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PRINCIPAL INVESTIGATOR: James H. Stuhmiller, Ph.D.

CONTRACTING ORGANIZATION: Jaycor
San Diego, California 92121-1190

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San Diego, California 92121-1190

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NLT Bioeffects Broad Issue Study

Final Report

Prepared by: James H. Stuhmiller
JAYCOR
9775 Towne Centre Drive
San Diego, California 92121-1996

Prepared for: **Air Force Human Systems Center**
Brooks Air Force Base, Texas 78235

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Introduction

As the United States becomes more of a peace broker, its military forces must have the appropriate equipment and training to bring peace to unstable regions. Consequently, the Department of Defense has devoted significant resources to developing weapons that apply an appropriate force against an adversary in order to subdue or repel him, without maiming or killing the intended target or innocent bystanders. The application of these nonlethal weapon (NLW) systems in world hot-spots has the potential to significantly reduce collateral damage, conflict escalation and enemy fatalities, while keeping friendly forces secure.

US military and law enforcement agencies are interested in acquiring and technology organizations are interested in developing effective weapons. There are, however, significant questions about the nature of the biological effects that are caused and the amount of harmful effects that can be tolerated by such systems.

Since these weapons are intended to be effective (cause immediate discomfort or incapacitation) and yet are not intended to cause permanent harm, the evaluation of these weapons has a requirement of demonstrating safety to the "target" that is in addition to the usual considerations of operational effectiveness and cost. Because these weapons are likely to be used in noncombat situations, the general population, including the old and young, may be incidentally exposed, increasing the complexity of evaluating the weapon safety.

Similarly, the complexity of the biological response and the long and expensive technology development cycle makes it critical to understand the biological effect concerns early on so that nonlethal technologies (NLT) with unacceptable characteristics can be screened out and so that research programs can include the necessary components needed to provide acceptable proof of safety.

Objective of Study

The purpose of the study is to identify the biomedical issues that the Department of Defense must resolve in order to develop, acquire, and use NLWs. The scope of the study will include, (1) interviewing a variety of government organizations to understand what questions must be answered, and (2) reviewing the scientific literature to understanding the data that will be required to answer these questions. The information on organizational concerns and scientific knowledge will be integrated.

To the extent possible, these concerns will be formulated for generic technologies, as opposed to specific weapons, so that the findings can be have the broadest application. It is realized, however, that when actual weapons are proposed, questions will be formulated in a specific context. To give the interview process as much reality as possible, general contexts are provided as a conceptual aid. It is acknowledged, however, that *standardization of the interview process could have had an influence on the interviewee's responses.*

The final product of the study will be a technical report synthesizing the organizational questions raised, summarizing the biological effects of directed energy weapons, and identifying research areas of greatest importance for biomedical research.

Methods

Interview Refinement Process

To obtain as consistent a response as possible from the various interviewees, a standardized interview process was sought. The first step was to formulate a set of questions based on experience with nonlethal weapon policy and research issues that had been raised in the past. These questions were organized by categories and reviewed by the staff of the Human System Center (HSC). Modifications to the questionnaire was made and a tentative list of prospective interviewees identified.

Next, the interview plan, questions, and interviewee list were reviewed by the Nonlethal Steering Group at Brooks AFB. Comments were received on the nature of the questions, the degree to which attribution should be given, and guidance to focus the effort on directed energy technology of interest to Armstrong Laboratory. A second version of the interview was developed, including background material to introduce the interviewees to the technical subject matter of directed energy weapons (RFR and acoustic).

The first round of interviews were conducted at Air Force Medical Operations Agency (AFMOA) with the considerable assistance of Maj. Meade Pimsler. The technical background presentation was well received and certain expansions made. A formal rearrangement of the questions was made to follow the natural flow of the initial interviews. A third version of the interview presentation package was constructed and reviewed by HSC and remained virtually unchanged throughout the remainder of the project.

Narrative Version of Interview

The presentation version of the interview materials are found in Appendix 2 of this report. Each interview began with a review of the background to the project, including the statement of work and the intended final report. The following section provided background on the technical nature of directed energy weapons.

Characteristics of Directed Energy NLT

Directed energy (DE) weapons transmit energy from a source to a target by means of propagating waves. Two classes of DE NLTs are considered: electromagnetic and acoustic. Either class can transmit its energy continuously or in bursts or pulses. In the continuous mode, the waves are characterized by the frequency of oscillation (1 Hz = one oscillation per second) or by the wavelength (spatial distance between peaks in intensity). The

frequency, f, the wavelength, λ, and the speed of propagation, c, are related by $\lambda = c / f$. The physical scale at which the energy acts is comparable to the wavelength.

Electromagnetic energy is the result of transverse oscillating electric and magnetic fields that propagate through space without requiring matter for transmission. For any frequency or amplitude of the wave, the wave propagates at the speed of light. EM waves are characterized by the frequency at which the electric and magnetic field oscillate. Some common designations are: radio frequency (f = 30 kHz to 300 MHz or λ = 10 km to 1 m), microwaves (f = 300 MHz to 300 GHz or λ = 1 m to 1 mm), and visible light (10^{15} Hz or λ = 1 to 0.1 μm). At considerably higher frequencies, EM radiation takes on a particle nature, best described by the energy per particle. These particles (x-rays, γ-rays, etc.) can be so energetic that they ionize the material they pass through.

Acoustic energy is the result of compression and rarefaction in the atmosphere and requires matter to be transmitted. At small amplitudes, all acoustic waves travel at the same speed, called the speed of sound, which depends on the properties of the transmitting material. For air at sea level conditions the speed of sound is about 300 m/s. Acoustic waves are also characterized by their frequency of oscillation: infrasound (f < 20 Hz or λ > 15m), auditory sounds (peak response around f = 1 kHz or λ = 30 cm), and ultrasound (f > 20 kHz or λ 1.5 cm).

As the acoustic amplitude increases, so does the speed of propagation. Since different parts of the wave travel at different speeds, the largest amplitudes travel more quickly and form a very abrupt and energetic front, called a shock wave. Shock waves are not characterized by their frequency, but by their total energy or strength. Shock waves can propagate in air as much as eight times faster than sound waves.

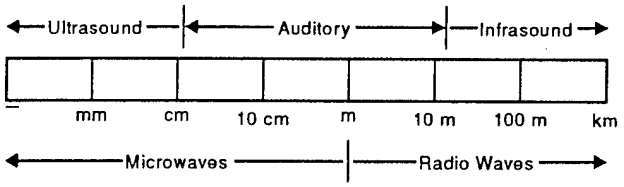

Figure 1. Variation of wavelength for common acoustic and electromagnetic waves.

Variation of Intensity from a DE NLT

The intensity field around an EM or acoustic NLWs share many common features which must be considered in making a determination of safety.

Focusing. A source of DE waves, without special controls, will radiate its energy in almost all directions. A single explosive will produce a truly spherical acoustic wave. A spherical EM wave is not allowed. Most NLTs, however, use sources that vary in strength sinusoidally in time and produce multipole patterns in space. Focusing of the energy can be

achieved either, (1) by using multiple sources whose timing has been adjusted to cancel the waves traveling in one direction and amplify the waves traveling in another, or (2) by physically blocking the waves in all but a desired direction. Either technique results in an equivalent aperture (hole) through which the wave is allowed to escape. The effective size of this aperture is related to the physical size of the apparatus itself.

The ability to focus these waves is related to the ratio of aperture to the wavelength: when the aperture is the same size of the wavelength, no focusing is possible. The lower frequency, long wavelength waves (infrasound and RF) will be more difficult to focus than higher frequency, shorter wavelength waves (ultrasound and microwaves). Since all of these wavelengths are much longer than light, one should not expect a pin point focus.

The resulting intensity pattern of a focused DE NLT will contain both an angular dependence (stronger in the direction "aimed" and decreasing off angle) and a distance dependence (decreasing with distance from the effective aperture).

Reflection and refraction. The waves will reflect from large solid objects (objects much bigger than a wavelength.) and refract around small objects (objects smaller than a wavelength. Regions of high wave intensity are usually created near flat walls and in corners. Refraction causes waves to "bend around a corner" and to be focused right behind objects that are the same approximate size as the wavelength. Changes in environmental conditions (temperature, humidity, etc.) can cause a partial refraction that leads to local variations in intensity (much more prevalent for acoustic waves).

Penetration. Normally, a wave encountering a solid object will either reflect off of or refract around the object. Depending on the properties of the object, however, energy can be transmitted through the material and into an inner cavity (a room, for example). This transmission, while often inefficient, provides a means to deliver the energy to a target that is completely hidden, although the ability to focus the energy may be reduced. Under ideal circumstances, when

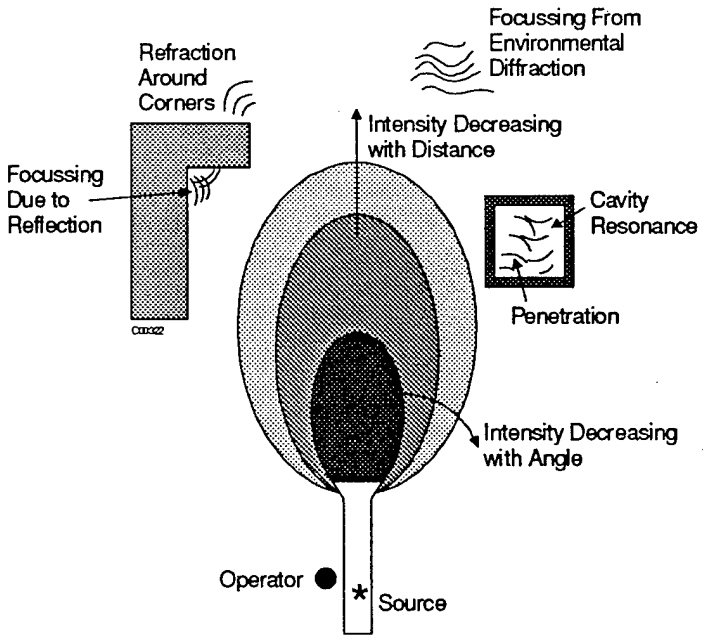

Figure 2. Intensity variations around directed energy sources.

the enclosure has dimensions that are approximately low multiples of the wavelength, a resonance can be created in which the energy can be built up to large levels.

Biological Effects

The body has two organ systems designed to respond to directed energy: the organs of hearing for acoustic energy in the 1 kHz range and the organs of seeing for electromagnetic energy in the visible range. Because these systems have evolved to be as sensitive as possible within the range of naturally occurring wave intensities, they are the most vulnerable to large intensity waves in these frequency ranges. Response of the body to DE effects outside of the naturally occurring frequency ranges is, by its nature, pathological and much less understood.

Categories of effects. Three categories can be distinguished. The first are *trivial*, they are neither effective from the operational point of view, nor do they produce any pathological effect of medical or legal concern. These may be observed, but are not of interest. The second category is *temporarily incapacitating*, resulting in a effect that is of benefit to the operational user, but that will resolve itself. The third category are *harmful*, producing permanent, medically undesirable outcomes.

Operational considerations will dictate what combinations of effects are acceptable. Under some circumstances, such as the control of a crowd for which no other dangers are present, actions that produce only a very small incidence of harmful effects may be acceptable. Under other circumstances, such as the control of a crowd that is about to do significant injury to others, actions that incapacitate with a modest probability of harming those in the vicinity may be acceptable.

Dose measures. The description of the effect begins with a proper description of the dose received. For the normal physiological range, the external measures that have proven useful are the intensities (decibels for noise and brightness for light). Improved doses are constructed by correcting for the body's frequency dependence. Further corrections are made for the attenuation achieved with hearing and eye protection.

For the pathological biological effects, the dose measures are less clear. Injury due to blast has been correlated with the energy delivered to the lungs through a mechanical coupling of the chest wall motion and low-speed compression wave in the lung parenchyma. The physiological effects of infrasound may involve the mechanical coupling to the motion of the diaphragm. Different measures of EM dose have been used for different observations (rate of energy absorption per body mass, W/kg, energy flux incident on the body, W/cm^2, etc.).

Probability of effect. The biological variability of individuals invariably leads to a variation of effect within a population to a given dose. This variability is most precisely expressed in terms of correlation of the probability of effect with dose. At low dose the probability approaches zero and at high doses the probability approaches one.

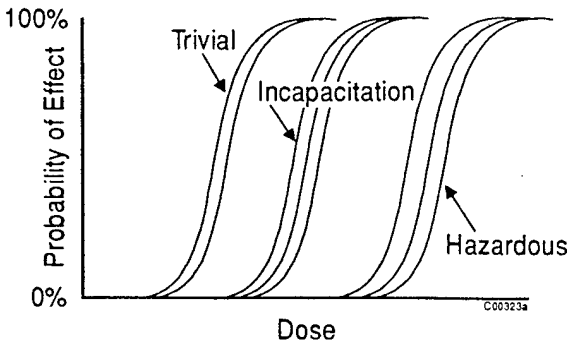

Figure 3. Probability of various effects.

Different effects have different dose-response curves. Generally, the onset of trivial effects occurs at a lower dose than the temporarily incapacitating ones, which in turn occur before the harmful effects. Even if this is true, it does not mean that the effects are neatly segregated, it is likely that a finite probability of harmful effects will occur at dose levels that produce a high probability of temporarily incapacitating effects.

Experimental considerations. The probability of effect curves ultimately depend on test data in which dose and effect on individual test subjects was collected. There are three considerations that impact the cost of obtaining the data for this correlation. First, effects differ systematically within the population, generally the small and the frail are more susceptible. The cost of data collection will depend on the breadth of the population that will be considered. Secondly, the confidence of the correlation depends on the total number of subjects tested and on the distribution of test conditions about the decision level. The higher the confidence demanded, the greater the number of subjects and cost. Finally, the time needed to gather the data depends on the degree that surrogates can be used and the nature of the effect being tested. Determining mutagenic effects from *in vitro* cell cultures will require far less time and cost that a prospective human study.

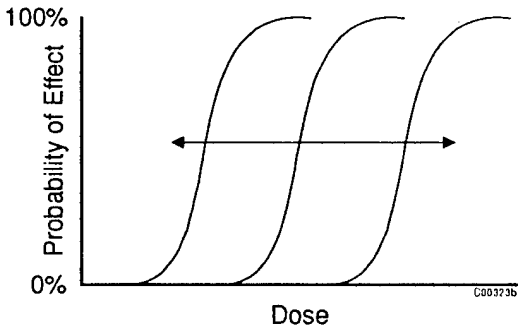

Figure 4. Variation among population.

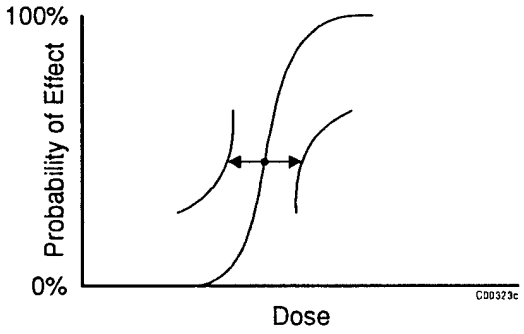

Figure 5. Confidence interval.

Possible Scenarios for NLT

There is a wide range of circumstances where temporarily disabling an adversary is preferable over applying lethal force. The exposure to the target and bystanders can be divided into three categories:

1. Control of individuals or crowds. The NLT provides a barrier which will be disabling if crossed.
2. Incapacitation of adversaries for interrogation. No innocents are involved so the use of NLT is for tactical advantage.
3. Incapacitating individuals who are using innocents as shields. Innocents must necessarily be exposed so the NLT must be effective but not harmful.

Since different populations are exposed and since different mission objectives and risks are involved, the concern for biological effects undoubtedly varies with each situation.

Question Checklist

The goal of the interview is to determine individual and organizational concerns about the biological effects of nonlethal technologies and relate them to scientific issues that can be addressed by researchers. Since these issues are still in a formative stage, we do not want to constrain responses. The following questions, however, provide some typical areas of concern that might be addressed or expanded upon.

