hoc), and decision processes that will be evaluated and approved by TOC and DOE. The Assessment Team charter will also include organizational principles for establishing an EAC (see below) along with clear roles and responsibilities for reviews and decision processes associated with the establishment of OELs and recommendations for new research. The Assessment Team and EAC will require administrative support to facilitate scheduling, meetings, record-keeping, budgets, and reporting requirements.

4.0 External Advisory Committee

An EAC will be established to provide the Assessment Team, TOC, and DOE with critical, external peer reviews of standard operating procedures and recommended OELs, and to serve in an advisory role for proposed research strategies. Like the Assessment Team, the EAC should include nationally recognized experts in risk assessment, exposure science, toxicology, occupational health, and industrial hygiene, who that can serve multi-year terms to maintain operational continuity and core expertise on tank farm occupational exposures. The final organization, roles, and responsibilities of the EAC will be delineated as part of the Assessment Team charter. Administrative assistants from the Assessment Team should be made available provided to the EAC to facilitate meetings, record-keeping, travel, and overall coordination of activities and recommendations.

5.0 Hanford Tank Farm Occupational Exposure and Risk Assessment Database

To assist the Assessment Team and EAC in their deliberations, we further recommend that an updatable electronic database be established that allows for the integration of

- existing and new data on tank vapor measurements (e.g., head space and site-specific emissions);
- existing and new industrial hygiene exposure surveys (e.g., personnel monitoring and biomonitoring);
- site-specific and worker-specific exposure simulations (e.g., vapor/aerosol transport and personal dosimetry);
- available environmental and toxicology literature (published and unpublished reports); and
- available exposure guidelines.

This database is not a substitute or duplication of existing industrial hygiene data bases (i.e. SWIHD or TWINS), but will incorporate information from those databases as well as other sources of data that is of key importance to the Assessment Team. This database should have a user-friendly, secure interface that is accessible to registered contributors and users of the data and information. It should also be based upon a platform that is most amenable to being updated over time as hardware and operating systems evolve. Sources for data and information that support the development of recommended exposure guidelines are provided in the Appendix.

6.0 Technical Details/Appendix

The appendix to this report contains additional technical details concerning recommended organizational structure and technical approaches that should be considered. These recommendations should be considered a starting point for the Assessment Team. It is fully anticipated that as strategies and procedures become implemented modifications will be implemented to improve the overall process.

Appendix A

Technical Details Concerning Recommended Organizational Structure and Approaches

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This appendix presents additional details regarding the recommended organizational structure of the standing Hanford Tank Farm Occupational Exposure and Risk Assessment Advisory Team (Assessment Team) and External Advisory Committee (EAC) that are to be established. Technical details are presented related to the updating of screening values/maximum headspace concentrations, a strategy for establishing acute/transient and chronic exposure limits, computational methods for predicting exposure and delivered dose, methods for prioritizing mixtures of concern, and methods for evaluating and prioritizing odor threshold and sensory/irritation response.

A.1 Tank Contractor Assessment Team and External Advisory Committee

A.1.1 Tank Contractor Assessment Team

A potential structure for the Assessment Team organization is illustrated in Figure A.1. As previously noted in the main body of this report, the team is a working technical group that will serve as a central resource for the Tank Operations Contractor. The team will be responsible for the integration of all information about tank farm emissions, exposure guidelines, and critical data or research needs that enable risk management decisions and stakeholder communication. The Assessment Team should be a Tank Operations Contractor function under the leadership of a senior manager who has overall responsibility for worker health. This individual will be the conduit for communication between the team, Tank Operations Contractor management, the U.S. Department of Energy (DOE), and the EAC. In addition, it is desirable to have a DOE participant on the team to provide oversight and guidance and to facilitate transparent communication between the team, TOC, and DOE. The Assessment Team is anticipated to include expertise, when available, from TOC as well as outside consultants/contractors (as needed) to be selected by TOC management. It is recommended that the key technical capabilities/stakeholders, as outlined in Figure A.1, include at a minimum the following technical expertise:

- **Analytical Chemistry.** A senior analytical chemist with expertise in quantitative analytical chemistry methods and free radical chemistry will support the identification of priority chemical tank farm vapor/aerosol constituents. Ideal candidates will have previous experience in analyzing tank farm vapors and/or experience in complex mixture chemistry. Along with expertise associated with the detection and identification of key contaminants, expertise associated with the identification of transient reactive chemical species would be useful to support environmental exposure modeling.
- **Modeling (Environmental).** Due to the inherent challenges associated with detecting and quantifying transient releases of tank vapors, it is imperative that alternative approaches for estimating tank vapor releases be in place. To accomplish this, the Assessment Team should include a scientist who has expertise in computational dispersion modeling of complex vapor mixtures. In addition, expertise in the modeling of complex atmospheric chemical reactions and dispersion kinetics is needed. It is anticipated that these modeling activities will be used to establish maximum atmospheric concentrations of tank vapors based upon headspace concentrations and relevant environmental conditions that will affect vapor concentrations and dispersion rates within the tank

farms. Results will be used to establish theoretical vapor concentrations for risk assessment in the absence of analytical quantification.

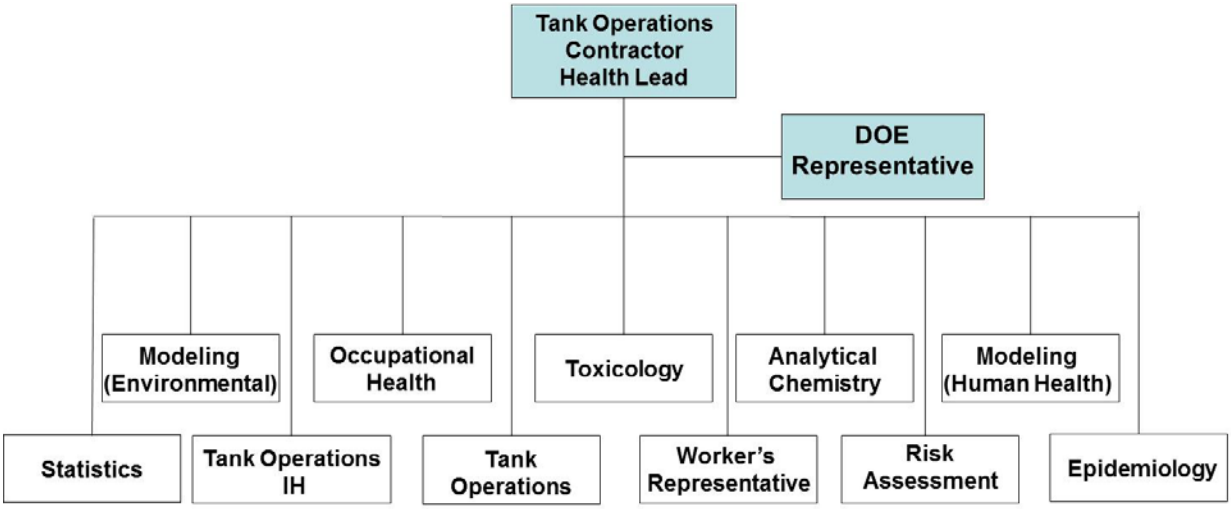

Figure A.1. Proposed Assessment Team Organization

- **Modeling (Human Health).** Quantitative dosimetry modeling should be used to predict delivered dose to target organ(s) based upon quantitative analytical chemistry assessment and/or computational dispersion modeling of vapors. Scientific expertise will be needed to support dosimetry model development for specific tank constituents and complex chemical mixtures. The approach should exploit both physiologically based pharmacokinetic and computational fluid dynamic modeling methods to quantify dose/exposure. Results should be used to support the assessment of occupational health risk and to establish target exposure guidelines.
- **Occupational Health.** The team should include an occupational physician who has specific experience dealing with worker exposure to tank vapors. The occupational health specialist should be capable of providing clinical perspective on the signs and symptoms associated with tank vapor exposures, and important linkage between exposures, clinical observations, and toxicological endpoints of concern. In addition, this team member should provide perspective on available epidemiology studies, particularly as it relates to both long- and short-term tank vapor health effects.
- **Risk Assessment.** Because a critical outcome for the Assessment Team is the recommendation of acute and chronic Occupational Exposure Limits (OELs), it is of key importance to include risk assessment expertise on the team. Statistically based risk assessment approaches (cancer and non-cancer) will be important for the establishment of acceptable thresholds of exposure. Technical approaches need to be based upon current best practices that are acceptable to both state and federal authorities (Occupational Safety and Health Organization (OSHA), National Institute for Occupational Safety and Health, U.S. Environmental Protection Agency (EPA), DOE, Washington State Department of Health).
- **Toxicology.** Health effects data based upon both human and animal (laboratory-based) chemical exposure studies are the key foundational components for establishing human health risk. The toxicological risk analysis should comprise hazard identification, dose-response (DR) assessment, and linkage to exposure assessment, based upon analytical chemistry determination and computational modeling of exposure.
- **Industrial Hygiene (IH).** The Assessment Team should include a senior Tank Operations Contractor IH member who has extensive experience associated with the tank farm IH program. This is

particularly important because an IH specialist can provide key insights into issues that are specific to the tank farms and can help guide the Assessment Team, particularly with regard to understanding what solutions are, or are not, feasible based upon the IH member's experience.

