



DoD DIRECTIVE 5160.05E

ROLES AND RESPONSIBILITIES ASSOCIATED WITH THE CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM

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Cancels:	Under Secretary of Defense for Acquisition, Technology, and Logistics Memorandum, "Implementation Plan for the Management of the Chemical Biological Defense Program," April 22, 2003, as amended
Approved by:	Kathleen H. Hicks, Deputy Secretary of Defense

Purpose: This issuance:

- Establishes policy and assigns responsibilities for the Chemical and Biological Defense Program's (CBDP's) research, development, and acquisition (RDA) of chemical and biological (CB) defense capabilities (medical and physical) required to support DoD operations in CB-impacted environments pursuant to Section 1522 of Title 50, United States Code (U.S.C.).
- Designates the Secretary of the Army as the DoD Executive Agent (EA) for the CBDP pursuant to Section 1522(c)(1) of Title 50, U.S.C., and in accordance with DoD Directive (DoDD) 5101.01.

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff (CJCS) and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”).

1.2. POLICY.

The DoD will:

a. Carry out a coordinated CBDP that:

(1) Is under the oversight of the Defense Acquisition Executive who will leverage and chair a special interest review process for the CBDP.

(2) Maintains close and continuous coordination between CB physical defense programs and CB medical defense programs.

(3) Develops and acquires integrated and interoperable CB defense capabilities, informed by risk management processes and current and future threats, that assure DoD executes its missions in CB-impacted environments.

(4) Integrates operations security requirements into CB defense plans, programs, and activities to protect critical information and indicators that could allow adversaries and potential adversaries to plan, prepare, and conduct chemical or biological operations against the United States.

(5) Is composed of a portfolio of individual efforts that are managed as separate programs, with acquisition category designations, as appropriate, based upon the anticipated expenditures of each program or level of senior interest.

b. Submit the DoD CBDP funding requests in the budget of the DoD for each fiscal year as a separate account with a single program element for each category of research, development, test, and evaluation (RDT&E); procurement; and military construction in accordance with Section 1522(d)(2) of Title 50, U.S.C.

c. Carry out the CBDP in accordance with applicable international obligations of the United States, including the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, and the Convention on the Prohibition of the Development, Production, Stockpiling, and use of Chemical Weapons and on their Destruction; and with associated implementation requirements in Parts 710-721 and Part 742.2 of Title 15, Code of Federal Regulations; Parts 120-130 of Title 22, Code of Federal Regulations; and DoD Instruction 2040.02. Address issues related to questions of compliance with these treaties in accordance with DoDD 2060.01.

SECTION 2: RESPONSIBILITIES

2.1. UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND SUSTAINMENT (USD(A&S)).

The USD(A&S):

a. Oversees:

(1) DoD CBDP RDA programs to ensure they support the National Defense Strategy, the National Biodefense Strategy, the DoD Strategy for Countering Weapons of Mass Destruction (CWMD), and other national and departmental guidance, as applicable, and enable the DoD to anticipate and address current and future CB threats through delivery of CB defense capabilities to the Military Departments.

(2) The DoD EA activities for the CBDP pursuant to DoDD 5101.01.

(3) Resourcing, in coordination with the Under Secretary of Defense (Comptroller)/Chief Financial Officer, Department of Defense, to enable the CBDP to execute the RDA requirements for developing and fielding priority DoD CB defense capabilities that address readiness and modernization of the Military Services to counter CB threats.

(4) The prioritization of mission-focused, risk-informed RDA of CB defense capabilities through a governance framework.

b. Reviews and approves all CBDP program objective memorandum (POM) recommendations.

c. Coordinates intelligence and counterintelligence support for the RDA of CB defense programs and activities with the Under Secretary of Defense for Intelligence and Security in accordance with DoDD 5143.01.

d. In coordination with the Under Secretary of Defense for Research and Engineering (USD(R&E)) and in accordance with DoDD 5137.02, formulates CB defense mission engineering policy, guidance, practices, and tools for analysis (including modeling and simulation) of operational warfighting concepts, functions, systems, and technologies in an end-to-end mission context.