Organizational

- How is your organization involved with NLTs?
- What issues related to bioeffects of NLTs have arisen in the past? How were they handled? What was the outcome?
- What other organizations get involved? How are they involved? Who would you recommend we talk to?
- What future involvement do you anticipate?

Regulation

- What statutes, laws, regulations, standards, etc. followed by your organization are related to biological effects?
- What statutes, etc. are being proposed?
- What is your perception of the political climate for either specific NLWs or for NLT in general?

Nature of Concern

- Is the nature of your interest operational effectiveness, safety, ethical, or policy?
- What specific concerns do you have for the (1) operator of the weapon, (2) the intended target, or (3) innocent bystanders.
- Are your concerns scenario-dependent?

Delayed and Long Term Effects

- Delayed effects are those not immediately observed. Long term effects include cancer, reproductive problems, etc. What concerns do you have for these?
- What is the relative importance of acute vs. long-term effects?
- Should the incidence of long-term effects be determined before the weapon is deployed? If the testing is long and costly? If the outcome is likely to be inconclusive?

Performance (Effectiveness Issues)

- What effects (behavioral, physiological, psychological) are expected of NLWs? What effects are desired? What are acceptable?
- What biological effect parameters must be quantified to be able to judge the NLW effectiveness (time to effect, duration of effect, probability of effect, etc.)?
- What ranges of these parameters would be meaningful?

Risk Assessment (Safety Concerns)

- What is the perceived risk: morbidity, mortality, cancer, etc.?
- What are the acceptable levels of risk?
- Are these levels situation dependent?
- What risk assessment procedures are recommended?

Accepted Research Protocols

- What kind of scientific data would be required?
- Would this data be adequate if it were obtained from (1) the open literature using similar exposure levels, (2) in vivo testing, (3) animal testing, or (4) human exposure tests?
- Can this data be provided by the technology developer or must an independent determination be made?
- What research protocols must be followed? Who approves these protocols? What are the guidance documents?

Human Trials

- Can exposure of the general population to NLWs be allowed if there have been no human trials?
- Could human trials to determine the nature of the temporary incapacitating effects be allowed if there is a chance of significant disability or death?

Summary of Organizations

The interviewees were selected to represent every point of view in the development, acquisition, and deployment of nonlethal technologies. One or more organizations were selected from each of the categories of medical, legal, policy, ethics, training and preventive medicine, requirements and acquisition, development, and operators. Developers of nonlethal technologies were specifically excluded, since the goal was to understand the issues that will be raised in the approval cycle.

The number of individuals and offices involved with nonlethal weapons is quite large and far-flung. The approximately 60 interviews conducted attempted to involve as much of this network as possible, but time and availability did not allow everyone to be contacted.

Air Force Medical Operations Agency (AFMOA), Bolling AFB, DC.

Major General Charles H. Roadman II is commander responsible for the formulation of policies and programs for the Air Force Medical Service for aerospace medicine, clinical medicine, clinical investigations, quality assurance, health promotion, family advocacy, bioenvironmental engineering, occupational medicine, military public health and radioactive material management.

US Army Center for Health Promotion and Preventative Medicine

Performs Health Hazard Assessments of Army systems according to detailed procedure. Result is a risk assessment code that estimates frequency of occurrence and severity of risk. If the risk is high, approval of higher officers in required to continue the development or procurement. Normally, only involved with operators, but can get involved with targets under training conditions.

Office of Assistant Secretary of Defense, Special Operations/Low Intensity Conflict

Office has responsibility for recommending DOD-wide policy on nonlethal technologies. Generated the recent policy DOD Directive 3000.3 "Policy for Nonlethal Weapons," which establishes DOD policies and assigns responsibilities for the development and employment of nonlethal weapons. This office will be involved in the NLT development programs, in parallel with operational users.

Office of Protection from Research Risks

OPRR reports to the Director of NIH, which is part of the Department of Health and Human Services and has governance for the rules concerning human and animal testing.

Founded in 1974, it also resolves disputes between local review committees. The Director serves as Chairman, Human Subjects Research Subcommittee of the Committee on Health, Safety, and Food (National Science and Technology Council). Every Federal agency, including the CIA and DOD are represented. Generally, almost all research institutes are pledged to comply with NIH guidance.

USACOM, J-3DA (Counter-drug Operations)

This office would be involved in NLT acquisition or deployment from the perspective of requirements: mission need statements dictate material requirements, lethal or non-lethal. The National Defense Authorization Act of 1989 limited DOD's role in drug enforcement to the support of primary drug enforcement agencies. DOD may assist in developing materiel requirements, but does not conduct counter-drug operations. This office interfaces with (1) the Joint Interagency Task Force, (2) the Future Operations and Readiness/Technology divisions of USACOM, and (3) the Executive Agent for NLW (USMC).

Office of Munitions, OUSD(A&T)/Strategic and Tactical Systems.

This is the cognizant office with OSD for the DOD-wide NLW program. The Director is the proponent for the NLW program in the DOD planning programming, and budgeting system and chairs the NLW Senior Steering Committee. This offices interfaces with the following organizations: (1) The EA for NLW (Commandant USMC) pursuant to the USD(A&T) Memorandum on NLW Program Implementation (22Mar96); (2) The NLW Integrated Product Team, which among other things reviews requirements and proposals of the individual services to avoid duplication and set priorities; and (3) two working groups of the IPT which are responsible for Concept Requirements and Acquisition.

Nonlethal Coordination Cell, Joint NLW Directorate.

The Coordination Cell has the role of independent technical advisor to the EA. Staffing, procedures, and responsibilities are evolving but may include: (1) catalog and monitor NLT efforts DOD-wide; (2) perform technical assessments; (3) coordinate security issues; and (4) coordinate studies and analyses. The Joint NLW Directorate was created by the IPT, while the Commandant's Warfighting Laboratory (CWL) focuses on Marine Corps-specific requirements. The Joint Directorate is responsible for the day-to-day activities of the EA and coordinating with the NLW program funding, ACTD programs, and the various NLW forums, but the actual hardware development and procurement will be the responsibility of the individual services.

Security Technology, Federal Bureau of Prisons, Dept. of Justice.

The mission of this office is "to identify, evaluate, assist, and develop technology initiatives and equipment that are appropriate and cost effective for use by the Bureau of Prisons." The terminology used in civilian law enforcement and corrections is "less than lethal force." The office examines, but does not develop, lethal and less than lethal equipment for adoption by the Bureau. Their primary contacts are with the National Institute of Justice (NIJ) and the correctional institutions. Current inventory includes pepper spray, smoke, baton, rubber bullets, flash-bang grenade, and stun gun.

Dismounted Battlespace Battle Lab (DBBL), US Army Infantry Center (AIC), Ft. Benning, GA.

The AIC is the Army lead for tactical applications of NLW. Their counterpart for law enforcement applications is the MP School, Ft. McClellan, AL. The DBBL focus is experimentation with NLW to determine requirements and develop tactics, techniques, and procedures. They interface with ARDEC (materiel developer), Marine Corps CWL, Army MP School, TRADOC, and the EA through the Joint Concepts Requirements Group. Primary focus on the MOUT ACTD which considered kinetic rounds, pepper spray, and sticky foam in some tests. Other programs that involve NLW include the Advanced Concepts and Technology II (ACT II) program and TRADOC's Concepts Experimentation Program (CEP). Some NLWs are being acquired under the Soldier Enhancement Program (SEP). Primary interest is mature technologies. Goal is to field multipurpose, easily trained, and inexpensive NLT.

Directorate of Combat Developments, US Army Infantry Center.

This office is responsible for identifying, developing, and monitoring requirements for the employment of directed energy weapons (DEW) in dismounted infantry and (2) protective devices against enemy use of DEW. Office has been involved with DEW systems: Stingray, LCMS, Outrider, Shortstop, and DEW-V. Most have been terminated because of biological concerns. On going systems are antimateriel, but there is still concern about biological effects.

US Central Command (USCENTCOM), CCJ3-PP.

Office is responsible for monitoring what NLW are available, their characteristics, and lessons learned from operational experience. Outside the command, contacts are maintained with OASD(SO/LIC), HQMC-DCS/Plans, Policies, and Operations, and component commands (Army, Navy, AF, Marine, and Special Operations Central Commands. Has been involved in establishing procedures in NLW use in Somalia.

US Special Operations Command (USSOCOM), J-5 Counter Proliferation and Policy Office.

This office is involved in the acquisition and deployment of NLW for counter proliferation (CP) use. They are responsible for coordinating requirements documents (MNS and ORD) and for ensuring that NLWs being acquired or developed possess operational capabilities matching the stated requirements.

Special Operations Acquisition Center (SOAC-DT), MacDill AFB, FL.

SOAC is responsible for the acquisition and life cycle support of equipment that is either peculiar to SOCOM or must be modified from the standard Service configuration for SOCOM purposes. SOAC is represented on both working groups supporting the DOD IPT for NLW: the Joint Concepts Requirements Group (JCRG—Chief, Requirements Section) and the Joint Acquisition Group (JAG—Chief, Advanced Concepts and Engineering Section). The Advanced Technology Branch of the Requirements Section monitors technical developments and maintains an electronic database on NLWs. This database has been transferred to the NLW Coordination Cell at Quantico.

General Findings

In the course of the interviews, concerns and opinions were identified that involved the biological effects, but do not lead to requirements for the biological research efforts. They are discussed by organizational category and serve to give to give insight into the different perspectives.

Political Issues

There is both a strong political and operational interest in accomplishing missions by using only the minimum amount of force necessary. NLT is viewed as having the potential to provide a continuum of options that will be both effective and humane. The support for these technologies is considerable.

The military accepts risk in training, but society is becoming less and less tolerant of injury (example of airbags and children). In fact, there is an unrealistic expectation that large peacekeeping operations can be accomplished without any casualties. NLT has a positive image at a time when no one is supposed to be hurt.

Because of the Gulf War experience and the perception that the Government has not be forthright in the past, the highly political issues will be effects on the unborn fetus, cancer, and sterility. The public will be more likely to accept NLW if incapacitation is quick to occur and quick to resolve. It will be unacceptable to inflict permanent, severe harm on the general population.

NLT will be the subject of international negotiation, where the perception of the weapons become as important as the science. It is the announced aim of the Human Rights Watch and the International Commission of the Red Cross (ICRC) is to build on their successful campaign against antipersonnel land mines and blinding lasers. It is expected that there will be more restrictions on weapons in the future brought about by public campaigns that put severe pressure on national leaderships.

Richard Perle, in a speech before the State Department's Open Forum on US National Security Issues in the 21st Century (17Apr96), included a statement on nonlethal force that "the best thing that the Pentagon could do for DOS was to provide instruments which add political-military policy options to the President's quiver." On the other hand, there is little support for the RDT&E component of NLT and that the current scope and funding of the EA is primarily for off-the-shelf items.

Operational commands are more ambivalent about deploying NLT. As OOTW becomes more common, there will be political pressure to use NLW, which will require increased training and attention on tactics, techniques, and procedures. This trend will result in operational limitations because of the concern that once they are deployed commanders will be pressured (politically or by culpability) to use them regardless of the circumstances. It will be more difficult to decide on the spur of the moment whether to use lethal or nonlethal weapons.

Concern expressed about the basic difference between law enforcement (which is using NLW) and military force: the mission of the former is to *capture* criminals, that of the latter is to *repel* opponents. The corresponding equipment cannot be the same.

Ethical Issues

The overarching guidance on animal and human experimentation comes from the Office of Protection from Research Risks (OPRR), part of the National Institutes of Health (NIH). "Federal guidance, local control" describes the way human and animal testing is approved and monitored. Human trials, in particular, are governed by Title 45 CFR Part 46: Protection of Human Subjects (Revised June 18, 1991).

Congressional concern over human subject testing is contained in GAO Report GAO/HESH-96-72: "Continued Vigilance Critical to Protecting Human Subjects." Provides a summary of previous commissions and investigations. Bottom line: system good, but not perfect.

A watershed piece of work is contained in the Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research." Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. National Research Act (Public Law 93-348, July 12, 1974). Goal of commission: identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and develop guidelines to assure that research is conducted according to those principles. While never adopted as law or regulation, the Belmont guidelines are implicitly followed. The basic ethical principles are:

1. Respect for Persons. Individuals should be treated as autonomous agents (able to decide for themselves) and individuals with diminished autonomy are entitled to protection.
2. Beneficence. Maximize possible benefits and minimize possible harms.

3. Justice. Ensure that the population being exposed is the population that will benefit.

The application of these principles requires the following considerations:

4. Informed Consent. Composed of three elements: information, comprehension, and voluntariness.

5. Assessment of Risks and Benefits.

6. Selection of Subjects.

In contrast to the opinion of many of the interviewees, human studies without benefit to the subject may be conducted. This situation is similar to 1st stage drug trials. A small number (20-80) normal people can receive doses. Goal is to establish hazardous levels (no benefit to the subject, but to future subjects and patients). Acceptance of this concept will vary with Human Use Committees (HUC); some will accept it, some will not.

The selection and care of human volunteers can also be much different than many interviewees think. For example, it is not common for the research institute to provide long term care to volunteers in the trials. Official guidance documents only require "equitable selection of subjects." NIH guidelines are discussed in OPRR Report 94-01: "Inclusion of Women and Minorities in Research."

Policy Issues

Several operational organizations expressed concerned for the potential culpability of the operator when he has both lethal and nonlethal weapons. To what extent does the availability of NLW expose field commanders and senior NCOs to legal claims of culpability for causing death or permanent injury when they use *lethal* weapons.

Concern over issue of precedence: if we allow the use of a technology, then we cannot object when the adversary uses it on us.

Interesting question: what are the implications in joint U.S.-foreign forces operations where our allies employ NLW that we do not allow?

Medical Issues

Most of the medical concerns have direct impact on the biological research and are, therefore, discussed in the next chapter. There is the gravest concern over any delayed effects and the medical community will be looked upon by the other decision makers to assess the likelihood of their occurrence.

Long term effects (cancer, etc.) are potential show stoppers. If there is a suspicion of effect (e.g. reports in the literature), then a study must be done. The fact that the study may be expensive or require a long time will not be grounds for a waiver.

The Secretary of Defense will ask the laboratory directors for an explicit statement of the nature of human and biological studies that have been conducted. The studies must be extensive and independently reviewed. This review is driven, in part, by press coverage into alleged DOD cover-ups of biological effects research.

While the current study focused on NLT, there was a sentiment that human health effects must be incorporated in all research, more broadly, into all AF activities. Appropriate accountability for human health effects should be considered in every weapon system and human health issues must be proactive.

Legal Concerns

By regulation, a legal review is needed only at the time of acquisition. Practically, there must be a review and consensus building all along.

There are two different bodies of military law that might govern NLW. For armed conflict, the concern is for unnecessary suffering. In domestic law enforcement, the concern is excessive force. In Operations Other Than War (OOTW) policing actions not allowed in armed conflict (hollow nose bullets, tear gas) may be allowed, but the application of the law is uncertain.

The Law of Armed Conflict is implemented by the DOD in the Law of War. Each service translates the Law into its own directives. There are two aspects of legality: (1) legality of the weapon requires that it does not cause unnecessary suffering and (2) legality of use requires that approval be given in certain, specified situations.

The requirement for a "memorandum of law" pertaining to a proposed acquisition program is cited in DoDD 5000.1. The pertinent laws and regulations on which this opinion is based include: (1) Hague Convention of 1907; (2) Chemical Weapons Convention (CWC); (3) Biological Weapons Convention (BWC); (4) Certain Conventional Weapons (CCW) Convention; Executive Order 11850 on Riot Control Agents; and FY96 National Defense Authorization Act.

The FY96 National Defense Authorization Act contained wording that, for the first time, imposed a Congressional provision affecting the legality of a US weapon, in this case, a 1 year ban on antipersonnel land mines in 1999.

