



Department of Defense INSTRUCTION

NUMBER 3200.19

May 17, 2012

USD(AT&L)

SUBJECT: Non-Lethal Weapons (NLW) Human Effects Characterization

References: See Enclosure 1

1. PURPOSE. In accordance with the authority in DoD Directive (DoDD) 5134.01 (Reference (a)), this Instruction:

a. Establishes policy, assigns responsibilities, and provides procedures for a human effects characterization process in support of the development of NLW, non-lethal technologies, and NLW systems.

b. Establishes the Human Effects Review Board (HERB) in accordance with DoD Instruction (DoDI) 5105.18 (Reference (b)) as an independent DoD board to ensure appropriate scientific processes are used to characterize the human effects of all DoD NLW programs.

c. Establishes the Human Effects Readiness Level (HERL) as a measure of the availability, sufficiency, and maturity of data and information of the human effects of NLW.

d. Establishes health care capability (HCC) indexes as a basis to determine the risk of significant injury (RSI) from NLW.

e. Focuses on the human effects on NLW targets. Effects of weapons on operators are covered in other DoD procedures as required.

2. APPLICABILITY. This Instruction applies to:

a. OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (hereinafter referred to collectively as the "DoD Components").

b. Requirements development for NLW.

c. Research, development, test, evaluation, and acquisition of all NLW within the Defense Acquisition System in accordance with DoDD 5000.01 (Reference (c)).

d. NLW human effects characterization data, reports, and related products that will inform NLW training and demonstration policies and employment decisions.

e. NLW research independent of the budget activities funding the research, the mission of the DoD organization conducting or supporting the research, the security classification of the research, the location of the research in the United States or a foreign country, or whether the research is conducted or supported under a program that is not considered research for other purposes.

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. NLW are intended to have relatively reversible effects (see Glossary) and minimize risk of fatalities, permanent injuries, or permanent damage to materiel; however, they shall not be required to have a zero probability of producing these effects in accordance with DoD Directive 3000.3 (Reference (d)).

b. Characterization of the human effects of NLW shall be conducted during the materiel development process to assess the likelihood of achieving the desired effect(s) and identify RSI for counter-personnel systems, as well as the RSI for collateral damage to humans from counter-materiel systems.

c. The RSI for any given weapon shall be identified by the combat developer to assist in materiel development and enable force commanders to understand the potential risks associated with the use of specific NLW.

d. NLW programs that involve animal subjects shall comply with DoD Instruction 3216.01 (Reference (e)) and implementing DoD Component issuances.

e. NLW programs that involve human subjects shall comply with DoD Instruction 3216.02 (Reference (f)) and implementing DoD Component issuances.

f. Secrecy oaths or other non-disclosure agreements will not be used to inhibit veterans from discussing health concerns with their doctors or seeking compensation from the Department of Veterans Affairs for potential service-related disabilities.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosures 3 and 4.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE

a. This Instruction is effective May 17, 2012.

b. This Instruction must be reissued, cancelled, or certified current within 5 years of its publication in accordance with DoD Instruction 5025.01 (Reference (g)). If not, this Instruction will expire effective May 17, 2022 and be removed from the DoD Issuances Website.



Frank Kendall
Acting Under Secretary of Defense for
Acquisition, Technology, and Logistics

Enclosures

1. References
2. Responsibilities
3. Procedures
4. HERB

Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5134.01, "Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L))," December 9, 2005
- (b) DoD Instruction 5105.18, "DoD Intergovernmental and Intragovernmental Committee Management Program," July 10, 2009
- (c) DoD Directive 5000.01, "The Defense Acquisition System," May 12, 2003
- (d) DoD Directive 3000.3, "Policy for Non-Lethal Weapons," July 9, 1996
- (e) DoD Instruction 3216.01, "Use of Animals in DoD Programs," September 13, 2010
- (f) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," October 20, 2011
- (g) DoD Instruction 5025.01, "DoD Directives Program," October 28, 2007
- (h) Joint Non-Lethal Weapons Directorate "Joint Capabilities Document (JCD) for Joint Non-Lethal Effects (JNLE), Version 1," January 22, 2008¹