2.2. ASSISTANT SECRETARY OF DEFENSE FOR NUCLEAR, CHEMICAL, AND BIOLOGICAL DEFENSE PROGRAMS (ASD(NCB)).

Under the authority, direction, and control of the USD(A&S), the ASD(NCB):

a. Is the principal advisor to the Secretary of Defense, Deputy Secretary of Defense, and USD(A&S) on CB defense, including matters related to the RDA of medical and physical materiel and DoD compliance with existing and prospective CB arms control treaties and

agreements pursuant to Section 138(b)(4) of Title 10, U.S.C.; DoDD 2060.01; DoDD 5000.01; and DoDD 5134.08.

b. Oversees and integrates RDA of CB defense capabilities to:

(1) Support the objectives of national and departmental strategies to reduce incentives for adversaries and actors of concern and their networks from pursuing, possessing, and employing CB weapons; increase barriers to the acquisition, proliferation, and use of CB warfare agents; manage risks, including terrorism risks; and deny the effects of current and future CB threats through integrated, layered defenses.

(2) Enable joint force resilience while anticipating and addressing current and future CB threats to achieve DoD-wide integrated and layered CB defense.

c. Is responsible for the overall coordination, oversight, and integration of the CBDP and may delegate this responsibility to a subordinate official within their authority, direction, and control.

d. Oversees the DoD EA for the CBDP, on behalf of the USD(A&S), pursuant to DoDD 5101.01 and DoDD 5134.08.

e. Coordinates and integrates activities with the DoD EA for the CBDP, the CJCS, the USD(R&E), the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), the Assistant Secretary of Defense for Space Policy, and the Secretaries of the Military Departments to direct CB defense RDA to address current and future CB threats in accordance with the National Defense Strategy, National Biodefense Strategy, and other national and departmental guidance as applicable.

f. Develops and provides risk-informed strategic guidance, priorities, goals, and objectives for CBDP RDA activities that:

(1) Align CB defense investments with national and departmental guidance.

(2) Balance acquisition investments to mitigate risks to the joint force and DoD missions and integrate with the planning, programming, budgeting, and execution process.

(3) Promote balanced doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy solutions for CB defense capability requirements across the joint force and Military Services.

(4) Deliver relevant CB defense capabilities that enable the joint force to fulfill critical DoD strategic missions.

g. Develops and makes milestone decision authority recommendations to the Defense Acquisition Executive for CBDP program(s) of record, as required.

h. Leads, endorses, and submits the CBDP POM recommendation to the USD(A&S) as required.

i. Designates CBDP defense-wide account funds management responsibilities to an appropriate office or agency pursuant to DoD 7000.14-R.

j. In coordination with the DoD Component heads, integrates risk-management and mission assurance-related processes, outputs, and concepts to inform CB defense capability RDA.

k. In coordination with the Assistant Secretary of Defense for Health Affairs (ASD(HA)) and the CJCS, and in accordance with DoDD 6420.02:

(1) Coordinates and collaborates on DoD biosurveillance-related CB defense activities and the RDA of CB defense capabilities to enhance and sustain the health protection and readiness of the force.

(2) Shares relevant information on environment, safety, and occupational health program activities that supports integrating that information with other biosurveillance-related information.

l. In coordination with the ASD(HA); the Director, Test Resource Management Center; the Director, Defense Advanced Research Projects Agency (DARPA); the Secretaries of the Military Departments; and the DoD EA for the CBDP, integrates and oversees DoD infrastructure required to perform CBDP-related RDT&E.

2.3. USD(R&E).

In coordination with the USD(A&S), the USD(R&E):

a. Establishes policy for laboratories critical to RDA of CB defense capabilities, including infrastructure.

b. Reviews and assesses science and technology related to CB defense capabilities.

c. Oversees, develops, and implements policy and guidance for conducting (including planning, execution, and reporting) developmental test and evaluation related to the DoD CBDP.

d. Develops CB defense mission engineering policy, guidance, practices, and tools for analyzing (including modeling and simulation) operational warfighting concepts, functions, systems, and technologies in an end-to-end mission context.

2.4. DIRECTOR, TEST RESOURCE MANAGEMENT CENTER.

Under the authority, direction, and control of the USD(R&E), and in accordance with DoDD 5105.71, the Director, Test Resource Management Center, coordinates with the ASD(NCB) and the Secretaries of the Military Departments on the infrastructure and personnel required to accomplish the test-and-evaluation mission as it relates to the RDA of CB defense capabilities.

