

WS Directive

2.430 06/07/04

CHEMICAL IMMOBILIZATION AND EUTHANIZING AGENTS

1. PURPOSE

To establish guidelines and training standards for Wildlife Services (WS) employees who administer immobilization and euthanasia (I&E) agents in a proper and professional manner and in compliance with all applicable laws and regulations.

2. REPLACEMENT HIGHLIGHTS

This directive replaces ADC Directive 2.430 dated 3/26/93.

3. BACKGROUND

Most of the substances used to I&E wild animals are regulated by State and Federal law because of their potential to contaminate human food or to be used illegally. Within WS, only personnel trained and certified in their appropriate use are authorized to possess and use WS approved I&E substances.

The Food and Drug Administration (FDA), which is primarily concerned with drugs and drug residues in food, regulates some drugs under authority of the Federal Food, Drug, and Cosmetic Act and the Animal Medicinal Drug Use Clarification Act (AMDUCA). The Drug Enforcement Administration (DEA), which is responsible for preventing illegal diversion of dangerous and addictive drugs, regulates drug storage and use in accordance with the Controlled Substance Act of 1970. DEA also establishes categories for sensitive drugs, i.e., schedules, which outline procedures for drug procurement, storage and use.

WS approved I&E methods place the utmost emphasis on the humane treatment and welfare of both wildlife and humans. WS approved I&E methods take into consideration the principles established in the Report of the American Veterinary Medical Association Panel on Euthanasia.

The WS Deputy Administrator has established the I&E Committee to review and approve immobilization, euthanasia, and accessory agents, and 2) establish training requirements for WS as described in Chapter 2 of the WS Field Operations Manual for the Use of Immobilization and Euthanasia Drugs.

4. POLICY

WS operations personnel using I&E agents must receive training approved by the I&E Committee prior to independent use or possession of I&E substances (Attachment 1). Only agents approved by the I&E Committee can be used by the WS program, unless under emergency situations (Attachment 2). WS operations personnel needing to regularly use I&E agents other than those listed should submit a request to the Chair of the I&E Committee for WS approval. In emergency situations, unapproved drugs can be used on a one-time or limited basis by operations personnel when approved by an attending/consulting veterinarian and the State Director or designee, provided that such use is in compliance with all applicable laws.

NWRC personnel using I&E agents must receive training approved by the I&E Committee prior to independent use or possession of I&E substances, unless otherwise noted (Attachment 1). NWRC personnel must use agents for I&E in accordance with protocols approved by the Institutional Animal Care and Use Committee (IACUC). If not otherwise specified, only agents approved by the I&E Committee may be used (Attachment 2). Official activities of Attending or Consulting Veterinarians and those working under the specific instructions of these individuals are excluded from the provisions of this policy.

All acquisition, storage, and use of I&E agents will be in compliance with applicable Federal, State, and local laws and regulations.

5. RESPONSIBILITY

The Regional Directors and the NWRC Director, as well as the appropriate State Director, will ensure that all personnel using I&E agents receive adequate training in accordance with the guidelines presented in the WS I&E Manual. State Directors are responsible for WS use of I&E agents within their area of responsibility. Additional training requirements will be identified and provided by State Directors and NWRC Program Managers. Proper care and use and chain of custody and security of I&E agents in all locations and circumstances are the responsibility of all WS employees who are trained and certified in their use.

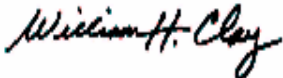
6. REFERENCES

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301-392), as amended Controlled Substances Act (21 U.S.C. 801).

21 CFR Part 511 - New Animal Drugs for Investigational Use.
Section 511.1 - New animal drugs for investigational use exempt from section 412(a) of the Act.

21 CFR Part 514 - New Animal Drug Applications, Section 514.1(b)8
- Evidence to establish safety and effectiveness.

- 21 CFR Part 1301 - Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Section 1301.21 - Persons required to register, Section 1301.22 - Separate registration for independent activities, Section 1301.90 - Employee screening procedures.
- 21 CFR Part 1308 - Schedules of Controlled Substances, Section 1308.03 - Administration Controlled Substances Code Number, Sections 1308.11 - 1308.15 Schedules I-V.
- Animal Medicinal Drug Use Clarification Act, 1996.
- American Veterinary Medical Association. 2001. 2000 Report of the AVMA Panel on Euthanasia. JAVMA 218(5):669-696.
- Wildlife Services. 2001. Field Operations Manual for the Use of Immobilization and Euthanasia Drugs. Dr. Mark Johnson, DVM, and I/E Committee, USDA/APHIS/WS, Riverdale, MD. 120 pp.