¹ Available from Joint Non-Lethal Weapons Directorate, Quantico, VA 22134, (703) 784-1977

ENCLOSURE 2

RESPONSIBILITIES

1. UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY, AND LOGISTICS (USD(AT&L)). The USD(AT&L), as the OSD Principal Staff Assistant for the DoD NLW Program, shall:

a. Oversee NLW human effects characterization in coordination with the DoD Executive Agent (EA) for NLW, consistent with Reference (d).

b. When appropriate, approve alternate exposure policies needed for NLW development where exposure requirements exceed existing policy limits (e.g., non-routine exposure of DoD personnel to NLWs above existing occupational safety and health standards for the purposes of demonstrations or training).

2. ASSISTANT SECRETARY OF DEFENSE FOR RESEARCH AND ENGINEERING (ASD(R&E)). The ASD(R&E), under the authority, direction, and control of the USD(AT&L), shall provide scientific and technical oversight and coordination on NLW human effects research and development with the DoD EA for NLW.

3. UNDER SECRETARY OF DEFENSE FOR POLICY (USD(P)). The USD(P) shall oversee DoD policy for the employment of NLW in consultation with the USD(AT&L) and the DoD EA for NLW, in accordance with Reference (d). Decisions on NLW employment policy will be informed by NLW human effects characterization data, reports, and related products.

4. COMMANDANT OF THE U. S. MARINE CORPS. The Commandant of the U.S. Marine Corps, as the DoD EA for NLW in accordance with Reference (d), shall:

a. Establish procedures pertaining to the characterization of NLW human effects.

b. Designate a DoD NLW Health Effects Officer.

(1) The DoD NLW Health Effects Officer shall hold credentials within the biomedical sciences. He or she will report to the director of the jointly manned activity conducting the day-to-day activities of the Joint NLW Program.

(2) The DoD NLW Health Effects Officer shall manage the day-to-day activities associated with NLW human effects, including the establishment, maintenance, and coordination of NLW human effects characterization processes and guidance on DoD NLW human effects research and development and risk assessment. This individual will serve as the primary point of contact on NLW human effects and as the chair of the HERB.

c. Identify a core of NLW human effects subject matter experts (SMEs), to include the DoD NLW Health Effects Officer, to assist DoD Component combat and materiel developers and program managers in the NLW capabilities development process, in assessment of human effects, and in conducting non-lethal-effects characterizations and risk assessments.

d. In coordination with the HERB, prescribe processes and procedures for the conduct of HERB reviews for all NLW programs.

e. Convene and conduct the HERB according to the procedures in Enclosure 4 of this Instruction.

f. Establish and maintain a repository for information related to NLW human effects, human effects characterizations, and risk assessments in order to provide a central resource for NLW human effects data and information for use by the DoD NLW community.

g. Coordinate NLW human effects matters with appropriate departments and agencies external to DoD as approved by the USD(AT&L) or USD(P).

5. DIRECTOR, OPERATIONAL TEST AND EVALUATION (DOT&E). The Director, DOT&E shall:

a. Advise the Secretary of Defense, the USD(AT&L), the Secretaries of the Military Departments, and the DoD EA for NLW with respect to operational test and evaluation of NLW as it relates to NLW human effects characterization.

b. Prescribe policies and procedures for the conduct of operational test and evaluation that involve human effects characterization, including:

(1) Counter-personnel systems.

(2) Counter-materiel systems that involve the RSI to humans from collateral damage (e.g., directed energy systems that may involve secondary non-lethal collateral damage effects to humans).

c. Provide guidance to and consult with the Secretary of Defense, the USD(AT&L) and the Secretaries of the Military Departments with respect to operational test and evaluation of systems that require human effects characterization.

d. Approve the adequacy of operational test plans that involve human effects characterization.

