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Review of Chemical, Biological, Radiological, and Nuclear (CBRN) Terminology in *Technical Guide 316 (TG 316)* and *Allied Medical Publication 8(C) (AMedP-8(C))*

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Executive Summary

The implementation of *Allied Medical Publication 8(C): NATO Planning Guide for the Estimation of CBRN Casualties* (hereafter referred to as *AMedP-8(C)*) within the United States requires coordination and alignment with related guidance and doctrine within the Department of Defense (DOD). The Institute for Defense Analyses (IDA) was asked by the U.S. Army Office of the Surgeon General (OTSG) to review and compare the terminology used in *AMedP-8(C)* and *Technical Guide 316: Microbial Risk Assessment for Aerosolized Microorganisms* (*TG 316*) for consistency. *AMedP-8(C)* is a North Atlantic Treaty Organization (NATO) standardization agreement (STANAG) that provides a methodology for estimating medical casualties at varying severity levels as a result of a chemical, biological, radiological, and nuclear (CBRN) attack. Prior to the ratification of *AMedP-8(C),* the U.S. Army Public Health Command published *TG 316*, describing an evolving methodology for characterizing health risks associated with aerosolized microorganisms and toxins.

Both of these documents incorporate dose-response data within the methodology and use one or more scales of severity associated with the outcome of an attack against the military forces and the general population. *TG 316* assigns dose/dosage values derived from dose-response data directly to the different levels along these scales. These dose/dosage values are the Biological Military Exposure Guidelines (hereafter referred to as BMEG) derived for each biological agent. *AMedP-8(C)* uses a set of submodels to describe the relationship between inhaled dose and the overall human response. The methodology further correlates different stages of illness to a severity scale based on clinical signs and symptoms. This document compares the severity scales and the associated definitions from both documents and examines the similarities and differences in the terminology used by each approach regarding biological agents.

This document also evaluates the concept and function of the two approaches. The Microbial Risk Assessment Methodology in *TG 316* is intended to align with an existing chemical risk assessment methodology, documented in *Technical Guide 230: Environmental Health Risk Assessment and Chemical Exposure Guidelines for Deployed Military Personnel* (*TG 230*), while *AMedP-8(C)* uses a biological agent-specific human response methodology to generate outputs consistent with those produced by its human response methodology for chemical, radiological, and nuclear agents and effects. The purpose of *AMedP-8(C)* is to provide a methodology for estimating casualties that occur

over time following a CBRN attack; these casualty estimates can then be used as inputs to operational risk assessment. In comparison, the purposes of *TG 316* are variously described in its many supplements, but generally it is intended to characterize health hazards and risks associated with exposure to aerosolized biological agents in an operational, occupational, or environmental setting, to guide biological agent detection system development and operation, and to support remediation efforts where microbial hazards are found to exist.

Overall, both methodologies can support medical and operational planning. The casualty estimates obtained through implementation of the *AMedP-8(C)* methodology can be used by several communities—medical planners, logistical planners, operational planners, and personnel planners—to aid in their planning efforts. The BMEGs derived in *TG 316* can be used by military health risk assessors, medical planners, operational planners, and defense system developers to characterize the health hazards and operational risks associated with exposure to bioaerosols. Although both methodologies are used to aid medical and operational planning, the individual methodologies may result in different interpretations of operational hazards and these differences (or similarities) will ultimately affect medical and operational planning.

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1. Introduction

The implementation of *Allied Medical Publication 8(C): NATO*[1] *Planning Guide for the Estimation of CBRN Casualties*[2] (hereafter referred to as *AMedP-8(C)*) within the United States requires coordination and alignment with related guidance and doctrine within the Department of Defense (DOD). The Institute for Defense Analyses (IDA) was asked by the U.S. Army Office of the Surgeon General (OTSG) to review and compare the terminology used in *AMedP-8(C)* and *Technical Guide 316: Microbial Risk Assessment for Aerosolized Microorganisms*[3] (*TG 316*) for consistency.

AMedP-8(C) is a NATO standardization agreement (STANAG) publication that provides a methodology for estimating medical casualties at varying severity levels as a result of a chemical, biological, radiological or nuclear (CBRN) attack. In particular, it describes the acute health effects expected to occur within the military population exposed to defined doses/dosages/insults of particular CBRN agents or effects. This methodology permits a quantitative approach to casualty estimation and can provide some input to risk assessment, an issue of particular import to the DOD.

Prior to the ratification of *AMedP-8(C)*, the U.S. Army Center for Health Promotion and Prevention Medicine (USACHPPM)[4] published *TG 316*, describing an evolving methodology for characterizing health risks associated with aerosolized microorganisms and toxins. It establishes the Biological Military Exposure Guidelines (BMEG), which are doses or concentrations of a biological agent in an environmental medium (i.e., air). The derived BMEGs are used in health risk assessments to evaluate the significance of exposures (short-term) during a military operation, aid medical and operational planning, and inform defense system requirements; they are not, however, intended to influence medical treatment decisions.[5] The BMEG concept is similar to the chemical MEG concept for evaluating health risks from chemical hazards, as contained in

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1 North Atlantic Treaty Organization.

2 North Atlantic Treaty Organization (NATO), *AMedP-8(C): NATO Planning Guide for the Estimation of CBRN Casualties* (Belgium: NATO, March 2011).

3 USACHPPM, *Technical Guide 316: Microbial Risk Assessment for Aerosolized Microorganisms* (Aberdeen Proving Ground, MD: USACHPPM, August 2009).

4 As of October 2009, CHPPM was renamed the U.S. Army Public Health Command (USAPHC).

5 USAPHC, *Technical Guide 316 Supplement F1: Preliminary biological military exposure guidelines for aerosolized ricin toxin* (Aberdeen Proving Ground, MD: USAPHC, February 2012).

