ARMY REGULATION
No. 70-65

HEADQUARTERS
DEPARTMENT OF THE ARMY
WASHINGTON, DC, *1 September 1979*

RESEARCH, DEVELOPMENT, AND ACQUISITION

MANAGEMENT OF CONTROLLED SUBSTANCES, ETHYL ALCOHOL, AND HAZARDOUS BIOLOGICAL SUBSTANCES IN ARMY RESEARCH, DEVELOPMENT, TEST, AND EVALUATION FACILITIES

Effective 1 October 1979

This is a new regulation. It prescribes policy and procedures for the management of controlled substances, ethyl alcohol, and hazardous biological substances used in executing the Army's research, development, test, and evaluation program.

Local limited supplementation of this regulation is permitted, but is not required. If supplements are issued, HQDA agencies or major Army commands will furnish one copy of each to HQDA (DASG-RDZ), WASH DC 20310. Other commands will furnish one copy of each to the next higher headquarters.

Interim changes to this regulation are not official unless they are authenticated by The Adjutant General. Users will destroy interim changes on their expiration dates unless sooner superseded or rescinded.

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CHAPTER 1
GENERAL

1-1. Purpose. This regulation prescribes policy for approval, requisitioning, receipt, accountability, security, inventory, and disposal of controlled substances, ethyl alcohol (hereinafter referred to as alcohol), and controlled hazardous biological substances (CHBS) in executing the Army's research, development, test, and evaluation (RDTE) program.

1-2. Applicability. This regulation—

a. Applies worldwide to all Army RDTE facilities, laboratories, and activities (hereinafter referred to as an RDTE activity) supported by the Army.

b. Does not apply to—

(1) Army contractors affiliated with accredited academic institutions, independent research organizations, pharmaceutical manufacturers, and other Federal agencies, unless included in the contract. These activities must comply with Drug Enforcement Administration (DEA) directives in accordance with the contract.

(2) The Army National Guard and US Army Reserve.

1-3. Objective. The aim is to ensure that uniform procedures and guidance exist for proper management of controlled substances, alcohol, and CHBS for all Army RDTE activities using these items.

1-4. Policy. Controlled substances, alcohol, reference and working stocks of CHBS will be—

a. Afforded protective measures to prevent their theft, pilferage, or misuse.

b. Accounted for in accordance with this regulation.

CHAPTER 2
CONTROLLED SUBSTANCES AND ALCOHOL

2-1. Explanation of terms. *a. Controlled substances.* Drugs listed by the Drug Enforcement Administration (DEA) in Chapter II, Part 1308 of Title 21, Code of Federal Regulations, as schedules I, II, III, IV, or V. This includes all derivatives of opium and other narcotics. The criteria for classifying these substances into schedules I through V are as follows:

(1) *Schedule I.* Drugs which have no accepted medical use in the United States and have high abuse potential (e.g., heroin, marihuana, and LSD). See appendix A.

(2) *Schedule II.* Drugs which have high abuse potential, severe psychological or physical dependence liability, and currently accepted medical use in the United States (e.g., amphetamines, morphine, codeine, meperidine, and pentobarbital).

(3) *Schedule III.* Drugs which have abuse potential less than those in schedules I and II, moderate or low physical dependence liability, and medical use in the United States (e.g., glutethimide; methyprylon; and aspirin, phenacetin, and caffeine (APC) with codeine).

(4) *Schedule IV.* Drugs which have abuse potential less than those in Schedule III (e.g., diazepam, phenobarbital, propoxyphene, and meprobamate).

(5) *Schedule V.* Drugs which have abuse potential less than those listed in schedule IV (e.g., diphenoxylate with atropine and elixir of terpin hydrate with codeine).

b. Alcohol. Tax-free ethyl alcohol. It is 95 percent United States Pharmacopeia (USP) or absolute reagent grade. It is listed as a Note R item in the Federal Supply Catalog C6505-GL, 1 September 1977.

c. Note R items. Substances which are classified as schedule II in the "Controlled Substances Act" (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513), along with ethyl alcohol and alcoholic liquors. They are listed as Note R items in the Federal Supply Catalog.

d. Note K items. Substances which are classified as schedule III, IV, or V in the "Controlled Substances Act." They are listed as Note K items in the Federal Supply Catalog.

e. Workbench quantity. Quantity of ethyl alcohol and barbital buffer solutions, as decided by the RDTE activity commander/director, to be maintained at the investigator's level without the need for formal accountability and storage control.

f. Investigator's laboratory notebook. An official notebook in which pertinent details of scientific research are recorded by the responsible investigator. These details will be recorded in accordance with paragraph 4-7, AR 27-60, and the respective RDTE activity commander/director's supplementing instructions.