6. SECRETARIES OF THE MILITARY DEPARTMENTS AND COMMANDER, U.S. SPECIAL OPERATIONS COMMAND (USSOCOM). The Secretaries of the Military Departments and the Commander, USSOCOM, shall:

- a. Ensure the policies and procedures in this Instruction are applied to all NLW programs.
- b. Ensure that a human effects characterization is completed in the development of NLW during the acquisition process in order to assess the likelihood of achieving the desired effect and to identify RSI associated with NLW in counter-personnel and counter-materiel applications.
- c. Ensure that NLW program managers incorporate assessment of human effects and the risks posed by NLW into project plans and test requirements.
- d. Ensure human effects assessment data is provided to the servicing legal office to support the legal review of non-lethal weapons required during the acquisition process. Legal reviews ensure weapons being acquired by DoD remain consistent with applicable law, including U.S. treaty obligations, customary international law, and the law of war. Early identification of legal issues of concern reduces costs and facilitates the development of viable systems.
- e. Plan for and provide adequate resources to aid in NLW requirements generation, and in assessment and characterization of human effects and risk.
- f. Appoint one member from their respective Surgeon General offices and one member from their respective safety centers (or equivalents), as applicable, to serve on the HERB.
- g. Ensure that NLW program managers adhere to the HERB procedures in Enclosure 4 of this Instruction.
- h. Ensure that RSI of NLW is addressed in appropriate capabilities documents (e.g., capability development and production documents).
- i. Develop formal processes for the use of NLW on DoD personnel (e.g., assessments, training, or demonstrations) when such use is not considered research involving a human subject by a DoD Component pursuant to Reference (f).

ENCLOSURE 3

PROCEDURES

1. CAPABILITIES DEVELOPMENT

a. Combat and materiel developers shall consult human effects and developmental and operational test and evaluation SMEs early in the NLW capabilities development process.

(1) Human effects SMEs shall advise combat developers in articulating NLW human effects requirements to support the development of suitable human effects-related performance attributes (e.g., duration of effect, reversibility, RSI).

(2) Developmental and operational test and evaluation SMEs shall advise combat developers on testing protocols and procedures to ensure NLW performance metrics are quantitatively or qualitatively verifiable.

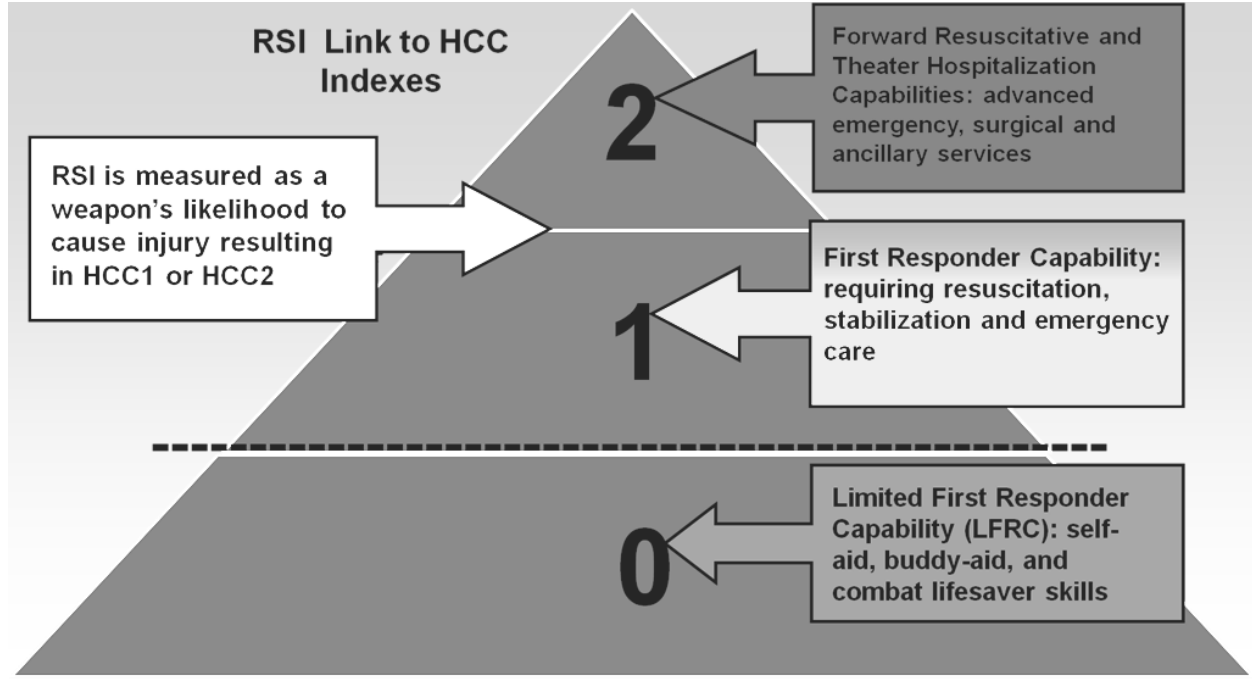
b. Combat developers, in consultation with human effects and developmental and operational test and evaluation SMEs, shall ensure NLW effectiveness and human effects-related performance attributes are addressed in appropriate capability documents (e.g., capability development and capability production documents).