2.5. DARPA.

Under the authority, direction, and control of the USD(R&E) and in accordance with Sections 1522(c)(2) and (d)(3) of Title 50, U.S.C., the Director, DARPA, may conduct a program of basic and applied research and advanced technology development of CB defense technologies and systems. If such a program is conducted, the Director, DARPA:

- a. Coordinates with the ASD(NCB) and the Military Departments to avoid unnecessary duplication of the CB defense RDA activities.
- b. Establishes a separate program element in the DARPA budget for these efforts.

2.6. UNDER SECRETARY OF DEFENSE FOR POLICY.

The Under Secretary of Defense for Policy:

- a. Establishes, coordinates, and oversees the implementation and integration of DoD CWMD and CB defense policy in accordance with the DoD Strategy for CWMD, DoD policy for preparedness and response to domestic CB incidents, and any national or departmental guidance related to CB defense preparedness and response.
- b. Coordinates with the ASD(NCB), or their designee, on CB defense planning and programming priorities for the RDA and use of CB defense capabilities.

2.7. USD(P&R).

The USD(P&R):

- a. In accordance with DoDD 5124.02, establishes policies, plans, and programs for health and medical affairs, including providing and maintaining readiness.
- b. Pursuant to DoDD 6420.02, serves as the office of primary responsibility for the DoD Biosurveillance Program activities and coordinates with the USD(A&S) on developing capabilities to execute the DoD Biosurveillance Program.

2.8. ASD(HA).

Under the authority, direction, and control of the USD(P&R) and in accordance with DoDD 5136.01, the ASD(HA):

- a. Serves as the principal advisor to the Secretary of Defense, the Deputy Secretary of Defense, and the USD(P&R) for:
 - (1) Health care and health surveillance aspects of CB medical defense programs.
 - (2) Deployment matters as they pertain to force health protection and readiness.

- b. Coordinates with the ASD(NCB) and the Secretaries of the Military Departments on:
 - (1) CB defense medical materiel RDA activities and developing CB medical defense policy for using preventative and therapeutic countermeasures for DoD personnel.
 - (2) Medical laboratory infrastructure, personnel, and facility utilization related to CB defense RDT&E.
 - (3) Medical readiness of joint forces to respond to CB threats regardless of threat origin.
 - (4) Preparing and submitting the DoD Unified Medical Program Budget to the Under Secretary of Defense (Comptroller)/Chief Financial Officer, Department of Defense, for CB defense-related activities, including the operational sustainment of biological defense vaccines and other CB medical materiel, in coordination with the Secretaries of the Military Departments and the Director, Defense Health Agency.
 - (5) Biosurveillance-related activities for CB defense in accordance with this issuance and overall situational awareness of health threats to the joint force in accordance with DoDD 6420.02.

2.9. UNDER SECRETARY OF DEFENSE FOR INTELLIGENCE AND SECURITY.

The Under Secretary of Defense for Intelligence and Security:

- a. Through the Director, Defense Intelligence Agency, and in accordance with DoDD 5143.01 and DoD Instruction 5000.02, provides all required intelligence support for validating and prioritizing CB threats to DoD personnel, systems, equipment, and facilities.
- b. Advises and assists the USD(A&S), and the heads of other Federal departments and agencies as appropriate, concerning CB defense acquisition programs that significantly affect defense intelligence, counterintelligence, and security programs or organizations pursuant to DoDD 5143.01.
- c. In coordination with the USD(A&S) and in accordance with DoDD 5143.01, identifies opportunities to use advances in technology to enhance CB-related intelligence, counterintelligence, and security capabilities of the DoD.
- d. Oversees RDT&E of national intelligence program-funded CWMD programs in coordination with the Director of National Intelligence, the USD(A&S), the USD(R&E), and other OSD Components, as appropriate.

2.10. DIRECTOR OF OPERATIONAL TEST AND EVALUATION (DOT&E).

The DOT&E:

- a. Serves as principal adviser to the Secretary of Defense , the Deputy Secretary of Defense, the USD(A&S), and the USD(R&E) on operational test and evaluation in the DoD and the principal operational test and evaluation official within the senior management of the DoD pursuant to Section 139 of Title 10, U.S.C., and in accordance with DoDD 5141.02.
- b. Prescribes policies, guidance and procedures for operational test and evaluation, including for CBDP acquisition programs designated for DOT&E oversight, and approves operational test and evaluation plans for programs under DOT&E oversight.
- c. Reviews and make recommendations on all budgetary and financial matters relating to operational test and evaluation, including operational test facilities and equipment supporting the CBDP.