g. Controlled Substances Custodian (CSC). A qualified person appointed (in writing) at the installation/activity level who will administer the overall controlled substances and ethyl alcohol program within the activity.

h. Controlled Substances Officer (CSO). A qualified person normally found at the organizational division or department level, but at least one level above the investigator, who will be so appointed in writing.

i. Investigator (User). A person qualified to conduct scientific studies authorized by an approved research protocol or an approved test plan or directive for material tests, projects, and/or studies.

j. Research protocol. A written plan to do research prepared by the intended principal researcher and/or associate investigator or research directed by an approved test plan or directive for materiel tests, projects, and/or studies, and approved by the activity commander. A plan or directive will include as a minimum:

(1) A statement of objective(s) for the research or test program.

(2) General technical approaches to be taken.

(3) Resources (personnel, facilities, and equipment) required.

2-2 Responsibilities. *a.* The Surgeon General (TSG) will—

(1) Develop all aspects of policy and staff supervision which pertain to DA RDTE activities involved with controlled substances and alcohol.

(2) Provide staff advice and assistance to HQDA Staff agencies, commands, and RDTE activities worldwide on matters which relate to controlled substances and alcohol.

(3) Monitor the Federal Register and Chapter II, Part 1308 of Title 21, Code of Federal Regulations, and provide any changes to the schedules of controlled substances to each RDTE activity on a timely basis.

b. The commander/director of each RDTE activity (hereinafter referred to as the commander) will—

(1) Manage the controlled substances and alcohol maintained within the RDTE activity.

(2) Establish and implement internal review procedures to ensure that use of controlled substances is warranted and authorized in support of approved research protocol, approved materiel test program, or project.

(3) Establish and implement a continuing comprehensive education and awareness program on the management of controlled substances and alcohol. This includes proper accountability, use, security, and disposal.

(4) Appoint (on orders) a qualified person as the Controlled Substances Custodian (CSC) to administer the overall controlled substances and alcohol program within the RDTE activity.

c. The Controlled Substances Custodian (CSC) will—

(1) Administer the overall controlled substances and alcohol program of his/her RDTE activity. This would include the approval, requisitioning, receipt, issue, accountability, security, and disposal of controlled substances and alcohol.

(2) Maintain a controlled substance Stock Accounting Record (DA Form 1296) for his/her RDTE activity. See paragraph 2-3*b*(2) and figure 2-1. Also see AR 710-2.

(3) Notify all CSOs of any changes to the schedules of controlled substances.

d. Controlled Substances Officer (CSO) will—

(1) Maintain the Controlled Substances Stock Record (DA Form 3862). See paragraph 2-3*b*(3) and figure 2-2. Also see AR 40-2.

(2) Safeguard and keep formal accountability of controlled substances and alcohol at the division or department level.

e. The Investigator (User) will—

(1) Safeguard and ensure proper use of controlled substances and alcohol to support approved studies, experiments, tests, or projects.

(2) Record the use of controlled substances or alcohol in the laboratory notebook according to paragraph 4-7, AR 27-60, and any supplementing instructions issued by the commander.

2-3. Procedures and reporting requirement, RCS MED-366. *a. Approval of requisitions.* Commanders will establish and implement internal review procedures for approving requisitions for controlled substances and alcohol from the supporting supply activity.

b. Receipt and accountability. Commanders will establish and implement procedures to ensure that—

(1) All requests for controlled substances, including no-cost research samples and bulk issues of alcohol, are centrally recorded and processed by the CSC or an authorized representative.

(2) A documented accountability system for all transactions involving controlled substances and alcohol is in effect from the CSC to the CSO. The CSC will use DA Form 1296 and keep a separate document register (DA Form 2064, Document Register for Supply Action) to record these transactions.

(3) The CSO maintains documented accountability of all controlled substances and alcohol by

recording all receipts and issues on DA Form 3862.

(4) The investigator maintains audit trail accountability of all schedules I and II controlled substances, with the exception of barbiturate anesthetics and their synthetic equivalents. Audit trail accountability for schedules III through V controlled substances and barbiturate anesthetics and their synthetic equivalents is not needed at the investigator's level. However, the use of these materials will be recorded in the Investigator's laboratory notebook. (See para 2-2*e*(2).)

(5) Audit trail accountability of workbench quantities of alcohol and barbital buffer solutions (common laboratory reagents) ends when issued to an investigator. What constitutes workbench quantities of alcohol and barbital buffer solutions will be decided and prescribed by commanders. (See para 2-1*e*.)

c. Security.