- **Tank Operations.** The inclusion of tank farm operations expertise can provide the Assessment Team with key perspective on operational procedures and, from a practical perspective, insight into the feasibility of implementing proposed personal protective equipment or safety procedures onsite. The operations as well as IH team members can also provide important insight into potential sources of exposure within each tank farm.
- **Worker's Representative.** The inclusion of a team member who is a representative for workers facilitates transparency and provides a voice for worker concerns on the Assessment Team.

A.1.2 External Advisory Committee

The inclusion of an EAC with the mandate to advise the TOC Assessment Team's activities should be a key component of the overarching strategy and of particular importance for demonstrating process transparency and external validation. A potential organizational structure for the EAC is illustrated in Figure A.2.The EAC would be expected to provide input on a number of key processes, including setting exposure guidelines (acute and chronic), developing strategies for evaluating mixture responses, determining the relationships between odor thresholds and adverse effects, determining the role of computational modeling, and identifying research gaps.

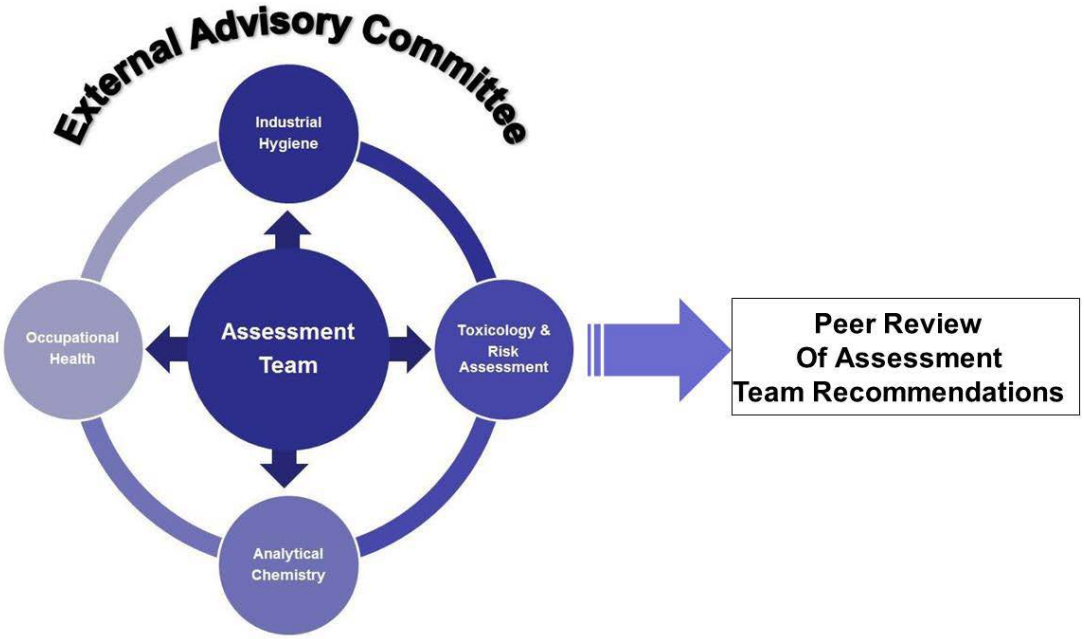

Figure A.2. External Advisory Committee Organization

The specific individuals who would be recruited for the EAC should be chosen by Tank Operations Contractor management with input from DOE. However as indicated in Figure A.2, it is recommended that senior scientists with technical expertise in the areas of industrial hygiene, occupational health, toxicology/risk assessment and analytical chemistry be considered for inclusion. EAC participants should be well recognized and respected in their fields of expertise and have some experience in dealing with complex mixture health effects. Tank Operations Contractor management with input from the Assessment

Team should specifically define the scope of responsibility for the EAC and the process that would be used for Assessment Team/EAC interactions.

A.2 Updating Screening Values/Maximum Headspace Concentration

A.2.1 Purpose

A previous evaluation and published report (Poet et al. 2006) identified the chemicals in the tank waste headspace (lacking established OELs) that should be further assessed for their potential health risks to tank farm workers. This was accomplished by establishing headspace concentration screening values for each chemical using available industrial hygiene and toxicological data. The primary goal for establishing screening values was to facilitate identification of chemicals that could be elevated to COPC, therefore requiring the establishment of both acute and chronic occupational exposure levels based upon their maximum headspace concentrations. Screening values were highly conservative and intended to be more than an order of magnitude below concentrations that may cause adverse health effects in workers, assuming a 40-hour/week occupational exposure. Screening values were compared to the maximum reported headspace concentrations and any chemical with a reported maximum concentration that exceeded the screening value was further evaluated. In light of the potential for new industrial hygiene and toxicology data and new data on maximum headspace concentrations for tank waste constituents updated screening values are warranted. In addition, the assessment of screening values should now include adverse health effects associated with transient short-term exposures, mixture interactions, and odor/sensory irritation thresholds versus toxicity effects.

Further analysis of chemicals with screening values below maximum headspace concentrations will include reevaluation of their presence in the tank headspaces to verify chemicals were correctly identified. New and more sensitive analytical tools need to be employed that are capable of identifying unknown species in the headspace to protect worker's safety. Chemicals verified to be components of the headspace will then undergo a more detailed toxicological revaluation to refine OEL guidelines and establish Acute Exposure Guideline Levels (AEGLs) for worker protection as needed. Sampling and analytical methods will be developed as necessary and deployed to determine which, if any, of these chemicals are present in the workers' breathing zone and at what concentrations. Based on these additional evaluations, workplace controls will be established as needed by the Assessment Team and peer-reviewed by the EAC. Chemicals deemed to present no health risks (with maximum headspace concentrations below their screening values) will be listed as low-risk chemicals and only reevaluated as new toxicological data become available.

Headspace characterization data that was collected after July 2005 (date of previous evaluation) and entered into the Tank Characterization Database via the Tank Waste Information Network System (TWINS) will be considered. In addition, any new data collected during tank-disturbing conditions (tank mixing) will be a high priority for evaluation as well as associated stack, ventilation, and vent system data.

The resulting data will be obtained by sample device and laboratory for each day of sampling from a given source (tank, vent system, etc.). This process will result in individual sample results thereby preserving the distinction between results from different devices (e.g., sorbent traps and SUMMA® canisters) and the various analytical laboratories involved. The sampling strategy should consider the following: Any changes toward sampling considerations and analytical methodology must be deliberated through a coordinated effort that includes the analytical team. Addressing sampling issues can be a complex issue which must include consideration for the end use of the data. Is the data to represent the breathing zone? What adjustments should be made to account for the environmental and meteorological

conditions (temperatures of the source and surroundings, boundary layer conditions such as wind speed and direction)? Are the contaminants lighter or heavier than air? How are replicate samples obtained (desorption tubes require chemistry considerations and multiple sampling trains, summa canisters provide sample for many analytical attempts)? Are the compounds thermally labile (thermal desorption sampling can destroy compounds or produce artifacts)?

These new data will be compared against previously reported concentrations that were used to establish screening values (Poet et al. 2006); further assessments will focus on previously unidentified chemicals and the chemicals where headspace concentrations are now greater than the analysis reported by Poet et al. (2006). When possible faster in situ data acquisition should be employed to capture sporadic transient species, accidental release of trace species, or unexpected leaks in the facility (Huckaby et al., 2004). On-line measurements are necessary for reactive and unstable free radicals and volatile organic compounds that are suspected to form and transform in the head space. Such measurements are complementary to the routine monitoring and they provide additional insight on the nature of potential short-term acute exposures (SRNL, 2014).

A.2.2 Establishing Headspace Concentration Screening Values

Screening values will be developed for each chemical as previously described (Poet et al. 2006). In brief, the data used to develop the screening values will be ranked according to relevance to occupational exposure. For example, screening values based upon inhalation exposure would take precedence over oral exposure, since inhalation is highly relevant to tank farm exposures. If no appropriate exposure guidelines for the chemical of interest are identified, an OEL based on a structurally related chemicals (surrogate) will be applied. When no OEL for the chemical or a chemical surrogate is available, the assessment will be based on identification of toxic effects that are most relevant to occupational exposure. Toxicological parameters will be assessed on the basis of metabolic analogies, persistence, chemical and physical properties, chemical structures, and biological activity.