(1) The effectiveness of NLW is critical to successful employment and shall be designated as a key system attribute (KSA) or key performance parameter (KPP) in capabilities documents.

(2) Combat developers, working with warfighter input, shall determine the human effects-related performance attributes of NLW, to include acceptable RSI. These attributes may be addressed in capabilities documents as attributes, KSAs, and KPPs. RSI shall be addressed as a KSA or KPP.

c. RSI shall provide the force commander a measure of the likelihood that employed NLW may directly cause injury requiring HCC Index 1 or 2. HCCs are depicted in the Figure, which illustrates the relationship between RSI and the HCC indexes. HCC 0 reflects limited first responder requirements such as self-aid or buddy-aid. HCC 1 reflects first responder care that could include resuscitation and stabilization. HCC 2 reflects forward hospitalization capabilities such as advanced emergency or surgical services. Common DoD terminology for HCC indexes is provided in the Joint Capabilities Document for Joint Non-Lethal Effects (Reference (h)).

Figure. HCC Indexes



2. HUMAN-EFFECTS CHARACTERIZATION

a. NLW program managers, in consultation with SMEs and the HERB, shall identify the knowledge gaps in the human effects data that need to be addressed to satisfy warfighter requirements. Assessment of human effects and the risks posed by NLW shall be conducted before milestone (MS) B (engineering and manufacturing development phase) approval or, for a system or program initiated at or beyond MS B, as soon as practicable.

b. Human effects SMEs shall determine the HERL, as described in the Table, for candidate NLW. The HERL is a measure of the availability, sufficiency, and maturity of human effects knowledge regarding a specific NLW. NLW shall not be required to achieve a particular HERL; rather the purpose of the HERL shall be to describe the scope of scientific research applicable to specific NLW.

Table. HERL Guide

LEVEL	DESCRIPTION
9	Human or surrogate participation in operational testing. Data validated from live fire experimentation and fielding.
8	Human or surrogate tests in field environment with mature prototype systems under realistic conditions.
7	Human studies or surrogates in lab or field environments with prototype systems under specific, highly controlled, exposure conditions.
6	Non-human primate or large-animal models confirm safety. Provide basis of limited human studies in laboratory to examine effectiveness.
5	Studies in large-animal models to more fully characterize effects, demonstrate technology effectiveness and safety.
4	Bioeffect mechanism accepted by the scientific community; small animal studies conducted to develop dose-response relationships.
3	Bioeffect mechanism clearly identified; studies to determine dose-response relationships planned or begun in small animal models.
2	In-vitro and cellular models used to study postulated bioeffect mechanisms; important dose-response parameters are postulated.
1	Bioeffect mechanism postulated through paper studies, theoretical analysis.

ENCLOSURE 4

HERB

1. PURPOSE

a. The HERB is established to independently review human effects analyses that apply to NLW. The implementation of the HERB review ensures that the human effects of NLWs are evaluated consistently.

b. The HERB advises program managers and milestone decision authorities (MDAs) of the quality and completeness of human effects information, identifies potential human effects risks, and provides recommendations for further research and considerations to mitigate these risks.