Technical Guide 230 (*TG 230*).[6] Although the BMEG derivation is informed by the chemical MEG derivation process, the *TG 316* methodology has evolved to incorporate differences that are necessary to develop MEGs for biological agents as demonstrated in the latest *TG 316* supplements.[7]

Differences in the standards provided by *AMedP-8(C)* and guidelines for internal DOD use developed in *TG 316* contribute to difficulties in establishing a cohesive approach for evaluating the risks associated with biological agent or toxin exposure. This document describes IDA's review of the similarities and disparities in terminology, concept, and function of the methodologies in *AMedP-8(C)* and *TG 316*. It compares the terms used in the various severity scales and the biological warfare terminology used throughout the two documents. It identifies differences, explains their sources, and discusses their implications. This document focuses exclusively on review and comparison of the terminology used and methodologies described in *AMedP-8(C)* and *TG 316*. A comparison of the derived parameters and values will be provided separately at a later date.

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[6] USAPHC, *Environmental Health Risk Assessment and Chemical Exposure Guidelines for Deployed Military Personnel, Technical Guide 230* (Washington DC: USAPHC, June 2010).

[7] USAPHC, *Technical Guide 316 Supplement D1: Preliminary biological military exposure guidelines for aerosolized Yersinia pestis (pneumonic plague)* (Aberdeen Proving Ground, MD: USAPHC, September 2012); USAPHC, *Technical Guide 316 Supplement E1: Preliminary biological military exposure guidelines for aerosolized Francisella tularensis causing pneumonic tularemia* (Aberdeen Proving Ground, MD: USAPHC, January 2012); USAPHC, *Technical Guide 316 Supplement F1*; USAPHC, *Technical Guide 316 Supplement G1: Preliminary biological military exposure guidelines for aerosolized Staphylococcal Enterotoxin B (SEB)*, (Aberdeen Proving Ground, MD: USAPHC, February 2012).

2. Terminology

A review of the terminology used in *AMedP-8(C)* and *TG 316* reveals several overlapping terms used to convey similar or different meanings. Both documents utilize one or more severity scales in the methodology and the terms in each scale are assessed in this chapter. The concept and function of the methodologies described in *AMedP-8(C)* and *TG 316* will be discussed in Chapter 3.

Table 1 lists the significant terms and their respective definitions that are used in *AMedP-8(C)* and *TG 316*. The terms *disease*, *injury*, and *illness* are used interchangeably in the two documents to refer to the adverse health effect(s) associated with a biological agent or toxin. Both documents consider only those injuries/illnesses and diseases resulting from acute exposures—those occurring over minutes to hours—although *TG 316* also considers cumulative dose from acute exposure periods (this will be discussed further in a later section).

Table 1. Terminology Comparison between *AMedP-8(C)* and *TG 316*[8]

Terms	*AMedP-8(C)*	*TG 316*
Disease	An internal disruption of organ or system function, not caused by external trauma. Used for biological agents and substituted for the term injury.	The presentation of signs and symptoms indicative of adverse health effect(s) associated with a particular pathogen.
Injury/Illness	Injury includes both wounds and disease resulting in the damage or deterioration of heath; only acute injuries are considered.	Synonymous to the term disease. Signs and symptoms associated with illness may be outwardly observable, or may only be detected by laboratory tests.

[8] NATO, *AMedP-8(C)*, 1-1 to 1-15; *Technical Reference Manual: NATO Planning Guide for the Estimation of CBRN Casualties, Allied Medical Publication-8(C)*, (hereafter *TRM,* IDA D-4082) IDA Document D-4082 (Alexandria, VA: Institute for Defense Analyses, August 2010); USAPHC, *Technical Guide 316 Supplement E1*; USACHPPM, *Technical Guide 316 Supplement C1: Potential Exposure Guidelines for Bacillus*[sic] *Anthracis Causing Inhalation Anthrax – Guidelines for Peer Review* (Aberdeen Proving Ground, MD: USACHPPM, September 2009).

Terms	*AMedP-8(C)*	*TG 316*
Acute exposure	Battlefield exposures that are expected to be quite short—on the order of several minutes to, perhaps, an hour in duration— so that the mitigating effects of cumulative dosing over time would be expected to be minimal.	A single exposure for a short time frame, from minutes to hours, is considered for derivation of Preliminary BMEGs. No data is available to inform long and chronic exposure duration.
Infected/Infection	All individuals who become infected will also manifest clinical signs and symptoms at some point in time	The state produced by the establishment of a microorganism. An infection may or may not result in clinical illness.
Casualty	In relation to personnel, any person who is lost to his organization by reason of having been declared dead, wounded, diseased, detained, captured, or missing.	Personnel who are expected to have incapacitating health effects that require immediate medical treatment or support.
Effective dose	One of the dose parameters used in the infectivity submodel for toxins (infective dose for organisms). The effective dose for toxins describes the dose at which a defined percentage of the population is expected to experience onset of signs and symptoms.	The dose corresponding to a prescribed health effect in a given percentage of an exposed population relative to a control response. Amount of microbe required/observed/anticipated to initiate infection.
Lethal dose	The dose resulting in lethality in a given percentage of exposed individuals. Median lethal dose (LD_{50}) is the dose resulting in lethality in 50% of exposed population	Dose that will cause death in a given percentage of an exposed population (LD_{xx}).
Threshold dose	In the absence of any other defined relationship between dose and infection, a sufficient level of pathogen to cause individuals to become infected; 100% probability of infection (probability of becoming symptomatic).	A level of pathogen (either spores of organisms) that is expected to initiate infection and result in observable, clinical disease.