A.3 Strategy for Establishing Acute/Transient and Chronic Exposure Limits

A.3.1 Purpose

A large number of volatile compounds have been identified in the headspaces of single- and double-shell tanks used to store mixed chemicals and radioactive waste at Hanford Site. Concern about the potential exposure of workers to vapors during tank farm operations has prompted efforts to evaluate the potential health risk associated with exposure to these chemicals. OELs have not been established for many of these chemicals.

The proposed process is based upon the strategy previously used for establishing and/or revising OELs for tank waste (Poet and Timchalk 2006) and represents a framework of technical guidance that is a common approach used by trained toxicologists and/or risk assessors. The overarching goal is to outline a process that can be used by the Assessment Team to assign OELs, AEGLs, and Protective Action Criterion (PAC) values needed to address both chronic/repeated exposures and very short-term transient exposures, respectively. The target agents are chemicals or families of chemicals that may not have established OEL/AEGLs/PACs or require revisions based upon new health effects information found in the available literature. An OEL is defined as a level of exposure to a given chemical expected to lead to no adverse health effects (8-hour time-weighted average [TWA]); whereas, the AEGLs represent acute exposure guidelines for human health effects from once-in-a-lifetime, or rare, exposure to airborne

chemicals. The AEGLs are threshold exposure limits ranging from 10 min to 8 hr. (10 min, 30 min, 60 min, and 4 and 8 hr.) of exposure with three levels of toxic-effect severity (AEGL-1, -2 and -3) as defined by the National Academy of Science (NAS 2001). Of particular relevance for transient exposures are the AEGL-1 action levels for short-term (10 min) exposures. DOE developed PACs based on AEGLs and Emergency Response Planning Guidelines (ERPGs) (Rusch 1993; Rusch et al., 2000; Rusch et al., 2002), and Temporary Emergency Exposure Limits (TEELs), in that priority, as the emergency exposure limits (DOE 2005, 2010, 2012). Similarly, successive PACs (i.e., PAC-1, -2, and -3) are benchmark values associated with increasingly severe acute health effects due to short-term (60 min) exposures (DOE 2008).

A.3.2 Established Exposure Guidelines

OELs are established in this country by the U.S. Department of Labor's OSHA and are legal obligations for defined industries. The National Institute for Occupational Safety and Health (NIOSH) is an arm of the Centers for Disease Control and makes recommendations to OSHA regarding OEL values. The American Conference of Governmental Industrial Hygienists (ACGIH) is a private organization that recommends OEL values to industry for voluntary application. Other human exposure standards have been published; e.g., by the ERPGs Committee of the American Industrial Hygiene Association (AIHA), the AIHA Workplace Environmental Exposure Levels, the AEGLs Committee of the EPA, and the NAS. However, their applicability as OEL/AEGL values must, in each case, be evaluated. The DOE mandates the need to comply with the OSHA and ACGIH standards in its contract with TOC; in cases where two standards exist, the more stringent of the two will be applied.

Because of the nature of potential sporadic short-term exposure of the complex and unique organic vapor mixtures at the Hanford Site and associated concerns about health effects, DOE PACs are proposed for assessment of acute toxic effects when AEGL or OEL values are not available. The DOE PAC data set encompasses more than 3100 chemicals present at various sites (DOE 2016a), covering more chemicals than the AEGLs and ERPGs combined. When neither OEL nor AEGL values exist for a chemical, PAC values can be developed. Although TEEL values were initially developed in the absence of concentration limits such as AEGL or ERPG values, their practicality and conservatism have been proven to be effective in operation planning for DOE (Craig et al. 1999; Craig et al. 2000). As a result, PAC values have been actively used by various DOE sites and complexes. The procedure for developing PAC values is well-established (DOE 2008), and it has been recently reviewed and updated (DOE 2008)[1].

AEGLs, ERPGs, and TEELs all serve the same general purpose—to provide PACs to those who are responsible for planning for and responding to chemical emergencies. For each level or guideline, there are multiple benchmarks for each chemical, and the benchmarks are associated with increasingly severe effects with higher levels of exposure.

The principal differences between AEGLs, ERPGs, and TEELs are how they are developed. There are also some subtle differences in how they are defined. AEGLs pertain to the "general population, including susceptible individuals," but ERPGs and TEELs pertain to "nearly all individuals." AEGLs are defined as the level "above which" certain health effects are expected, while ERPGs and TEELs are defined as the level "below which" certain health effects are not expected. ERPGs refer to an exposure duration of 1 hr. (with shorter periods for some chemicals); AEGLs are developed for five time periods; and TEELs are defined for a 15 min period (Craig et al. 1999). When TEELs were first developed, the exposure severity was based on a peak 15 min TWA concentration (DOE 2008). In recent revisions, PAC values are recommended to be developed by direct comparison with the 60 min AEGLs (DOE 2008). Considering

[1] This new DOE handbook is currently under review.

the nature of acute exposure and sporadic occurrences of vapor release, the 15 min TEELs may be preferable for the tank farm application.

A.3.3 Overview of Approach

The NAS (1983, 1994, 2001; GAO 2001) has provided overall guidance for chemical risk assessment as further developed and applied by U.S. regulatory agencies. The process for establishing exposure guidelines for tank waste chemical exposure is modeled after the generalized scientific approaches used by OSHA and ACGIH to establish OELs for worker exposure; the scientific approach used by other regulatory agencies such as the NAS/EPA to establish AEGLs for airborne pollutants are also considered.

A flow diagram illustrating the key steps in the assessment process is illustrated in Figure A.3. The approach first requires identifying specific chemical agents or classes of chemical agents that are detected in the tank headspace at or above previously established screening values. Chemical agents that exceed the screening values will undergo a more extensive evaluation to establish with the goal of establishing suitable OEL, AEGL, or PAC values for tank farms operations.

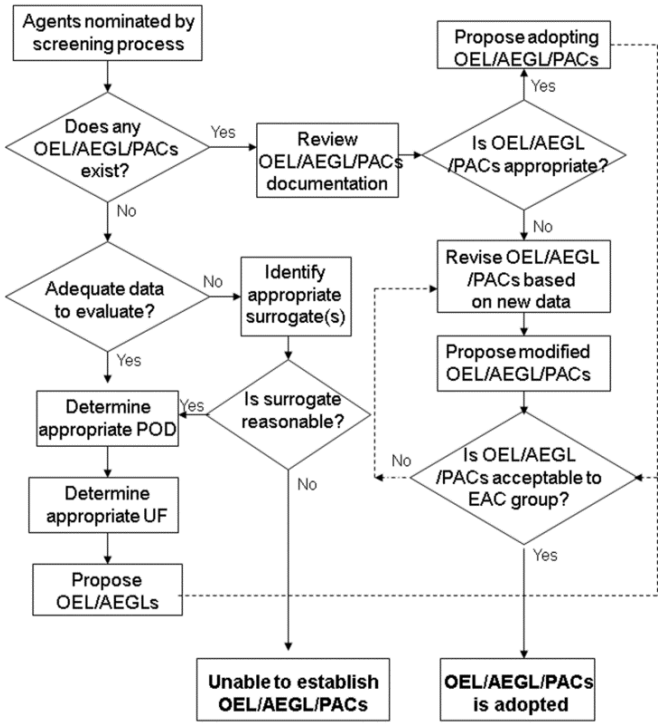

Figure A.3. Strategy Outline for Establishing Occupational Exposure Limits (OEL), Acute Exposure Guideline Levels (AEGLs), and Protective Action Criteria (PACs) Values

Exposure Guideline Evaluation

First, a detailed review of relevant exposure guidelines will be undertaken. In the absence of appropriate exposure guidelines, available epidemiology and toxicology information about a given chemical or chemical class will be reviewed to identify potential hazards, select critical effects, and estimate DR to determine suitable exposure levels (Haber and Maier 2002). Consistent with the technical approaches ACGIH uses for establishing a Threshold Limit Value (TLV), the exposure guidelines will be based on the best scientific information available and will include a critical evaluation of all supporting information

(ACGIH 2005). The goal of the process will be to delineate the most important adverse effects for specific chemicals within the waste tanks. In evaluating the health effects, human data such as epidemiology studies would be of prime importance, but for many of the chemicals of concern there will be little, if any, available human data. The second tier evaluation will focus on the most relevant and sensitive animal toxicity data for the chemical and/or chemical class. In this case, the basis for the exposure guidelines will be the DR relationship of the toxic effects of greatest concern, and the point of departure (POD) for calculating the OELs/AEGLs/PACs will be the associated no-observed-effect-levels/lowest-observed-effect-levels (NOELs/LOELs). The rationale for the selection of a given toxic effect for establishing the exposure guidelines will be documented.

When setting an exposure guideline, an appropriate risk assessment approach will be used; it will be selected based on the critical toxicological effect, the observed DR, and the quality of the data used for the assessment (ACGIH 2005). This approach may include the use of quantitative DR models such as the benchmark dose (BMD), and/or the application of added safety factors to a NOEL/LOEL to address uncertainty.