Deputy Administrator

Attachment 1

WS IMMOBILIZATION & EUTHANASIA TRAINING REQUIREMENTS

The WS I&E training and certification program is provided for personnel under direct supervision of the WS program directors who administer I&E drugs. Training guidelines have been established to ensure that WS personnel receive adequate training to administer agents used for immobilization and euthanasia in a professional and proper manner and in compliance with all applicable laws and regulations.

I. Initial Certification Requirements

For new employees, current employees who have not been previously certified, or current employees whose certifications have expired:

1. Satisfactory completion of a 24 hour, approved I&E training course. The WS Field Operations Manual for the Use of Immobilization and Euthanasia Drugs must be used as the training document. The training consists of:

a. 16 hours classroom. Veterinary medical portions of the training must be taught by a veterinarian. Qualified WS personnel may assist the veterinarian in teaching non-medical topics.

b. 8 hours hands-on/lab training. A veterinarian must supervise the instruction.

c. Receive a passing grade on the WS I&E Test (70%). The WS I&E Test will be a proctored exam.

2. Completion of the WS I&E Distance Learning Module (DLM) with a passing grade can serve for the classroom portion of training. The same hands-on/lab training and testing as described above is required.

3. Documentation (certificate, letter, DLM grade record) of training for each employee must be provided to the Chair of the I&E committee as proof of training.

II. Continuing Education Requirements

WS I&E Certification is valid for 5 years from the date on the training document. To maintain I&E certification, certified employees must:

1. Complete 20 hours of continuing education within the 5 year period. A minimum of 4 of the 20 hours must cover I & E drugs. The remaining 16 hours may include: laws, recordkeeping, safety,

first aid/CPR, I & E equipment and supplies, animal handling, wildlife disease, or other topic approved by the committee.

2. Re-take the WS I&E test and receive a passing grade (70%).

3. Documentation (certificate, letter, DLM grade record, proctored WS I&E test grade) of training for each employee must be provided to the Chair of the I&E committee as proof of continuing education training.

III. Interim Training

If there is a critical need (as determined by the State Director) for a WS employee to use I&E drugs as part of their job responsibility before formal I&E training can be provided, a qualified (certified and experienced) WS employee may train the new employee in the appropriate procedures. A written description of the training signed by the WS trainer will be provided to the Chair of the I&E Committee as proof of training. The interim certification will automatically expire at the end of 1 year. Seasonal employees may not substitute interim training for certification training.

Attachment 2

WS APPROVED IMMOBILIZATION&EUTHANASIA AGENTS*

The list below contains I&E agents/drugs that are approved by the I&E Committee for WS use. Agents or drugs not listed must be approved by the I&E Committee prior to use. Depending on the situation, listed drugs may be used independently or in combination.

Scheduled drugs are regulated by the DEA. All drugs used on or in animals, even if not scheduled, must be approved for use by the FDA. Both FDA and DEA set standards for accountability and storage.

The following agents are approved for use by WS personnel.

a. Anesthetics

- (1) Ketamine HCL: e.g., Ketaset®, Vetalar®
- (2) Tiletamine HCL + Zolazepam: i.e., Telazol®*
- (3) Acepromazine
- (4) Alpha-chloralose (INAD)
- (5) Propriopromazine (INAD): e.g., TTD

b. Sedative

- (1) Xylazine: e.g., Rompun®, Cervizine™, AnaSed®

c. Accessory Drugs

- (1) Yohimbine HCL
- (2) Tolazoline
- (3) Antibiotics: e.g., Crystiben®, Crystacillin®, Dual-Pen®; oxytetracycline LA-200®, Oxyject®, Liquamycin®.
- (4) Atropine
- (5) Doxapram: e.g., Dopram-V®, Dopram®.

d. Euthanasia Agents

- (1) Sodium Pentobarbital*: e.g., Beuthanasia®-D Special, FP-3®, Euthanasia-6®, Euthanasia Solution®, Sleepaway®.

* Check the local or state requirements for concentrations of these drugs.