Defining Completeness of Exposure Assessment Program Elements

Prepared by: John Heiel
Steven D. Jahn, CIH
Senior Technical Advisor
Health & Safety Programs

Reviewed by: John Heiel
John J. Hill, CIH
IH Programs Lead
Health & Safety Programs

Approved by Tim Bolen
Health & Safety Programs Manager
Summary
Clear definitions for the terms “exposure assessment baseline” and “exposure assessment surveys” are needed for common understanding by the industrial hygiene staff, management, and customer. These terms have historically been used interchangeably by the auditors. Since the exposure assessment process is cyclical, a clear understanding of when baseline or survey efforts are “complete” is needed. This paper provides definitions that will establish consistency for use of those terms, and allow management to measure progress with Exposure Assessment Program implementation.

Background
A root cause analysis was undertaken by procedure when Savannah River Nuclear Solutions (SRNS) management declared a Recurring Concern around the exposure assessment process. During the review of all available information and contributing causes to the decision to classify a Recurring Concern, the analyst identified that auditors (particularly) and non-industrial hygienists (in general) did not have an appreciation for the exposure assessment process, and as a result freely used terminology that was quite specific to industrial hygiene performance. In accordance with the Root Cause process, corrective actions were assigned to address deficiencies (ref: STAR Item 2009-CTS-000373). This paper establishes very specifically what is meant by exposure assessment baseline, and exposure assessment survey, and when each may be deemed “complete”.

Discussion
Historically, DOE and others have issued several documents addressing what constitutes an “adequate characterization of exposure”.

An initial attempt was made by J. Cohen at Lawrence Livermore National Laboratory in 1993. “Exposure Assessment Reviews” was prepared by the DOE Industrial Hygiene Technical Center for Excellence for Exposure Assessment under DOE HQ project management. It made reference to the same AIHA 1st edition of Exposure Assessment Strategy that was used for earlier site procedures. It relies heavily upon “expert judgment” without supporting data. (2)

Dated references include the DOE Tech Standard 6005-2001, which defines expectations for industrial hygiene practices. It defines terminology in accordance with the 2nd Edition of “The Occupational Environment – Evaluation and Control” (OEEC). Published in 1998, OEEC refers to the exposure assessment first as characterization (baseline work), then refining exposure determinations as acceptable, uncertain or unacceptable through additional information gathering (monitoring work). Routinely used as a training text for master’s level industrial hygienists, an exposure assessment baseline is that documented review of the people, processes and places that offer exposure to workers. It allows prioritization for limited resources, with the highest risk (greatest harm to greatest numbers of workers) assigned the first priority. Exposure Assessment Surveys are the means by which information is gathered to understand the
exposure, whether simply compliance decision against a standard, or a robust data set supporting future epidemiological research. (3)

DOE’s Implementation Guide for use with DOE Order 440.1 (DOE G 440.1-3) was the first attempt in 1998 by DOE to construct more formal guidance on the level of effort needed to meet Office of Worker Health and Safety expectations to “adequately characterize” a workspace. It relied heavily upon the 2nd edition of the AIHA Strategy Book, and offered the following definition of an “exposure assessment”:

“Exposure Assessment: The systematic collection and analysis of occupational hazards and exposure determinants such as work tasks; magnitude, frequency, variability, duration, and route of exposure; and the linkage of the resulting exposure profiles of individuals and similarly exposed groups for the purposes of risk management and health surveillance.”

The guideline goes on to establish that a baseline (called a Qualitative Exposure Assessment) captures hazard characterization data with a second step of screening for potential exposure. Quantitative Exposure Assessment infers the monitoring survey, where additional data is captured around the duration and variability of exposures. Attachment 2 shows the overview of the Exposure Assessment process as revealed in the guideline. (4)

10 CFR 851, Worker Safety and Health Program, has codified the use of the American Industrial Hygiene Association (AIHA) text on exposure assessment through its recommendations in the preamble and appendices. “A Strategy for Assessing and Managing Occupational Exposures”, 3rd edition, establishes a cyclical process for identifying all hazards, evaluating the magnitude and duration of exposures to the hazard, proposing and instituting controls (including prescription of PPE), and then validating exposures through sampling. Attachment 1 shows the fundamental process of exposure assessment as created by AIHA. (1)

Specific guidance in the Implementation Guide for use with 10 CFR Part 851 Worker Safety and Health Program in DOE Guide 440-1.8 published 12-27-2006 cites the requirement from 851.21 (a) to “identify and assess risks” (5). This essentially is the statement of the baseline. It offers a more precise definition of “appropriate monitoring” as any of the following:

1. Workplace monitoring (personal, area, wipe and bulk sampling) and [direct] measurement of physical hazards;
2. Biological monitoring;
3. Observations
4. Projections of potential exposures based upon modeling or product and industry literature searches.
All of these are currently allowed in the most recent Exposure Assessment procedure used by SRNS and Savannah River Remediation (SRR) (Manual 4Q1.1 Procedure 101A Exposure Assessment).