(1) The security need for controlled substances and alcohol at the CSC level will be according to paragraphs 3-3, 3-4, and appendix, AR 190-50.

(2) The CSO will follow AR 190-50 for security of controlled substances. The need for security at the CSCs level for alcohol will be the same as that for schedules III through V controlled substances (i.e., a single locked container with adequate ventilation).

(3) The investigator will—

(a) Follow AR 190-50 for security of schedules I and II controlled substances, except for barbiturate anesthetics and their synthetic equivalents, for which the same level of security will be provided as for schedules III through V controlled substances.

(b) Exercise care to safeguard workbench quantities of alcohol and barbital buffer solutions. The need for security is not required unless directed by the commander.

d. Inventory.

(1) The commander will—

(a) Appoint a disinterested commissioned officer, senior noncommissioned officer, or civilian (GS-7 or above) to conduct a monthly inventory of controlled substances and alcohol. The same person will not be appointed on a continuing monthly basis.

(b) Provide the monthly inventory officer with written instructions on inventory procedures.

(c) Take proper actions to correct all discrepancies before the next inventory, and report the irreconcilable shortages, to the RDTE activity, and report the irreconcilable shortages, to the RDTE activity commander as prescribed by local procedures.

(2) The Inventory Officer will—

(a) Inventory all controlled substances and alcohol down to the CSO level. Also, at least 10 percent of the controlled substances (less alcohol and barbital buffer solutions) held at the investigator level will be audited monthly. This will be done so that all controlled substances within a research activity are audited at least yearly. This audit will be conducted by ensuring that quantities of controlled substances and alcohol recorded on accounting records at storage locations at the CSC and CSO level agree with quantities on hand, and by verifying all other entries.

(b) Conduct a sampling of transactions recorded on the accounting records at storage locations after the last inventory.

(c) Ensure that each transaction is supported by a properly signed transaction document filed with the CSCs Stock Accounting Record.

(d) Record the balance on hand on the Stock Accounting Record by a separate line entry on the DA Form 1296 (CSCs level) and DA Form 3862 (CSOs level), and include the date, "Per Inventory," quantity on hand, and his/her signature and grade.

(e) Submit a report of the monthly inventory to the Commander and include any discrepancies noted. (RCS: MED-366.)

e. Disposal.

(1) When an investigator has no further use for controlled substances or alcohol, they will be turned in to the CSO for disposal in accordance with paragraph 3-48, AR 40-61, if the substance has been used or has expired.

(2) The Commander will establish procedures by which the CSC and CSO will review their stockage of controlled substances and alcohol at least twice a year. Results of each review will be recorded on their stock accounting

records. All stocks found to be excess will be turned in through proper supply channels.

(3) Contaminated alcohol and barbital buffer solutions may be disposed of by the Investigator or at the CSO level according to established procedures.

f. Records. All records required by this regulation will be kept for a minimum of 3 years after the last entry. After 3 years, they will be disposed of in accordance with AR 340-18-14.

g. Labeling. Whenever controlled substances are repackaged, the new container will be labeled to include, as a minimum, the name, common synonyms, manufacturer's control number, and a large "C" with Roman numerals designating the schedule.

h. Synthesis of controlled substances. Synthesis of controlled substances or their precursors (less alcohol) is not permitted without prior approval by TSG and authorization by proper registration with DEA.

i. Schedule I controlled substances. Use of Schedule I controlled substances will be approved by TSG and DEA, before submitting requisitions for these substances according to paragraph 4*d*, AR 40-7.

j. Clinical research. Controlled substances used for clinical research will be managed according to chapter 7, AR 40-2.

k. Transfer of controlled substances. Only the CSC may transfer controlled substances between CSOs. Controlled substances will not be transferred from one research activity to another. Transfer of schedule I substances needs TSG approval.

STOCK ACCOUNTING RECORD

STOCK NUMBER 6505-00-104-9000 | STOCK NUMBER 6505-00-104-9000

SERVICE STOCK

DATE 19 79	VOUCHER NUMBER	ORGAN-IZATION	DEMAND NON-RECUR	DEMAND RECUR	GAIN	LOSS	BALANCE ON HAND	DATE 19	VOUCHER NUMBER	ORGAN-IZATION	DEMAND NON-RECUR	DEMAND RECUP	GAIN	LOSS	BALANCE ON HAND
	BALANCE BROUGHT FORWARD						100								
3 Jan	9003 0001	Pharmacy		10		10	90								
4 Jan	9004 0323	W23MYC			100		190								
5 Jan	Per Inventory			John Jones, Capt			190								
									BALANCE CARRIED FORWARD						

SUMMARY OF DEMANDS

MONTH	Jan																
RECUR	1/10																
NON-RECUR	0/0																

STOCK ACCOUNTING RECORD
(AR 711-16)

DA FORM 1296 1 AUG. 55 (REPLACES DA FORM 1296 (TEST) 1 APRIL 55 WHICH IS OBSOLETE)

STOCK ACCOUNTING RECORD
(AR 711-16)

Figure 2-1.