Before establishing and implementing a formal exposure guideline for worker protection in the tank farms, the Assessment Team will submit the proposed exposure level for a given chemical and/or chemical class to the EAC for peer review. Ideally, the peer reviewers will include a range of health and science professionals, who could include representatives from occupational health, toxicology, risk assessment, industrial hygiene, analytical chemistry, and worker groups. The objective of the review will be to critically assess the rationale for establishing the OELs/AEGLs/PACs, provide the broad base of stakeholders an understanding of the rationale for the exposure limits, and provide stakeholders an opportunity to submit appropriate input to the assessment.

A.3.4 Database and Literature Evaluation

Database Searches

It is imperative that relevant human exposure, epidemiology, and toxicological information be considered when establishing exposure guidelines. A methodical analysis of the available literature as it relates to hazard identification and quantitative DR toxicity evaluation is central to the risk assessment process. Internet databases such as The Toxicology Data Network (TOXNET®), TOMES®, PubMed®, the International Agency for Research on Cancer (IARC), and/or STN® should be primary sources for initiating searches. The searches should include both the name and Chemical Abstracts Service registry number of the compound of interest (see Table A-2). These databases contain information applicable to toxicological assessment of chemicals, and the information they provide may overlap. For example, both TOXNET and TOMES contain the Registry of Toxic Effects of Chemical Substances (RTECS®) and Hazardous Substances Data Bank (HSDB®) files. In the event RTECS and/or HSDB files do not exist for a compound or are considered insufficient, the TOXNET literature and/or PubMed databases should be searched and the original literature evaluated for any relevant information. If relevant information is not located in this manner, PubMed may be searched directly and/or the chemical abstracts database searched through STN. If information is found in one or more of the above sources but is incomplete, conflicting, or considered insufficient, other sources such as the National Institute of Environmental Health Sciences National Toxicology Program (NIEHS/NTP), IARC, EPA, and Agency for Toxic Substances and Disease Registry Monographs (ATSDR) may also be searched. Frequently, more in-depth information about the chemical of interest or its surrogate can be located in this way and may be useful in assigning an exposure limit.

A.3.5 Literature Evaluation of Published Exposure Guidelines

Initial efforts should focus on a comprehensive evaluation of the available literature that will identify any published exposure guidelines for the chemical of interest or for a reasonable surrogate. The summary documentation used to support the establishment of the exposure limits should be reviewed to ascertain its relevance, and any exposure limit that is adopted based on these published OEL/AEGLs should include appropriate documentation justifying the scientific rationale for it use.

Surrogate

If there are no appropriate exposure guidelines for the chemical of interest, it may be reasonable to identify and assign an exposure limit based on a structurally related chemical (surrogate). In addition to being structurally related, ideal surrogates could have a similar toxicological profile (i.e., similar target organs and response), although they may display greater or lesser potency that the chemical of concern. The basis for the choice of the surrogate should be explained and the explanation should include a brief discussion of the rationale for the assigned exposure limit for the surrogate.

A.3.6 Toxicology Evaluation

Toxicity Review Criteria

In evaluating the toxicity profile for a chemical or chemical class, the assessment should be prioritized based on identification of toxic effects that are particularly relevant for occupational exposure. This would include the following steps:

- Identify chemical agents that have a high acute toxicity potential, such as Category 1 chemicals, as defined by the Organization for Economic Co-operation and Development (OECD 2004). Chemicals in Category 1 that are considered by OECD to have high acute toxicity potential have Lethal Dose for 50% of test population (LD_{50}) and Lethal Concentration for 50% of test population (LC_{50}) values of ≤ 5 mg/kg oral and ≤ 100 ppmV inhalation, respectively. These would be of particular concern if the LD_{50}/LC_{50} values do not have large safety margins (<100) between observed toxicity and potential exposure levels.
- Give priority to the evaluation of studies that use the most relevant occupational exposure routes (Inhalation >> Oral > Dermal > Others [intravenous/ intraperitoneal]).
- Give priority to well-characterized DR toxicity studies, particularly those that include a more comprehensive evaluation of the toxicity, which includes quantitative in vivo (Acute → Sub-Chronic → Chronic) experiments.

The toxicity testing paradigm suggests that with increasing length of chemical exposures (i.e., acute → chronic) the effective dose levels generally decrease such that the lowest NOEL/LOEL will be determined from long-term studies. In addition, long-term chronic studies can identify chemicals that have the potential to produce a broad range of chronic health effects. An important strength of this testing paradigm is that it provides a fairly comprehensive in vivo toxicological evaluation that can be used to link DR results across a very broad range of exposure routes (oral vs. inhalation), doses (low vs. high), durations (sub-chronic vs. chronic), and species (rat vs. dog). The use of this type of testing data will provide greater confidence (i.e., less uncertainty) in the exposure limit that is established.

Minimal Data Sets

As discussed by Haber and Maier (2002), a number of regulatory authorities including the Health Council of the Netherlands (HCN 2000) and the EPA (1994), have established minimum data requirements based on the rationale that any value derived from data that is less than the minimum prescribed would have too much uncertainty. An alternative approach is to identify the types of data that are particularly useful and use a weight-of-evidence approach in the evaluation that looks at the sum total of all available information (SCOEL 1999; Haber and Maier 2002). In this case, a weight-of-evidence review for the development of exposure guidelines would focus on evaluating the types of studies that have greater relevance to occupational exposure and can be utilized to establish a DR relationship.

For the purpose of this assessment process, a minimum data set will not be established and a weight-of-evidence approach will be used. Due to the anticipated lack of robust toxicity data, a minimum data set would most likely be hard to achieve for the broad number of chemical agents being evaluated, particularly when there is a need to apply surrogate chemical data in the assessment. The documentation and the peer reviewers are anticipated to provide the means to assess the degree of confidence that should be placed on the exposure limit. It is important to recognize that with the unique chemistry associated with chemical/radioactive tank waste, appropriate toxicity data on the chemicals of interest or their reasonable surrogates may be absent, making the establishment of a defensible exposure limit problematic. In these cases, it may not be possible to establish OELs/AEGLs with any confidence, pending the availability of additional toxicity data from the literature.

Use of Surrogate Toxicity Data

When forced to use a surrogate chemical or chemical class for developing an exposure guideline, it is important that the surrogate have as robust a toxicology database as possible. The use of a surrogate chemical with a well-characterized toxicity database means that it will have a clear DR relationship and a clearly defined NOEL to use as a point of departure for establishing OELs/AEGLs. Substantially more uncertainty should be assigned when using surrogates that lack a robust toxicity database. A written assessment of the overall strengths and weaknesses of the surrogate chemical should be included in the documentation.

Procedure for Calculating OELs/Acute Exposure Guidelines

Point of Departure

The overarching goal in evaluating the toxicity databases is to determine a point of departure for developing an exposure guideline. Haber and Maier (2002) defined the point of departure as the concentration to which uncertainty factors are applied to derive an OEL. The point of departure is most likely the NOEL/LOEL that was determined from the most appropriate toxicity study. In practice, this is usually the lowest determined NOEL that was experimentally derived. It is also possible to use a benchmark dose approach, as described below, to determine a point of departure, particularly when the experimental studies did not identify a NOEL (Fillipsson et al. 2003; Haber and Maier 2002; Crump 1984; Dourson et al. 1985).

Approach for Developing Exposure Limits for Non-Cancer Effects

As suggested by Bailey (2002) and others, there are numerous sources of uncertainty in the establishment of an acceptable exposure level. The approach used for identifying an acceptable exposure level for the general population or for occupational-related exposures is to adjust the NOEL or LOEL downward. The magnitude of the downward adjustment reflects the degree of uncertainty concerning the acceptable

exposure limits. To address these uncertainties, empirical factors may be used to account for inadequate experimental data, interspecies variability, human variability, or extrapolation for short-term to long-term studies (EPA 2002; Dorne and Renwick 2005). In addition to uncertainty factors, additional modifying factors (MFs) have also been occasionally used by some regulatory agencies such as EPA to reflect uncertainties not addressed by other factors. Equation (A.1) will be used to calculate the OEL/AEGLs.

$$OEL / AEGL = \frac{NOEL \text{ or } LOEL}{UFxMF} \quad \P \qquad (A.1)$$

The application of empirical uncertainty factors to determine the exposure guideline is based on the methods the EPA uses for deriving a Reference Concentration (RfC; EPA 2002). The default uncertainty factor (UF) generally covers a single order of magnitude (i.e., 10^1), or a value of 3 is used in place of one-half powers (i.e., $10^{0.5}$). Additional factors could also be considered for inadequate data and for extrapolation from less than lifetime to lifetime exposures. As the EPA suggests, supporting documentation should include the justification used for the individual factors selected. In addition, as recommended by the EPA (2002), it is advisable to limit the total UF applied to any particular chemical to no more than 3000 and avoid deriving an exposure guideline that involves the full 10-fold UF in four or more areas of extrapolation. The following uncertainty and MFs could be applied:

- ***Extrapolation from animal data to humans (interspecies UF)***. This factor is intended to account for the uncertainty in extrapolating animal data to the case of average healthy human. It assumes that humans are more susceptible to the toxicity than the animal species evaluated.
- ***Variability in the human population (intraspecies UF)***. This factor is intended to account for the variation in sensitivity among humans.
- ***LOEL to NOAEL UF***. This factor is intended to address the uncertainty associated with extrapolation from LOELs to NOELs.
- ***Sub-chronic to chronic duration UF***. This factor is intended to account for the uncertainty in extrapolating from less than chronic NOELs to chronic NOELs.
- ***Inadequate database UF.*** This factor is intended to account for the inability of any single animal study to adequately address all possible adverse outcomes in humans.
- ***Modifying factors MF***. This factor is intended to account for any other scientific uncertainties in the study or databases that are not explicitly treated by other UFs. The magnitude of the MF principally depends on professional judgment.

