

TUTORIAL

THE RISK ASSESSMENT PROCESS USED IN THE ARMY'S HEALTH HAZARD ASSESSMENT PROGRAM

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Health hazard assessment is a critical aspect of a risk management acquisition program. Past programs developed without attention to human systems integration have suffered expensive delays, created long-term health and safety problems, and encountered difficulty and expenses during maintenance and demilitarization/disposal. The Army Health Hazard Assessment (HHA) Program uses risk assessment techniques to characterize health hazards associated with new materiel systems. This article provides the acquisition community with an overview of the risk assessment process used in preparing HHA reports and the key roles played by Army Medical Department organizations. This paper also shows how HHA Reports are integral components of a Program Manager's overall risk management plan.

ffective risk assessment and risk management are essential components of successful acquisition programs. Program Managers (PMs) and the entire program team must perform risk assessments early in the acquisition life cycle to identify critical risks and incorporate mitigations using the systems engineering process. Occupational health risks associated with acquisition systems

are one of the many risk areas that PMs need to address early in the acquisition life cycle.

Department of Defense and Army guidance require that environmental, safety, and health risk management be integrated into the system engineering process (Department of Defense [DOD], 2002; Department of the Army [DA], 1997). The Army's Health Hazard Assessment (HHA)

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Program supports the overall risk management process by providing the acquisition community with assessments of health risks associated with new Army materiel systems (to include non-developmental and commercial off-the-shelf items) and upgrades or modifications to existing systems. Members of the acquisition community should be aware that health risks associated with military weapon systems need to be assessed and managed along with other program risks.

The Army's HHA Program is designed to identify and eliminate health hazards, or to reduce them to some acceptable level during the life-cycle management (LCM) of materiel systems. Medical per-

"Two key organizations that support the Army's HHA Program are USACHPPM and the U.S. Army Medical Research and Materiel Command (USAMRMC)." sonnel assess the health hazards inherent to or resulting from the operation, maintenance, storage, and disposal of materiel systems. The focus of the HHA is on potential health hazards that may occur during user training and combat scenarios; however, health hazard issues throughout the LCM may be addressed. The results of

this assessment are documented in a formal health hazard assessment report (HHAR). This report provides developers, testers, evaluators, and users an analysis and assessment of health hazards related to a materiel system.

This article focuses on the risk assessment process used by Army Medical Department (AMEDD) professionals to estimate and report potential health hazards. It describes how health risks should be viewed just as all other risks are considered by PMs. Key AMEDD organizations and their role in the HHA process are provided throughout this article.

U.S. ARMY HEALTH HAZARD ASSESSMENT PROGRAM

ORGANIZATION AND RESPONSIBILITIES OF THE HHA PROGRAM

The Army leadership created the formal HHA Program in 1981 as a result of an extensive weapon modernization in the late 1970s. The fielding of the M198 155-mm Towed Howitzer is one example of why the leadership decided to include an assessment of health risks early in the system engineering process. Soldiers firing the M198 experienced pain and internal injuries resulting from the blast overpressure exposure. In order to control the health hazard, firing restrictions were placed on the number of rounds fired per day. The Office of the Army Surgeon General (OTSG) is the proponent for the HHA Program and is responsible for providing HHAs for Army materiel systems (DA, 1991). Gross and Broadwater (1993) provide a comprehensive historical description of the Army's HHA Program. Additional information about the HHA Program is found in references by Bratt, Doganiero, and Spencer (1997); Mc-Devitt, Bratt, and Gross (1998); and Murnyak, Spencer, Chaney, and Roberts (2002).

Two key organizations that support the Army's HHA Program are U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) and the U.S. Army Medical Research and Materiel Command (USAMRMC). Both are major subordinate commands of

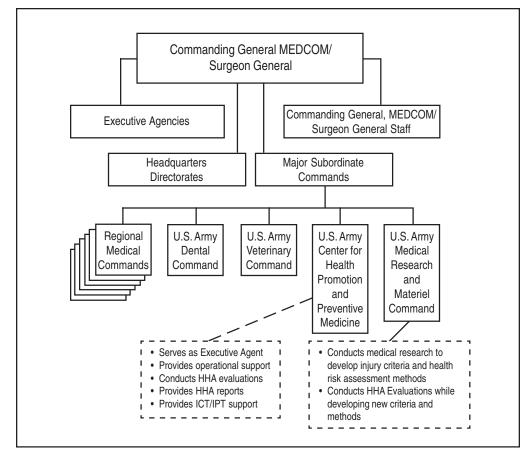


Figure 1. The Army Medical Department Organization

the U.S. Army Medical Command (MEDCOM) (Figure 1).