The definition in the *Stedman's Medical Dictionary* for the term "infect" is "for a microorganism to enter, invade, or inhabit another organism, causing infection or contamination" and for the term "infection" is "invasion of the body with organism that have the potential to cause disease."[9] *TG 316* defines the term "infection" as the

[9] *Stedman's Medical Dictionary*, 27th Edition, (Baltimore, MD: Lippincott Williams and Wilkins, 2000).

colonization of a host organism by microorganisms and the individual may or may not exhibit clinical illness. The definition of infection in *TG 316* is in complete agreement with the definition provided by the medical dictionary. However, *AMedP-8(C)* makes the assumption that an individual who is infected will eventually display clinical signs and symptoms. The reason for the assumption is because most of the infectivity submodels in *AMedP-8(C)* were generated from dose-response data that associated dose with manifested illness and do not evaluate dose in the subclinical stage. Therefore, the *AMedP-8(C)* infectivity submodels do not measure "infection" as defined in *TG 316* or more broadly, in the infectious disease community.

NATO defines a "Biological Casualty" as a person who is lost to his organization by reason of having been declared dead, wounded, or diseased as a result of exposure to a biological agent.[10] Three terms are used to describe the status of the casualties: killed in action (KIA), wounded in action (WIA), and died of wounds (DOW) and their definitions are shown in Table 2. *TG 316* defines "casualty" similarly as one who has incapacitating health effects that require medical attention.

Table 2. *AMedP-8(C)* Casualty Status Definitions

Casualty Status	Definition
Killed in Action (KIA)	A battle casualty who is killed outright or who dies as a result of wounds or other injuries before reaching a medical treatment facility.
Wounded in Action (WIA)	A battle casualty other than "killed in action" who has incurred an injury due to an external agent or cause. The term encompasses all kinds of wounds and other injuries incurred in action, whether there is a piercing of the body, as in a penetrating or perforated wound, or none, as in the contused wound; all fractures, burns, blast, concussions, all effects of biological and chemical warfare agents, the effects of exposure to ionizing radiation or any other destructive weapon or agent.
Died of Wounds (DOW)	A battle casualty who dies of wounds or other injuries received in action, after having reached a medical treatment facility (may be referred to as a "delayed fatality").

Note: The definitions in this table are extracted verbatim from *AMedP-8 (C)*.

"Effective dose" (ED_{xx}) has contrasting meanings while the term "lethal dose" (LD_{xx}) conveys the same meaning in the two documents. In *AMedP-8(C)*, "effective dose" is one of the dose parameters used in the infectivity submodel to characterize the dose for toxins that cause clinical signs and symptoms. The comparable dose parameter

[10] NATO, *AAP-6: NATO Glossary of Terms and Definitions (English and French)*, STANAG 3680 (Belgium: NATO, 2008), 2-C-2.

for organisms is termed "infective dose" (ID_{xx}). In *AMedP-8(C)*, the probability of illness or death is determined using dose-response functions and typically only the median dose values (ID_{50}, ED_{50} and LD_{50}) and some associated variance are represented. ED_{50} and ID_{50} represent the dose at which the 50% of the population is expected to become ill (i.e., manifest signs and symptoms) and LD_{50} means the dose at which 50% of the population is expected to die. In *TG 316*, "effective dose" is the dose necessary to elicit the specified incidence (xx%) of the identified effect (identified signs and symptoms associated with specific illness categories) for both microorganisms and toxins. The effective dose is expressed as the amount of an agent for which a percentage of an exposed population will exhibit the defined effect. In *TG 316*, the derived BMEGs are associated with different ED_{xx} or LD_{xx} values that correlate to various points on their severity scales.

In *AMedP-8(C)*, the infectivity submodel describes the probability of an individual becoming infected and symptomatic given their dose. Dose-response functions are derived from available data; both the type of function used and the associated parameters will vary by agent. For example, infectivity is modeled as a lognormal function in some cases, and as a threshold response in others, where everyone who receives a dose greater than or equal to a specified magnitude will become infected and symptomatic. Similarly, *TG 316* defines threshold dose as the dose above a given level that will cause an adverse effect whereas exposure below such a level will not.

Table 3 compares the terminology used within each severity scale from *AMedP-8(C)* and *TG 316*. *AMedP-8(C)* uses the "injury severity scale" to describe the progression of the injury with "definitions based on the *AMedP-13*[11] terms and further elaborated to include both medical requirements and operational capabilities of an individual following an event."[12] *TG 316* has two severity scales: the "illness categories" and "hazard severity levels."

The early phase of *TG 316* distinguishes disease severity within individuals into four categories including very severe, severe, moderate and mild.[13] *TG 316* later evolved to combine signs and symptoms to describe the progression of illness in the five "illness" categories shown in Table 3.[14] The signs and symptoms may be outwardly observable and/or measurable, or may only be detectable by laboratory tests. Each maximum illness level describes a spectrum of signs and symptoms that is associated with dose. The

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[11] *NATO Glossary of Medical Terms and Definitions*, *AMedP-13(A)* (Belgium: NATO, May 2011).

[12] NATO, *AMedP-8(C)*, 1–5.

[13] USACHPPM, *Technical Guide 316 Supplement C1*, 36.

