United States Department of Agriculture
Animal and Plant Health Inspection Service

WS Directive

2.430 07/06/09

CONTROLLED CHEMICAL IMMOBILIZATION AND EUTHANIZING AGENTS

1. PURPOSE

To establish guidelines for use and training standards for certification of Wildlife Services (WS) employees who administer Controlled Dangerous Substances, Veterinary Prescription Drugs, and/or other related WS approved Immobilizing and Euthanizing substances (hereafter collectively referred to for the purposes of this Directive as I&E Drugs). To emphasize that such I&E Drugs must be used in compliance with all applicable Federal and State laws and regulations. This Directive refers to the use of only those I&E drugs which are specifically related to the immobilization and euthanasia of wild animals.

2. REPLACEMENT HIGHLIGHTS

This directive replaces WS Directive 2.430 dated 06/07/04.

3. BACKGROUND

Most of the substances used to immobilize and euthanize wildlife are regulated by State and Federal law because of their potential hazard to animals or humans and for their potential for abuse. Within WS, only properly trained personnel are certified to possess and use WS approved I&E Drugs.

The Food and Drug Administration (FDA), which is primarily concerned with drugs and drug residues in food, regulates some drugs under 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.

The WS Deputy Administrator has established the WS I&E Committee to 1) review and approve immobilization, euthanasia, and accessory I&E drugs, and 2) establish training and certification requirements for WS as described in Attachment 1 of this Directive and also in Chapter 2 of the WS Field Operations Manual for the Use of Immobilization and Euthanasia Drugs.

4. POLICY

WS personnel using I&E drugs must receive training approved by the WS I&E Committee prior to independent use or possession of I&E drugs (Attachment 2).

Only I&E drugs approved by the WS I&E Committee can be used by WS personnel, unless under emergency situations (Attachment 2). WS personnel needing to regularly use I&E drugs other than those listed should submit a written request to the Chair of the WS I&E Committee for Committee approval. In emergency situations, unapproved I&E drugs can be used on a one-time or limited basis by WS 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. A Consulting Veterinarian may be any graduate veterinarian that is formally consulted regarding a veterinary issue including handling, immobilization, anesthesia, analgesia, and euthanasia of wildlife. An Attending Veterinarian may be any graduate veterinarian associated with a research institution and who has a contractual relationship with a WS program.

NWRC personnel must also use I&E drugs for immobilizing and/or euthanizing procedures in accordance with protocols approved by the Institutional Animal Care and Use Committee (IACUC). If not otherwise specified, only I&E Drugs approved by the WS I&E Committee may be used (Attachment 2).

All acquisition, storage, and use of I&E drugs will be in compliance with applicable program, Federal, State, and local law 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 drugs receive adequate training in accordance with the guidelines presented in Attachment 1 of the WS I&E Directive. State Directors are accountable for WS use of I&E drugs within their area of responsibility. Additional training requirements will be identified and provided by State Directors and NWRC Program Managers. Proper care, use, chain of custody, and security of I&E drugs in all locations and circumstances are the responsibility of all WS employees.

States will obtain their own DEA license. This license will be issued to employees identified as "WS employees" or as "USDA-APHIS Wildlife Services," but not as personal agents or individually named employees.

States will obtain a written agreement with a local (or at least, regional) consulting veterinarian to document the presence of a veterinarian-client-patient relationship where possible. Local is defined as within the State or States under the purview of the State Director. USDA APHIS VS veterinarians can be used as consulting veterinarians if willing and licensed.

If no local veterinarian is found who agrees to perform the duties of a consulting veterinarian, any WS veterinarian may be contacted for assistance in finding one. Depending on the situation, a WS veterinarian may serve on an interim or emergency basis, not to exceed one year, if mutually agreeable.

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 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 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. AVMA Guidelines on Euthanasia, June 2007.

Wildlife Services. 2009. Revised 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.

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Acting Deputy Administrator

Attachment 1

TRAINING AND CERTIFICATION 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 I&E drugs used for immobilization and euthanasia in a professional and proper manner and in compliance with all applicable laws and regulations. Documentation (certificate or letter signed by the trainer; WS I&E Distance Learning Module (DLM) grade record) of training for each employee must be provided to the Chair of the WS I&E committee as proof of training.

I. Initial I&E Certification Requirements

Satisfactorily complete a WS I&E Committee approved 16-hour or longer I&E training course. Any approved non-WS training course must use The WS Field Operations Manual for the Use of Immobilization and Euthanasia Drugs to supplement course materials.

Complete the DLM and receive a passing grade (70%) on the written test within 90 days prior to attending the approved 16-hour I&E training course. Tests for proctored exam are available through the WS I&E Committee.

WS I&E Certification is valid for 3 years from the date on the 16-hour training course document.