The OTSG appointed the USACHPPM as the executive agent for the HHA Program in 1994 (DA, 1995). Therefore, USACHPPM provides operational support to the Army acquisition program. As Executive Agent, USACHPPM represents the OTSG on all matters pertaining to the HHA program, which includes facilitating AMEDD support, developing and coordinating policy issues, attending program meetings, and providing Health Hazard Assessment Reports (HHARs) on Army materiel systems. The HHA Program office is located in USACHPPM's Directorate of Occupational Health Sciences. When HHA Program health professionals assess materiel systems, they engage the expertise of other USACHPPM scientists and engineers in 10 technical programs. These include the Environmental Health Engineering, Hearing Conservation, Entomological Sciences, Industrial Hygiene, Industrial Health Physics, Toxicity Evaluation, Laser and Optical Radiation, Radio frequency and Ultrasound, Ergonomics, and the Occupational and Environmental Medicine Programs. Its Military Operational Medicine Research Program (MOMRP) provides the USAMRMC's support to the HHA Program. The MOMRP is a medical research program that provides biomedical solutions to protect and enhance soldier performance in multistressor operational and

"The MOMRP is organized into three medical research areas: neuropsychology and performance, energetics and environmental medicine, and injury sciences." training environments. The MOMRP is organized into three medical research areas: neuropsychology and performance, energetics and environmental medicine, and injury sciences. Major research projects in the energetics and environmental medicine, and the injury sciences areas produce

health risk criteria and health risk assessment methods for the HHA Program.

The MOMRP research also provides soldier survivability assessment tools for the Army Research Laboratory's Survivability/Lethality Analysis Directorate (SLAD), and biomedically-valid design criteria for materiel developers. The MOMRP's current research program includes projects to develop injury criteria and HHA methods for heat-related injuries, neck injury from head-supported devices, blunt trauma injury from shoulderfired weapon recoil, and injuries from exposures to repeated jolt in ground vehicles.

The following USAMRMC laboratories conduct the MOMRP's energetics and environmental medicine, and injury sciences research: the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; the U.S. Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; the U.S. Army Aeromedical Research Laboratory, Ft. Rucker, AL; and the WRAIR's U.S. Army Medical Research Detachment (USAMRD) at Brooks City Base, San Antonio, TX. In addition to its core USAMRMC laboratory capabilities, the MOMRP relies on strong collaborative research relationships with other military service laboratories, commercial research facilities, and university laboratories.

THE HEALTH HAZARD ASSESSMENT PROCESS

The HHA process is a coordinated effort between materiel developers and the medical community (Figure 2). It requires communication and information exchange between acquisition program offices, the U.S. Army Materiel Command (USAMC) Office of the Surgeon, USACHPPM, and USAMRMC. The materiel developer initiates the HHA process by requesting HHA support from the USAMC Office of the Surgeon. The USAMC Surgeon serves as the acquisition community's liaison with the Army Medical Command. The USAMC Surgeon reviews requests for HHA support and forwards them to USACHPPM's HHA Program for action.

The USACHPPM serves as the Army Surgeon General's Executive Agent for the HHA Program and provides support to developers in the form of HHA reports, review of program documents (e.g., ORDs, test plans, MANPRINT [Manpower and Personnel Integration] and System Safety documents) and attendance at select integrated product teams. When USACHPPM completes an HHAR, the report is sent through the AMC Surgeon to the developer. The USAMRMC plays an essential role in the HHA process by developing injury criteria and health risk assessment methods when no suitable criteria or methods exist for militaryunique occupational exposures. One of USAMRMC's challenges is keeping abreast of the Army's future plans in order to identify military-unique occupational health risks posed by emerging weapon system technologies, and to plan and program medical research projects to address those unique risks.