[14] USAPHC, *Technical Guide 316 Supplement C6: Data Qualification Report for the Development of Interim Biological Military Exposure Guidelines for Aerosolized Bacillus Anthracis Causing Inhalation Anthrax,* Interim Revision 01 (Aberdeen Proving Ground, MD: USACHPPM, January 2012).

maximum *illness* level links the *hazard* severity level to the BMEG doses that are derived from published dose-response data. All five illness categories may not be relevant to specific biological agents due to the nature of the associated disease. In general, *TG 316* assumes that with increasing dose, the likelihood and severity of the illness increases, the duration of the illness increases, and the incubation period before onset of signs and symptoms decreases.[15]

The hazard severity levels are defined by three separate documents to describe the potential impact a biological agent exposure has on an operation. Each level uses the doctrinal definitions published in *Field Manual (FM) 5-19*, *Composite Risk Management*;[16] the definition guidelines from Joint Staff Memorandum MCM 0028-07 (CJCS 2007);[17] and infectious disease definitions recommended in *TG 316* for use in BMEG development. The hazard severity categories defined in FM 5-19 describe the degree to which an incident will impact combat power, mission capability, or readiness. *TG 316* also includes the definition guidelines from the CJCS Memorandum to provide clarification for force health protection. From the CJCS Memorandum, the biological effects are aligned with the definition guidelines for acute effects to describe the expected extent or intensity of adverse health effects and the effect on the ability to accomplish mission tasks after exposure to a biological agent. Biological effects are generally expected to occur hours to days after exposure and because this time course is not specifically described in the CJCS Memorandum, the biological effects have been aligned with the acute effects (defined as relatively immediate onset—seconds to hours) instead of chronic effects (defined as typically delayed onset—months to years). Note that the infectious disease definitions are under development and are expected to be finalized as part of *TG 316 Supplement A5* (BMEG Framework document).[18]

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[15] USAPHC, *Technical Guide 316 Supplement C6,* 11.

[16] *Composite Risk Management*, *FM 5-19* (Washington, DC: Headquarters, Department of the Army (HQDA), July 2006).

[17] Chairman, Joint Chiefs of Staff (CJCS), "Procedures Deployment Health Surveillance," Joint Staff Memorandum MCM 0028-07 (Washington, DC: CJCS, 2007).

[18] *Technical Guide 316 Supplement A5: BMEG Framework* (Aberdeen Proving Ground, MD: USAPHC, to be published).

Table 3. Severity Scale Terminology Used in *AMedP-8(C)* and *TG 316*[19]

***AMedP-8(C)* Injury Severity Levels**	***TG 316* Illness Categories**	***TG 316* Hazard Severity Levels**
Very severe	**Lethal Illness**	**Catastrophic**
Injury manifesting symptoms (and signs for biological agents) of such severity that life is imminently endangered. Indicators are unfavorable—condition may or may not reverse even with medical intervention; prognosis is death without medical intervention; individual is unable to conduct the assigned mission and is not expected to return to the mission due to severity of injury.	This maximum health effect category encompasses signs and symptoms where host-pathogen interactions lead to lethal illness (death). Signs and symptoms for this maximum health effect category could include: respiratory failure, cardiac failure, tissue necrosis, hemorrhagic complications, multi-organ failure, sepsis, and severe shock. An example is severe pneumonia.	FM 5-19: Complete mission failure or the loss of ability to accomplish a mission. Death or permanent total disability. MCM 0028-07: Casualties with severe incapacitating effects requiring immediate and significant medical attention and/or additional support for survival. Increasing number of fatalities is expected. Exposed personnel unable to perform critical tasks. Infectious Disease Interpretations: Severe to Lethal Illnesses (Inpatient care or Death)
Severe	**Severe Illness**	**Critical**
Injury manifesting symptoms (and signs for biological agents) of such severity that there is cause for immediate concern, but there is no imminent danger to life; individual is acutely ill and likely requires hospital care. Indicators are questionable—condition may or may not reverse without medical intervention; individual is unable to conduct the assigned mission due to severity of injury.	This maximum health effect category results in signs and symptoms that may require in-patient medical intervention and support. Signs and symptoms for this maximum health effect category could include: respiratory distress, pneumonia, severe pain, seizures/convulsions, paralysis, and shock. An example is severe bronchitis.	FM 5-19: Severely degraded mission capability or unit readiness. Permanent partial disability or temporary total disability exceeding three months. MCM 0028-07: Personnel are expected to have incapacitating health effects that require immediate medical treatment or support (e.g., are considered 'casualties'). There may be limited numbers of fatalities. Personnel not experiencing these more serious effects are expected to have at least noticeable but not incapacitating health effects. Exposed personnel will have

[19] NATO, *AMedP-8(C),* 1–5; *TRM*, IDA D-4082, 14; USAPHC, *Technical Guide 316 Supplement D1*, 6–9.

AMedP-8(C) **Injury Severity Levels**	*TG 316* **Illness Categories**	*TG 316* **Hazard Severity Levels**
		limited ability to perform most critical tasks. Note: Ability to accomplish complex tasks likely to be degraded. Infectious Disease Interpretations: Predominantly Moderate to Severe Illness (inpatient care) Limited Lethal Illness (Death)
Moderate	**Moderate Illness**	**Marginal**
Injury manifesting symptoms (and signs for biological agents) of such severity that medical care may be required; general condition permits treatment as outpatient and some continuing care and relief of pain may be required before definitive care is given; condition may be expected to interrupt or preclude ability to conduct the assigned mission.	This maximum health effect category results in signs and symptoms that may require out-patient medical care. Affected individuals may seek professional medical care if signs and symptoms are significant enough. Signs and symptoms for this maximum health effect category could be similar to, but more severe in nature, as to those experienced with mild illness. An example is a typical case of strep throat.	FM 5-19: Degraded mission capability or unit readiness. Lost days due to injury or illness not exceeding 3 months. MCM 0028-07: Many exposed persons are expected to have noticeable but not incapacitating health effects. Observable effects require minimal, if any, medical attention but may reduce some individual physical capabilities and/or may enhance stress-related casualties. Exposed personnel able to perform most critical tasks. Note: Ability to accomplish complex tasks may be degraded. Infectious Disease Interpretations: Mild to Moderate Illnesses (Outpatient care)
Mild	**Mild Illness**	**Negligible**
Injury manifesting symptoms (and signs for biological agents) of such severity that individuals can care for themselves or be helped by untrained personnel; condition may not impact ability to conduct the assigned mission.	This maximum health effect category encompasses signs and symptoms where host-pathogen interactions lead to observable illness. Signs and symptoms are mild; individuals are capable of providing self-treatment. Signs and symptoms for this maximum health effect category could include: fatigue, malaise, headache, fever, mild muscle/joint pain,	FM 5-19: Little or no adverse impact on mission capability. First aid or minor medical treatment. MCM 0028-07: Few exposed personnel (if any) are expected to have noticeable health effects during mission. Exposed personnel are expected to be able to effectively perform all critical tasks during mission operations. Minimal to no