One individual applies three tests in determining the legality of a weapon: (1) Is there a specific international prohibition on using this weapon? (2) Is the weapon, in principal, indiscriminate? (Example: omni-directional infrasound weapons are likely to harm innocent bystanders and would most likely result in a negative legal opinion.) (3) Is there a proper correlation between military necessity and human suffering? (Example given of using depleted uranium in armor penetrating rounds. Although it increases the potential of radiation injury and heavy metal poisoning, it is needed for penetration.)

Another individual uses three questions to guide the decision of legality of a weapons: (1) Is there a military need? (2) Is the weapon prohibited by any international treaty? And (3) Does the weapon cause "unnecessary suffering"? With respect to this last issue, a key element is whether the NLW is more or less discriminant than a currently approved weapon. Concern over an omni-directional infrasound was expressed.

Whenever people are exposed, someone will sue, which is view as part of the cost of doing business. Defense against punitive claims for cancer, etc. is the opinion of the medical community that there was no undue risk. Suits filed by foreign nationals are handled by the Foreign Claim Act. The claims are ex gratia (we don't have to pay). There are exclusions for combat usually, but there are questions for OOTW. The claims are always settled politically.

Tort law (negligence) can apply during development or use. Negligence occurs during use if: (1) use is made without authorization; (2) authorization was given without the defined information; or (3) the weapon guidelines were not precisely followed. The weapon guidelines must be carefully written.

If the technology is developed by the Government, but is used in the private sector (e.g. law enforcement), the product liability will go back to the Government. If a private company makes the weapon for the Government, they will probably have product liability exposure.

Most third world nations will want to ban new technologies that they can't afford themselves. Consequently, establishing an international consensus that the NLT is safe is critical to treaty negotiation. Scientific peer review of data is necessary and open publications are best.

Acquisition Activities

The Navy has only one draft mission need statement (MNS) for NLT; it applies to Law Enforcement and Drug Interdiction Missions (because of the latter, the document is classified, but the title or subject is not). The draft has not been staffed. The functional

requirement essentially is to stop a vessel without inflicting permanent injury to crew or damage to vessel. Functional requirements include: compatibility with U.S. ships and aircraft and foreign law enforcement; day and night capability; effective from stand-off (but unspecified) distances; must not jeopardize friendlies. The MNS is a generic document; more specific data are contained in operational requirements documents (ORDs) or required operational capability statements (ROCs) developed to meet an identified MNS.

The Army has a single mission need statement (MNS) for NLWs, covering all Army NL requirements categories, and five approved operational requirements documents (ORDs) for items that are being procured as part of the Soldier Enhancement Program (SEP). All Army ORDs require a Health Hazards Assessment and environmental review. (NOTE: these items, unlike the older nonlethal equipment for MP use, do not yet show up in the modified tables of organization and equipment, MTOEs, for the MP units that will receive this materiel):

- nonlethal protection for riot control
- 5.56 mm nonlethal projectile
- 40 mm nonlethal projectile
- stun grenade (flash/bang device)
- riot control agent dispenser (liquids, CS aerosol)

At the present time, the Air Force has only one approved MNS for nonlethal weapons (NLWs); it was initiated by the former Strategic Air Command (SAC), now Air Combat Command (ACC), and is a requirements document for "denial systems for nuclear weapon security assistance." There are several MNSs in the works, however, all for AF Special Operations Command (AFSOC), that will be coordinated through SOCOM HQ, not Air Force Staff. There are currently no approved ORDs for NLWs, but several are being developed responding to the AFSOC draft MNSs.

Several other programs within the Navy have interest in NLT. The Military Operations in Urban Terrain (MOUT) advanced technology concept demonstration (ACTD) program is of top interest and the Sea Dragon ACTD has high interest. There may be a request for a separate ACTD to concentrate on NLWs.

Significant Biological Effects Issues

The interview process produced a wide diversity of responses and opinions on the importance of biological effects in the development, acquisition, and deployment of non-lethal weapons. The responses have been synthesized into eight issues that have implications for researchers studying these effects. Those eight issues are:

1. Overlap of incapacitating and harmful acute effects
2. Operational effectiveness
3. Countermeasures and protection
4. Care and treatment of individuals affected
5. Quantification of long term effects
6. Operator safety
7. Credibility of data
8. Human exposures

A detailed discussion of each area is contained in the following sections. The essence of the responses have been restated in a narrative form that leads to specific data or actions, which researchers can take that will provide data for making key decisions. Not all responses fit neatly into these categories and many secondary, but interesting points were made. Selected comments are included at the end of each section to give a feeling for the diversity of the responses.

Issue 1. Overlap of Effects

There is an expectation that NLWs will produce significant, temporary incapacitation, without causing significant, long term harm, yet to some degree these two extremes occur at the same time.

Discussion

The first concern involves the nature of the "harmful" effects of the technology. In most cases, there is little more than anecdotal accounts of exposure of humans to similar dose levels so the possibility exists that some dangerous outcomes are overemphasized or that others are not even considered.

Since the decision to employ such weapons depends on a particular scenario, the amount of effect that is "significant" will vary from case to case. For example, causing even a single fatality in dispersing a benign crowd may be unacceptable, whereas such an outcome would be acceptable in situation where the only other options would have resulted in a large number of casualties.

A second concern involves the "nonspecific" nature of NLT, that is that the degree to which the dose cannot be concentrated on the intended target. For the medical, ethical, legal, and operational decision makers to determine when a particular weapon can be used requires data that presents the probability of various outcome versus the operational settings, with primary emphasis on "harmful" outcomes. Such data comes from two separate factors: (1) the variability of the dispersion pattern of the weapon and (2) the variability of effect in the target.

Since many of the weapons have a broad dispersion pattern that is affected by specific environmental conditions (reflections from structures, dispersion by atmospheric conditions, etc.), it is first necessary to understand how the external strength of the weapons (kinetic energy of the projectile, energy flux of a wave, concentration of a chemical, etc.) will vary with location. The greater this variation, especially to the extent that the variation is beyond the operator's control, the more conservative the application must be.

The response of the target to the external dose is the second factor in quantifying the outcome. Even within a uniform population (same age, weight, sex, etc.) there is a variation in response that comes from factors that are not controllable. Therefore, a spectrum of outcomes will occur, from no effect to trivial to harmful, at each exposure level. The percentage of the population showing a particular effect at a particular exposure level is

called the dose-response curve. The degree to which these curves overlap determines the discrimination of the weapon.

When the population being exposed to the weapon is not homogeneous, such as in crowd control, then there could be different dose-response curves for young vs. old, male vs. female, big vs. little, etc. In this circumstance, it necessary to have data that indicates the variability that occurs with these factors so that a composite dose-response can be developed.

A final concern involves the possibility of secondary effects. Recent examples include the unexpected interaction with other medications or with pre-existing conditions. These effects affect population estimates either through the individual components (number of people with pace makers, asthmatics, etc.) or through a common factor (high environmental temperatures, inoculation of an entire soldier population, etc.)

Implications for Research

Research must provide the dose distribution patterns for a range of physical conditions and the dose-response curves for the exposed population appropriate to the scenario envisioned. There should be some indication of the confidence in the values.

Ideally, the research into the biological effects of a given weapon or technology would quantify the dispersion pattern and dose response curves for all scenarios and populations. Armed with such general knowledge, all scenarios could be considered. Practically, establishing even a few dose-response curves with reasonable confidence is difficult and expensive, so the number of possibilities must be limited.

Specific products of the biological research effort should include the following.

1. Identification of harmful effects.
2. Quantification of dose-distribution and dose-response curves.
3. Correction for population effects.
4. Identification of potential side-effects.

Comments

• Every effect should be considered until it is proven to be unimportant. Just because it has not been reported in the literature does not mean it can be ignored.

• The Army would like to see a matrix of dose and effect rather than a graph

• Would like to know the variation in the physical intensity distribution ("are there side lobes that would affect a pacemaker of a patient in a hospital?")

• General rule: physiological effects that are not understood would be highly worrying and would require much more research.

• Occupational Safety: visible effects are well understood and hazard can be established with high confidence. Pulsed effects have less margin for error. RFR effects are more controversial; much of the research is considered questionable and many effects are difficult to extrapolate from animal data.

Issue 2. Operational Effectiveness

Nonlethal weapons should offer new alternatives for dealing with a situation, but fit within the current system that it augments.

Discussion

The primary reason to introduce NLT is to give the commander another level of response to complete a mission. To be able to evaluate the technology, the mode of effectiveness must be clearly understood. There was a general feeling that the way in which NLTs "worked" was not understood.

Ideally, the desired effects and the nature of their onset would be specified in the Operational Requirement Document (ORD). All of the parameters that are important to that requirement would be specified, including the acceptable ranges. Practically, most of the NLT concepts are technology-driven so that an iterative exchange between what is feasible operationally and what is feasible technically is unavoidable.

The deployment of nonlethal weapons ultimately comes at the expense of lethal weapons and their materiel support requirements. That is, the additional weight and cubic space for nonlethal weapons comes at the expense of those for lethal weapons, ammunition, and spare parts, both in terms of strategic lift constraints, tactical in-theater logistics constraints, and individual soldiers' load. These tradeoffs must be kept into account to ensure we stay focused on the ultimate objective, which is to deploy an effective military force for the mission.

NLW are assumed to cause physical discomfort or instill fear. In practice, psychological effects are the most important in scenarios where NLW are likely to be used. Time to effect is critical in stopping a sniper, but may not be critical in controlling a crowd. This point indicates that even the parameters are scenario dependent.

The Bureau of Prisons has a list of ideal characteristics for NLT: quick and effective, inexpensive (<$3K), no liability, minimum training, long shelf life, low maintenance, variable strength and coverage, easy cleanup, difficult to defeat, and no long term effects. The effects expected depend on the specific application and circumstance. Two categories are physical (incapacitate) and psychological (deter others from following).

The Army is concerned about making NLW "soldier proof": built in controls to override bad operator decisions or operator errors. Simple weapons require only limited effort, but complex technologies, like direct energy weapons, will require a much greater effort.

Without safeguards, DEW are perceived to have a high probability of causing permanent injury to targets and innocent bystanders alike.

Implications for Research

1. Define the mode of effectiveness.
2. Quantify the operational parameters (rapidity of effect, duration of effect, etc.) required for the particular mission.

Comments

• Duration of effect is important. If adversaries are disoriented and armed, will they pose a greater threat?

• How effective will these weapons be in a crowd scenario if the target is shielded by the mass of surrounding people? The target may actually be less susceptible (younger, stronger, protected) that the innocents, therefore requiring even greater "dose" which in turn produces greater side effects to the innocents.

• Military adversaries will develop protective technologies. Strategies and tactics may change and escalate to lethality. If there is no lethal threat, the adversary may become bolder.

• Pain is not a good end point because pain killers are cheap and readily available.

• Define biological end points (effects) first. The select weapon technologies to develop that are operationally useful, reversible, and for which there is a willingness to test humans.

• What if someone cannot feel the "pain" (the deterrent effect), because they are on medication, impaired, etc. and get overexposed?

• How are accidental exposures prevented ("child wanders in front of weapon")?

• Probability of effect is the most important parameter and should be determined in a formal test and evaluation process. To determine the desired goals and minimum acceptable probabilities, computer-based models must be used as part of the requirements definition process and the cost and operational effectiveness analysis (COEA).

• Would like to see NLW on the same platform as lethal weapons. Reduces the need for training and the intended targets do not know what to expect.

Issue 3. Countermeasures and Protection

Nonlethal technologies that are easily countered will be ineffective. Conversely, our use of these technologies will allow adversary use for which we need protection.

Discussion

Countermeasures and protection are the point-counterpoint of an adversary's active response to the nonlethal technology. As for any weapon system, we want our use to be effective, while being able to defeat the adversary's use. Such an advantage can be maintained when the effects are overwhelming and there is a considerable technology difference, but will be more difficult when the effects are marginal.

The first concern is that adversaries will easily develop protective strategies that negate the NLW mode of effectiveness. If complex and expensive countermeasures are required, the concern is no different than any other weapon system. If the countermeasure is simple (wearing ear plugs, goggles, or EM screens), then the system will be become ineffective after a few engagements.

The correctional institutions are especially concerned about the ease of countermeasures. The Bureau of Prisons has witnessed a major rise in the sophistication of the prison population; inmates have the time and ability to study new technology 24 hours a day. As a result, pepper spray is countered by wet towels, stun guns by jury-rigged body armor, lasers by eye protection. Compared to law enforcement targets, inmates are more militant, better informed, and more likely to have countermeasures.

The second concern is that once we use the technology, it will be used against us and therefore we must develop protective strategies. There is both a medical readiness and operational component to this concern. Both components want to identify additional equipment or procedures that will be needed.

Implications for Research

1. Identify countermeasures for the NLT.

Comments

• Medical readiness concern: What protection can be built into current systems. Are there regimes that will increase resistance?

• Operational: While the CINC's feels very strongly that NLWs should be "part of the kit," backed by lethal force, there is great concern about the ease with which countermeasures can be devised. Information about countermeasures and the impact on operational effectiveness should be presented as part of the RD&A strategy.

Issue 4. Care and Treatment

There are legal, medical, ethical, and operational needs to care for and treat the targets and bystanders affected; these needs will have significant operational impact.

Discussion

The responsibility for care and treatment of the "casualties" produced are called out in the rules of engagement. It can be expected that care, treatment, and even rehabilitation will be required after the area has been secured. In the cases of NLT applied to crowd situations, the number of people affected may be large and diverse.

The first concern is one of identification. How do you identify the individuals who have been affected? What are the signs and symptoms? How long can the effects last? Will special instrumentation be required to detect or monitor effects?

The second concern is for treatment. How are the affected individuals to be treated? What rules of triage should apply? Finally, does the operator have to have special training or do medical personnel have to be available? In correctional institutions, a doctor is ready.

The third concern is for at-risk populations. If one group is more susceptible or faces a greater hazard (EM effects on pace makers, pepper spray on asthmatics), what special diagnoses and treatments are required?

The final concern is overloading the medical system, when the NLWs are applied to a crowd. If many individuals are affected, the medical system could become overloaded in the assessment phase or, if there are a considerable number needing care, in the treatment phase.

Implications for Research

1. Guidance on signs and symptoms and duration of effects.
2. Guidance on treatment modes and triage.
3. Identification of special considerations for populations at risk.

Comments

• The NLW should not disable other systems (alarms, ventilation, automatic doors, lights, telephones, etc.) that may be critical to caring for the victims or for continued normal operation.

• Research must determine how long the acute effects persist. Will the victim lose some critical function (not be able to drive a car, etc.) and therefore pose a threat to himself and others?

• The correctional institutions are concerned about the treatment of individuals: "you have to live with the wounded ... we must pay for any healing of injuries that are inflicted and for rehabilitation as necessary." In practice there is a great emphasis on the need to minimize permanent injury.

• The operational users are concerned about "wounding" the targets because they would become a burden to evacuate and provide medical care.

• There is an operational concern about treating a downed individual with a mob around: it would be easy to get jumped. An entire operation could be tied up trying to provide medical assistance for victims and for protection of soldiers.

Issue 5. Long Term Effects

Long term effects (cancer, reproductive and central nervous system disorders, blindness, and fetal endangerment) must be understood for the technology to be politically acceptable and may bring into question the legality of the weapon.

Discussion

A parallel has been drawn with environmental damage. The law of war imposes limits on acceptable damage to the environment by prohibiting weapons that cause "severe, long-term, and wide-spread damage." Weapons that meet all three criteria are illegal. The interpretation of "long term," based on past jurisprudence, is "measured in decades." Herbicides, which have both a short and long term effect, can be used in war legally, but EO 11850 requires that only the President can authorize their use. At some stage there would need to be a national position on what is the "acceptable" level of risk of permanent injury from NLWs.