Throughout the course of an occupational health hazard research project, USAMRMC researchers directly support the HHA Program and acquisition PMs by providing system-specific, best-available HHAs. These system-specific assessments provide USAMRMC researchers an

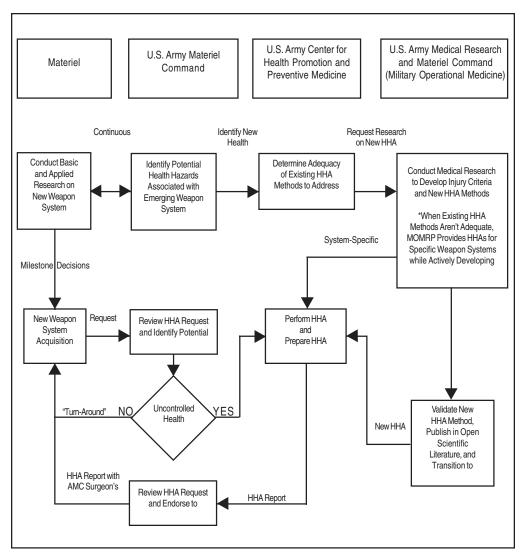


Figure 2. The Health Hazard Assessment Process

opportunity to evaluate evolving methods and criteria, while providing answers to support current acquisition programs. However, the ultimate goal of USAMRMC's occupational health hazard research is to develop generic injury criteria and assessment methods that apply to a broad range of systems.

The blast-injury problems associated with the M198 Howitzer, described earlier, also serve as an example of how the

"...[T]he ultimate goal of USAMRMC's occupational health hazard research is to develop generic injury criteria and assessment methods that apply to a broad range of systems." USAMRMC researchers support the HHA process. When the problems with blast-injuries were first noted, the medical community did not have tools to accurately assess the potential health risk. The USAMRMC researchers implemented a longterm research project to develop tools that can help assess the potential health risks associated

with exposure to blast energy. The end product is a biomechanical injury model that estimates the risk of injury when the weapons are fired.

USAMRMC relies on the scientific community to validate its injury criteria and HHA methods. All of USAMRMC's medical research programs, including those that produce criteria and methods for the HHA Program, receive peer review by members of the scientific community who are independent of the Department of Defense. Additionally, USAMRMC publishes its research findings in the open, peer reviewed scientific literature. This process of external review and validation ensures that the injury criteria and assessment methods intended to protect soldiers from occupational health risks are the very best available.

The final step in USAMRMC's development of health risk assessment methods for the HHA Program is to document and package the method in a user-friendly format that can be used by USACHPPM health hazard assessors. The final transition of a biomedically valid HHA method to USACHPPM marks the successful completion of a USAMRMC occupational health hazard research project.

HHA RISK ASSESSMENT METHODOLOGY

The HHA risk assessment methodology, as depicted in Figure 3, is a stepwise process that is followed by independent medical assessors to identify and analyze potential health risks associated with systems. The process is compatible with the System Safety model in MIL-STD-882 and the Army's Risk Management process described in FM100-14 (DA, 1998; DOD, 2000). The major components of an HHA include hazard identification, exposure assessment, and hazard assessment. The following describes these components.

Hazard identification is the first step in the HHA process where potential health hazards are recognized. Hazard identification consists of determining what specific chemical, physical, and biological agents or environmental conditions are associated with the operation and maintenance tasks of a new system. The medical assessor uses experience from previous systems, safety assessments, human factor assessments, operational requirement documents, management documents, test documents, user manuals, field observations, and expert

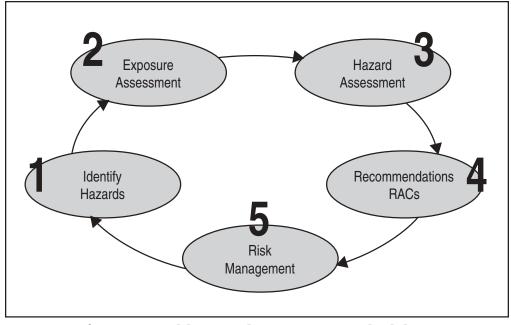


Figure 3. Health Hazard Assessment Methodology

knowledge to aid in the identification of health hazards.

The *exposure assessment* is fundamental to the HHA process. The medical assessor evaluates information available on the levels of the specific agents, potential routes of exposure, duration of exposure, frequency of exposure, and population at risk.

Exposure levels can be determined from data acquired by sampling and measuring actual conditions during training or simulated combat situations. The system developer normally collects these data during user or technical tests. For some categories of health hazards, the medical assessor may conduct a test and collect health hazard data (e.g., lasers and radiation). For some applications, modeling techniques can yield useful potential exposure data at less cost and in less time than actual monitoring (e.g., heat and cold stress). It is also possible to use biological indices to estimate the significance of the health hazard (e.g., carboxyhemoglobin blood levels that are used to estimate the health effect from carbon monoxide exposure). In those cases when critical data are incomplete or not available, a professional judgment or inference based on the medical assessor's experience and reasoning may be necessary.