CONTROLLED SUBSTANCES STOCK RECORD

CONTROLLED SUBSTANCES STOCK RECORD

For use of this form, see AR 40-2; the proponent agency is Office of The Surgeon General.

STOCK NUMBER: 6505-864-8092

DESCRIPTION: Codeine Phosphate Injection, 30 mg (1/2 gr), 1 ml

UNIT AS RECEIVED: Box

CONVERSION FACTOR: 20

ACCOUNTABLE UNIT: Cartridge (each)

DATE	DEBIT (Receipts)	DEBIT (VO.) OR CREDIT (RX) NO	CREDIT (Expenditures)	BALANCE ON HAND	DATE	DEBIT (Receipts)	DEBIT (VO.) OR CREDIT (RX) NO	CREDIT (Expenditures)	BALANCE ON HAND
BALANCE BROUGHT FORWARD				70					
26 Nov 76		A00921	10	60					
2 Dec 76	60	5032-078		120					
7 Jan 77	INVENTORIED	AND FOUND CORRECT		120					
1 Feb 77		A00922	10	110					

DA FORM 1 JUNE 72 3862

REPLACES DA FORM 8-235, 1 AUG 51, WHICH WILL BE USED.

Figure 2-2.

CHAPTER 3
CONTROLLED HAZARDOUS BIOLOGICAL SUBSTANCES

3-1. Explanation of terms. *a. Controlled hazardous biological substances (CHBS).* A hazardous biological organism (pathogen) or toxin found to need formalized restrictive procedures for handling and use. Criteria for designation of CHBS are based on degree of human pathogenicity, transmissibility to humans, lack of effective therapy, and seriousness of potential threat posed by unauthorized use. CHBS are listed at appendix B.

b. Reference stock. The lowest passage (earliest culture) of a strain of microorganisms with a documented history and defined characteristics kept in a centralized collection. Since toxins are nonreplicating and must be prepared anew from biological sources for each lot, there are no reference stocks of toxins for purposes of control.

c. Working stock. Any passage of a strain of microorganisms or toxins in any quantity authorized by the commander to meet needs clearly identified in approved research protocols, test plans, and project/study directives. Ordinarily volumes of bench working stocks seldom exceed 100 milliliters. Experimental working stocks may comprise several liters.

d. Toxin. Substance produced by an organism which is poisonous to humans.

e. Level 4 biohazard containment. A maximum containment system including the necessary microbiological practices and facilities for the safe handling of high hazard organisms. Specifications for such a system and the organisms requiring such containment are described in "Classification of Etiologic Agents on the Basis of Hazard," a US Public Health Service Publication of the Center for Disease Control, Office of Biological Safety, Atlanta, GA 30333, as revised.

3-2. Responsibilities. *a.* Commanding General, Materiel Development and Readiness Command (CG, DARCOM), will approve initial acquisition and use of experimental batch working stocks of CHBS for materiel RDTE.

b. TSG will—

(1) Approve initial acquisition and use of reference stocks of CHBS for medical research.

(2) Be responsible for control, maintenance, and security of reference stocks of CHBS and establish procedures for their release from reference stocks to RDTE activities or other appropriate agencies. After release from reference stocks, CHBS become working stock of the receiving activity.

(3) Approve modifications to the list of designated CHBS.

c. The commander of each RDTE activity will establish and implement local procedures specific for that RDTE activity for the use of working stocks of CHBS. This is to ensure the security and accountability of the material and safety of personnel.

3-3. Reference stock procedures and reporting requirement, RCS MED-367. *a. Protection.* All US Army reference stocks of CHBS will be kept at the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Ft Detrick, MD. The CG, USAMRIID, will ensure that all reference stocks are—

(1) Protected at all times to minimize the potential for their appropriation by unauthorized persons or for unapproved research or medical purposes.

(2) Stored under conditions conducive to the maintenance of viability in the central repository. They must meet the following minimum criteria and conditions:

(a) Primary CHBS containers will be sealed in leakproof, crimpsealed, or soldered metal cans.

(b) Cans containing CHBS will be stored in refrigerated containers. Built-in container locks will be supplemented with a high security lock (MIL-P-43607C(GL) or MIL-P-17802C).