2. MEMBERSHIP

a. The HERB is comprised of the DoD Health Effects Officer, members representing the Surgeon Generals of each Service (including the Medical Officer of the U.S. Marine Corps) and USSOCOM, as applicable, and a safety representative from each Service and USSOCOM.

b. The DoD NLW Health Effects Officer serves as the chair of the HERB.

3. PROCESSES AND PROCEDURES

a. A HERB review involving a specific NLW is scheduled based on recommendations of the DoD NLW Health Effects Officer and by request of the MDA or NLW program manager to the DoD Health Effects Officer. The HERB review shall be conducted prior to acquisition decision points, to include the materiel development decision point.

b. HERB members shall be provided relevant reference material from the NLW program manager and human effects SMEs in advance of the review. Each HERB review meeting includes presentations from the NLW program manager, human effects SMEs, and other invited speakers on the NLW under review; however, none of the invited participants shall be allowed to participate in the Board's deliberations.

c. The HERB shall produce a memorandum that provides an assessment and recommendations on the NLW evaluated to the NLW program manager and MDA. The HERB memorandum additionally can be used by the NLW program to support legal, treaty, and policy reviews.

GLOSSARY

PART I. ACRONYMS AND ABBREVIATIONS

DoDD	DoD Directive
DoDI	DoD Instruction
DOT&E	Director, Operational Test and Evaluation
EA	Executive Agent
HCC	health care capability
HERB	Human Effects Review Board
HERL	Human Effects Readiness Level
KSA	key system attribute
KPP	key performance parameter
MDA	milestone decision authority
MS	milestone
NLW	non-lethal weapons
RSI	risk of significant injury
SME	subject matter expert
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics
USD(P)	Under Secretary of Defense for Policy
USSOCOM	U.S. Special Operations Command

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Instruction.

combat developer. Command or agency that formulates doctrine, concepts, organization, material requirements and objectives. May be used generically to represent the user community role in the material acquisition process.

counter-materiel. Directed effects against materiel (vehicles, vessels, aircraft, buildings, facilities, structures, weapon systems, ammunition, weapons of mass destruction, etc.). Non-lethal counter-materiel effects must remain non-lethal to personnel.

counter-personnel. Effects directed against individual(s).

effect. The physical or behavioral state of a system that results from an action, set of actions, or another effect; the result, outcome, or consequence of an action; a change to a condition, behavior, or degree of freedom.

effectiveness. The extent to which specific NLW achieve the intended effect.

HCC Index 0. Limited first-responder capability including self-aid, buddy-aid, and combat lifesaver skills.

HCC Index 1. First responder-capability including resuscitation, stabilization, and emergency care.

HCC Index 2. Forward resuscitative and theater hospitalization capabilities including advanced emergency, surgical, and ancillary services.

HERL. A measure of the availability, sufficiency, and maturity of human effects knowledge regarding a specific NLW.

human effect. The physical impact on, or behavioral response of, a human resulting from a stimulus or set of stimuli.

human effects characterization. A formal process for fully describing the compendium of physiological- and behavioral-effects knowledge associated with a given NLW. It establishes the baseline human effects understanding of NLW, identifies risks and data gaps in human effects knowledge, and facilitates presentation and communication of its human effects.

incapacitate. To disable, inhibit, or degrade one or more functions or capabilities of a target to render it ineffective.

joint NLW program. Joint efforts related to research, development, test, and evaluation under DoD EA for NLW oversight.

materiel developer. A command or agency responsible for research and development, production, and fielding of a new materiel system.

NLW. Defined in Reference (d).

non-lethal technology. Technology being considered or utilized as an NLW.

permanent injury. Physical damage to a person that permanently impairs physiological function and restricts the employment or other activities of that person for the rest of his or her life.

reversibility. The ability to return the target to its pre-engagement functionality. It is usually measured by the time and level of effort required for recovery of the target.

RSI. The potential of NLW to directly cause injury requiring HCC Index 1 or higher HCC index treatment, permanent injury, or death. RSI is the parameter used to describe reversibility of NLW as it relates to human effects.

target. An area, complex, installation, force, equipment, capability, function, or behavior identified for possible action to support a commander's objectives, guidance, and intent.