The routes of exposure for chemical and biological hazards include inhalation, dermal absorption, ingestion, and injection. Those for physical hazards (e.g., radiation, temperature extremes, noise, shock, and vibration) depend on the characteristics of the specific energy as it is transferred to the body. Each potential hazardous agent needs to be analyzed with respect to how it might impact human health. The duration and frequency of exposure will depend on how the developer intends for soldiers to use and maintain the system. Consequently, it is imperative for the developer to supply the HHA Program with an accurate and complete system description and use scenario.

Hazard assessment combines the exposure assessment and the hazard identification steps to evaluate the extent of the health hazards. The exposure estimates are compared with established health exposure limits to assess the significance of the hazards. Examples of established health exposure limits include militaryunique standards, Occupational Safety and Health Act (OSHA) Permissible Exposure Levels (PELs), and American Conference of Governmental Industrial Hygienist (ACGIH) Threshold Limit Values (TLVs)^{TM.1}

RECOMMENDATIONS, RISK, AND

DOCUMENTATION

The goal of the HHA Program is to identify potential health hazards early in the acquisition life cycle so that developers can eliminate the hazards in their system designs or devise operational strategies to adequately control the hazards. The medical assessor recommends actions to reduce, control, or eliminate the potential health hazards. Such recommendations may include engineering controls, specified work practices, use of personal protective equipment, administrative controls, or a combination of these strategies. The medical assessor conveys the magnitude of the system's health risks to the materiel developer by assigning a risk assessment code (RAC) for each health hazard. The medical assessor's recommendations and RACs are documented in an HHAR that is provided to the materiel developer.

When a health hazard cannot be eliminated, the medical assessor characterizes the uncontrolled hazard by estimating its *severity* and *probability* of occurrence. The hazard severity and hazard probability are combined and represented by a RAC that is assigned by the medical assessor. RACs are used to characterize health risks to personnel who will be operating or maintaining Army systems during testing, training, or combat. The process of assigning RACs for HHAs is described in the Army's HHA regulation (DA, 1991). This process was adopted

Hazard Severity Categories						
Numerical Designation	Classification	Possible Hazard Outcomes				
I	Catastrophic	May cause death or total loss of a bodily system				
II	Critical	May cause severe bodily injury, severe occupational illnes, or major damage to a bodily system				
	Marginal	May cause minor bodily injury, minor occupatinal illness, or minor damage to a bodily system				
IV	Negligible	May cause minor bodily injury, minor occupational illness, or minor damage to a bodily system				

 Table 1. Numerical Designations and Descriptions

 for Hazard Severity Categories

Hazard Probability Categories						
Descriptive Word	Level	Specific Individual Item	Fleet or Inventory			
Frequent	Α	Likely to occur frequently	Continuously experience			
Probable	В	Will occur several times in the life of an item	Will occur frequently			
Occassional	С	Likely to occur some time in the life of an item	Will occur several times			
Remote	D	Unlikely but possible to occur in the life of an item	Unlikely, but can reasonably be expected to occur			
Improbable	E	So unlikely, it can be assumed occurence may not be experienced	Unlikely to occur, but possible			

Table 2. Alphabetical Designations and Descriptionsfor Hazard Probability Categories

from a system safety military standard (DOD, 2000).

The hazard severity component of a RAC reflects the worst possible adverse health consequence. This consequence can be defined by the degree of bodily injury, occupational illness, or health-related performance degradation that may occur from exposure to a system-related health hazard. Table 1 describes hazard severity in terms of four categories ranging from catastrophic to negligible. These categories are designated with Roman numerals from I to IV, respectively. Hazard probability refers to the likelihood that a health hazard will occur and can be based upon a variety of factors (e.g., a person's proximity to the exposure, exposure in terms of cycles or hours of operation, and affected population). The medical assessor assigns a letter from A to E for probabilities ranging from frequent to improbable, respectively. Table 2 describes the hazard probability categories.

The RAC is developed by considering both hazard severity and probability and is reported as an Arabic number that ranges from 1 to 5. Table 3 shows how severity and probability assignments are combined to produce RACs that reflect high-level risks (RAC 1 or 2), mediumlevel risks (RAC 3), or low-level risk (RAC 4 or 5). A residual RAC is assigned to each recommended control action to estimate the health risk remaining after the developer implements the control action.