AMedP-8(C) Injury Severity Levels	*TG 316* Illness Categories	*TG 316* Hazard Severity Levels
	diarrhea, and congestion/cough. An example is a typical case of the common cold.	degradation of abilities to conduct complex tasks are expected. Infectious Disease Interpretations: Mild Illnesses (Self-treatment)
No Observable Effects (NOE)	**No Illness**	**None**
Although exposure to an agent or effect may have occurred, no observable injury (as would be indicated by manifested symptoms) has developed.	Interaction between host and pathogen may be detectable only by serological/hematological biomarkers. This maximum health effect category encompasses host-pathogen interactions characterized by no outwardly noticeable signs and symptoms. Biomarkers (e.g., cytokine or chemokine changes) may be detected, indicating that an individual has been exposed to an agent and the host responded to and successfully cleared the pathogen prior to development of outwardly noticeable disease.	FM 5-19*:* – MCM 0028-07*:* No effects are anticipated. Infectious Disease Interpretations: No Illness.

Note: The definitions in this table are extracted verbatim from *AMedP-8 (C)* and *TG 316*.

The highest level in the severity scales is "Very Severe" in *AMedP-8(C)* and "Lethal Illness" and "Catastrophic" in *TG 316*. Both documents identify this level as the most severe level that will lead to death or permanent total disability. *AMedP-8(C)* states that with an injury or disease at this severity level, an "individual is unable to conduct the assigned mission and is not expected to return to the mission due to severity of injury."[20] *TG 316* states that this hazard severity level would result in "Complete mission failure or the loss of ability to accomplish a mission"[21] (in accordance with *FM 5-19*) or "Exposed personnel unable to perform critical tasks"[22] (in accordance with MCM 0028-07).

[20] NATO, *AMedP-8(C),* 1–5.

[21] USAPHC, *Technical Guide 316 Supplement D1*, 6.

[22] Ibid.

The second level is titled "Severe" in *AMedP-8(C)* and "Severe Illness" for the illness category and "Critical" for the hazard severity level in *TG 316*. According to *AMedP-8(C)*, injuries at this severity level are a "cause for immediate concern, but there is no imminent danger to life; individual is acutely ill and likely requires hospital care…unable to conduct the assigned mission due to severity of injury."[23] *TG 316* agrees with *AMedP-8(C)* but adds a timeframe to the hazard level, "permanent partial disability or temporary total disability exceeding three months and degraded mission capability and ability to accomplish complex tasks."[24]

The next level in *AMedP-8(C)* is "Moderate" and in *TG 316* is "Moderate Illness" and "Marginal" hazard severity level. At this level, the exposed individual requires outpatient medical care and the capability to accomplish a mission is interrupted and degraded. *TG 316* places a time limit of no more than three months of lost days due to the illness.

The fourth level described in both documents is also in agreement. The term "Mild" is used in *AMedP-8(C)* and the terms "Mild Illness" and "Negligible" are used in *TG 316*. At this level, the injury/illness will result in individuals capable of self-treatment or who can be helped by untrained personnel. The injury will have little or no impact on mission capabilities with minimal or no degradation of abilities to conduct complex tasks.

The final level is termed "No Observable Effects (NOE)" in *AMedP-8(C)* and "No Illness" and "None" in *TG 316*. At this level, an individual may have been exposed to the pathogen, but no observable signs and symptoms are present. Therefore, the mission capabilities are not affected.

[23] Ibid.

[24] Ibid.

3. Methodology

This chapter presents the concepts and functions of the methodologies from *Technical Guide 316* and *AMedP-8 (C).*

A. *U.S. Army Public Health Command (USAPHC) Technical Guide 316 (TG 316)*

The BMEG development process is divided into three phases.[25] Phase I is the "initial analysis and development of "stop-gap" preliminary BMEGs."[26] For the first phase, the literature review and analyses utilize publicly available sources of data, particularly published dose response data that correlates dose with an observed response or health effects. Literature that does not include dose-response data, while not appropriate for the actual BMEG derivation, is used to provide background information useful for understanding the disease. Phase II is a comprehensive analysis and development of interim BMEGs that includes, but is not limited to, more thorough literature review to include government source data, formal data qualification, more comprehensive dose-response modeling, application of physiologic extrapolation modeling, and consideration of deposition and reaerosolization. The final phase, Phase III, includes a review and revision of the interim BMEGs, "using an analytical-deliberative process across the Joint community, into Draft-Final and Final BMEGs."[27] Currently, Phase I preliminary BMEGs are completed for anthrax, plague, tularemia, ricin, and Staphylococcal Enterotoxin B (SEB). The Phase II process has been started with most of these agents with anthrax being the furthest along.

BMEGs are doses or associated air concentrations of a biological agent that estimates the level above which adverse health effects might occur to impact military operations.[28] They are decision aids to assess health risks to deployed forces and civilians from biological agent exposures. Analysis of available dose-response data provides doses as BMEG values that are back-calculated to airborne exposure concentrations to express

[25] USAPHC, *Technical Guide 316 Supplement E1*, 3–4.

[26] USAPHC, *Technical Guide 316 Supplement D1,* 2.