Establishing a NOEL Using Benchmark Dose

As noted by Dorne and Renwick (2005) the use of a benchmark dose as proposed by Crump (1984) defines a lower statistical confidence for the dose that corresponds to a predefined low level of increase in adverse effects over background. The benchmark dose approach provides a more quantitative alternative to the first step in the DR assessment of the NOEL/LOEL process (EPA 2000). This is particularly useful when a NOEL has not been adequately defined from the experimental data.

The EPA guidance document (EPA 2000) provides a detailed discussion of a number of important considerations, including the types of studies that are appropriate for benchmark dose, selection of the benchmark response values, choice of models for computing benchmark dose, and details concerning the computation of confidence limits for the benchmark dose. Based on the EPA criteria, a 10% response is at or near the limit of sensitivity in most cancer and non-cancer bioassays, and will be used as an appropriate effective dose10 (ED10) for the benchmark dose. As indicated in the EPA guidance (EPA 2000), the

primary goal of the mathematical modeling is to fit a model to DR data, particularly at the low end of the observable DR range. The recommended criteria for selection of an appropriate model for computation of the benchmark dose Limit (BMDL) is the Akaike's Information Criterion (AIC). The AIC values are computed for each of the models used in the benchmark dose calculation and compared to select the most appropriate model from the analysis. Once a benchmark dose value is selected, a lower confidence is placed on the benchmark dose to obtain a dose (benchmark dose limit) that assures with high confidence (95%) that the benchmark response is not exceeded. The benchmark dose limit can then be used in the numerator of Equation ((A.1) to calculate an Acceptable Occupational Exposure Limit (AOEL), as described above.

Carcinogens

For those chemical that are known or suspected carcinogens, the ability to derive an OEL depends upon the intrinsic toxicological properties of the compound in question. The U.S. EPA in developing their guidelines notes the importance of elucidating a mode of action (MOA) for a particular cancer response in animals or humans (EPA, 2005). In this regard, as suggested by the Health Council of the Netherlands (HCN) (HCN,2012), four general categories of carcinogen MOAs can be distinguished:

- Non-genotoxic carcinogens. These compounds can promote various phases of the cancer process, without directly or indirectly damaging DNA.
- Genotoxic carcinogens with a non-stochastic mechanism of action. These compounds do not directly interact with DNA, but can ultimately result in indirect DNA damage.
- Genotoxic carcinogens with a stochastic mechanism of action. These compounds can directly interact with DNA, thus resulting in DNA damage.
- Genotoxic carcinogens with an unknown mechanism of action.

In considering MOAs for chemical carcinogens in a risk assessment context initial efforts should focus on determining if MOAs are associated with a linear or non-linear (threshold) dose-responses. Where a linear response assumes that even one molecule has the ability to damage DNA and initiate cancer; whereas, a non-linear threshold response assumes there is a dose, below which, compensatory mechanisms are in play that effectively do not lead to a carcinogenic response. Based upon these definitions the linear dose-response is by far more conservative. In this regard, some MOAs are anticipated to be mutagenic and have historically been considered genotoxic with no threshold and have subsequently been assessed with a linear approach. Other MOAs may be modeled with either linear or nonlinear approaches after a rigorous analysis of available data (i.e., weight of evidence) under the guidance provided in the framework for mode of action analysis (EPA, 2005). Those carcinogens with a non-genotoxic or non-stochastic genotoxic mechanism are generally assumed to exhibit a specific threshold concentration (dose) that needs to be exceeded to result in a cancer response. The establishment of OELs for these chemicals may be addressed utilizing similar approaches as described for non-carcinogens where a point of departure (POD) is defined and additional safety factors can be applied to establish an exposure limit based upon known criteria and uncertainty. According to EPA (2005) a point of departure marks the beginning of extrapolation to lower doses. The point of departure is an estimated dose (usually expressed in human-equivalent terms) near the lower end of the observed range, without significant extrapolation to lower doses. However, for genotoxic carcinogens with a stochastic mechanism of action or unknown mechanism of action, current scientific insights do not allow for establishing a safe exposure levels where there is no risk. In this regard, any level of exposure is assumed to entail a certain risk of developing cancer. Hence for these chemicals, a cancer risk value is an exposure level (i.e., air concentration) corresponding with a predefined extra risk of developing cancer (HCN, 2012).

Linear Approach

The EPA guidelines on carcinogen risk assessment (EPA, 2005) notes that linear extrapolations should be considered when the mode of action for a carcinogen is expected to have a linear component below the point of departure, which can be anticipated for chemicals that are DNA-reactive and have direct mutagenic activity. In addition, linear extrapolation is likewise the procedure of choice when the weight-of-evidence evaluation for all available data is insufficient to establish a plausible mode of action. Whereas, the EPA recommends the use of non-linear approaches when there is adequate data supporting a mode of action that is non-linear at low-doses and the agent does not demonstrate mutagenic activity (i.e., linear response) at low doses (HCN, 2012). For linear extrapolation the assessment does not use uncertainty factors (UFs) but rather a straight line is drawn from the point of departure for the observed data to the origin (zero). The slope of this line is called the cancer slope factor and is utilized to calculate excess cancer risk. For occupational cancer risk, a working period of 40 years (8 hours per day, 40 hours per week) is assumed and risk estimates are determined based upon available human epidemiology data and/or animal carcinogenicity studies.

In evaluating cancer risk for COPCs that do not have U.S. or internationally recognized risk assessments, it is recommended that careful consideration be given to establishing risk levels which should be based upon approaches that are utilized by government and non-government entities that historically evaluate cancer risk. Below is an example from the Health Council of the Netherlands (HCN, 2012) illustrating a potential range of risk levels for limiting occupational and environmental exposure to carcinogens.

Risk levels used for limiting exposure to carcinogens in the workplace and in the environment (taken from HCN, 2012)

		Risk Period	Exposure Period[1]	Risk Level
Occupational Health and Safety	Prohibitive Risk	Life	Working Life One Year	4×10^{-3} 1×10^{-4}
	Target Risk	Life	Working Life One Year	4×10^{-5} 1×10^{-6}
Environment	Maximum Tolerated Risk	Life	Lifetime One year	1×10^{-4} 1×10^{-6}
	Negligible Risk	Life	Lifetime One year	1×10^{-6} 1×10^{-8}

[1] For the calculation of the risk related to the exposure during a full (working) lifetime, a period of 40 years for workplace exposure and a period of 100 years for environmental exposure is taken into account.

Procedure for Developing TEELs/PACs

TEEL values are developed for chemicals that do not have AEGL or ERPG values. TEEL values are also developed for chemicals that have missing AEGL or ERPG values. TEEL values differ from AEGL and ERPG values by the methods and the sources of data used to develop them. The processes used to develop AEGL and ERPG values are both painstaking and time-consuming. To produce exposure limits

in a more timely fashion while maintaining high quality, TEEL values are developed using a methodology that incorporates existing published exposure limits and toxicity data.

Sources of Data

The three principal sources used for developing TEELs are 1) RTECS, (2) Sax's Dangerous Properties of Industrial Chemicals (Sax), and (3) the HSDB (Fonger 1995; Lewis 2004; Fonger et al. 2014). A hierarchy of sources is used for developing TEEL values. The most frequently used exposure limits to develop TEELs include the following:

- TLVs adopted by the ACGIH
- Workplace Environmental Exposure Levels (WEELs) adopted by the AIHA until 2011
- Permissible Exposure Limits (PELs) promulgated by the OSHA
- Recommended Exposure Limits (RELs) and Immediately Dangerous to Life or Health values recommended by the NIOSH
- Level of Concern values developed by the EPA.