2.11. ASSISTANT SECRETARY OF DEFENSE FOR SPECIAL OPERATIONS AND LOW-INTENSITY CONFLICT.

The Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict, in accordance with DoDD 5111.10 and pursuant to Sections 138(b)(2) and 167 of Title 10, U.S.C.:

- a. Serves as a Principal Staff Assistant to the Secretary of Defense in exercising authority, direction, and control of all special operations-peculiar administrative matters relating to the organization, training, and equipping of special operations forces.
- b. Ensures budgets account for operating and sustaining special operations forces-peculiar CB defense equipment and materiel.
- c. Provides special operations forces-peculiar CB defense-specific POM recommendations and submits for consideration to the ASD(NCB).
- d. Supports the CBDP and the DoD EA for the CBDP to conduct joint development, acquisition, and sustainment.

2.12. SECRETARIES OF THE MILITARY DEPARTMENTS.

The Secretaries of the Military Departments:

- a. Organize, train, equip, and otherwise prepare their respective active and reserve component forces to operate successfully in CB environments.
- b. Develop and integrate CB defense into risk-informed concepts and capability requirement documents for joint and Military Service-specific missions.
- c. Budget for operating and sustaining CB defense equipment and materiel.

- d. Develop and provide to the ASD(NCB) CB defense-specific POM recommendations.
- e. Support the CBDP and the DoD EA for the CBDP to conduct joint development, acquisition, and sustainment.
- f. Manage and sustain infrastructure required to perform CBDP-related RDT&E.

2.13. SECRETARY OF THE ARMY.

In addition to the responsibilities in Paragraph 2.12., the Secretary of the Army, pursuant to Sections 1522(c)(1) and (d)(4) of Title 50, U.S.C., and in accordance with DoDD 5101.01, in their capacity as the DoD EA for the CBDP:

- a. Coordinates and integrates RDT&E and acquisition requirements of the Military Departments for the CBDP.
- b. Reviews all funding requirements for the CBDP.

2.14. CJCS.

The CJCS:

- a. Pursuant to Sections 163 and 181 of Title 10, U.S.C., advises the Secretary of Defense by identifying, assessing, approving, and prioritizing joint force CB defense gaps to meet the National Defense Strategy.
- b. Advises the Secretary of Defense on CB defense risk management to support the responsibilities in Sections 153 and 163 of Title 10, U.S.C.
- c. In coordination with the other DoD Component heads, and pursuant to DoDD 5105.77 for National Guard forces, validates and prioritizes critical deficiencies and strengths in joint force capabilities related to CB defense and CB-related threats against DoD personnel, equipment, and weapon systems.
- d. Integrates CB defense requirements through the Joint Capabilities and Integration Development System to support the CBDP planning, programming, budgeting, and execution process and the Defense Acquisition System.
- e. Ensures alignment with CB defense-related biosurveillance activities to support enhanced coordination between DoD global public health reporting and biodefense in accordance with DoDD 6420.02.

2.15. CHIEF, NATIONAL GUARD BUREAU.

In accordance with DoDD 5105.77 and pursuant to Section 10502 of Title 10, U.S.C., the Chief, National Guard Bureau:

- a. Serves as a principal advisor to the Secretary of Defense, through the CJCS, on CB defense matters, including CB defense capability requirements, involving non-federalized National Guard forces to support homeland defense and civil support missions.
- b. Advises the CJCS, the Secretary of the Army, and the Secretary of the Air Force on CB defense matters involving non-federalized National Guard forces to support homeland defense and civil support missions.
- c. Develops and validates CB defense operational concepts and annexes to joint CB defense capability requirement documents and guidance for non-federalized National Guard forces to support homeland defense and civil support missions.
- d. Coordinates with the Secretary of the Army and the Secretary of the Air Force to program and budget for operating and sustaining CBDP equipment provided to the National Guard.