(c) The room housing the container(s) will serve no other purpose. It will be so constructed

as to impede casual entry and will have a barrier door of substantial metal construction.

(d) The door to the repository will be secured with two high-security locks (MIL-P-43607C(GL) or MIL-P-17802C).

(e) The repository will be equipped with an intrusion detection system wired to a central location and monitored on a 24-hour basis. The intrusion detection system will be tested at least monthly. The date, time, and name of the tester will be recorded and maintained as a permanent record.

(f) The repository will have a viewing device (peephole) permitting external surveillance of the interior.

b. Access. The CG, USAMRIID, will appoint (in writing) a minimum number of personnel who will have access to keys and combinations for the CHBS reference stock repository and refrigerated container(s). All other personnel needed to be present in the repository (e.g., maintenance personnel) must be monitored by one of these appointed individuals. Also:

(1) An approved roster of personnel authorized access keys and combinations to the CHBS reference stock repository will be kept, updated, reviewed by the Chief, Animal Assessment Division, and certified twice a year by the CG, USAMRIID.

(2) Logs will be kept by the Chief, Animal Assessment Division, to record entry into the CHBS reference stock repository and the opening of each refrigerated container holding CHBS reference stocks.

(3) A responsible person appointed by the CG, USAMRIID, will perform periodic visual checks inside of the CHBS reference stock repository by means of the viewing device to ensure that—

(a) No one is inside.

(b) There is no evidence of forced entry or tampering with the barrier door, refrigerated container, or the locks.

The times and results of these checks and the identity of the person performing them will be recorded. These records will be kept for at least 30 days.

c. Key and lock control.

(1) A person authorized access to the CHBS reference stock repository will be appointed (in writing) to issue and keep adequate records of all keys, combinations, and locks used to secure CHBS reference stocks.

(2) No person, acting alone, will be allowed access to, nor be permitted the use of, the key(s) or combination(s) to the lock(s) on the CHBS reference stock repository or container(s). The commander will prescribe procedures that will ensure that the two-man rule is continuously enforced. Depositories that contain keys and combinations to the CHBS reference stock repository and containers will be secured with two locks. No person will be allowed access to the keys or combinations of both locks.

d. Inventory.

(1) The first inventory of reference stocks will be conducted by the Chief, Animal Assessment Division at USAMRIID, upon implementation of this regulation. A report will be prepared and submitted to HQDA(DASG-ZA), WASH DC 20310, with an information copy to the Commander, US Army Materiel Development and Readiness Command, ATTN: DRDLDC, 5001 Eisenhower Avenue, Alexandria, VA 22333, within 60 days. After TSG approval, quantities of CHBS in the first inventory will become the first official reference stock holdings.

(2) Inventories will be conducted at least yearly to reflect quantities on hand as of 30 September and a report (RCS: MED-367) submitted to HQDA(DASG-ZA), WASH DC 20310, with an information copy to Commander, US Army Materiel Development and Readiness Command, ATTN: DRDLDC, 5001 Eisenhower Avenue, Alexandria, VA 22333, not later than 1 November.

(3) CG, USAMRIID, approves changes to the official reference stock holdings and maintains an audit trail of these changes according to *e*(1) below.

(4) The yearly inventory of reference stocks will be recertified upon additions, deletions, reductions, or transfers to working stocks. The updated inventory report will be submitted to HQDA(DASG-ZA), WASH DC 20310, with an information copy to Commander, US Army Materiel Development and Readiness Command, ATTN: DRDLDC, 5001 Eisenhower Avenue,

Alexandria, VA 22333, within 30 days of the update action.

e. Records management.

(1) The CG, USAMRIID, will establish and keep records of inventories of CHBS reference stocks that will permit ready accountability of the amounts on hand at any particular time. This would include additions, deletions, transfers to working stocks and the institution, responsible person, and date working stocks received.

(2) Required documentation includes—

(a) At a minimum, copies of the latest two inventories reported to TSG according to *d*(1) and (2) above.

(b) Copies of any recertified amendments to the latest two inventories reported to TSG according to *d*(4) above.

(c) Copies of correspondence providing TSG approval for modifications of the list of CHBS reference stocks.

(d) Transaction documents (e.g., certificates of destruction, receipts for issue of material from CHBS reference stocks to investigators, receipts and transportation documents reflecting approved transfer of material from CHBS reference stocks to other agencies) supporting any changes to reported or recertified inventories.

3-4. Working stock procedures. *a. Protection.*

(1) The Commander will ensure that CHBS working stocks are protected at all times to minimize the potential for their appropriation by unauthorized persons or for unapproved purposes. Protective measures applied to working stocks of CHBS during laboratory processing or active use will be selected in each case so as to be consistent with operational and safety requirements.