In February of 2008, DOE HQ issued an Independent Oversight Special Review of Workplace Exposure Monitoring. This report noted that across the DOE complex, “a number of workplace exposures ... had not been adequately identified, analyzed, monitored (emphasis added), and/or documented.” This affirms the experiences of the staff of the industrial hygiene program at SRS, where it has been stated that not enough had been done to meet the nebulous “adequately characterized” terminology. (6)

The 3rd edition of the AIHA Strategy Book established a higher expectation of addressing uncertainty in decisions of exposures than either of the previous editions. As a result, a formality of decision logic emerged to focus limited resources towards reducing uncertainty. Since the purpose of “surveying” by industrial hygiene is to demonstrate compliance or gain better understanding of an exposure profile, there can reasonably be a lengthy period where insufficient data is available to render an “acceptable exposure decision”. Further, with a limited number of occupational exposure limits (OELs) available for purposes of the comparison, a great many uncertain exposures cannot be reduced to “acceptable” decisions; we can only reduce uncertainty with other efforts, such as toxicological research.

**Proposed Solution**

In an attempt to clearly communicate expectations to the staff and explain the Exposure Assessment progression from a baseline with uncertainty to a baseline with defined “acceptable” exposures, SRNS proposes that a specific definition for “complete baseline” and “complete survey” are needed.

**A. Creation of an Exposure Assessment Baseline**

An Exposure Assessment Baseline is considered “complete” when the following elements of review are conducted and documentation created:

- All similar exposure groups (SEGs) have been defined;
- All hazards from products in use by the SEG members, and including hazards from activities and areas;
- Initial ratings of the exposure potential are recorded for each, yielding acceptable, uncertain, or unacceptable exposure decisions or that minimal assessment criteria are met as outlined in reference 7;
- Management has concurred with the review and set priority for the next set of actions by those resources made available.
B. **Creation of Exposure Assessment Surveys**
A complete Exposure Assessment Baseline Survey has been created when the following elements of review are conducted and documentation created:

- Each rated uncertain exposure from the baseline has resulted in a decision that sampling is available;
- A monitoring worksheet has been completed for each agent;
- Resource commitments have been made by line management to coordinate the scheduling, staffing and funding to acquire and analyze the sample;
- And evidence exists that the process is resulting in data being acquired.

At any point in time, information may be less than fully created (there is some data but not enough for statistical decision making). This is normal and part of the flow of information that drives continuous improvement. Such circumstances are the norm given thousands of exposure opportunities and limited resources with which to collect more information. SRNS would consider such information as an “adequate characterization”.

An “inadequate characterization” would be demonstrated when uncertain exposure decisions were the end point, with no demonstration by the line management of further commitment to resolve or reduce the uncertainty.

**Conclusion**
This document provides a clear distinction between what constitutes an exposure assessment baseline from exposure assessment surveys, and when each may be considered complete (“adequate”). The definitions proposed and approved in this document provide clarity in the differences in these terms.

Changes may be made to this document if a review of regulatory and industry sources (10 CFR 851, DOE IH Technical Guide, AIHA, EISM/DOEHR, etc.) warrant an update in the definitions and applications of the information.
References

Attachments
1. Overview of AIHA 3rd Edition of Exposure Assessment Process
2. Figure 1 from DOE 440.1-3 Implementation Guide for DOE Order 440.1, 3-30-98; Overview of the Exposure Assessment Strategy
3. Exposure Assessment
Define Similar Exposure Groups

Similar exposure groups (SEGs) are groups of workers having the same general exposure profile for the agent(s) being studied because of the similarity and frequency of the tasks they perform, the materials and processes with which they

![Flowchart of Exposure Assessment Process]

Figure 1.2 — A strategy for assessing and managing occupational exposures.
Figure 1. Overview of the Exposure Assessment Strategy