The TEEL development methodology incorporates calculations and default assumptions to fill gaps resulting from a lack of data. Structure-Activity Relationships (SARs) and health Hazard Ratings (HRs) have been used to develop a full set of TEEL values when no other data are available.

Toxicity-Based TEELs

Because published concentration limits do not exist for many chemicals, existing published toxicity parameters are used to derive TEELs. For chemicals with determined parameters, published Toxic Concentration Low (TC_{LO}) and Toxic Dose Low (TD_{LO}) toxic-effect values can be used to estimate TEEL-2 limits, and LC_{50}, Lethal Concentration Low (LC_{LO}), LD_{50}, and Lethal Dose Low (LD_{LO}) lethal-effect parameters can be used to derive TEEL-3 limits. For TEELs derived from published concentration limits, a priority order is recommended to derive TEELs from toxicity parameters. Namely, data from human exposures are given primary consideration over data from other species; because of their relative abundance, data from rat exposures are preferred over other non-human species. Similarly, because TEELs are concerned primarily with airborne concentration, parameters derived from inhalation experiments are preferred over data from other routes of administration (i.e., skin absorption).

Adjustment Factors for Human-Equivalent Toxicity Data

To adjust human-equivalent toxicity data converted from other toxicity parameters for calculating TEELs, the relationship between ERPGs and human and animal toxicity parameters was evaluated. It was assumed that any model based on ERPGs would also be valid for TEELs. A mathematical model was developed based on the relationship between human and animal toxicity parameters versus existing ERPGs. This model was used to derive adjustment factors that are applied to human-equivalent toxicity data that, in turn, were converted from animal toxicity data, unless the data were human to begin with, which precluded the animal-to-human conversion step. The adjusted human-equivalent toxicity data are then used for calculating TEELs (Craig et al. 2000).

Parameter Selection

Parameters are selected for deriving TEELs by species, route of administration, the value of the parameter, and time. Data from humans are preferred, followed by data derived from rats, mice, rabbits, guinea pigs, dogs, cats, pigs, and monkeys. Data derived by inhalation are preferred. Oral data are selected next, followed by data from skin, intraperitoneal, intravenous, subcutaneous, intramuscular, or

other routes of administration. The lowest value of the selected parameter is chosen. Parameters need to be adjusted by the duration of the experiments, which requires selecting the data for the one nearest to a duration of 15 min. Although several sets of toxicity data may be selected and entered into the TEEL input sheet for any one TEEL, only one set is actually used by the TEEL development program to derive a TEEL value. The selection of the data to use in TEEL derivation is automatic and calculated with an embedded peer-reviewed algorithm following the selection hierarchy.

Adjustment to Human-Equivalent Concentration

Extrapolating results from animal experiments to humans requires making adjustments for the many differences. For purposes of deriving TEELs, the most important differences between humans and experimental animals are body weight and breathing rate. Default values for mean body weight (kg) and breathing rate (m^3/day) are suggested for this adjustment (DOE 2008).

Time Considerations

All toxic concentration data (LC_{50}, LC_{LO}, TC_{LO}) are reduced to a 15 min exposure time. If the exposure time is not given, 15 min is assumed for concentration-dependent (Y) chemicals and 60 min for dose-dependent (N) chemicals. The exponent "n" in the equation used to reduce the data from other exposure times (t_{exp}) to a 15 min exposure time (t), $[(t_{exp}/t)^n]$ depends on whether the acute toxic effects are Y (n = 1/2) or N chemicals (n = 1.0). The choice of square root is somewhat arbitrary. The intention is to reduce the influence of exposure time for chemicals whose acute effect is primarily determined by the concentration because exposure time is not the main factor in determining the toxic consequences of Y chemicals (Craig and Lux 1998).

Route Adjustment Factors

The amount of a chemical absorbed varies with the route of administration. For example, intravenous administration is one of the most efficient means (i.e., the proportion of the administered chemical that is absorbed systemically is high), and administration on the intact skin is one of the least efficient. Consequently, it is important to adjust the absorbed dose depending on the route of administration. Route adjustment factors (RAFs) are also recommended in the TEEL development handbook (DOE 2008). These values are estimates. In practice, these values would vary from chemical to chemical, depending on solubility in body fluids, metabolic changes, and other factors. The RAFs for inhaled material are used only when data are given in dose units (i.e., mg/kg) (Lewis 2004).

TEELs when Exposure Limits and Toxicity Parameters are Missing

TEELs can be developed at all levels (i.e., TEEL-1, -2, and -3) for a chemical when there is a strong need. Several rules have been developed for deriving TEELs for which concentration limit-based or hierarchy-based values, toxicity-based TEEL-2 values, or toxicity-based TEEL-3 values are unknown. SARs and health HRs are also bases from which to derive TEELs. When there is only sufficient information to derive one TEEL value but not others, multiplication factors are used to convert known TEEL values to other severity levels. Other technical guidance should also be followed when developing TEELs (DOE 2008).

Format for Exposure Guideline Documents

The OELs/AEGLs/PACs documentation for a given chemical or chemical class will include the following sections. The Summary will be in an abstract format that reasonably communicates the overall process and conclusions of the analysis. A Methodology section will briefly describe the approach used for developing the OELs/AEGLs/PACs. This section will be followed by a section that describes the

Available Guidelines that are particularly relevant to developing the OELs/AEGLs. The Toxicology Results section will review pertinent human epidemiology and animal toxicology results that are directly relevant to setting OELs/AEGLs/PACs. This will not entail a detailed description of all the available data, but will focus on the key studies and results that are pertinent to the evaluation. The Data Analysis section will describe the process used for setting the OELs/AEGLs/PACs.

A.4 Computational Approaches for Predicting Exposure and Delivered Dose

As noted in the TVAT report (SRNL 2014) and described in detail in Appendix I of that report, computational modeling was previously used to study fugitive tank vapor emissions (Droppo 2004). The Droppo report simulated measured tank ventilation rates under worst-case meteorological conditions and concluded, *"Peak concentrations over a few second time-period can involve exposure to relatively undiluted air from the tank. Such exposures are limited to being quite localized because of the very small volumes of air."* The TVAT report (SRNL 2014) also acknowledged that given the limited volume of any release and the potentially narrow plume path that the probability of any worker encountering the plume is low and sporadic. Hence, the ability to actually "capture" a plume event for analytical quantification may remain particularly challenging.

Although the TVAT report (SRNL 2014) recommends a number of technical strategies for measuring plume release and dynamics, and for developing sampling and analytical methods to measure *"all chemicals of health concern,"* it is also recognized that the consistent measurement of potentially random events is problematic; hence, alternative computational approaches for simulating plume behavior, reactive chemistry, and human dosimetry are clearly warranted.

A.4.1 Exposure Modeling

A proposed computational modeling strategy will focus on predicting exposure based upon both plume behavior under relevant meteorological conditions as well as the dynamics of reactive chemistry. The TVAT report (SRNL 2014) clearly notes the importance of considering radiolytically generated free radicals (Bryan and Pederson 1995; Stock 2004) that would not be readily detected by most standard analytical methods because of their transient nature. Although previous strategies have primarily exploited computational fluid dynamic (CFD) modeling to simulate plume behavior, a more robust computational strategy, similar to what is used to simulate the complex integrated nature of atmospheric chemistry, is envisioned to be warranted. Extensive computational capabilities do exist, including modeling for atmospheric dispersion, chemical atmospheric mixing, trace gas and aerosol chemistry transport, and multi-scale modeling frameworks that can be exploited to support exposure assessment. These strategies have been developed to advance the prediction of highly complex chemical and meteorological atmospheric interactions at scales ranging from localized/regional events to global climate change. In addition, the capability to couple the toxicity evaluation of chemical mixture releases with atmospheric dispersion models can be appealing for consequence assessment near real time that provide protective measure for workers' safety. Feasibility has been demonstrated for such applications (Yao 2014). It is anticipated that these computational models could be exploited to simulate and predict transient vapor plume chemistry and behavior under a broad range of environmental conditions and therefore can be used to estimate worker exposures (see http://www.pnnl.gov/atmospheric/modeling/).

A.4.2 Biologically Based Modeling (Personal Exposure)

Although exposure modeling clearly provides important insight into tank vapor plume chemical concentrations available for inhalation, these models cannot directly predict the dose of chemical vapors/aerosols delivered to the respiratory tract (i.e., delivered dose). The ability to simulate and predict the delivered dose of inhaled toxicants under a broad range of environmental conditions and human behaviors represents a major advancement in our ability to understand health risk, particularly under the highly transient worker exposure scenarios suggested by the TVAT report (SRNL 2014). Recent advance in the development and application of computational fluid dynamic/physiologically based pharmacokinetic (computational fluid dynamic/physiologically based pharmacokinetic) modeling of dosimetry in the human respiratory tract could be exploited (Corley et al. 2012, 2015; Schroeter et al. 2008). These models are well suited to calculating respiratory tissue exposure to inhaled materials, particularly under realistic, transient breathing patterns (Corley et al. 2015). The ability to model breath by breath exposure (i.e., transient) is of high relevance for simulating sporadic tank vapor plume exposures that may last for a few seconds or minutes. A computational fluid dynamic/physiologically based pharmacokinetic model was recently used to simulate exposure to mixtures of relevant aldehydes (acrolein, formaldehyde, and acetaldehyde), and with additional chemical-specific model parameters such models can be advanced to address a broader range of chemical species of relevance to the tank farms.