From the prospective of the overall NLW development effort, long term effects are viewed as critical. The incidence and severity of long term effects should be quantified, otherwise a decision to field the technology would be difficult to justify. No limit on the time and cost requirements should be set, but admittedly there will have to be a limit in practice.

Several operational organizations felt that extraordinary effort must be made to quantify long term effects because the DOD had lost credibility with the public for being concerned about the health of their own troops (agent orange, Gulf War syndrome). In their estimation, NLT cannot be developed unless these effects can be estimated.

Implications for Research

1. Long term effects must be identified and estimated.
2. Plans to develop successive refinements of these estimates should be made.

Comments

• Delayed effects will always exist and are too difficult to quantify, therefore money should not be spent. The original approval of the weapon development program must decide to accept the long term risk.

• The legal defense against cancer claims would be based on the opinion of the medical community. That is, the medical community must be willing to say that they did not believe that there was undue risk.

• Long term risk must have an estimated upper bound. Approval of weapons with potential long term effects will depend on the political climate and the issue should be reviewed with policy people to see what the political climate is before conducting the research.

Issue 6. Operator Safety

The operator of the weapon is considered to have a working lifetime of exposure, therefore he must be as safe as any other occupation.

Discussion

Generally, this issue has the least controversy. It is universally assumed that the operator should be fully protected and that, generally, the current occupational standards are sufficient. The existing preventive medicine organizations, responsible for evaluating safety during training, feel comfortable in evaluating most systems.

Despite the general acceptance of current standards, there were individual concerns about specific areas. First, several individuals expressed concern that current standards do not properly reflect women's health issues and that further investigation might lower the exposure levels allowed. This is not a NLT researcher's concern, per se, but it is part of the expanded population exposure issue. Second, concern was raised about cumulative effects of RFR exposure that go beyond the traditional occupational exposure scenarios. Finally, nonauditory effects of acoustic weapons continue to be a concern.

The final set of operator concerns are deployment-related. Although several hypothetical examples were given (operator incapacitated with system "on," unexpected reflections expose operator, etc.), the theme was one of built in protection measures.

Implications for Research

1. Demonstration that occupational standards are met
2. Identification of situations (in the context of the application) where automatic overrides are required

Comments

• There should be safety features, such as a dead man's switch, which ensures that the weapon does not cause harm if the operator is incapacitated.

Issue 7. Credibility of Data

Credibility of biological effect data, especially generated by the DOD, will be challenged in policy, political, and international venues.

Discussion

The principal product of the biological effects research is data that will address the concerns of the various organizations that must approve the development, acquisition, and deployment phases. The credibility of the data and the conclusions drawn from the data is critical to acceptance.

Knowledge of the harmful effects of the weapon is the most critical because these effects will be most closely scrutinized. The strong emotional impact of harmful effects requires a corresponding strong credibility in the assessment. It was pointed out in the earlier discussion about long term effects that considerable cost or time is not, by itself, reason for not collecting sufficient data. In fact, it was explicitly noted during the interviewing process that missing or uncertain data would be a strong reason for not approving a weapon. Furthermore, "data," independent of its quantity, has a varying degree of credibility based on its nature: human trials under exact conditions are highly credible, expert opinion has low credibility. Animal and mathematical models fall somewhere in between.

One aspect was universally agreed upon: ***Independent confirmation of the data is desirable, independent (non-DOD) review is necessary.*** It was appreciated that resources do not generally allow duplication of all biological studies and that the unique and sometimes classified nature of NLT effects may mean that the necessary facilities for conducting confirming research do not exist. However, review of the biological data, by organizations and individuals who are independent of the development system is absolutely necessary.

The question of whether DOD could even pay for the review was raised. It was felt that there were many examples of the DOD using scientific advisors in venues which guarantees their independence, that the proper scientific integrity could be assured.

Implications for Research

1. Wherever possible, plan for a number of tests that will give statistical significance to the results.

2. As early as possible in the research, seek a buy-in from all parties (medical, legal, policy, etc.) on the nature and number of tests.
3. Plan for an independent review of the data and conclusions.

Comments

• There must be developed a standard methodology that describes and regulates the research process into human health effects. There must be rules of evidence for defining the trail of how the particular course of research was chosen.

Issue 8. Human Exposures

In development, human exposure is controlled by Human Use Committees, afterwards in training by preventive medicine. If human exposures are never allowed, there will be a perception that the NLT is too dangerous.

Discussion

Before a weapon is accepted and deployed, human exposure comes under the authority of Human Use Committees. After deployment, human exposure is an issue of training and is controlled by the evaluations of preventive medicine. Exposure of humans to hazardous conditions that could produce lethal results are ethically allowed in research (phase I drug trials) and by the military (training with "live" conventional weapons). Human exposures, therefore, are not out of the question.

The interview process did not identify any absolute need for human exposure. The nonscientific elements (policy, legal, operational) would defer to an independent, scientific and medical assessment that surrogate results (for example, animal tests) were valid estimates. The legal opinion, however, was that if human tests were not conducted, then there must be a careful, adequate documentation backing the decision.

The first specific concern is that cognitive effects of the weapon cannot be properly assessed in animal models. A corollary to this concern is that there are serious cognitive effects that only occur or can only be observed in humans.

The second concern raised is the relevance of animal models, especially small animal models. There are far more small animal tests, but the confidence of scaling is low. In non-auditory effects of blast, for example, small animals have proven to be more susceptible, even when body mass dose scaling is used.

A third concern is that care and treatment modes cannot be developed without human trials. Like the question of cognitive fidelity, the validity of animal models to reproduce signs, symptoms, and to respond to procedures and medicines in the same way as humans may be difficult to establish.

Finally, if human exposures are used, it is unlikely that all population groups will be allowed (the aged, pregnant women, children). If these components of the population are critical to the scenarios envisioned, then it is more likely that young, male, human data will be acceptable for extrapolation to these components than will animal data.

Implications for Research

1. The decision of whether to employ human trials must be made early in the research effort. If so, then the ethical support must be sought; if not, then the legal acceptance of this decision must be secured.

Comments

• How can safe exposures be determined (is there an equivalent to temporary threshold shift used in auditory research)?

• Human studies might be more justifiable if these weapons are used on our troops. There would be ethical concerns about exposing enemy troops or populations as a means of gaining exposure effects data.

• Wherever possible, animal tests should be used.

• Ethics: human studies without benefit to the subject may be conducted, a situation similar to 1st stage drug trials. A small number (20-80) normal people can receive doses with the goal of establishing the hazardous level. Acceptance of this concept will vary with Human Use Committee. Official guidance documents only require "equitable selection of subjects." NIH guidelines in OPPR Report 94-01: "Inclusion of Women and Minorities in Research."

NLW Acquisition Policy, Process, and Program

Overview

The acquisition of nonlethal weapons (NLWs) essentially follows the same process and procedures as for any lethal weapon system. This chapter summarizes the DoD weapon system acquisition process and describes how it is, or can be, tailored for NLWs. This is followed by a description of DoD policy for development, acquisition, and use of NLWs, including the recent establishment of the DoD Executive Agent for the NLW Program. The chapter concludes with a description of the present DoD NLW Program for 1998-2003.

Defense Acquisition Management Process

For 25 years, DoD Directive (DoDD) 5000.1 and Instruction (DoDI) 5000.2 have been the centerpiece of defense acquisition policies and procedures. These documents describe a disciplined management approach for acquiring systems and materiel to satisfy approved military needs. Since DoDD 5000.1 was first promulgated in July 1971, under the leadership of then-Deputy Secretary of Defense David Packard, these documents have been revised periodically to reflect the evolutionary changes in defense acquisition policies and procedures. But throughout this period, the basic acquisition management process remained unchanged until this year. The 1996 update of the DoD 5000 series documents, promulgated 15 March, represents real change in the spirit of acquisition reform. Specifically, major changes include:

- Institutionalization of integrated product and process development (IPPD) and integrated product teams (IPTs). The IPPD is a total quality management concept that integrates all essential acquisition activities through the use of multidisciplinary teams (i.e., IPTs) to optimize simultaneously the design, manufacturing, and supportability processes in lieu of the separate and sequential activities of the traditional "pipeline" or functional organizations. This change reflects DoD's recognition of the importance of working as cross-functional or integrated teams, a process that maximizes overall performance, not just the performance of individual functional areas.
- Emphasis on the use of commercial specifications and standards; and preference for the acquisition of commercial items.
- Implementation of performance-based specifications in lieu of "how to" prescriptions.

- More emphasis on tailoring, i.e., determining if, how, and when the various core activities are to occur as a function of program size, risk, complexity, and other factors. Key to this flexibility is the separation of *mandatory* policies and procedures from *discretionary* practices in the current update. DoDD 5000.1 establishes guiding principles for all defense acquisitions, from fighter aircraft to combat helmet. DoD Regulation 5000.2-R (which replaces DoDI 5000.2) specifies mandatory policies and procedures for Major Defense Acquisition Programs (MDAPs) and Major Automated Information System (MAIS) acquisition programs. The Defense Acquisition Deskbook (which is accessible in electronic format) contains discretionary information to which program managers and other participants can turn for assistance in applying the guiding principles and mandatory procedures.

- Implementation of streamlining, not only by incorporating new laws such as the Federal Acquisition Streamlining Act (FASA) of 1994, but by reducing the size and complexity of 5000.1 and 5000.2-R compared to their predecessors, and by eliminating a large number of acquisition-related DoDDs and DoDIs.

It is not our intent here to review DoD acquisition policy in detail. We assume that the reader is more or less familiar with the general acquisition policy and process. For reference purposes, however, we will summarize below the generic model for the acquisition management process – a model that equally applies to the acquisition of NLWs.

The framework for the core acquisition activities is called the acquisition life cycle[1]. The life cycle of an acquisition program begins with planning before the program is formally approved (pre-Phase 0 activities) and takes the program through research, development, production, deployment, support, upgrade, and eventually, demilitarization and disposal (post-Phase III activities). Total life cycle costs (LCC) of a system include all costs associated with the system, literally from "cradle to grave." Major defense systems may take 12 to 15 years from identification of a deficiency (or technical opportunity) to fielding a system to satisfy the requirement. Completion of a program often means deploying or fielding the system so that a predetermined number of operational forces have the system and the capability of using it, a point called initial operational capability (IOC). During those 12 to 15 years from need identification to IOC, the program is controlled through a series of steps involving periodic business and technical decisions. These decisions are

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[1] The description that follows has been adapted, in part, from Joseph H. Schmoll, *Introduction to Defense Acquisition Management.* 2nd Ed., Ch. 6 and Ch. 5. Fort Belvoir, VA: Defense Systems Management College Press, July 1996.

scheduled into the overall acquisition strategy. They provide both the program manager (PM) and senior officials in the Service or Agency, and Office of the Secretary of Defense (OSD) officials the framework on which to review major programs, monitor and administer progress, identify problems, and take corrective action. The generic model for this process is shown in Figure 1.

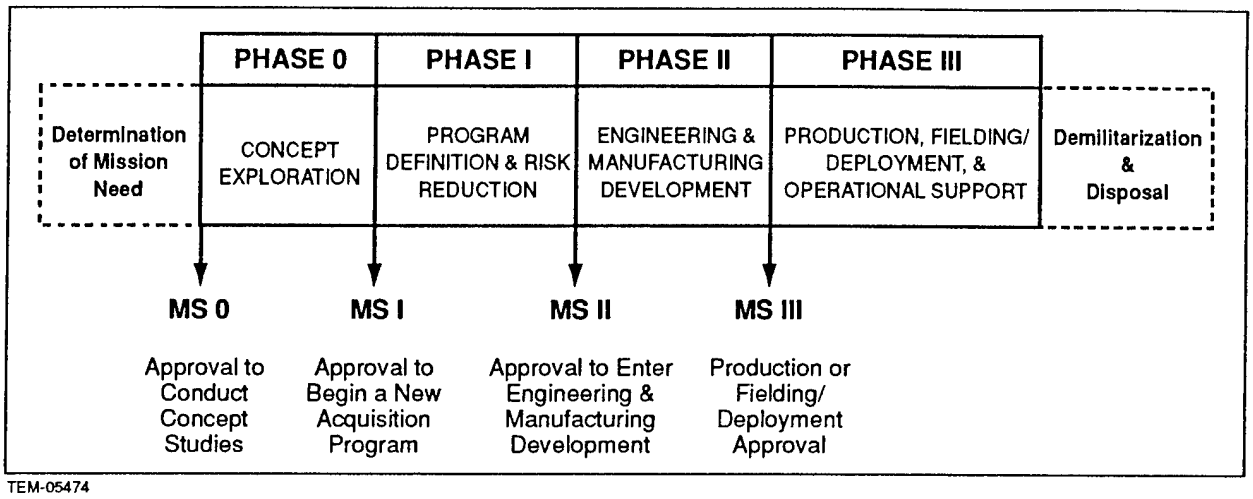

Figure 1. Acquisition milestones and phases.

Most programs follow the model illustrated in this Figure 1. However, if a new system is an upgrade of an existing one, or is one in which a proven or available technology or system is to be used (i.e., a so-called nondevelopmental item or NDI), such a program would normally omit one or more milestones and phases, or accomplish multiple phases simultaneously (called concurrency) to accelerate the process. Adjusting the life cycle model to fit the particular set of circumstances of a program is often referred to as tailoring. The number of phases and decision points are tailored by the PM based on an objective assessment of the program's category, risks, and urgency of user's need. Milestone decisions for major weapon systems are made by the USD (A&T) after program review by the respective Overarching Integrated Product Team (OIPT) and the Defense Acquisition Board (DAB). For less than major programs, the cognizant Program Executive Officer (PEO), or his designee, is the Milestone Decision Authority.

Acquisition category (ACAT) is defined in terms of program cost as follows[2]:

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[2] Our focus is acquisition programs, not automated information systems, hence we are skipping the ACATs defined for the latter.

- ACAT I programs are MDAPs, defined as programs estimated by USD(A&T) to require more than $355 million for RDT&E or over $2.135 billion for procurement (both in FY96 constant dollars), or designated by USD(A&T) as ACAT I for other reasons.

- There are two subcategories for ACAT I programs:

1. ACAT ID, for which the MDA is the USD(A&T), with the "D" referring to the Defense Acquisition Board (DAB) which advises the USD(A&T) at major decision points;

2. ACAT IC, for which the MDA is the DoD Component Head, or, as delegated, the Component Acquisition Executive (CAE), with "C" referring to Component.

3. The USD(A&T) designates programs as ACAT ID or ACAT IC.

- ACAT II programs, defined as those that do not meet the criteria for ACAT I, but do meet the criteria for a "major system," which is a program estimated by the DoD Component Head to require more than $75 million for RDT&E or over $300 million for procurement (both in FY80 constant dollars, which equates to $140 million and $645 million in FY96 constant dollars, respectively).

- ACAT III programs, defined as those that do not meet the criteria for ACAT I or II.

The MDA is designated by the CAE and shall be at the "lowest appropriate level."

A brief description of each phase and milestone follows, including any special requirement in the case of NLW acquisition programs. It is emphasized that NLW programs typically are ACAT III, hence subject to less stringent requirements than those prescribed for the general case of ACAT I programs.

Requirements Generation (pre-Phase 0)

Requirements generation is based on a continuing process of assessing the capabilities of the current force structure (people and materiel) to meet the projected threat, while taking into account opportunities for technological advancement, cost savings, and changes in national policy or doctrine. The process involves the identification of needs based on mission area assessments (MAAs), which are conducted in the Army by the Training and Doctrine Command (TRADOC), in the Navy by the Center for Naval Analysis (CNA) in support of Office of the Chief of Naval Operations (OPNAV), in the Marine Corps by Marine Corps Combat Development Command (MCCDC), and in the Air Force by the operational commands (Air Combat Command, Air Mobility Command, etc.).