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(NCB)	Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
CB	chemical and biological
CBDP	Chemical and Biological Defense Program
CJCS	Chairman of the Joint Chiefs of Staff
CWMD	countering weapons of mass destruction
DARPA	Defense Advanced Research Projects Agency
DoDD	DoD directive
DOT&E	Director of Operational Test and Evaluation
EA	executive agent
POM	program objective memorandum
RDA	research, development, and acquisition
RDT&E	research, development, test, and evaluation
U.S.C.	United States Code
USD(A&S)	Under Secretary of Defense for Acquisition and Sustainment
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USD(R&E)	Under Secretary of Defense for Research and Engineering

G.2. DEFINITIONS.

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

TERM	DEFINITION
biosurveillance	Defined in DoDD 6420.02.
biosurveillance-related information	Defined in DoDD 6420.02.
CB defense	Measures taken to anticipate and counter vulnerabilities to and/or effects of: <div style="padding-left: 40px;">A chemical hazard or incident, or biological hazard or incident.</div>

TERM	DEFINITION
	Applied or enhanced chemical- and/or biological-related science and technology, including its enablers (e.g., artificial intelligence and quantum computing).
environmental health	Defined in DoDD 6420.02.
health surveillance	Defined in DoDD 6490.02E.
mission assurance	Defined in DoDD 3020.40.
RDA	<p>The complete RDA measures and activities to deliver warfighting capabilities, including, but not limited to:</p> <ul style="list-style-type: none">Basic and applied research.Advanced technology development.Advanced component development and prototypes.Concept of operations studies and analysis.Advanced concept technology demonstrations.System prototypes.Experimental development.System development and demonstration (engineering and manufacturing development).Operational system development.Loan of equipment and materiel for the purpose of RDT&E or prototyping.Developmental testing and evaluation of system and subsystem efforts.Evolutionary acquisition or spiral development efforts associated with low-rate initial production or production programs.

REFERENCES

- Code of Federal Regulations, Title 15
- Code of Federal Regulations, Title 22
- Department of Defense, “Department of Defense Strategy for Countering Weapons of Mass Destruction,” September, 2023¹
- “Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,” April 10, 1972²
- “Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (CWC),” January 13, 1993³
- DoD 7000.14-R, “Department of Defense Financial Management Regulation,” current edition
- DoD Directive 2060.01, “Implementation of, and Compliance with, Arms Control Agreements,” June 23, 2020
- DoD Directive 3020.40, “Mission Assurance (MA),” November 29, 2016, as amended
- DoD Directive 5000.01, “The Defense Acquisition System,” September 9, 2020, as amended
- DoD Directive 5101.01, “DoD Executive Agent,” February 7, 2022
- DoD Directive 5105.71, “Department of Defense Test Resource Management Center (TRMC),” March 8, 2004
- DoD Directive 5105.77, “National Guard Bureau (NGB),” October 30, 2015, as amended
- DoD Directive 5111.10, “Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict,” May 5, 2021
- DoD Directive 5124.02, “Under Secretary of Defense for Personnel and Readiness (USD(P&R)),” June 23, 2008
- DoD Directive 5134.08, “Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB)),” January 14, 2009, as amended
- DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- DoD Directive 5137.02, “Under Secretary for Defense for Research and Engineering (USD(R&E)),” July 15, 2020
- DoD Directive 5141.02, “Director of Operational Test and Evaluation (DOT&E),” February 2, 2009
- DoD Directive 5143.01, “Under Secretary for Defense for Intelligence and Security (USD(I&S)),” October 24, 2014, as amended
- DoD Directive 6420.02, “DoD Biosurveillance,” September 17, 2020
- DoD Directive 6490.02E, “Comprehensive Health Surveillance,” February 8, 2012, as amended
- DoD Instruction 2040.02, “International Transfers of Technology, Articles, and Services,” March 27, 2014, as amended

¹ Available on the Internet at https://media.defense.gov/2023/Sep/28/2003310413/-1/-1/1/2023_STRATEGY_FOR_COUNTERING_WEAPONS_OF_MASS_DESTRUCTION.PDF.

² Available on the Internet at <https://www.state.gov/wp-content/uploads/2022/06/BWC-Full-Text.pdf>.

³ Available on the Internet at <https://2009-2017.state.gov/t/avc/trty/127917.htm>.

DoD Instruction 5000.02, “Operation of the Adaptive Acquisition Framework,” January 23, 2020, as amended

National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security, current edition

National Defense Strategy, current edition

National Military Strategy, current edition

United States Code, Title 10

United States Code, Title 50