Although biologically based modeling is useful for quantifying delivered dose, it is unrealistic to exploit this modeling strategy for the broad range of COPCs associated with tank vapors. Rather, careful consideration should be given to using biological modeling, in particular where the modeling of delivered dose can provide significant insight into health risk from tank vapor exposures.

A.5 Prioritizing Mixtures of Concern

As noted in the TVAT report (SRNL, 2014) the OSHA Mixture Rule was utilized to evaluate the impact of mixtures of chemicals that have similar health effects. The generalized approach was to group detectable chemicals at each sampling location (i.e., tank) according to their toxic effects and adding together the mean concentrations divided by the OEL in accordance with the OSHA formula (see Equation A.2). If the equivalent exposure calculation (*Em*) is greater than unity (>1) then mixture interactions are plausible. The TOC IH program action level for mixtures was set at Em ≥ 0.5.

$$Em = \frac{C1}{L1} + \frac{C2}{L2} + \cdots \frac{Cn}{Ln} \quad \P \tag{A.2}$$

Acute toxicity (any route of exposure), skin corrosion or irritation, serious eye damage or eye irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity (single or repeated exposure), aspiration hazard, and asphyxiant all pose potential hazardous health effects (29 CFR Part 1910). Acute and chronic are generally used to differentiate between health effects according to severity or exposure duration. Acute effects usually happen rapidly in response to short-term exposures. Chronic effects occur because of long-term exposure. A most frequently used definition of acute effects from the American Standards Institute (ANSI) refers to irritation, corrosivity, sensitization, and lethal dose. Other target organs, such as respiratory and nervous systems, may also suffer from short-term exposures.

When grouping toxic health effects, the chemical mixture methodology (CMM) developed by the DOE Subcommittee on Consequence Assessment and Protective Actions (SCAPA) should be considered (Craig et al., 1995). The chemical mixture methodology assesses mixtures of chemicals that can be separated are separable into their component elements or compounds by pure physical processes. The mixtures are defined at the receptor location; the individual chemicals may have been stored as a mixture

prior to the event that initiated their atmospheric release or may have been stored separately and only mixed after their release to the atmosphere. The chemical mixture methodology does not account for chemical reactions in the atmosphere between source and receptor. The chemical mixture methodology uses the "additive" model (Craig et al. 1999); therefore, it gives a conservative estimate of potential hazardous health effects.

The chemical mixture methodology quantifies the effects of exposure to the individual chemicals in a mixture based on Target Organ System Effect and Specific Target Organ Effect (Yu et al. 2016). Both short-term (i.e., acute) and long-term (i.e., chronic) toxic health effects are included.

The threshold delineating acute and chronic effects in the chemical mixture methodology is 7 days considering the nature of unplanned or accidental occurrence of chemical emergency events. In addition, the shorter duration for acute exposures indicated in Sax's Dangerous Properties of Industrial Materials (Lewis 2004), lack of sub-acute health code numbers (HCNs), and the indication time (sometimes months) for chronic exposures led to this definition (Lewis 1998; Lewis 2004; NIOSH 2008). Consequently, chronic exposure is defined as any toxic effects longer than 7 days. A period of 14 days is the threshold chosen by other agencies.

The chemical mixture methodology assumes that impacts on different target organ groups are independent of each other unless there is evidence to the contrary. This approach allows the chemical mixture methodology to separately consider the impact on organ systems from each chemical in a mixture and then add the effects of all chemicals to yield a cumulative impact for each target organ group. This approach yields more realistic results for cumulative health impact than two other commonly applied alternatives:

- Treating all chemicals in a mixture independently and assuming that there is no cumulative impact on the exposed individual (i.e., the human health impact is estimated by the exposure to the chemical that would do the most harm). This non-conservative approach tends to underestimate human health impacts.
- Adding the exposures to all of the chemicals, regardless of the different target organs affected by the chemicals. This conservative approach tends to overestimate cumulative health effects.

The HCN values assigned to each chemical indicate which target organ groups are affected by exposure to that chemical. HCNs offer a convenient way of categorizing identical or similar target organ effects. HCNs are similar to medical diagnostic codes in that they are code numbers and identify specific acute or chronic toxic effects on individual target organs. Currently, 63 different HCNs are available for characterizing the potential target organ or health effects caused by exposure to a chemical (Yu et al. 2010). Table A.1 lists the HCNs, their associated target organ effects, and their rank for emergency planning and response applications.

Hazardous health effects from irritants are evaluated by different target organs using the chemical mixture methodology. Depending on the severity of the health effects, severe, moderate, or mild, weighting factors are applied to more properly represent potential health effects (Yu et al. 2013).

The TVAT report indicated that mixture interactions associated with similar health effects are a real potential (i.e., irritation); hence, under tank conditions capable of producing a transient vapor/gas plume, acute interactions between COPCs with common modes of action (e.g., respiratory tract irritation) are highly plausible. Of particular concern are interactions in for transient plumes in which combinations of relative high (but transient) concentrations of chemicals can overwhelm protective detoxification metabolic pathways, resulting in greater than additive effects (i.e., potentiation). To address this issue, the following approaches should be further considered:

- For COPCs at their respective OEL-, identify which chemicals are anticipated to have similar toxicological effects (i.e., respiratory irritation) based upon the Quantitative Structure-Activity Relationships (QSARs) and known mode of action(s) (MOAs).
- Evaluate published literature for all toxicity interaction studies for the grouping of chemicals.
- Consider interactions that are not based upon quantitative structure activity relationship or mode of action, such as COPCs that might modify metabolism, bioactivation, and/or detoxification of other COPCs.
- Where feasible, consider exploiting computational modeling approaches to evaluate dose-dependent mixture interactions (see Corley et al. 2015).
- Consider in vitro and/or in vivo toxicological studies to assess interactions for COPC mixtures at OEL concentrations.

Table A.1. Health Code Numbers (HCNs) Used to Classify Toxic Effects by Target Organ. The HCNs are listed in the order adapted from Craig et al. (1999). Rank indicates the importance in terms of emergency response and planning.

Rank	HCN	Target-Organ Effect
30	1.00	OSHA carcinogen (29 CFR 1910.1000)--chronic effect
31	1.01	Bladder carcinogen--chronic effect
32	1.02	Liver carcinogen--chronic effect
33	2.00	Suspect carcinogen or mutagen--chronic effect
34	2.01	Kidney carcinogen--chronic effect
35	2.02	Liver carcinogen--chronic effect
56	3.00	Systemic toxin--chronic effects
46	3.01	Bladder--chronic effects
42	3.02	Hematological effects--chronic, unspecified
47	3.03	Bone--chronic effects
43	3.04	Bone marrow--chronic blood-forming system and other chronic effects
36	3.05	Brain--chronic effects
48	3.06	Eye--chronic ocular effects
45	3.07	Gastrointestinal tract--chronic effects
29	3.08	Heart, Cardiovascular system--chronic effects
41	3.09	Kidney--chronic effects
44	3.10	Liver--chronic effects
53	3.11	Skin--chronic effects including dermatitis and sensitization
55	3.12	Skin perforation--nasal septum perforation and other chronic effects other than skin absorption
14	4.00	Systemic toxin--acute short-term high hazard effects
9	4.01	Eye--acute, other than irritation
21	4.02	Nose--acute effects other than irritation
27	4.03	Bladder--acute effects
24	4.04	Bone marrow--acute blood-forming system and other acute effects
16	4.05	Brain--acute effects
23	4.06	Hematological effects--acute, unspecified
26	4.07	Gastrointestinal tract--acute effects
15	4.08	Heart, Cardiovascular system--acute effects
22	4.09	Kidney--acute effects
25	4.10	Liver--acute effects
52	4.11	Skin--acute effects other than irritation
54	4.12	Skin perforation--acute effects other than skin absorption