[27] Ibid.

[28] USAPHC, *Technical Guide 316 Supplement C6,* Glossary-5.

how much of a pathogen is present in the air over a short period of time. The exposure guideline air concentrations are utilized to compare values gathered from detectors that measure air concentration. The air concentrations provide a starting point for the test and evaluation process.

A summary of the derivation of the BMEG values is illustrated in Table 4. The hazard severity levels are aligned with the maximum illness categories that are associated with a notional target dose for each level. The process of translating dose-response data into BMEG values is still under development but the currently available *TG 316* supplements provide the developing concepts. The available dose-response data provide threshold dose values that are linked to a combination of signs and symptoms to define a disease and provide insight into the severity of the illness. The expected maximum illness associated with a given dose establishes the exposure guidelines (BMEGs). Furthermore, the maximum illness categories (from lethal illness to no illness in Table 3) is aligned with the military hazard severity levels (from catastrophic to negligible in Table 3) to predict the potential impact and level of risk a biological agent will have on an operation.

The notional target dose and notional BMEG values shown in Table 4 are all theoretical and are subject to change based on the biological agent. The specific data for each pathogen will allow selection of specific target doses for a particular BMEG. Additionally, the nature of the biological agent will dictate whether all five illness categories may be relevant and thus impact the BMEG values generated.

Table 4. Alignment of Hazard Severity, Illness Categories, and Notional Effective Dose to Derive BMEG Values[29]

Hazard Severity	Associated Maximum Illness Categories (Predominant Population Effects)	Selection of the Boundary to Enter the Severity Category		
		Illness Category	Notional Target Doses	Notional BMEG Preferences
CATASTROPHIC	Severe to Lethal Illness (Inpatient care or death)	Lethal Illness	ED_{16} (death) = LD_{16}	LD_{16}
		Severe Illness	ED_{50} (severe)	
CRITICAL	Moderate to Severe Illness (Limited fatalities can occur; Inpatient care)	Lethal Illness	ED_1 (death) = LD_1	ED_{16} (severe)
		Severe Illness	ED_{16} (severe)	
		Moderate Illness	ED_{50} (moderate)	
MARGINAL	Mild to Moderate Illness (Outpatient care)	Severe Illness	ED_1 (severe)	ED_{16} (mild)
		Moderate Illness	$ED_{16\text{-}50}$ (moderate)	
		Mild Illness	ED_{16} (mild)	
NEGLIGIBLE	Mild Illness (Self-treatment)	Mild Illness	ED_1 (mild)	ED_1 (mild)
		No Illness	ED_{50} (biomarker)	
			ED_{100} (survival)	

The BMEGs are designed specifically for use within the composite risk management framework (*FM 5-19*[30]) supporting the commander's decision making process by providing a method to assess health risk within the standardized risk assessment matrix shown in Figure 1. The risk estimate is determined by both the hazard severity—the degree to which mission capability is lost—and probability—the likelihood of exposure to the hazard. Risk, severity, and probability are all portrayed on a scale, with

[29] USAPHC, *Technical Guide 316 Supplement C6*, 13.

[30] U.S. Army, *FM 5-19*, 1–8.

various degrees of risk associated with specific combinations of severity and probability. The derived BMEGs are only linked to the hazard severity levels and not the probability axis in the military risk assessment matrix.

Risk Assessment Matrix						
Severity		**Probability**				
		Frequent A	**Likely B**	**Occasional C**	**Seldom D**	**Unlikely E**
Catastrophic	I	E	E	H	H	M
Critical	II	E	H	H	M	L
Marginal	III	H	M	M	L	L
Negligible	IV	M	L	L	L	L
E - Extremely High H - High M - Moderate L - Low						

Figure 1. *FM 5-19* Risk Assessment Matrix[31]

B. *Allied Medical Publication 8(C) (AMedP-8(C))*

AMedP-8(C) describes a methodology developed for calculating the expected numbers of casualties that occur over time following a CBRN attack against deployed military forces. The methodology also provides the capability to describe the physical effects of CBRN exposure in terms of the severity of the resulting injury over time. For biological agents and toxins, the methodology assumes that exposure occurs via inhalation of aerosolized agent and all inhaled agent is retained. Casualties occur when the injury severity reaches a user-defined level of severity. The period during which an individual is ill is subdivided into one or more stages with associated signs and symptoms that are correlated to an injury severity level that ranges from no observable effect (NOE) to very severe as described in Table 3. Each category within the injury severity scale provides a description on the medical requirements and operational capabilities of an individual after exposure to a CBRN agent or effect.

[31] USAPHC, *Technical Guide 316 Supplement C6*, 8.

The methodology considers both non-contagious and contagious biological agents. The human response approaches for both types of biological agents are derived from an underlying set of five submodels characterizing various aspects of the disease and describing the disease progression in dose-dependent probability or time-based submodels—infectivity, lethality, incubation/latent period, injury profile, and duration of illness. Most submodels for the biological diseases are represented stochastically by a probability distribution modeled as a lognormal function or estimated as a threshold response.

An infectivity submodel estimates the number of individuals who will become ill, given their dose of biological agent. An incubation or latency period submodel estimates when those individuals develop signs and symptoms. A lethality submodel estimates the number of ill individuals who will die. A duration of illness submodel estimates the length of time between onset of symptoms and recovery or death. Lastly, an injury profile submodel describes clinically differentiable stages of disease and the severity (the injury severity scale from "very severe" to "no observable effects" shown in Table 3) of the associated signs and symptoms over time.