(2) Working stocks (bench level and experimental batch quantities) require procedures for secure storage under conditions conducive to maintenance of viability.

(3) Activity commanders will publish and implement directives that will give adequate decentralized security measures for the safeguard of working stocks of CHBS under their control.

b. Control and accountability. Working stocks of CHBS will be accounted for and controlled at the RDTE activity level. Broad guidance to subordinate commands will be issued by the CG, DARCOM, for materiel RDTE and by TSG for medical research.

c. Transfer. Request for authorization to transfer CHBS working stocks between RDTE activities will be addressed as follows:

(1) When only DARCOM activities are involved, send the request to the Commander, Materiel Development and Readiness Command, ATTN: DRDLDC, 5001 Eisenhower Avenue, Alexandria, VA 22333.

(2) When only medical RDTE activities are involved, send the request to HQDA (DASG-ZA), WASH DC 20310.

Joint approval of TSG and CG, DARCOM, is required to authorize transfer of CHBS working stocks between DARCOM and medical RDTE activities.

3-5. Safety and reporting requirement, RCS MED-368. *a.* A formal Biological Safety Program will be established at each RDTE activity using CHBS or toxins. The aim of this program is to protect the public as well as the personnel engaged in RDTE activities.

b. The commander will—

(1) Appoint a Biological Safety Officer.

(2) Implement the provisions of AR 385-10, relating to safety aspects pertaining to biological substances in RDTE activities.

(3) Establish policies and procedures for precluding or reducing exposures and occupational illnesses.

(4) Include organizational elements and procedures for determining the criteria for design and construction of safe handling facilities, taking due notice of National Standards promulgated by the Department of Health, Education, and Welfare; Center for Disease Control; and National Institute of Health.

(5) Follow procedures and protocols for use, containment (packaging), decontamination, safe transporting, and disposal for all operations necessary for the conduct of research, development, and testing with CHBS and toxins.

(6) Ensure proper immunization of all personnel having risk of exposure, and provide for continuous close coordination with the supporting Medical Department Activity (MEDDAC) to ensure that informed personnel and facilities are available for effective treatment of accidental exposures.

(7) Implement an organizational accident reporting system for prompt reporting of spills and potential or known exposures. The system must ensure that occupational illnesses caused by CHBS are reported under AR 385-40. (The occurrence of certain diseases is also reported through MEDDAC channels in accordance with AR 40-5.) In addition to the reporting requirements of AR 385-40 and AR 40-5, serious or potentially serious accidents or exposures involving CHBS will be promptly reported in accordance with the following guidance: Since a conclusive determination of accidental infection usually cannot be made until the characteristic incubation period of the pathogen has passed, judgment will be exercised in the reporting of potential exposures. Consideration will be given to the potential seriousness of the disease, the immunological status of potentially exposed personnel, and the probability of exposure as shown by the circumstances of the accident. As soon as they are known, the following events will be reported (RCS: MED-368) through channels by electrical means to CDRDARCOM ALEX VA// DRDLDC/DRCSP//, for all DARCOM RDTE activities, or to DA WASHDC //DASG-ZA//, for all medical RDTE activities who will in turn notify DA WASHDC //DAMA-CSS// and DA WASHDC //DAMO-NCC//.

(a) Probable exposure of personnel to a toxin or a pathogen designated as a CHBS.

(b) Suspected or confirmed release from a containment facility of any pathogenic organism or toxin.

(c) Verified disease or illness produced by any pathogen or toxin where there is reasonable grounds to suspect that infection was or may have been related to RDTE activities.

(8) Include periodic inspections and tests to ensure the integrity of the containment facility as well as a system of scheduled preventive maintenance and servicing of expendable system components, such as ventilation air filters.

(9) Ensure that the safety committee of RDTE facilities and their organizational elements are effectively and aggressively involved in promoting the Biological Safety Program.

(10) Institute a regular training program to ensure that all personnel working with hazardous biological materials are properly trained in the safety aspects.

(11) Implement plans and procedures for evaluating the program's effectiveness on at least a quarterly basis.

(12) Identify the factors which cause occupational hazards and develop countermeasures.

3-6. Transportation of CHBS. *a. Shipping practices.* The potential hazards associated with the shipment of CHBS require compliance with all Federal regulations/directives governing shipping practices. In the context of shipping practices, CHBS and etiologic agents are synonymous.

b. Interstate shipment.

(1) Personnel coming under the purview of this regulation will adhere to appropriate Federal directives when engaged in transporting CHBS in interstate commerce.