Rank	HCN	Target-Organ Effect
28	4.13	Bone--acute effects
50	5.00	Reproductive toxin--acute effects
51	5.10	Reproductive toxin--chronic effects
4	6.00	Cholinesterase toxin--acute effect
19	7.00	Nervous system toxin--acute effects
17	7.01	Central nervous system--acute effects
38	7.10	Nervous system toxin--chronic effects
37	7.11	Central nervous system--chronic effects
18	8.00	Narcotic--acute effect
40	9.00	Respiratory sensitizer--chronic effect
39	10.00	Respiratory toxin--chronic effects
20	11.00	Respiratory toxin--acute effects other than irritation
10	11.01	Respiratory irritant--acute severe or moderate but not mild irritant effects
11	11.02	Respiratory irritant-acute moderate
58	11.03	Respiratory irritant - mild
49	12.00	Blood toxin, anemia--chronic effect
3	13.00	Blood toxin, methemoglobinemia--acute effect
6	14.00	Severe irritant
5	14.01	Eye irritant--severe
12	14.02	Skin irritant--severe
8	15.00	Moderate irritant
7	15.01	Eye irritant--moderate
13	15.02	Skin irritant--moderate
59	16.00	Mild irritant
57	16.01	Eye irritant--mild
60	16.02	Skin irritant--mild
1	17.00	Asphyxiants, anoxiants--acute effect
2	18.00	Explosive, flammable safety (no adverse effects with good housekeeping)
61	19.00	Generally low-risk health effects--nuisance particles, vapors or gases
62	20.00	Generally low-risk health effects--odor

The evaluation and prioritization of COPC mixtures for tank headspace constituents should focus on the following specific actions (TVAT recommendations):

- Evaluate tank vapor mixture toxicological interactions at concentrations associated with transient plume exposures to modify OELs to accommodate mixture effects (**DR-7**).
- Use the OEL-C from analysis or subsequent toxicological testing to characterize the hazard index and risk from the tank vapor mixtures, and control to 10% of the value (**RCH-3**).

A.6 Odor Threshold and Sensory Irritation

As noted in the TVAT report (SRNL 2014), many of the identified tank vapor chemical constituents are respiratory irritants, but the term irritation is generally used without any discrimination between pathophysiological or sensory irritation (Paustenbach 2000). Pathological irritation involves local redness, swelling, pruritus, or pain. Chemosensory effects produce temporary but undesirable consequences on the eyes, nose, or throat that involve trigeminal nerve simulations (Arts et al. 2006). Odors can stimulate olfactory receptors; hence, it particularly challenging to differentiate MOA based upon symptomology, particularly when dealing with complex mixture interactions within the respiratory system (SRNL 2014).

Odors are routinely noted in the vicinity of the tank farms (SRNL 2014). Although it is reasonable to equate smell with a chemical exposure, exposure intensity cannot be determined based on odor

(Greenberg et al. 2014; Paustenbach and Gaffney 2006; Arts et al. 2006), and odor cannot by itself imply a medically significant exposure. In addition, the identification of a particular odor (e.g., pungent) may not be construed to be an indication of exposure to a specific chemical constituent in a complex mixture like tank headspace vapors. Nonetheless, ~33% of the nearly 1000 chemicals for which OELs have been established have odor/irritation as their most sensitive effect (Paustenbach 2000); hence, exposure to tank waste chemicals is anticipated to involve a range of odors and produce a range of respiratory irritations.

When evaluating COPCs and establishing OEL and OEL-C levels, efforts should focus on establishing odor thresholds and the relationship between odor detection and OEL/OEL-C atmospheric concentrations. Efforts should also focus on establishing the dose relationship between odor detection and irritation response for both individual tank farm vapors and relevant COPC mixtures. Many chemicals produce both odors and sensory or pathological irritation, making it extremely challenging to differentiate biological responses particularly when dealing with mixtures. Therefore, engaging researchers who have specific expertise in odor/irritant response may be warranted to help identify strategies for differentiating between odor detection and sensory/pathological irritation.

Respiratory irritants are important in evaluating potential adverse health effects of sporadic tank farm releases. Using the revised chemical mixture methodology, respiratory irritants are categorized as mild, moderate, and severe according to their toxic effects on the respiratory tract. Weighting factors that correspond to each severity level (similar to how skin, eye, and other irritants are treated in the chemical mixture methodology) are used. Implementing the revised chemical mixture methodology can provide more accurate assessment of the acute pulmonary health effects of COPC mixtures (Yao et al. 2016)[1].

The evaluation and prioritization of odor and sensory/irritation response for tank headspace constituents should focus on the following specific actions (TVAT recommendations):

1. Conduct additional evaluations of COPC toxicological studies to provide insight into the sensory and pathophysiological irritation response, including the role of mixture interactions and the potential need for additional toxicological evaluation (DR-3).
2. Perform a comprehensive evaluation of acute odor thresholds and toxicity effects for all COPCs to facilitate the establishment of action levels based upon the relationship between odor and toxicity threshold (DR-4).
3. Perform a comprehensive evaluation of respiratory health effects for all COPCs to facilitate the assessment of chemical mixture toxicity based upon the respiratory irritant severity (DR-4).

A.7 Odor Threshold and Sensory Irritation

A.7.1 Tank Headspace and Emissions Data

Previously, the primary data source for identifying COPC was the Tank Characterization Database (TCD) within the TWINS. The TCD included analytical characterization of both single- and double-shell tank headspace and waste sampling (TWINS, 2005). Although the TCD within TWINS will remain an important data source for the identification of priority COPCs, efforts will also focus on obtaining the most up-to-date headspace characterizations particularly under tank-disturbing conditions consistent with the recommendations (DR-1) of the TVAT (SRNL 2014). This is of particular importance because, as noted by the TVAT, static tank measurements may not reflect the maximum chemical headspace

[1] This technical report is currently going through PNNL internal review. We expect to have a clearance number soon.

concentration, particularly under transient conditions when vapor/gas plumes may be generated. Secondly, the TWINS database was compiled over 10 years ago and does not account for potential dynamic changes in tank headspace constituents and their concentrations over time. In addition, stack sampling or personal monitoring data, which were not a component of the original strategy for prioritization, should now be incorporated into a database and used to prioritize COPCs.

A.7.2 Available Environmental and Toxicology Literature

The assessment of the toxicology literature will use a strategy similar to the one used to establish initial screening values of tank vapor constituents (Poet et al. 2006). Table A.2 lists a number of key databases that will be used to assess relevant literature concerning health effects of COPCs. The analysis will consider all relevant human exposure, epidemiology as well as toxicology (human/animal/in vitro) DR data when conducting these reviews. Internet databases include TOXNET®, TOMES®, PubMed®) along with international databases such as that of the IARC. These databases contain information applicable to the toxicological assessment of chemicals. Both TOXNET and TOMES contain the RTECS® and HSDB® files. If information found from any of the above sources is incomplete, conflicting, or considered insufficient other sources such as the NIEHS-NTP, IARC, EPA, and the ATSDR will be exploited.

Table A.2. Key Databases Used to Assess Relevant Literature Concerning the Health Effects of COPCs

TOXNET®	The Toxicology Data Network, a set of databases covering toxicology, hazardous chemicals, and related areas; it is maintained by the National Library of Medicine (NLM). (http://toxnet.nlm.nih.gov/)
HSDB®	Hazardous Substances Data Bank. Accessible through TOXNET. Provided by the NLM.
PUBMED®	PubMed, provided by the NLM, contains citations for biomedical articles back to the 1950's; sources include MEDLINE and additional life science journals. (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed).
RTECS®	Registry of Toxic Effects of Chemical Substances, provided by Thomson Micromedex, Inc. Accessed through TOMES®, which has the same provider.
STN®	STN is the Scientific & Technical Information Network, provided by FIZ Karlsruhe, the American Chemical Society, and the Japan Science and Technology Corporation (JST). It links to published research in the world's journal and patent literature back to the beginning of the 20th century.
TOMES®	Registry of Toxic Effects of Chemical Substances, provided by Thomson Micromedex, Inc.

A.7.3 Available Exposure Guidelines

For each chemical of potential interest and current COPC, available databases will be systematically evaluated to identify published OELs and threshold values for inhalation and carcinogenicity ranking as previously described (Burgeson et al. 2004). The types of inhalation OELs and chronic exposure levels will include PELs, TLVs, RfCs for Chronic Inhalation Exposure, RELs, and short-term exposure limits among others. To accommodate a more comprehensive evaluation of acute-transient exposure concerns, a number of databases focused on acute exposures will likewise be evaluated, including: NAS AEGLs, Spacecraft Maximum Allowable Concentration for Airborne Contaminants, WEELs, the ERPG series from the AIHA, TEELs, and Submarine Escape Action Levels among others. In the absence of available exposure guidelines, quantitative structure activity relationship analysis can be implemented to predict the

toxicological properties of a specific chemical (or class of chemical) based upon structural similarities to known chemical toxicants. The subsequent classification (i.e., COPCs, needing further evaluation or of low concern) will be based upon predicted toxicological significance using available OELs/model simulations vs. measured or simulated tank maximum tank vapor concentrations as previously described (Burgeson et al. 2004).

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