If the mission need cannot be satisfied through nonmateriel solutions (such as doctrine, tactics, organization, training), the Component documents the requirement and determines whether the potential materiel solution could result in an ACAT I program. Two documents are used in the DoD to describe requirements, the Mission Need Statement (MNS) and the Operational Requirements Document (ORD). The MNS is generated first, based on an analysis of warfighting mission areas. It describes a warfighting deficiency, or an opportunity to provide new capabilities, in broad operational, not system specific terms. Once alternatives to satisfy the mission need have been studied and a system concept selected, an ORD is prepared to describe the system solution.

Every MNS must be validated and approved by a requirements validation authority to confirm that the need exists and cannot be resolved by a nonmateriel solution. The validation authority also determines joint service potential and then forwards approved MNSs to the appropriate MDA for Milestone 0 review, while disapproved MNSs are returned to their originators. The Joint Requirements Oversight Committee (JROC) is the validation authority for MDAPs (ACAT I). For non-MDAPs (ACAT II and III), the Chiefs of the Military Services, Heads of Defense Agencies, and Commanders-in-Chief (CINCs) of unified commands validate and approve their own MNSs.

The JROC, which is composed of the Vice Chairman JCS and the Vice Chiefs of Staff of the Services, is responsible for reviewing every MNS for a (potential) ACAT I (and for reviewing all major programs prior to acquisition milestone decisions). Until mid-1994, this MNS review was largely a formality, with any individual Service MNS approved in the JROC's monthly meeting as long as the need could not be met with a nonmateriel solution. Since mid-1994, the JROC has expanded the scope and significance of this review by setting up a more structured review process, known as Joint Warfighting Capability Assessments (JWCAs), intended to cut down service rivalries, eliminate unnecessary duplications of effort or redundant systems, and to surface the best possible requirements statements to meet current and future threats. The JWCAs divide military missions into nine broad mission areas, each with a primary Joint Staff advocate or sponsor (see Figure 2). Several of those mission areas may include NLW needs. The designated JWCA sponsor is responsible for drafting assessment issues and options twice a year. Those issues and options are coordinated with Joint Staff, Services, OSD, and DoD Agencies and then briefed to the CINCs and Service Chiefs for comment. The final product is then submitted either as the Chairman's Program Recommendation, intended to influence the Defense Planning Guidance (DPG), or as the Chairman's Program Assessment (CPA), intended to influence the President's budget submission. The agreed-to issues and options also represent the framework for each JWCA's review of the MNSs falling under its jurisdiction and its

resulting recommendations for approval or disapproval to the JROC. To gain approval, the MNS must clearly benefit DoD's overall warfighting capability, be affordable, and not result in redundancy. If approved, the MNS for ACAT I is forwarded to USD(A&T), as the MDA, for a Milestone 0 decision. MNSs for ACAT II and III level programs are sent to the respective Service or Component Acquisition Executive for a Milestone 0 decision.

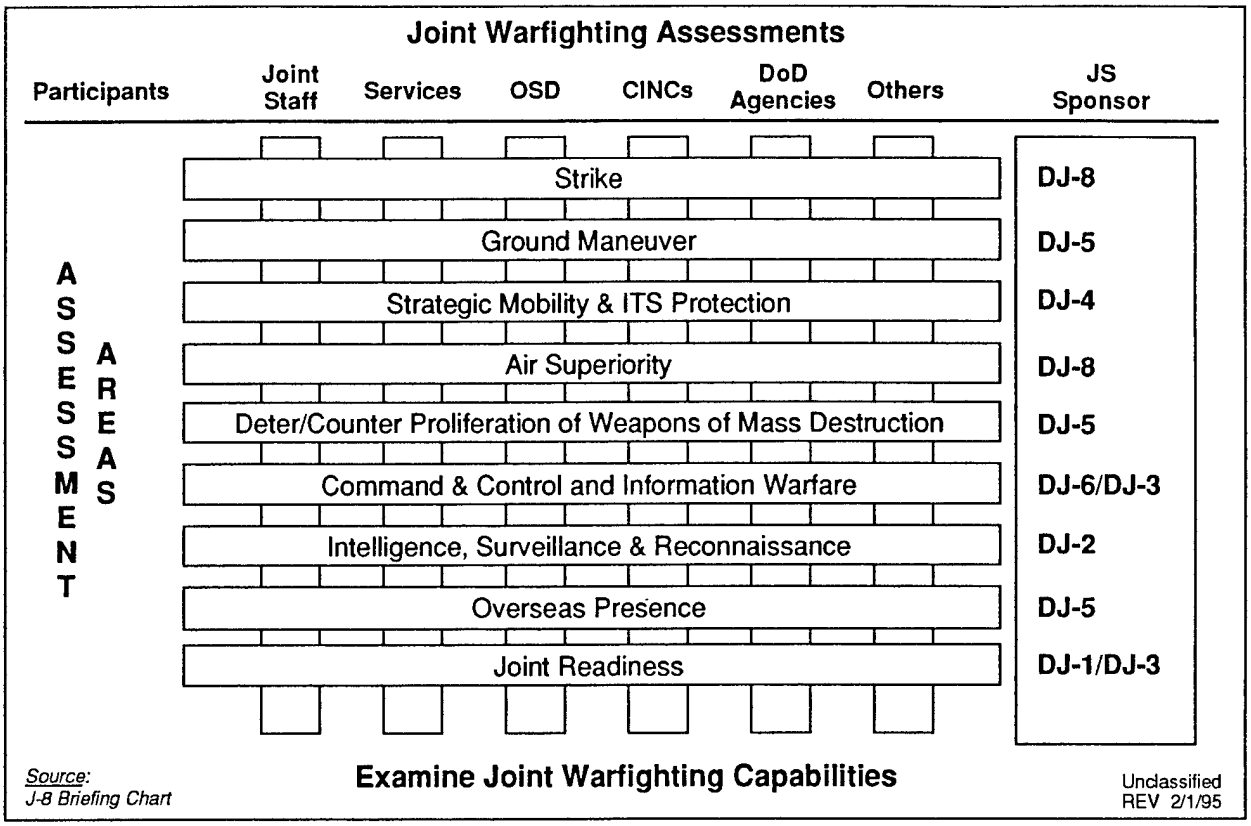

Figure 2. Joint warfighting capability assessments.

Milestone 0: Approval to Conduct Concept Studies

The MDA generally specifies the minimum set of alternatives to be examined, the lead organization, and exit criteria for Phase 0. Alternatives have the following order of precedence:

- Use or modification of an existing U.S. weapon system
- Use or modification of an existing commercially-developed or Allied system, i.e., nondevelopmental item (NDI) approach
- Cooperative research and development program with one or more Allies
- New Joint Service program
- New Service-unique development program.

Phase 0: Concept Exploration (CE)

Competitive, parallel, short-term studies are conducted to define and evaluate the feasibility of alternative concepts and to provide a basis for assessing the relative merits of these concepts at the next milestone decision point. The concept exploration phase is normally short (1-2 years in duration) and relatively low cost. During this phase, the user will develop an ORD to describe the objectives and minimum acceptable requirements (thresholds) for operational performance of the proposed system concept.

The current management process does not specify anything peculiar in this phase for NLW system requirements. Based on our survey, we believe that policy and process should make clear that there are indeed some unique characteristics associated with NLW systems. In this phase, the key point is that the ORD must include performance criteria, risk goals, and acceptable levels of risk to be addressed in test and evaluation during system development phases. While there is no consensus on the criteria to be used for NLW systems, we believe that the following set of criteria provides a good starting point to be tailored to the particular ORD:

- Type of effect: pain, fear, or incapacitation (or a combination of all three)
- Time to effect
- Duration of effect
- Probability of effect (physiological/behavioral/psychological)
- Likelihood and severity of collateral damage/injury
- Ease of countermeasures
- Risk of permanent injury/lethal effects (acceptable level varies by mission: OOTW vs. combat)
- Possibility of long-term or delayed effects.

Conceptually, while the performance of a lethal weapon normally is captured by a single measure, probability of kill (Pk), NLWs require a more discriminate assessment, involving at least three metrics: probability of nuisance effect (Po); probability of intended effect (Pi) (which, in turn, may be subdivided by type of effect if necessary); and probability of permanent injury or worse (Pk). The sum of those three probabilities, of course, is 100 percent. The ideal NLW has maximum Pi and minimal Po and Pk; in practice, certain levels of Po and Pk are unavoidable. By quantifying these measures in the ORD, they become performance measures that are subject to test and evaluation and will receive needed visibility in the management review process.

Milestone I: Approval to Start New Acquisition Program

The Milestone I review, if positive, constitutes approval for initiation of a new program to meet the approved MNS with the proposed concept, and entry into Phase I. The review includes: approval of the acquisition strategy and concept baseline; cost and operational effectiveness analysis (COEA) results, with the advantages and disadvantages of the various alternatives studied in the previous phase, providing an analytic underpinning for program decisions; identification of cost as an independent variable (CAIV) objectives; review and approval of the draft Test and Evaluation Master Plan (TEMP); and establishment of exit criteria that must be accomplished during Phase I.

Again, no special requirements have been specified for NLW programs. We believe that the process should explicitly recognize two special requirements for the initiation of NLW programs:

- A legal review of the ORD as well as the recommended system concept (concept baseline)
- A medical opinion of the recommended system concept.

With respect to the former, current policy (as stated in DoDD 5000.1) only requires legal reviews at Milestones II and III; and encourages nonprogram-specific legal reviews for the potential application of novel technologies. We believe that these requirements should be complemented with a legal review of the ORD for NLWs to verify the legality of the specified performance criteria (i.e., whether a NLW that meets those performance criteria would be consistent with applicable treaties and the laws and customs of war). The time to do so is at Milestone I when the first draft ORD normally is promulgated.

With respect to our recommendation for medical review or opinion at Milestone I, the current acquisition management process (as described in DoD 5000.2-R) includes broad guidance for "a programmatic environmental, safety, and health evaluation" to be initiated

at the earliest possible time, usually Milestone I. This evaluation "describes the PM's strategy for meeting environmental, safety, and health requirements, establishes responsibilities, and identifies how progress will be tracked"[3]. The same document cites the analyses that must be conducted "to integrate environmental, safety, and health issues into the systems engineering process" to ensure compliance with "applicable federal, state, interstate, and local environmental laws and regulations, Executive Orders, treaties, and agreements."[4] Specifically, under System Safety and Health:

"The PM shall identify and evaluate system safety and health hazards, define risk levels, and establish a program that manages the probability and severity of all hazards associated with development, use, and disposal of the system. All safety and health hazards shall be managed consistent with mission requirements and shall be cost-effective. Health hazards include conditions that create significant risks of death, injury, or acute chronic illness, disability, and/or reduced job performance of personnel who produce, test, operate, maintain, or support the system. Each management decision to accept the risks associated with an identified hazard shall be formally documented. The CAE shall be the final approval authority for acceptance of high risk hazards. All participants in joint program shall approve acceptance of high risk hazards. Acceptance of serious risk hazards may be approved at the PEO level."[5]

The additional requirement for NLWs, compared to traditional weapon systems, is that the safety and health review must also address the biological effects on the intended target(s). This is a new requirement that in general will add at least a year to the acquisition cycle for medical tests and verification of effects. To ensure this added requirement will be addressed in the acquisition program with minimum time impact, a logical step would be to include this issue as one of the mandatory items in the Milestone I review. The medical opinion, at this stage, would be qualitative; it would serve to summarize the state of medical knowledge of the biological effects of this particular type of NLW and identify the specific program requirements for medical testing to meet a Milestone III production decision.

Phase I: Program Definition and Risk Reduction

Previously known as demonstration/validation, this phase includes various activities designed to reduce the risk of incorporating new or unproved technologies, such as early

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[3] DoD 5000.2-R, Part 3, Section 3.3.6.

[4] *Ibid*, Part 4, Section 4.3.7.

[5] *Ibid*, Part 4, Section 4.3.7.3.

prototyping and testing. Phase I is typically short in duration (2 to 3 years), although major programs with prototype development can stretch this to 5 years or more. Cost drivers, cost-performance trades, interoperability, and acquisition strategy alternatives are typical examples of possible issues addressed in this phase.

Milestone II: Approval to Enter Engineering and Manufacturing Development (EMD)

The Milestone II review approves (or, defers) entry into EMD. The acquisition strategy, development baseline, final TEMP, and CAIV objectives (revised, as necessary) are approved. Exit criteria that must be accomplished during Phase II are established, and low-rate initial production (LRIP) quantities (if any) are identified. Milestone II is an important milestone. Historically, many programs do not pass this milestone for various reasons, especially budgetary reasons. For nonmajor programs that involve relatively mature technologies – such as may be the case for many kinds of NLW programs -- Milestones I and II often are combined into one single review.

By policy, a legal review of the program is required to be presented at this Milestone. This would be the first legal review for those programs with a combined Milestone I/II review. For NLW acquisition programs with separate Milestone I and II reviews *and* a satisfactory legal review completed by Milestone I, we believe that another legal review within such a short timeframe would represent unnecessary duplication. Thus, if the above recommendation (legal review at Milestone I) is adopted, we believe that the MDA should have the authority to waive the legal review at Milestone II.

The specifics with regard to the safety and health review at this Milestone would depend on the specific circumstances. In general, however, considering the importance of this issue for NLW programs, we believe that it should be addressed routinely at every Milestone review, with increasing specificity and detail.

Phase II: Engineering and Manufacturing Development (EMD)

During this phase the system design is completed and manufacturing and production processes are validated. There is a heavy emphasis on testing – developmental test and evaluation (DT&E) to ensure system specifications are met, and operational test and evaluation (OT&E) to ensure the system is operationally effective and operationally suitable. This initial OT&E (IOT&E) uses prototype hardware (as close as possible to production configuration) and uniformed operator personnel (representative of the user population) in an operational environment. More extensive follow-on OT&E (FOT&E), using production hardware in the field environment, is performed in the production phase. Depend-

ing upon acquisition strategy, favorable IOT&E often is followed by LRIP approval before the formal Milestone III.

Phase II represents a major investment of effort and resources; in duration, it may take on the order of 4 to 6 years. The DoD acquisition process is essentially designed to avoid committing those resources unless the program is very likely to go into production. In other words, programs that make it into Phase II but are terminated short of production are and should be the rare exception.

Milestone III: Production Approval

The Milestone III review approves entry into production for a MDAP. Acquisition strategy and production baseline are approved. Exit criteria that must be accomplished during Phase III are established. Initiation of full rate production will be based on further approval from the MDA. (For ACAT I programs there is normally only one production decision, either low-rate or full-rate, at the Defense Acquisition Board (DAB) level).

By policy, a second legal review is required by Milestone III. This makes sense, considering the significant time lapse since the first legal review at Milestone II and the more exact knowledge of system performance based on testing. Likewise, a safety and health review should again be conducted; this time resulting in a "medical certification" rather than the "medical opinion" that might suffice at the previous milestone reviews. Policy guidance and customary rules are not very specific on this point. It would be a good idea for medical community and materiel developers to convene a working group to define the specifics if this has not yet been done by the working groups supporting the DoD Executive Agent for NLW (see final section below).

Phase III: Production, Fielding/Deployment, and Operational Support

This phase often partially overlaps Phase II, especially when LRIP is part of the acquisition strategy. During this phase, the system is produced and delivered, along with logistics support infrastructure, to the field for operational use. FOT&E may be conducted to assess performance and quality, compatibility, and interoperability. System status is monitored to ensure the system continues to meet the user's needs. The potential for modifications to the fielded system may be identified throughout its operational life. Such modifications, if sufficiently complex and costly, may qualify as ACAT I programs and be managed as separate acquisition efforts; otherwise, they are considered part of the program being modified.

Disposal (post-Phase III)

At the end of a system's useful life it must be demilitarized and disposed. The PM is responsible for ensuring that disposal minimizes DoD's liability due to environmental, safety, security, and health issues. In the case of NLW systems, there may be increased potential for reutilization of the material by non-DoD government agencies such as law enforcement.