The health hazard assessor documents and provides the HHA, recommendations, and RACs to the materiel developer. This information is assembled into an HHAR that generally is forwarded through command channels to PMs. The specific contents of a typical HHAR include references, summary, background information, identification of health hazards, assessment of health hazards, recommendations, and assessor identification. Some of the key characteristics of HHARs are shown in Table 4. Additional information about HHARs can be found

High 🗲					→ Low	
		Hazard Probability				
	Severity	Α	В	С	D	E
High	I	1	1	1	2	3
	II	1	1	2	3	4
		2	3	3	4	5
Low	IV	3	4	5	5	5
	Numbers 1 and 2 are considered to be high risk levels, number 3 is a medium risk level, and numbers 4 and 5 are low risk levels.					

Table 3. The Risk Assessment Code Matrix

in Army Regulation 40-10 (DA, 1991) and in Gross and Broadwater (1993). The later publication also has an example of an HHAR.

An Initial Health Hazard Assessment Report (IHHAR) may be prepared during the early stages of a developmental effort (DA, 1991). Usually at this phase of development there is not sufficient information to prepare a definitive HHAR. However, the IHHAR can identify design guidance and data deficiencies that the developer can plan for and acquire

Table 4. Characteristics of the Health Hazard Assessment Report

- · Focuses on potential health hazards from training, combat, maintenance, and disposal.
- Reports and documents the assessment done by a multidisciplinary team of Army Medical Department scientists and engineers.
- Addresses nine potential health hazard issues: acoustic energy, biological substances, chemical substances, oxygen deficiency, radiation energy, shock, temperature extremes and humidity, trauma, and vibration.
- Assigns Risk Assessment Codes (RACs) for potential health hazards.
- Formally analyzes health risks of materiel systems for developers, testers, evaluators, and users.
- Provides recommendations for eliminating or controlling hazards.
- Supports milestone decisions, safety releases, materiel releases, etc.

during developmental testing. As additional information is acquired during testing (technical and operational), IHHARs are updated.

THE RELATIONSHIP BETWEEN THE PROGRAM MANAGER'S RISK MANAGEMENT PROCESS AND THE HEALTH HAZARD ASSESSMENT PROCESS

One premise of this discussion is that materiel developers, as risk managers, should handle the risks identified during the HHA process in the same manner that they handle other programmatic risks. The previous section described the HHA process and risk assessment methodology. This section shows how HHA recommendations can be integrated with and support risk management decisions that program managers routinely make.

THE MATERIEL DEVELOPER'S RISK MANAGEMENT PROCESS

Acquisition decision makers identify and assess program risks that may impede or cause a program to be unsuccessful. Generally, risk management is integrated into the overall management of a materiel development program (DOD, 2002). The following paragraphs contain definitions from the *Defense Acquisition Deskbook* (DOD, 2002) for risk, risk management, and management elements that are truncated purposely for the scope of this paper. The reader should refer to the deskbook for more detailed definitions and explanations.

In acquisition, *risk* is a measure of the potential inability to achieve overall program objectives within defined cost, schedule, and technical constraints.

Consequently, *risk management* is the act or practice of dealing with such risk. It includes planning for risk, assessing risk areas, developing risk-handling options, monitoring risks to determine how they change, and documenting the overall risk management program (Figure 4).

Risk planning is the process of developing and documenting an organized and comprehensive, strategy for identifying and tracking risk areas, developing risk-handling plans, performing continuous risk assessments to determine program risks and resource needs. Risk assessment is the process of identifying and analyzing program areas and critical technical process risks to increase the probability/likelihood of meeting cost, schedule, and performance objectives. It includes prioritizing risks in terms of their probability of occurrence, severity of consequence/impact, and relationship to other risk areas or processes. Risk handling is the process that identifies, evaluates, selects, and implements options in order to set risk at acceptable levels given program constraints and objectives. Risk monitoring is the process that systematically tracks and evaluates the performance of risk-handling actions. It feeds information back into the other risk management activities of planning, assessment, and handling.

How the HHA Program Supports the Program Manager's Risk Management Program

There are several similarities between the HHA and the PMs risk management processes. The hazard identification step of the HHA process is analogous to the risk identification that PMs perform as