For non-contagious agents, *AMedP-8(C)* uses a convolution approach to combine the stochastic submodels and derive the mathematical representations of the time-course of illness. For contagious agents, *AMedP-8(C)* uses a common Susceptible-Exposed/infected-Infectious-Removed (SEIR) approach to modeling contagious disease, with modification to account for the efficacy of prophylaxis and time-varying disease transmission.[32]

Once the user selects the injury severity casualty criterion, the non-contagious biological human response output or the contagious human response estimation output can be used to determine the number of casualties that are WIA or DOW. Biological agents are assumed to produce no KIAs because of the length of associated incubation/latency periods.[33]

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[32] *TRM*, IDA D-4082, 182.

[33] NATO, *AMedP-8(C),* 4–11.

4. Discussion

The first and foremost fundamental difference between *AMedP-8(C)* and *TG 316* is the purpose of each methodology. The *AMedP-8(C)* methodology is designed to estimate expected number of casualties resulting from an anticipated CBRN attack against a military population at risk. The estimates of expected casualties can then be used as inputs to operational planning, including operational risk assessment. In contrast, BMEGs are not designed to generate casualty estimates but rather intended to determine the qualitative level of risk posed to the military or general population when exposed to a biological agent. The qualitative risk rank adopts the terms that are derived from the military risk management model.

While the purpose of the methodologies is different, both documents are ultimately used to aid medical and operational planning. The casualty estimates provided by *AMedP-8(C)* assist medical planners, logisticians, operational, and personnel planners in the quantification of requirements for medical personnel, medical material stockpiles, patient transport, and physical protection or evacuation capabilities. The casualty estimates also allows for quantification of facilities needed for patient decontamination, triage, treatment, and supportive care. The methodology described in *AMedP-8(C)* is "proposed solely for deliberative or crisis planning purposes and does not account real-time or dynamic use. The [This] methodology is not intended for use in deployment health surveillance or for any post-event uses including diagnosis, medical treatment, or epidemiology."[34] Similarly, BMEGs derived in *TG 316* are used in risk assessments to rank and compare health-based risks, to inform medical surveillance follow-up activities, and to inform development of protective measures, techniques, or actions. "TG 316 is not intended to be used during an event" but "is designed to be used as a preplanning or post-event tool for bioaerosol [occupational, environmental or intentional] releases."[35]

Although, the Microbial Risk Assessment Methodology in *TG 316* is based on existing chemical risk assessment methodology in *TG 230*, the *TG 316* methodology has evolved to incorporate differences that are necessary to develop MEGs for biological agents. The concept of exposure duration for acute and chronic exposures is deeply

[34] NATO, *AMedP-8(C),* 1–2.

[35] USACHPPM, *Technical Guide 316*, 1.

embedded in the chemical methodology as described in *TG 230*. The phenomena of toxic load and the physiological mechanisms of toxin clearance, if not adequately understood, can at least be modeled with some basis in experimental data. The process of immune response and clearance of microorganisms is much more difficult to capture analytically and associate with specific exposure durations. Therefore, the BMEG derivation considers only acute exposures with short time frame (minutes to hours) and also assumes that exposure dose is cumulative and variations in agent air concentration are expected even over short exposure time.

AMedP-8(C), also, assumes the likelihood of illness is strictly a function of the magnitude of exposure, and does not account for exposure duration and hence does not consider biological clearance and immune response. The primary reason for this is that *AMedP-8(C)* is designed to consider battlefield exposures that are expected to be quite short—on the order of several minutes to, perhaps, a few hours in duration—so that the mitigating effects of cumulative dosing over time would be expected to be minimal.

BMEGs are derived from dose-response data that correlates specific doses to a spectrum of signs and symptoms. The combination of signs and symptoms provides insight into the severity of the illness as described by the maximum illness levels and these levels are linked to the standard military hazard severity categories to establish the level of health hazard and risk. *TG 316* assumes hazard severity can be modeled as a function of dose. In contrast to *TG 316*, *AMedP-8(C)* associates the injury severity levels directly to the clinically differentiable stages of the disease with related signs and symptoms over time as described in the injury profile submodel and does not model injury severity as a function of dose. Instead, *AMedP-8(C)* uses the dose-response data to estimate the probability of infection or death after exposure to a biological agent.

AMedP-8(C) characterizes the dose-response relationship in its entirety as probability distributions for illness and death. The probabilities of illness or death are typically represented as the median dose values (ID_{50}, ED_{50} and LD_{50}) and an associated variance about the median. In *TG 316*, the derived BMEGs are associated with different ED_{xx} or LD_{xx} values that correlate to various points on their severity scales. *TG 316* considers only selected points of the response function and associates specific symptoms at a nonspecific time point to the derived BMEG values. The derived BMEGs are intended to represent a threshold response level, or the safe-sided estimate of the level above which a small percentage of individuals will suffer the associated effects.

One way to consider the impact of the difference between the BMEG values and those in *AMedP-8(C)* is to note the differences in outcome when the former are assessed within the framework of the latter. Analysis and comparison of the derived BMEG values

to those in *AMedP-8(C)* for SEB demonstrate their discrepancies. The derived SEB "Catastrophic" BMEG value is 1.21 nanogram (ng)/kilogram (kg) and corresponds to 10% mortality (LD_{10}).[36] This is equivalent to a human dose of 0.085 micrograms (μg). The *AMedP-8(C)* methodology uses a different dose response model, and from that a human dose of 0.085 μg would cause 90% of the population to become ill (ED_{90}) and 0.01% of the population to die ($LD_{.01}$), which is a 1000 fold difference in mortality rates between the two methodologies.[37] A comparison between the two methodologies at the "Negligible" level provides closer estimates. The BMEG SEB "Negligible" hazard severity level is 0.09 ng/kg, or a human dose of 6.3 ng, corresponding to an ED_{10}. At the same human dose of 6.3 ng, the *AMedP-8(C)* methodology would estimate 5% (ED_5) of the population would become ill, only a two-fold difference between the two methodologies.