Policy for NLW Acquisition

DoDD 3000.3, "Policy for Non-Lethal Weapons," was issued on July 9, 1996. It applies to all NLW development and acquisition programs and the employment of fielded NLWs. It defines NLWs as "weapons that are explicitly designed and primarily employed so as to incapacitate personnel or materiel, while minimizing fatalities, permanent injury to personnel, and undesired damage to property and the environment."

Importantly, for purposes of the present discussion, this policy document specifically states that NLWs "shall not be required to have a zero probability of producing fatalities or permanent injuries."

It establishes functional responsibilities as follows:

- ASD(SO/LIC): policy oversight for development and employment of NLWs
- ASD(Strategy and Requirements): policy oversight for consideration of NLWs in OPLAN development
- USD(A&T): oversight for the DoD NLW Program
- Chairman JCS: assess military requirements for NLWs, monitor Service NLW programs, and develop/promulgate joint doctrine incorporating capabilities of NLWs
- CINCs: identify warfighting requirements and ensure procedures exist to integrate NLWs into OPLANs
- Secretaries of the Military Departments and CINC USSOCOM: development/ implementation of employment concepts, doctrine, tactics, training, security procedures, and logistics support for fielded NLWs; ensure legal review of NLW acquisitions; issue guidelines for NLW acquisition to ensure:

a) an appropriate balance between the competing goals of low probability of permanent injury and high probability of desired antipersonnel or antimateriel effects, (b) no easy defeat by enemy countermeasures, and (c) achieving effects that are worth the difficulty of providing intelligence support for mission planning and damage assessment

- Secretary of the Navy to designate Commandant of the Marine Corps as Executive Agent for the DoD NLW Program

- ASD(C3I): provide direction for development of capabilities to enable effective use of NLWs and guidance when NLW matters involve DoD information warfare.

DoD NLW Program

The management structure responsible for the DoD NLW Program, as currently constituted, is illustrated in Figure 3. It evolved in early 1996 pursuant to Congressional direction in the FY96 National Defense Authorization Act (NDAA), which required the DoD to establish a centralized management structure for NLW; adopt a coordinated approach for policy, doctrine, legal, and operational questions concerning NLW; and ensure improved budgetary focus. In response, the USD(A&T) convened a special program review from 14 February to 18 March to review all NLW activities, evaluate alternative management approaches, recommend additional funding as needed, and prepare a report complying with the FY96 NDAA language. Based on that review, the USD(A&T) issued on March 22, 1996 his decision memorandum "NLW Program Implementation," establishing the management structure illustrated below and announcing the reprogramming of FY96 procurement and RDT&E resources into specific NLW program requirements. The key management elements illustrated in Figure 3 are as follows:

- The Office of the USD(A&T) exercises NLW Program oversight, with the Director, Strategic and Tactical Systems as lead. A Senior Steering Committee (SSC), in the role of Overarching Integrated Product Team (OIPT), assists in program oversight. This body is chaired by the Director, Strategic and Tactical Systems. Members are senior officials representing Service Acquisition Executives, Commandant Marine Corps, Chairman JCS, USD (Comptroller), USD(Policy), DDR&E, ASD(SO/LIC), DUSD(AT), Director PA&E, and Director Special Programs.

- The Commandant of the Marine Corps, in his role as the DoD Executive Agent for NLW, is responsible for program recommendations and coordinating NLW requirements. Specifically, the responsibilities of the Executive Agent are: (1) serve as the primary DoD POC for NLW; (2) ensure coordination between materiel development and combat development communities; (3) provide program guidance to include user testing/evaluation; (4) coordinate joint requirements, training, and doctrine efforts; and (5) recommend appropriate funding levels for 6.1 through 6.4 project requirements.

- The NLW Integrated Product Team (IPT) supports the Executive Agent. The IPT is chaired by the Marine Corps Deputy Chief of Staff for Plans, Policies, and Operations

(DC/S PP&O), a three-star general. Vice chair is the Army Assistant Deputy Chief of Staff, Operations (ADCS OPS), for Force Development. Members are representatives of the research, development, and acquisition (RDA) and user communities of Navy and Air Force, CINCs, Joint Staff (J-3/J-8), OASD(SO/LIC), and OUSD(A&T). Representatives of Department of Justice (DOJ), Department of Energy (DOE), and Department of Transportation (DOT) can attend as observers. Requirements or proposals of the individual Services are reviewed by the IPT to avoid duplication, to agree on prioritization of projects, and to ensure a balanced program.

- Two working groups support the IPT: Joint Concepts Requirements Group (JCRG) and Joint Acquisition Group (JAG), both chaired by designated senior Marine Corps officials, Deputy Commanding General, Marine Corps Combat Development Command (MCCDC) and Commander, Marine Corps Systems Command (MARCORSYSCOM), respectively. For day-to-day coordination and administrative support, the IPT is supported by a Joint NLW Directorate, with a "NLW Coordination Cell" located at Marine Corps Base Quantico, Virginia. Most of the actual work and discussions take place at these working level forums.

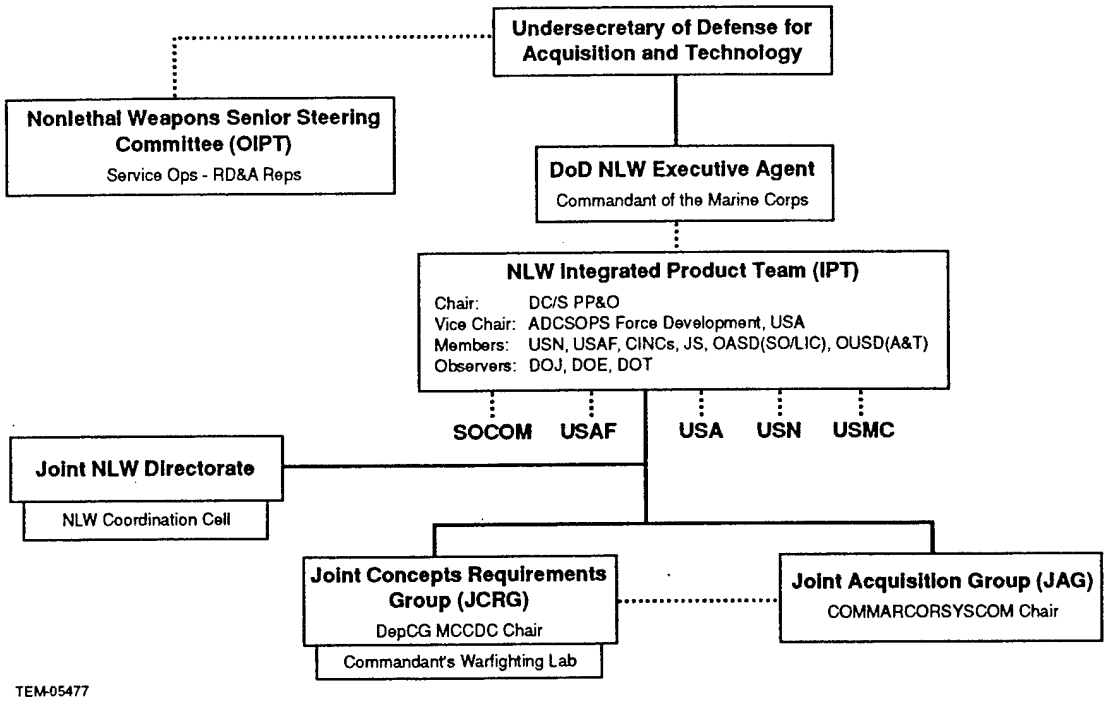


Figure 3. NLW program management organization.

The scope of the DoD NLW program that falls under the auspices of the Executive Agent is determined by the Memorandum of Agreement (MOA) between the Services, which includes charters for the supporting forums. To achieve consensus, the scope has been narrowed for the time being to mature technologies and off-the-shelf NLWs applicable to dismounted infantry (close combat) needs.

Staffing of the Joint NLW Directorate began only recently. The NLW Operational Concept was completed in draft form by the Concepts Division of MCCDC late December 1996. Once this is approved it will serve as the basis for NLW program planning using the system approach known as Concept Based Requirements System (CBRS) (see Figure 4). The NLW requirements process as it is evolving under the Executive Agent can be summarized as follows:

1. Service representatives report and discuss NLW requirements in working groups under the JCRG forum.

2. JCRG conducts annual NLW program review, determines program priorities, and drafts (updates) the NLW Master Plan. This entire process is based on the CBRS.

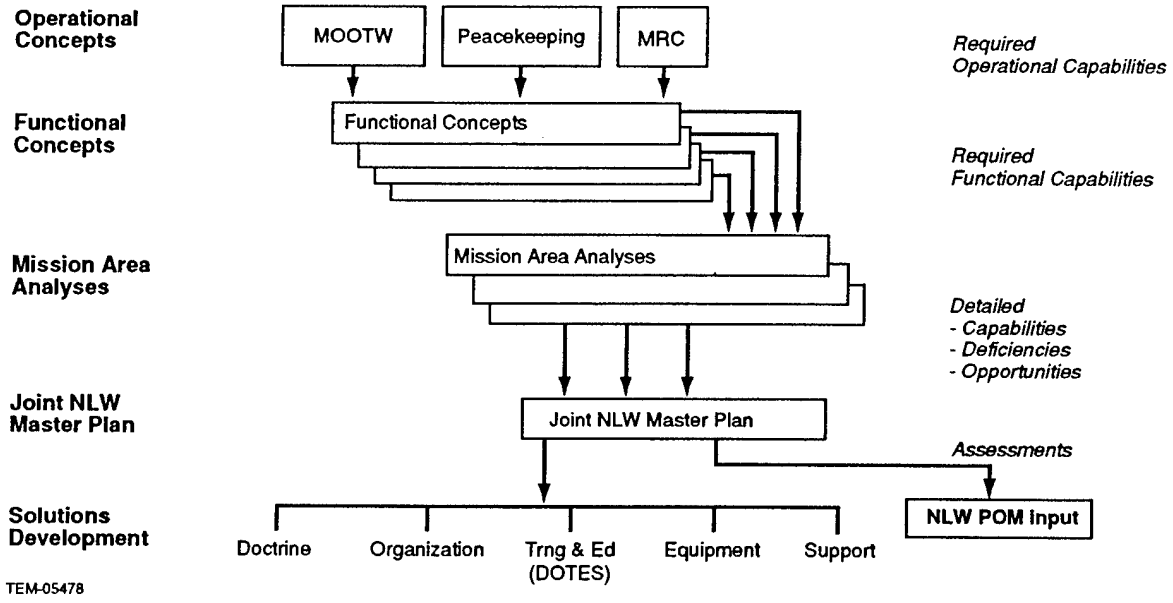


Figure 4. Concept-based requirements system.

3. JAG is responsible for preparing the Joint NLW RDA Plan that satisfies the NLW Master Plan; it also helps define the NLW Program for POM submission.

4. Services are responsible for NLW R&D and procurement in accordance with designated lead role.

The DoD NLW Program, developed by the JAG, approved by the IPT, and reflected in the FY98-03 Program Objectives Memorandum (POM), was for the first time publicly released at a NLW Conference in Washington, DC on 5 November 1996. Importantly, it is a "stop gap" program in the sense that it only covers RDT&E, no procurement, and is based on "immature" requirements (i.e., not based on the CBRS process); hence, it serves as a bridge to the next POM submission cycle in 1998 for the FY00-05 POM. The overall NLW program funding (including augmentation) is illustrated in Figure 5. (The "augmentation" refers to planned reprogramming of resources over the POM amounts and projects that are discussed below.) In comparison, the FY96 budget for NLW, after reprogramming actions, was $27 million; that for FY97 amounts to $30.2 million ($25.2 million for RDT&E, $5.0 million for O&M).

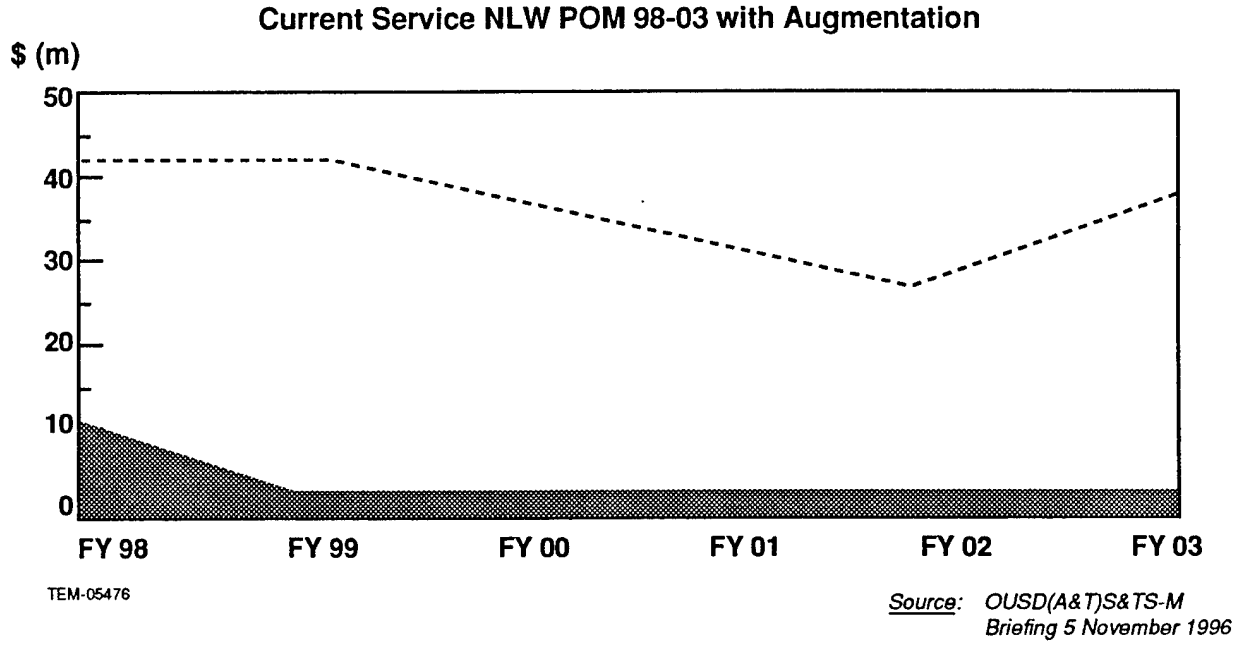


Figure 5. NLW POM FY98-03 (with augmentation).

The total NLW Program of $176 million is broken down by Service as follows: Army - 54%, Marine Corps - 2%, OSD - 21%, and Executive Agent - 23%. Navy, Air Force, and USSOCOM have expressed interest in several NLW projects but have not been assigned as "lead service" for any specific NLW project, therefore they do not show up in this breakout.

A perhaps more useful breakout is by type of NLW or program category. That breakout is shown in Table 1 and described below.

Table 1. DoD NLW POM 98-03 ($million)

Program Category	FY98	FY99	FY00	FY01	FY02	FY03	Total
Exec. Agent Support	0.7	0.5	0.5	0.5	0.5	0.5	3.2
Modeling/Simulation	3.4	3.9	4.1	4.2	4.5	4.5	24.6
Experimentation	3.0	3.0	3.0	3.0	0.5	0.5	13.0
Subtotal EA:	7.1	7.4	7.6	7.7	5.5	5.5	40.8
Kinetic NLWs	5.603	6.159	2.945	0.87	0.475		16.052
Entanglement NLWs	2.835	5.87	3.25	1.15	0.45		13.555
Vehicle stoppers	3.1	4.13	1.6	1.6	1.5	2.1	14.03
Acoustics	4.71	5.63	7.03	9.76	8.805	8.28	44.215
Riot Control	1.345	2.391	2.94	1.525	0.4		8.601
Delivery Methods	0.5	0.5	0.5	0.5	0.5	0.1	2.6
Subtotal Army/MC: (Army:95.21/MC:3.84)	18.093	24.68	18.265	15.405	12.13	10.48	99.053
PSEAG (OSD)	5.5	6.363	7.184	6.785	6.435	4.255	36.522
Grand Total	30.693	38.443	33.049	29.89	24.065	20.235	176.375

Source: OUSD(A&T) S&TS-M, Briefing 5 November 1996.