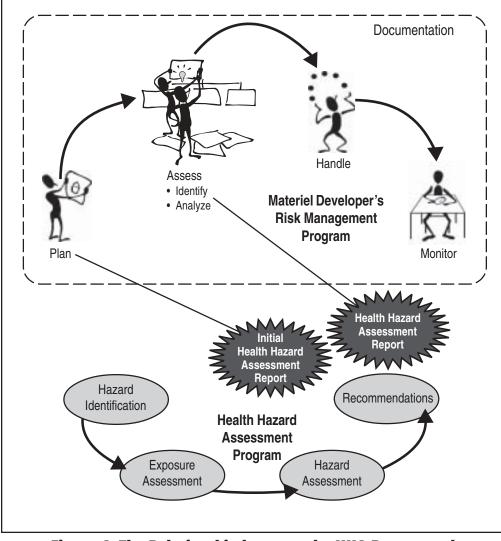


Figure 4. The Relationship between the HHA Process and the Materiel Develop's Risk Management Model

part of risk assessment (risk management model). Both focus on identifying events and items that can cause potential problems with a system's life cycle. The combination of exposure assessment and hazard assessment in HHA is similar to risk analysis that PMs perform as part of risk assessment. Both evaluate how various factors may influence those concerns previously identified (i.e., during HHA hazard identification and program manager risk identification).

Now that the HHA process and the PM's risk management process have been described, it can be shown that the two are not mutually exclusive. The previous paragraph described the similarities of the two processes. The following

paragraphs will explain how they are related and thus how the HHA can be a tool for the PM in the overall system risk management plan.

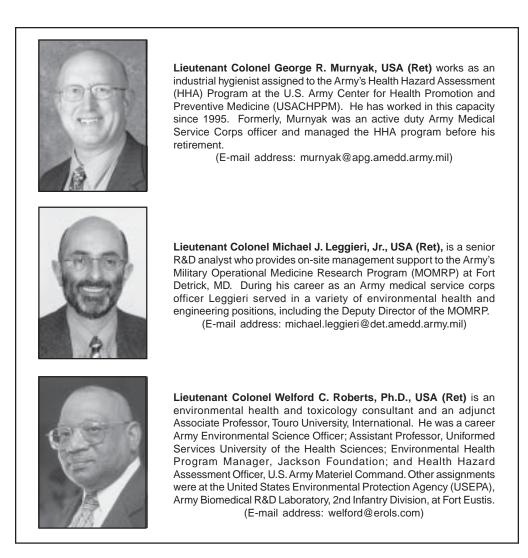
The definition for risk in acquisition refers to technical constraints as one of the issues that PMs must manage. Health hazard concerns could be considered in this category of issues because of the engineering and design features that are applied during development to prevent hazardous exposures and adverse health outcomes. However, when the HHA Program is incorporated into the overall risk management plan, the PM is spared the burden of doing the assessment and preparing associated documentation. Figure 4 illustrates this point. AMEDD assessors provide thorough and unbiased HHARs that are independent of the developers and milestone decision authorities (MDAs) (DA, 1991). The independence of the AMEDD provides some assurance to the acquisition managers and MDAs that their decisions are based on sound HHA recommendations. When a health assessment is performed, independent medical assessors do the assessment and provide it to the PM in the form of an HHAR. This provides the developer with a completed assessment and a report for documentation. The HHA can enter the risk management phase of the PM's risk management program at the point where the health risks are handled and monitored.

The HHA provides recommendations for PMs to use in the "handle the risk" element of their risk management program. The RACs in the HHAR supports the risk acceptance procedures employed by the PM. An IHHAR should be requested by the PM early in the development cycle and should be used during the planning phase. The IHHAR also can assist the PM with planning for the financial resources required for HHA support. Specifically the IHHAR provides valuable information used to develop test plans that ensure data is collected to support completion of an HHAR later in the process. If the IHHAR does recommend specific health hazard data requirements, it is prudent to invite CHPPM representatives to participate in Test and Evaluation Integrated Product Teams (IPTs). The HHAR is prepared by the AMEDD and provided to the materiel developer as risk management documentation. The HHARs provide health hazards risks that should also be incorporated in the acquisition programs System Safety hazard tracking system and the MANPRINT issues tracking system.

SUMMARY

The U.S. Army's Health Hazard Assessment Program supports the Army's leadership commitment to field materiel systems that are safe and effective. The program is also a critical component of the Army Medical Department's mission "to conserve the fighting strength." This paper describes how the HHA program uses health risk assessment techniques to provide combat and materiel developers with health risk assessments for use in their risk management program and subsequently to make informed management decisions. It outlines an approach amenable to risk management, sustainability and life cycle cost management (i.e., total ownership cost) in many types of acquisition programs.

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ENDNOTE

1. TLV is a registered trademark of the American Conference of Governmental Industrial Hygienists, Cincinnati, OH. Use of trademarked names does not imply endorsement by the Army but is intended only to assist in the identification of a specific product.