(2) Instructions contained in the following directives will apply to packaging, labeling, and shipment of CHBS:

(a) Chapter I, Part 72, Section 72.25 of Title 42, Code of Federal Regulations.

(b) Chapter I, Part 173, Sections 173.24, 173.386 through 173.388, title 49, Code of Federal Regulations.

(c) Guide for Grants and Contracts, Vol. 4, No. 1, February 7, 1976, National Institutes of Health (NIH), Department of Health, Education, and Welfare. (Copies may be obtained from the Office of Research Grants Inquiries, NIH, 5333 Westboard Avenue, Bethesda, MD 20205.)

(d) Guide for Transportation of Hazardous Materials, Vol. 4, no. 1, February 10, 1975, National Institutes of Health (NIH), Department of Health, Education, and Welfare. (Copies may be obtained from the Office of Research Grants Inquiries, NIH, 5333 Westboard Avenue, Bethesda, MD 20205.)

(e) AR 740-32, Responsibilities for Technical Escort of Dangerous Materials.

(f) AR 40-12, Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces.

c. Importation. Part 71, Section 71.156 of Title 42, Code of Federal Regulation. Any CHBS imported or subsequently received by transfer from within the United States are subject to the importation requirements of this regulation and AR 40-12.

APPENDIX A
LIST OF SCHEDULE I DRUGS

Schedule I will consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

a. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol 9601
(2) Allylprodine 9602
(3) Alphacetylmethadol 9603
(4) Alphameprodine 9604
(5) Alphamethadol 9605
(6) Benzethidine 9606
(7) Betacetylmethadol 9607
(8) Betameprodine 9608
(9) Betamethadol 9609
(10) Betaprodine 9611
(11) Clonitazene 9612
(12) Dextromoramide 9613
(13) Diampromide 9615
(14) Diethylthiambutene 9616
(15) Difenoxin 9168
(16) Dimenoxadol 9617
(17) Dimepheptanol 9618
(18) Dimethylthiambutene 9619
(19) Dioxaphetyl butyrate 9621
(20) Dipipanone 9622
(21) Ethylmethylthiambutene 9623
(22) Etonitazene 9624
(23) Etoxeridine 9625
(24) Furethidine 9626
(25) Hydroxypethidine 9627
(26) Ketobemidone 9628
(27) Levomoramide 9629
(28) Levophenacylmorphan 9631
(29) Morpheridine 9632
(30) Noracymethadol 9633
(31) Norleyorphanol 9634
(32) Normethadone 9635
(33) Norpipanone 9636
(34) Phenadoxone 9637

(35) Phenampromide 9638
(36) Phenomorphan 9647
(37) Phenoperidine 9641
(38) Piritramide 9642
(39) Proheptazine 9643
(40) Properidine 9644
(41) Propiram 9649
(42) Racemoramide 9645
(43) Trimeperidine 9646

b. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine 9319
(2) Acetyldihydrocodeine 9051
(3) Benzylmorphine 9052
(4) Codeine methylbromide 9070
(5) Codeine-N-Oxide 9053
(6) Cyprenorphine 9054
(7) Desomorphine 9055
(8) Dihydromorphine 9145
(9) Drotebanol 9335
(10) Etorphine (except hydrochloride salt) 9056
(11) Heroin 9200
(12) Hydromorphinol 9301
(13) Methyldesorphine 9302
(14) Methyldihydromorphine 9304
(15) Morphine methylbromide 9305
(16) Morphine methylsulfonate 9306
(17) Morphine-N-Oxide 9307
(18) Myrophine 9308
(19) Nicocodeine 9309
(20) Nicomorphine 9312
(21) Normorphine 9313
(22) Pholcodine 9314
(23) Thebacon 9315

c. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position, and geometic isomers):

(1) 4-bromo-2,5-dimethoxy-amphetamine 7391
Some trade or other names: 4-bromo-2,5-dimethoxy -α- methylphenethylamine; 4-bromo-2,5-DMA.

(2) 2,5-dimethoxy-amphetamine 7396

Some trade or other names: 2,5-dimethoxy -α- methylphenethylamine; 2,5-DMA.

(3) 4-methoxyamphetamine 7411

Some trade or other names: 4-methoxy -α-methylphenethylamine; paramethoxyamphetamine; PMA.

(4) 5-methoxy-3,4-methylenedioxy amphetamine 7401

(5) 4-methyl-2,5-dimethoxy-amphetamine 7395

Some trade and other names: 4-methyl-2,5-dimethoxy -α- methylphenethylamine; "DOM"; and "STP".