II. I&E Recertification Requirements

Complete 16-hours of hands-on, continuing education training over 3-years. A WS I&E Committee approved proficiency evaluation should be completed at the end of the hands-on portion of any training. The I&E Committee can provide guidance on the evaluation process.

After 16 hours of training, and towards the termination of the 3-year certification, complete the DLM and receive a passing grade (70%) on the written test.

WS I&E Recertification is valid for 3 years from the date of passing the DLM written exam. Curriculum for the 16 hours of training must be approved by the WS I&E Committee and must include at least 4 hours on I&E drugs. The remaining content must meet must address required training on I&E issues covered in the Training Manual including: I&E drugs, safety, safe animal handling, etc.

Continuing education training can come from training provided by State agencies, other Federal agencies, professional society workshops, local and attending veterinarians, qualified (certified and experienced) WS personnel, and other Committee approved courses. Only graduate veterinarians can provide training on veterinary medical aspects of using I&E drugs, however, non-medical aspects can be provided by other qualified

individuals. All continuing education training needs to be approved by the I&E committee.

III. Interim and Seasonal 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 hands-on procedures. A written description of the training signed by the WS trainer will be provided to the Chair of the WS I&E Committee as proof of training. The DLM must still be completed with a passing grade of 70% on the written exam prior to the hands-on training. Interim hands-on training and certification cannot be used, in whole or part, to satisfy initial I&E certification requirements.

IV. Alpha Chloralose (AC) Training

All WS employees that use AC must be trained by a WS Certified AC Trainer prior to using AC. Training will consist of 3 parts: 1) classroom training of approximately 6 hours, 2) a field exercise that results in the successful capture of waterfowl, coots, rock doves or ravens and 3) completion of an AC Applicator exam with a passing grade of 70%.

WS employees who have completed training requirements will have their names submitted by the AC Trainer to the AC subcommittee for approval. The AC trained WS employees will then be recommended to the appropriate regional director for certification as AC Applicators.

In order for WS employees to become AC Trainer/Applicators they must have been: 1) AC Applicators for at least 1 year and then complete training by the Primary AC Trainer or 2) complete the training by the Primary Trainer and then use AC for at least 1 year before their names are submitted as AC Trainer/Applicators. Training for AC Trainer/Applicators will consist of 3 parts: 1) classroom training of approximately 8 hours, 2) a field exercise that results in the successful capture of waterfowl, coots, rock pigeons or ravens and 3) completion of an AC Trainer/Applicator exam with a passing grade of 70%.

V. Tranquilizer Trap Device (TTD) Training

All WS employees who use TTDs in routine field operations must be trained by a WS Certified TTD Trainer prior to applying them. WS personnel must also be certified before using TTDs in the routine capture of coyotes or wolves for research purposes where the TTD itself is not being researched. Training will consist of two parts, as outlined in the TTD Handbook: 1) classroom training of approximately 3 hours, and 2) completion of a TTD Applicator exam with a passing grade of 70%.

WS employees who have completed training requirements will have their names submitted by the TTD Trainer to the TTD Subcommittee for approval. The TTD trained WS employees will then be recommended to the appropriate Regional or NWRC Director for certification as TTD Applicators.

In order for WS employees to become TTD Trainer/Applicators they must successfully complete a "Train the Trainer" instruction course. The timing and location of "Train the Trainer" courses will be determined by the appropriate Regional or NWRC Director.

To maintain TTD Certification, certified WS employees must:

Complete a DLM with a passing grade once every 5 years for either TTD Applicators, or if a Trainer, complete and pass a DLM for TTD Trainer/Applicators.

Attachment 2

WS APPROVED I&E DRUGS FOR USE BY INDIVIDUALS WHO ARE CERTIFIED IN THEIR USE FOR IMMOBILIZATION & EUTHANASIA

The following is a list of I&E drugs that are approved by the WS I&E Committee for use by certified individuals. WS I&E drugs not listed must be approved by the WS I&E Committee prior to use.

a. Anesthetics
   (1) Ketamine HCL: e.g., Ketaset®, Vetalar®
   (2) Tiletamine HCL + Zolazapam: i.e., Telazol®*
   (3) Alpha-chloralose (INAD: requires separate certification)

b. Sedatives
   (1) Xylazine: e.g., Rompun®, Cervizine™, AnaSed®
   (2) Medetomidine hydrochloride: e.g. Domitor®

c. Tranquilizers
   (1) Acepromazine
   (2) Proprioprомazine (INAD: TTD; requires separate certification)

d. Accessory Drugs/substances
   (1) Yohimbine HCL
   (2) Tolazoline
   (3) Doxapram: e.g., Dopram-V®, Dopram®.
   (4) Atropine
   (5) Atipamezole hydrochloride: e.g. Antisedan
   (6) Topical Antibiotics (over-the-counter only)

e. 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 Controlled Substances and/or Veterinary Prescription Drugs.