Executive Agent (EA). EA support refers to administrative support for the Joint NLW program by the Joint NLW Directorate, Quantico, VA. Most of the cited funding will support two purposes: (1) development of the Joint NLW Concept (in-house with contractor support; completion of draft is expected by end December this year); and (2) database of NLTs, requirements, and activities. Modeling/Simulation covers development of NLW modules for current or new simulation models in support of tactics development, training, evaluation of lethal/nonlethal mix in operational scenarios, modeling of bioeffects, and force-on-force war gaming. Experimentation covers NLW demonstrations/evaluations in the MOUT and Sea Dragon ACTDs. It also covers cost of any commercial off the shelf (COTS) prototype hardware for field tests in support of requirements/operations concept definition.

Kinetics Program. This covers engineering and manufacturing development (EMD) of the following devices:

MCCM-Claymore (i.e., nonlethal mine: filled with rubber balls that, when detonated, hit and put people down); NL Mk 19 Grenade; Air/Water Jet; 5.56mm muzzle launched ordnance (MLO); Variable Velocity Barrel; Vortex Ring Gun; NL Crowd Dispersing Round; 12 Ga Blunt Round; 12 Ga Distraction Round; Liquid Bullets; Paint Ball Munition; NL Marker Munition. All of these are in EMD at start of or prior to FY98, with sole exception of NL Grenade and Variable Velocity Barrel. At other extreme, some of the items on the shopping (procurement) list for FY99 have completed EMD on or before FY98; e.g., the 40mm Sponge Grenade. Current inventory items are: 12 Ga batons, Stinger Rounds, and Bean Bags; and 40 mm Stinger Rounds.

Entanglement Systems. This covers development of both antipersonnel and antimaterial systems. The cited funds are for EMD of the following devices: 40mm net munition; 40 mm sticky net munition; NL bounding net munition; Volcano delivery system (modifications); and Volcano Intrusion Detector. (Note: by direction, the name of the Volcano mine/munition delivery system, when used as NLW delivery device, will be changed to CLAW: canister launched area denial weapon).

Vehicle Stoppers. This covers EMD of three items: Speed Bump Mine, Vehicle Stopper, and EM Pulse Mine. The plan is to complete EMD of those in FY00, 99, and 04, respectively, with procurement to start in the subsequent year.

Acoustics Program. This covers exploration of infrasound generators to incapacitate humans and evaluation of tactical utility of audible and ultrasound systems. While the objective is to have a nonlethal, tunable, high power acoustic weapon, it is recognized that biological effects must be fully understood before this technology can be fielded. The specific line items in this category are: bioeffects study, acoustic munitions, combustion-driven sources, electric-driven sources. Acoustic munitions is the first one to complete EMD, with procurement planned to start in FY05. The other items are ongoing through FY03 and beyond.

Riot Control Program. This covers the following projects: Dispenser (mid-size), LVOSS 66mm, NL Mk 19 CS Round, NL Pepper Round, Aqueous Foam, and Sticky/ChemRigid Foam. The latter two stay in Tech Base through FY99, with no EMD planned; the others complete EMD in the POM years, with procurements planned to start in FY99 (dispenser), FY00 (LVOSS), FY02 (NL M19 CS Rd), and FY03 (NL Pepper RD). They will supplement the current inventory items: Mk 46 Riot Extinguisher, Mk 4 Riot Dispenser, and Mk 9 Riot Dispenser.

Delivery Methods. This involves development of UAV/light aircraft dispensing systems for delivery of nonlethal payloads and examination of technical feasibility of precision delivery devices. (Breakout by year shown in the above table is JAYCOR's estimate. Original data only show the total sum of $2.6 million).

Physical Security Action Group (PSEAG). This continues NLT program covering directed energy applications. Specific items shown include: Saber 203 (low-power laser illuminator fitted into M203 grenade launcher); ESATA (eye-safe at the aperture) project (to result in eye-safe, glare producing device that can be fitted onto any rifle); and active denial technology (ADT), applying nonlethal DEWs against variety of threat targets.

Conclusions

The objectives of the study were met. A wide range of organizations were interviewed, under similar circumstances and in approximately the same time frame, to obtain their concerns for the biological effects of nonlethal weapons. Despite the variance in points of view and familiarity with these technologies, a finite set of concerns were identified with corresponding, specific impact on biological research. The concern for long term effects (cancer, etc.) was most prevalent. An analysis of the data available in the open literature can provide a starting point for addressing these concerns with additional research.

Despite the overall success, several shortcomings of the study should be noted. First, although over 60 individuals were interviewed, the sampling was far from complete and several key individuals and organizations (known and unknown) were missed. Second, the DOD establishment of a NLW Executive Agent and the associated support organizations, personnel, and procedures were rapidly changing during the interview period. Many of the interrelations between organizations and the direction for future weapon development were in evolution. Third, the use of a standardized interview format may have focused the interviewee toward certain issues. Nonetheless, many unexpected issues and concerns were raised that were outside the original list of questions. Finally, time did not permit revisiting each contributor to obtain a second opinion or a chance to review our assessment of their position. We hope that the perspectives have been correctly captured.

The survey produced a list of biological effect concerns that should help guide the planning of research so that critical issues are addressed. A summary of the implications for research follows.

1. Identification of harmful effects
2. Quantification of dose-distribution and dose-response curves.
3. Correction for population effects
4. Identification of potential side effects
5. Definition of mode of effectiveness
6. Quantification of operational parameters for the particular mission
7. Identification of countermeasures
8. Guidance on signs, symptoms, and duration of effects
9. Guidance on treatment modes and triage
10. Identification of populations at risk
11. Identification of long term effects and their incidence
12. Demonstration that occupational standards are met
13. Identification of situations where automatic overrides are needed
14. Consensus on the number and type of tests
15. Plan for independent review of data and conclusions
16. Early on decision whether to use human testing.

Of course, no research program can address all of the concerns of all of the reviewers with unlimited accuracy. These points must be considered and a consensus arrived at among all of the decision makers (policy, legal, medical, operational, ethical, etc.) on what will constitute an acceptable data package.

Some refinements in DoD or Air Force acquisition policy and procedures are desirable to better exploit the potential of nonlethal weapons. We recommend two categories of changes: (1) tailoring the acquisition process for nonlethal weapons, and (2) addressing voids in current policy for nonlethal weapons. The first, and most important, category involves mandatory requirements for milestone reviews and expanded organizational responsibilities. These changes are modeled after the procedures that have been implemented DoD-wide over the past ten years to accommodate *life fire testing* – a statutory requirement for lethal weapons system programs that exhibits, in our view, some parallels to the requisite bioeffect certification for nonlethal weapons. These changes also draw from the U.S. Army's Health Hazard Assessment process that has been in effect since 1981. The second category of recommended changes is concerned with two areas that are not adequately addressed, in our view, in current policy: the need for NATO standardization and interoperability of nonlethal weapons; and the development and evaluation of countermeasures to each and every nonlethal weapon that is being developed, in parallel with and as part of each nonlethal weapon development program.

One final conclusion concerns the further validation of these findings. As was mentioned above, we have made only one pass through the organizations and interviewees. There has been no chance for these first impressions to be assimilated and a consensus built. It is recommended that HSC conduct a follow up to the distribution of the report involve polling the organizations with the goal of achieving a formalized list of biological concerns and agreement on the data required to resolve the issues so that research can proceed smoothly.

Appendix 1: Interview Brief

Survey of Concerns about Biological Effects of Nonlethal Technologies (NLT) (Broad Issues Study)

Sponsor: Air Force Human Systems Center (HSC), Brooks AFB, TX
COTR: Capt. Harold Andrews; (210) 536-4456

Contractor: JAYCOR
Principal Investigator: Dr. James H. Stuhmiller, (619) 535-3110
Additional POC (McLean, VA, office): Mr. Frans Nauta, (703) 847-4126.

Objective: Identify concerns about biomedical effects of NLT that must be resolved before nonlethal weapons (NLW) are developed, acquired, and fielded. Relate those concerns to research requirements.

Focus/Scope: Specific interest in Directed Energy technologies, including lasers, microwaves and acoustic, with application to combat, peace keeping, and law enforcement.

Product: Technical report summarizing the concerns related to biological effects of NLT and the requirements for biomedical research to address or overcome those concerns.

Interviewees: Sample of 30-40 individuals in OSD, the Services, and relevant nonmilitary organizations who are representative of the various points of view: proponent, legal, medical, ethical, policy, operation, training, testing, development, environment, occupational safety.

Survey Questionnaire

Organizational:
- What is your organization's involvement with NLTs? What other organizations and how?
- What issues related to biological effects of NLTs have arisen? Details.

Regulations:
- What regulations/standards does your organization follow with respect to biological effects?
- What is your perception of political climate for NLWs or NLT in general?

Nature of Concern:
- Is your interest (1) operational effectiveness, (2) safety, (3) ethical, or (4) policy?
- What are your concerns for (1) operator, (2) intended target, or (3) bystanders?

Delayed and Long-Term Effects:
- What concerns do you have for delayed effects (not immediately observed)?
- What concerns for long term effects (cancer, reproductive problems, etc.)?
- What is the relative importance of acute and long-term effects?
- Should long-term effects be assessed before deployment, regardless of time or cost?

Performance (Effectiveness Issues):
- What effects (behavioral/physiological/psychological) are expected/desired for NLWs?
- What biological effect parameters (onset, duration, percent) measure NLW effectiveness?

Risk Assessment (Safety Concerns):
- What is the perceived risk: morbidity, mortality, cancer, etc.?
- What are acceptable levels of risk? Are these levels situation dependent?
- What risk assessment procedures do you use or recommend?

Research Protocols:
- What data is required? What protocols should be followed?
- What independent scientific confirmation is necessary?
- Are human trials required? Can they be conducted if there is significant risk?

T674-96-0707/1996

Appendix 2: Interview Presentation Materials

Nonlethal Technology (NLT) Bioeffects Broad Issues Study

Version 1.5 2997

Directed Energy (DE) Technology:
Laser, Radiofrequency Radiation,
and Acoustic

March 1997

9775 Towne Centre Drive
San Diego, California 92121-1996
(619) 453-6580 ✦ Fax (619) 453-1267

JAYCOR
Simulation, Engineering & Testing

Goals of Interview

2997-04/03-97

- **Collect specific concerns to be addressed by proponents**
  - Nature of scientific data to be collected
  - "Show stoppers"
- **Capture differing points of view**
  - Medical, Legal, Operational, Policy
  - Occupational Safety, Training, Testing, Environmental
  - Weapon Development, Acquisition, Deployment
  - Combat, Law Enforcement, Peace Keeping
- **Refine the interview process**
  - Identify additional concerns
  - Sharpen the issues

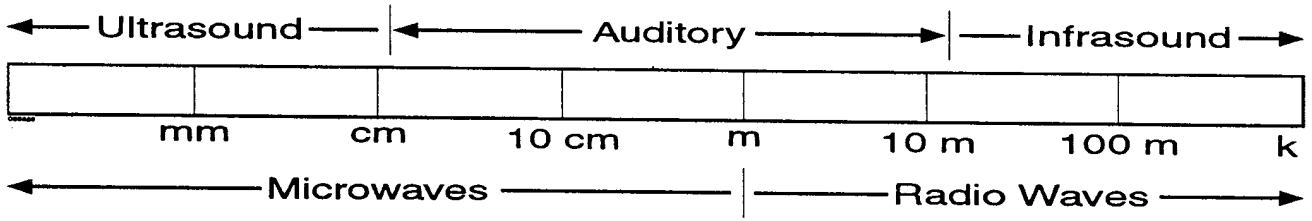
Summary of Study

2997-04/03-97

- **Purpose**
  - Identify bioeffect concerns related to deployment and use of (generic) NLT
  - Identify (general) research priorities based on observed effects
- **Scope**
  - Directed Energy (DE) NLT: radio frequency radiation, acoustic, laser
  - Collect concerns:
    - Formulate interview, within the DE NLT bioeffect context
    - Conduct interviews to identify organizational concerns and interconnections
    - Summarize organizational concerns in terms of bioeffects issues
  - Summarize biological effects:
    - Summarize existing scientific literature
    - Characterize biological effects by intensity level
- **Product: Final Report**
  - Organizational concerns, interconnections, and bioeffects issues
  - Summary of scientific literature and known effects

Common Physical Characteristics

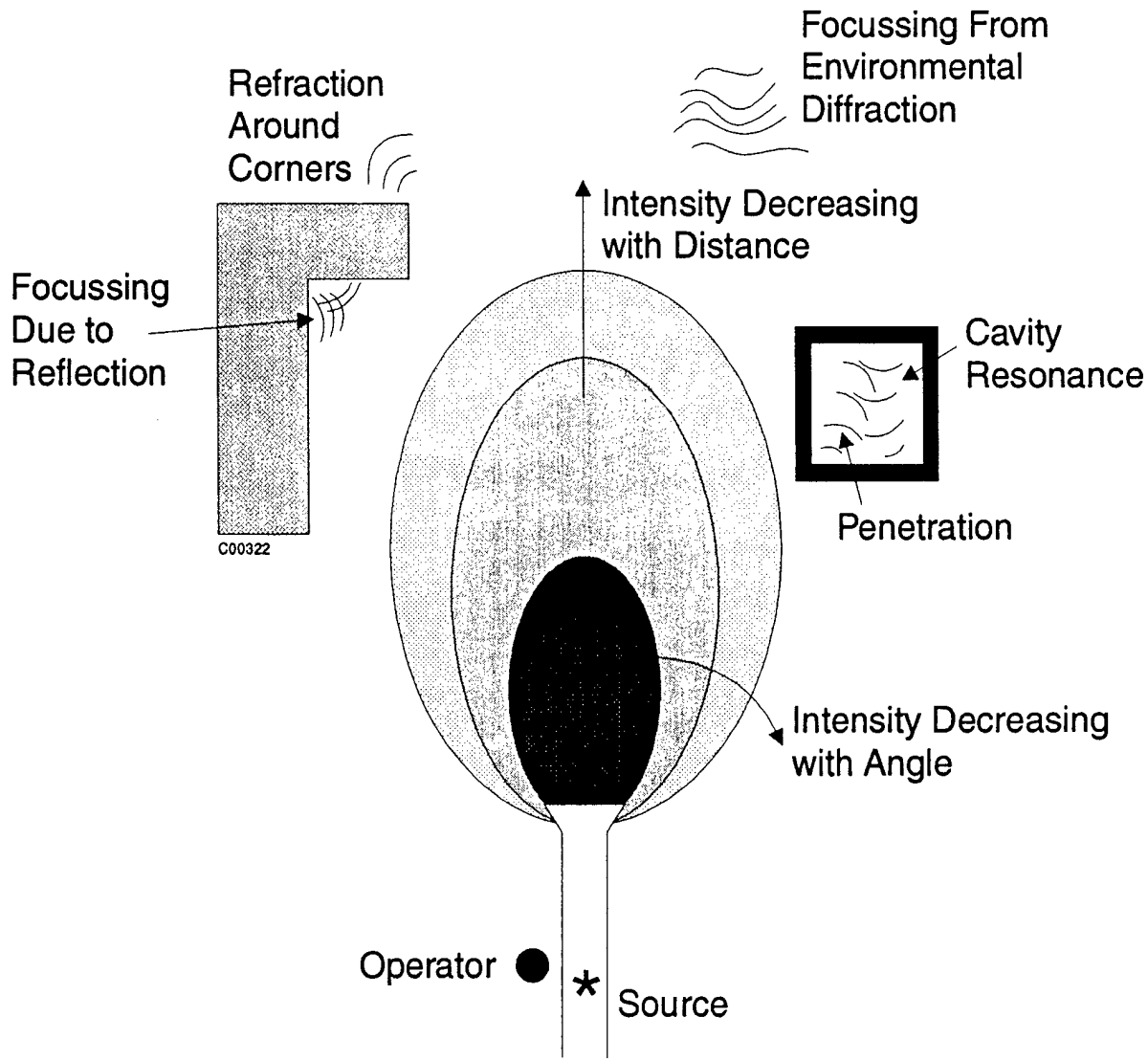
- **Wave Nature**
  - Propagation speed, c
    - EM: speed of light
    - Acoustic: speed of sound (blasts travel up to 8 times faster)
  - Wavelength, $\lambda = c / \text{frequency}$