Perhaps the highest impact on the implementation of each methodology is using the casualty estimation methodology in *AMedP-8(C)* and the BMEGs in *TG 316* to predict the operational risk of a mission. The *TG 316* approach would consider risk to a mission extremely high in cases where a large percentage of the population is exposed to doses that would be considered "Catastrophic" or "Critical." In comparison, *AMedP-8(C)* estimates the number of casualties that is expected from exposures to those concentrations of a biological agent for specified times (dependent on the operational scenario), and requires the commander to estimate the resultant risk to the mission. Depending upon the urgency and priority of the mission, the end result or advice to the commander from using the two approaches might differ widely, or be surprisingly similar despite their inherent differences.

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[36] USAPHC, *Technical Guide 316 Supplement G1*, 41.

[37] Human response parameters for SEB are currently being added to the *AMedP-8(C)* document although the parameters have already been analyzed, derived, and published in an IDA document: C. A. Curling, J. K. Burr, M. C. Hebner, L. A. LaViolet, P. J. Lee, K. A. Bishop, *Parameters for Estimation of Casualties from Exposure to Specified Biological Agents: Brucellosis, Glanders, Q Fever, SEB and Tularemia*, IDA Document D-4132 (Alexandria, VA: Institute for Defense Analyses, November 2010).

5. Conclusions

In conclusion, *AMedP-8(C)* and *TG 316* describe methodologies for acute exposures to aerosolized biological agents and toxins that are different in concept and function. *AMedP-8(C)* offers a method to estimate casualties by utilizing one set of severity definitions (Table 3) to describe both medical requirements and operational capabilities to aid medical, logistical, operation, and personnel planning. *TG 316*, on the other hand, correlates the derived BMEG values to the hazard severity scale and the illness categories (Table 3) to outline operational and medical impacts and determine the health hazards and risks after exposure to biological agents or toxins.

Many of the terms used to describe biological warfare and severity levels have overlapping definitions in each document despite a few terms that are defined differently. Although the title of each level in the severity scales from both documents may not always be the same (i.e., the highest level is "Very Severe" in *AMedP-8(C)* and "Lethal Illness and Catastrophic" in *TG 316*), the definitions are similar for each level. The few biological terms that are different (i.e., effective dose and infected/infection) do not have significant impact on the implementation of each methodology.

Both documents use dose-response data in their respective methodologies. In *AMedP-8(C)*, the data is used directly to derive the infectivity and lethality submodels as part of the human response parameters. *TG 316* derives BMEG values using the dose-response data and takes the relationship between dose and illness and correlates it to the hazard severity. Hence, the hazard severity scale is a dose-dependent function. In contrast, the injury severity scale in *AMedP-8(C)* is modeled by the injury profile submodel with clinically differentiable stages.

In summary, *AMedP-8(C)* and *TG 316* use similar dose-response data reported in literature to develop two distinct methodologies with different, but overlapping, purposes. Although the purpose of the methodologies is different, both documents can be used to aid medical and operational planning. The individual methodologies may result in comparable or very dissimilar interpretations of operational hazards and these differences (or similarities) will ultimately affect medical and operational planning.

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Appendix C
Abbreviations

AMedP-8(C)	*Allied Medical Publication 8(C): NATO Planning Guide for the Estimation of CBRN Casualties*
BMEG	Biological Military Exposure Guidelines
CBRN	Chemical, Biological, Radiological, or Nuclear
CJCS	Chairman, Joint Chiefs of Staff
COA	Course of Action
DOD	Department of Defense
DOW	Died of Wounds
ED_{xx}	XX% Effective Dose
FDA	Food and Drug Administration
FM	Field Manual
IDA	Institute for Defense Analyses
ID_{50}	Median Infective Dose
ID_{xx}	XX% Infective Dose
kg	kilogram
KIA	Killed in Action
LD_{50}	Median Lethal Dose
LD_{xx}	XX% Lethal Dose
MEG	Military Exposure Guidelines
NATO	North Atlantic Treaty Organization
ng	nanogram
NOE	No Observable Effect
OTSG	U.S. Army Office of the Surgeon General
POD	Point of Departure
SEB	Staphylococcal Enterotoxin B
SEIR	Susceptible-Exposed/infected-Infectious-Removed
STANAG	Standardization Agreement
TG	Technical Guide
μg	microgram
USACHPPM	U.S. Army Center for Health Promotion and Prevention Medicine
USPHC	U.S. Army Public Health Command
WIA	Wounded in Action

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14. ABSTRACT

The implementation *of Allied Medical Publication 8(C): NATO Planning Guide for the Estimation of CBRN Casualties (AMedP-8(C))* within the United States requires coordination and alignment with related guidance and doctrine within the Department of Defense (DOD). The Institute for Defense Analyses (IDA) was asked by the U.S. Army Office of the Surgeon General (OTSG) to compare the terminology used in *AMedP-8(C)* and *Technical Guide 316: Microbial Risk Assessment for Aerosolized Microorganisms (TG 316)* for consistency. *AMedP-8(C)* is a North Atlantic Treaty Organization (NATO) standardization agreement (STANAG) that provides a methodology for estimating medical casualties at varying severity levels as a result of a chemical, biological, radiological, and nuclear (CBRN) attack. Both methodologies can support medical and operational planning. The casualty estimates obtained through implementation of the *AMedP-8(C)* methodology can be used by several communities to aid in their planning efforts. The Biological Military Exposure Guidelines (BMEG) derived in *TG 316* can be used by military health risk assessors, medical planners, operational planners, and defense system developers to characterize the health hazards and operational risks associated with exposure to bioaerosols. Although both methodologies ultimately aid in medical and operational planning, the two approaches may, in certain cases, result in different outcomes.

15. SUBJECT TERMS

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