(6) 3,4-methylenedioxy amphetamine 7400

(7) 3,4,5-trimethoxy amphetamine 7390

(8) Bufotenine 7433

Some trade and other names: 3-(β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N,N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine.

(9) Diethyltryptamine 7434

Some trade and other names: N,N-Diethyltryptamine; DET.

(10) Dimethyltryptamine 7435

Some trade or other names: DMT.

(11) Ibogaine 7260

Some trade and other names: 7-Ethyl-6,6,β,7,8,9,10,12,13-octahydro-2-methoxy-6, 9-methano-5H-pyrido [1', 2':1,2] azepino [5, 4-b] indole; tabernanthe iboga.

(12) Lysergic acid diethylamide 7315

(13) Marihuana 7360

(14) Mescaline 7381

(15) Peyote 7415

Meaning all parts of the plant, presently classified botanically, as *Lophophora Williamsii Lemaire*, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salts, derivative, mixture or preparation of such plant, its seeds or extracts.

(Interprets 21 USC 812(c), Schedule I(c)(12))

(16) N-ethyl-3-piperidyl benzilate 7482

(17) N-methyl-3-piperidyl benzilate 7484

(18) Psilocybin 7437

(19) Psilocyn 7438

(20) Tetrahydrocannabinols 7370

Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

Δ 1 cis or trans tetrahydrocannabinol, and their optical isomers.

Δ 6 cis or trans tetrahydrocannabinol, and their optical isomers.

Δ 3,4 cis or trans tetrahydrocannabinol, and its optical isomers.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(21) Thiophene Analog of Phencyclidine 7470

Some trade or other names: 1-(1-(2-thienyl) cyclohexyl) piperidine; 2-Thienyl Anaolg of Phencyclidine; TPCP.

d. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

mecloqualone 2572

[39 FR 22141, June 20, 1974, as amended at 40 FR 19813, May 7, 1975; 40 FR 28611, July 8, 1975; 41 FR 4016, January 28, 1976; 41 FR 43401, October 1, 1976; 42 FR 15679, March 23, 1977]

APPENDIX B
LIST OF CONTROLLED HAZARDOUS BIOLOGICAL SUBSTANCES

B-1. Pathogens (biological organisms). Reference stocks of strains of the following pathogens that require level 4 biohazard containment will require central inventory accountability and control:

a. Fransciella Tularensis (tularemia)

b. Yersinia pestis (plaque)

c. Bacillus anthracis (anthrax)

d. Smallpox virus

e. Herpes B. virus

f. Congo-crimean hemorrhagic fever virus

g. Junin virus (Argentinean hemorrhagic fever)

h. Lassa virus (lassa fever)

i. Machupo virus (Bolivian hemorrhagic fever)

j. Marburg virus (African hemorrhagic fever)

k. Ebola virus (Africian hemorrhagic fever)

l. Tick-borne encephalitis virus

B-2. Toxins. The following toxins require decentralized local control and accountability:

a. Botulinum toxin

b. Staphylococcal enterotoxin

c. Ricin

d. Anthrax toxin

e. Palytoxin

f. Saxitoxin

g. Shellfish toxin

h. Tetrodotoxin

i. Tubocurare

APPENDIX C
REFERENCES

AR 27-60	Patents, Inventions and Copyrights
AR 40-2	Army Medical Treatment Facilities: General Administration
AR 40-7	Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances
AR 40-12	Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces
AR 40-61	Medical Logistics Policies and Procedures
AR 70-1	Army Research, Development, and Acquisition
AR 190-50	Physical Security for Storage of Controlled Medical Substances and Other Medically Sensitive Items
AR 385-10	Army Safety Program
AR 385-40	Accident Reporting and Records
AR 740-32	Responsibilities for Technical Escort of Dangerous Materials
TB MED 291	Guidance for Inventory, Control and Accountability of Drugs and Injection Devices of Potential Abuse at Medical Treatment Facilities Worldwide

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Chapter II, Part 1308, Title 21, Schedules of Controlled Substances, 1 April 1978.

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Guide for Grants and Contracts, Vol. 4, 7 February 1976, National Institutes of Health (NIH), Department of Health, Education, and Welfare.

Guide for Transportation of Hazardous Materials, Vol. 4, 10 February 1975, National Institutes of Health (NIH), Department of Health, Education, and Welfare.

Classification of Etiologic Agents on the Basis of Hazard, 4th Edition, July 1976.

The proponent agency of this regulation is the Office of The Surgeon General. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to HQDA (DASG-RDZ) WASH DC 20310.

By Order of the Secretary of the Army:

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General, United States Army
Chief of Staff

Official:
J. C. PENNINGTON
Major General, United States Army
The Adjutant General

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