- **Intensity Variation Around Source**
  - Near field ($x < 2\lambda$): intensity and direction variable
  - Far field ($x >> \lambda$): intensity varies as $1/\text{Distance}^2$
- **Focusing Depends on "Aperture" Size, D**
  - Cannot control direction if $D < \lambda$

Intensity Variations Around Directed Energy Source

2997-04/03-97



Common Biological Characteristics

2997-04/03-97

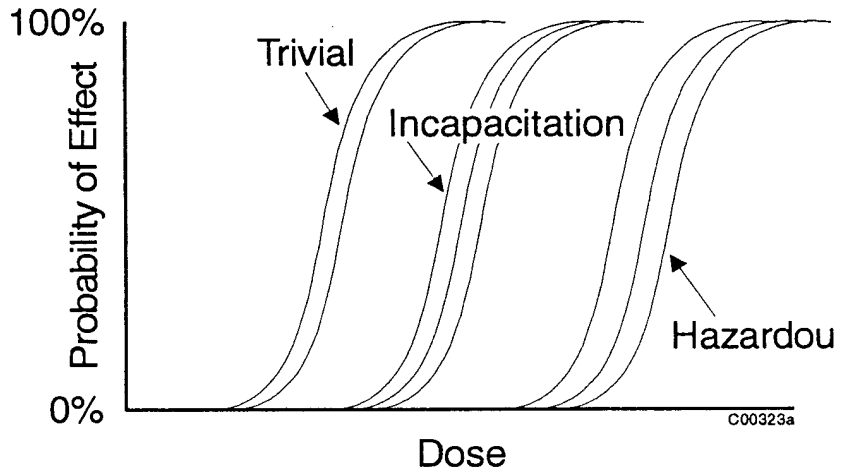
- **External fields measured as fluxes (power/area)**
  - EM: watts/m^2
  - Acoustic: decibels
- **Bioeffects correlate with energy deposited per body mass**
  - EM: Specific Absorption Rate, SAR (power/body mass)
  - Acoustic (blast): Work/body mass
- **Trivial, Incapacitating, and Hazardous Effects**
  - May be separated (very approximately) by an order of magnitude
    - SAR: 0.4, 4.0, 40 W/kg
    - Normalized Work: 0.02, 0.2, 2.0
- **Pulsed waves**
  - Standards allow higher fluxes for pulses
    - EM: 40,890 vs. 50 W/m^2 (European Prestandard @ 2 GHz)
    - Acoustic: 120 dB vs. 85 dB (Mil. Std 1474C unprotected ears)
  - Biological mechanisms, effects, and tolerances not completely understood

Effects Described by Probability

2997-04/03-97

- **Categories of effect**
  - Trivial
  - Incapacitating
  - Hazardous
- **Generally, effects overlap**
- **Very few effects have been quantitatively correlated**

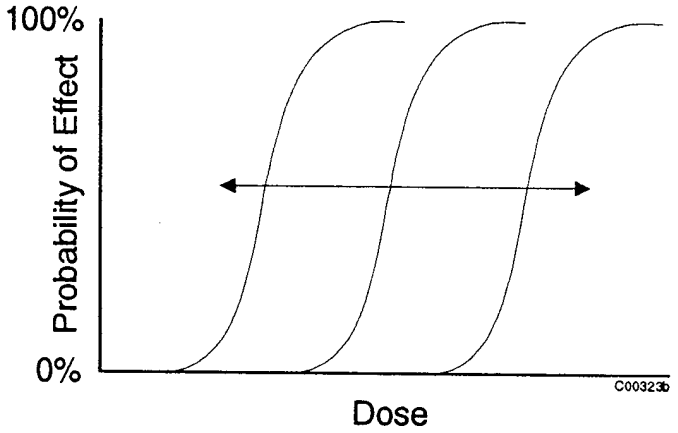
Probability of Various Effects



Variability

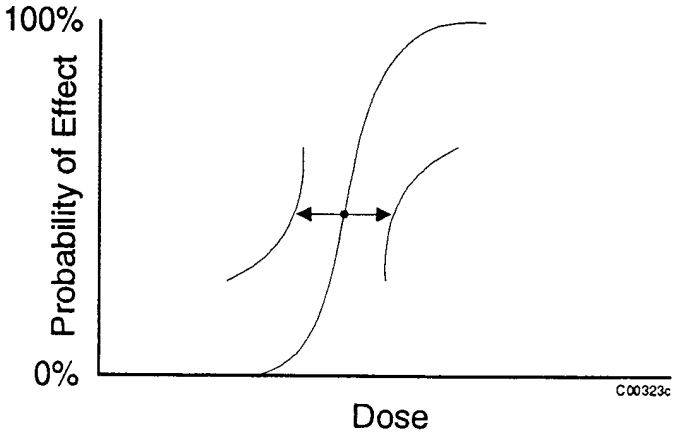
- **The variation in the population as a whole is due, in part, to variable susceptibility and physical characteristics**
- **The risk (at a given exposure) must be in terms of the population segment.**

Variation Among Population



- **The confidence of the correlation depends on**
  - the number of test subjects used
  - the distribution of dose values

Confidence Interval



Common Tasks For Anti-Personnel NLT

2997-04/03-97

- **Task 1: Incapacitate Individual**
  - In building
  - In crowd
  - Fleeing
- **Task 2: Distraction**
  - In room
  - In crowd
- **Task 3: Seize Individual**
  - In crowd
  - Single/stationary
  - Moving
- **Task 4: Stop Vehicle**
  - Approaching
  - Retreating
- **Task 5: Deny Access**
  - Vehicles
  - Personnel
- **Task 6: Control Crowds**
  - Stop approach
  - Cause dispersal

- **Examples:**
  - Disable sniper
  - Disable enemy hiding in crowd
  - Capture scout for interrogation
- **Examples:**
  - Distract hostage-taker for rescue
  - Distract crowd to protect VIP
- **Examples:**
  - Seize insurgent hiding in crowd
  - Seize person trying to enter a facility
  - Seize person running a barricade
- **Examples:**
  - Stop vehicle at border
  - Prevent escape of terrorists
- **Examples:**
  - Prevent crossing a bridge
  - Deny access to embassy compound
- **Examples:**
  - Prevent movement down a street
  - Disperse crowd around embassy

Question Checklist

2997-04/03-97

❑ Organizational

- ○ How is your organization and/or you personally involved in the approval, acquisition, or deployment of NLT?
- ○ What issues related to the biological effects of NLT have arisen in the past? How were they handled? What was the outcome?
- ○ What other organizations get involved? How are they involved? Who would you recommend we talk to?
- ○ What future involvement do you anticipate?

❑ Regulation

- ○ What statutes, laws, regulations, standards, etc. followed by your organization are related to biological effects?
- ○ What statutes, etc. are being proposed?
- ○ What is your perception of the political climate for either specific NLWs or for NLT in general?

Question Checklist *(Cont'd)*

2997-04/03-97

- **Nature of Concern**
  - Is the nature of your interest
    - Operational effectiveness
    - Safety (legal, medical, training)
    - Ethical
    - Policy
  - What specific concerns do you have for
    - The operator of the weapon
    - The intended target
    - Innocent bystanders
  - Are your concerns scenario-dependent?

- **Delayed and Long-Term Effects**
  - Delayed effects that are not immediately observed
  - Cancer, reproductive problems, etc.
  - What is the relative importance of acute vs. long-term effects?
  - Should the incidence of long-term effects be determined
    - If the testing is long and costly?
    - If the outcome is likely to be inconclusive?

Question Checklist *(Cont'd)*

- **Performance (Effectiveness Concerns)**
  - What effects are expected? desired? acceptable?
    - Behavioral
    - Physiological
    - Psychological
  - What (biological effect) parameters must be quantified?
    - Time to effect
    - Duration of effect
    - Probability of effectiveness
  - What ranges of these parameters would be meaningful?

- **Risk Assessment (Safety Concerns)**
  - What is the perceived risk: morbidity, mortality, carcinogenicity, etc.?
  - What are the acceptable levels of risk?
  - Are these levels situation dependent?
  - What risk assessment procedures do you use or recommend?

Question Checklist *(Cont'd)*

2997-04/03-97

❑ Acceptable Research Protocols

- ○ What kind of scientific data would be required?
- ○ Would this data be adequate if it were obtained from
  - – The open literature using similar directed energy forms ?
  - – In vivo testing (cell cultures, etc.)?
  - – Animal testing (small animals with scaling to humans)?
  - – Human exposure tests?
- ○ Can this data be provided by the technology developer or must an independent determination be made?
- ○ What research protocols must be followed? Who approves these protocols? What are the guidance documents?

❑ Human Trials

- ○ Can exposure of the general population to NLW be allowed if there has been no human trials?
- ○ Could human trials to determine the nature of the temporary incapacitating effects be allowed if there is a chance of significant disability or death?

Appendix 3: Interviewee List

Major Vaughn Ary
Legal Advisor to CJCS, USMC
(703) 697-1208 (or -1137)

Col. Carla Beechie
Pediatrics, AFMOA
Bolling AFB, DC

Marianne Bentz
Compliance Oversight Coordinator, Office of Protection from Research Risks (NIH)
6100 Executive Blvd.
Rockville, MD 20892-7507
(301) 496-8101

Art Blankenship
NSWC-DD/J41, Navy
Naval Surface Warfare Center
Dahlgren, VA 22448
(540) 653-1778

Jerry Brammer
Laser/RFR
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

Col. Brown
AFMOA
Bolling AFB, DC

MAJ Rene Burgess
Head of NL, US Army Infantry Center
Fort Benning, GA
(706) 545-6198

CAPT John Carroll
US Army Infantry Center
Fort Benning, GA
(706) 545-6198

John Cline
Deputy Systems Manager for NL Programs
US Army ARDEC
Picatinny, NJ 07806-5000
(201) 724-6244

Dr. Susan Crandall, MD
Assurance Coordinator, Office of Protection from Research Risks (NIH)
6100 Executive Blvd.
Rockville, MD 20892-7507
(301) 496-8101

Dr. David Dickson
DCSOPS
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

LT Daniel E. Dzinitis
HQ Dept. of Navy, N-85
The Pentagon, Room 5E515
Washington, DC 20350
(703) 695-1444

Dr. Gary B. Ellis
Director, Office of Protection from Research Risks (NIH)
6100 Executive Blvd.
Rockville, MD 20892-7507
(301) 496-8101

Col. Bob Ferguson
AFMOA
Bolling AFB, DC

Jeanne D.C. Fravel
NSWC-DD/J41, Navy
Naval Surface Warfare Center
Dahlgren, VA 22448
(540) 653-1778

Lt. Col. Karl Frieldl
Research Area Directorate
US Army Medical Research and Material Command
Ft. Detrick, MD
(301) 619-7301

LTC Mike Hawrylak
CCJ3-PP, USCENTCOM
MacDill AFB, FL
(813) 828-6339

Dr. Fred Hegge
Director, Research Area Directorate
US Army Medical Research and Material Command
Ft. Detrick, MD
(301) 619-7301

Don Henry
Office of Munitions, OUSD (A&T)/ Strategic & Tactical Systems
The Pentagon
Room 3B1060
Washington, DC 20301-3140
(703) 695-1407 (or -1453, -1468)

LTC Paul Hughes
OUSD Peace Keeping and Humanitarian Assistance

MAJ Arthur Johnston
Action Officer for Law Enforcement/ Liaison Officer for MP School, US Army, TRADOC HQ
Ft. Monroe, VA
(804) 727-2539

Col. Jordan
AFMOA
Bolling AFB, DC

Jack B. Keller, Jr.
Foreign Science Information Officer
US Army Medical Research and Material Command
Ft. Detrick, MD
(301) 619-7301

Ms. Susan LeVine
Chief, Nonlethal Coordination Cell (NLCC), Joint NLW Directorate
Quantico, VA
(703) 784-5715

Dr. Melody Lin
Deputy Director, Office of Protection from Research Risks (NIH)
6100 Executive Blvd.
Rockville, MD 20892-7507
(301) 496-8101

Jim Mahan
Chief, Security Technology, Federal Bureau of Prisons, US Dept. of Justice
Washington, DC
(202) 307-3191

Wesley Marshall
Laser/RFR
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

CDR McDermott
USSOCOM J-5, Counter Proliferation and Policy Office
MacDill AFB, FL
(813) 828-4185

Mr. Phil Meek
SAF/CGI
1740 Air Force Pentagon
Washington, DC 20330-1740
(703)697-4234

Angela Mersiowsky
NSWC-DD/J41, Navy
Naval Surface Warfare Center
Dahlgren, VA 22448
(540) 653-1778

Dr. Roy Metker
Chief, Toxicology
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

Col. (Ret.) George Murnyak
HHA Officer
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

John R. ("Randy") Murphy
Asst. Program Manager (Logistics), Special Operations Acquisition Center (SOAC-DT)
MacDill AFB, FL
(813) 828-9367

Patricia Norris
Communications Director, National Bioethics Advisory Commission
6100 Executive Blvd.
Rockville, MD 20892-7507
(301) 496-8101

Col. Parkinson
AFMOA
Bolling AFB, DC

Hays Parks
Esq., Dept. of the Army Judge Advocate, Int'l. and Operational Law, Special Assistant for Law of War Matters
(703) 695-3170

Maj. Mead Pimsler
AFMOA
Bolling AFB, DC

Mr. Procaccino
AF/JACT

Dr. Thomas Puglisi
Chief, Compliance Oversight Branch, Office of Protection from Research Risks (NIH)
6100 Executive Blvd.
Rockville, MD 20892-7507
(301) 496-8101

Ms. Judy Regan
AF/JACE

Dr. James Reitman
Bioethicist
59 MDW/PSMM
2200 Bergquist Dr., Suite 1
Lackland AFB, TX 78236
(210) 670-2673

Brad Roberts
RFR Program, Laser/RFR
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

Mr. Felix Sachs
Bioacoustics
US Army Center for Health Promotion and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

Major Stephen Sawyer
Oper. Rqmts. Directorate, Weapons & Nuclear Deterrence Rqmts. Div., HQ USAF/XORW
1480 Air Force Pentagon
(703) 614-0760

Dr. Steve Schuschereba
US Army Medical Research and Material Command
Ft. Detrick, MD
(301) 619-7301

Col. Courtney Scott
Flight Medicine, AFMOA
Bolling AFB, DC

James O. Shannon
Science Advisor for NLW to CINC USACOM
HQ USACOM, J-36SP
1562 Mitscher Ave., Suite 200
Norfolk, VA 23551-5100
(804) 322-5018

Kenneth A. Sines
Directed Energy Warfare Specialist, US
Army Infantry Center
Fort Benning, GA
(706) 545-5052

Dr. David Sliney
Manager, Laser/Optical Radiation
Program, Laser/RFR
US Army Center for Health Promotion
and Preventative Medicine
Aberdeen Proving Ground, MD 21010
(800) 222-9698

Cdr. Jeff Stratton
Special Warfare Office, USN

Dr. Bruce E. Stuck
US Army Medical Research and Material
Command
7914 A. Drive, Building 176
Brooks AFB, TX 78235-5138
(201) 536-4621

Mr. Charles Swett
OASD/SOLIC
2B525 The Pentagon
Washington, DC 20301-2500
(703) 693-5208