

NEW YORK STATE  
VETERINARY MEDICAL SOCIETY

**Veterinary Facility Accreditation Program Standards**

Compiled as a member resource and benefit



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**New York State Veterinary Medical Society  
Veterinary Facility Accreditation Program**

**Standards for Excellence Updated January 2012**

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**Veterinary Facility Accreditation Standards**

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## Standards for Excellence

The NYSVMS Veterinary Facility Accreditation Program (VFAP) standards offer NYSVMS members a solid and practical foundation on which to evaluate their practices. VFAP evaluators work with hospital owners to help them ensure their facility is in compliance with acceptable standards of practice as well as with state and federal laws and regulations.\*

Membership in the NYSVMS facility accreditation program signifies a commitment to excellence in facility professionalism, appearance, maintenance, and quality patient care. Evidence of adherence to these standards is determined through an on-site evaluation by a trained and experienced veterinarian evaluator every three years.

Three-year VFAP-accredited facilities receive a door decal, are listed in the NYSVMS publication, *Veterinary News*, and receive a VFAP certificate suitable for framing that lists the practice areas evaluated. Veterinary hospitals that successfully complete a three-year VFAP evaluation may use the VFAP logo in advertising, including telephone directory listings.

In 2011, the NYSVMS executive board approved an accreditation fee of \$350 to cover program and evaluation costs. All member facilities, including AAHA members, are assessed the \$350 fee. Practices that do not employ at least one NYSVMS member in good standing at the hospital location will be assessed \$1,000 in addition to the current VFAP evaluation fee. If a veterinarian at the practice applies for membership and pays that year's state and regional dues, the \$1,000 additional fee will be waived.

Veterinary facilities owned by a lay corporation and leased to a veterinary practice are eligible for VFAP accreditation and assessed the regular evaluation fee if at least one NYSVMS member veterinarian works at the evaluated facility.

Members interested in receiving more information or in having their facility evaluated are invited to contact NYSVMS headquarters, (800) U-R NY-VMS (876-9867)

*\*Participation in the Veterinary Facility Accreditation Program does not guarantee full compliance with local, state, and federal laws and regulations.*

## **EXTERIOR OF FACILITY**

### **I. Building Exterior**

The exterior should have an attractive, professional appearance and should be well-maintained and kept in good repair. The building should reflect favorably on the veterinary profession. Veterinary offices are regarded as “places of public accommodation” under the Americans with Disabilities Act and new buildings must be ADA-compliant.

### **II. Exterior Lighting**

Exterior lighting should be in good taste and be appropriate for identification of the facility, the safety of clients, and the security of the premises.

### **III. Signs**

Signs should be large enough to be useful in locating and identifying the facility, yet not so large as to exhibit garishness. Signs should be well-maintained and kept in good repair.

### **IV. Parking**

Parking areas should be sufficient to accommodate the vehicles of clients, tradespersons and employees. Handicapped parking spaces should be provided. Parking areas, sidewalks, and steps should be kept in good repair.

### **V. Grounds**

- A. Grounds around the facility should be kept in a neat, attractive and safe condition.
- B. Rubbish, papers and waste from animals should be picked up from lawns, flowerbeds, walkways and parking areas on a regular schedule and when a problem is noted.

### **VI. Refuse Collection Area**

- A. Refuse collection should be frequent and regular. The refuse collection area should be maintained in an orderly manner. The use of plastic bags is a necessity. Vermin control is essential.
- B. Used bedding and manure should be disposed of in a manner that does not attract vermin or produce offensive odors.

**VII. Regulated Medical Waste Disposal**

Regulated medical waste must be handled in a manner that meets the requirements stated in the New York State Regulated Medical Waste Law. See "Managing Regulated Medical Waste" at the NYS Department of Health's website, <http://www.health.state.ny.us/facilities/waste/>.

**VIII. Emergency Instructions**

Emergency instructions should be posted. See Interior of Facility, I-B-2 (below) for complete description.

**INTERIOR OF FACILITY**

**I. Reception Area**

**A. Reception Room**

The reception room and furnishings should be clean, neat, attractive, well-maintained and odor free. The area must be appropriate for the clients and animals served by the veterinary practice.

**B. Posting of General Information for Clients**

**1. Hours of Operation**

The owner of any animal patient who will be kept at the facility on an in-patient basis should be advised of the hours during which veterinary staff will be present in the facility to care for the animal; this information may be provided on a sign posted in a conspicuous place.

**2. Emergency Contact**

A sign should be posted at the entrance of the veterinary facility with a telephone number and location where veterinary care is available when the veterinary facility is closed.

**3. Licensed Staff**

The names and field of licensure of all the principal licensees engaged in practice in the facility should be conspicuously posted.

**4. Licensee Registrations**

A current NYS Education Department Registration Certificate for each practicing veterinarian and licensed veterinary technician must be posted.

**5. "Don't Flush Your Drugs" Poster**

Veterinary offices must post the informational poster developed by DEC to encourage consumers not to flush unwanted medications down the drain in an area where it can be seen and read by clients of the practice. Information on the

Drug Management and Disposal Act and a pdf version of the poster are available at [www.dec.ny.gov/chemical/67736.html](http://www.dec.ny.gov/chemical/67736.html).

- C. Receptionist/Records Room  
The receptionist's area should be large enough to be efficient and should be maintained in an orderly manner.

## II. Medical Records

- A. Individual Medical Record
  1. A LEGIBLE individual medical record must be maintained for every patient.
  2. In a food animal practice, where individual animal records might not be retained, sufficient written information should be offered to the owner or caretaker of the herd so that veterinary services can be continued in a logical manner and proper public health safeguards can be observed. Recordkeeping in a food animal practice is extremely important, especially the record of any drug use in the animals, which is closely regulated by FDA and USDA.
  3. A *Medical Records Release Form* should be available. A client's right to the medical records of the patient is guaranteed by NYS law, and must be provided by the veterinarian upon the client's written request.
- B. Medical Record Information  
The medical staff must record sufficient information to justify the diagnosis and the treatment. No prescribed format is required; however, the hospital director should require the meticulous recording of information. All records should be maintained in such a manner as to be accurately interpreted by another veterinarian. The NYSVMS website - [www.nysvms.org](http://www.nysvms.org) - contains guidelines for keeping medical records in the Knowledgebase section.
- C. Treatment Consent  
It is important for veterinarians to obtain the consent of clients before proceeding to treat animals. A signed consent form with an estimate of the costs of treatment is recommended. The policy on owner consent adopted by AVMA lists the items that should be included in the consent to treatment obtained from the owner before starting veterinary treatment – see [www.avma.org/issues/policy/owner\\_consent.asp](http://www.avma.org/issues/policy/owner_consent.asp)
- D. Euthanasia Consent and Disposition of Remains  
When euthanasia is agreed upon, a euthanasia release must be signed by the animal's owner or the owner's representative prior to the procedure. After the animal is euthanized, or whenever an animal dies, the method of cadaver disposal must be chosen by the client on a pet disposal form that complies with the

requirements in the Pet Cemetery Law (see §750-s – Pet Disposal Form in the pet cemetery law, found at [www.dos.state.ny.us/cmtty/petcemetery.html](http://www.dos.state.ny.us/cmtty/petcemetery.html) ).

A sample copy of a combined euthanasia consent / pet disposal form is available online at [www.nysvms.org](http://www.nysvms.org) in the Knowledgebase section (under “euthanasia consent” and “pet disposal form”).

E. Medical Records

1. Content -- The medical records should include:

- patient identification
- client identification (name, address, home telephone number, work telephone number, emergency number)
- major and minor complaints of present illness
- medical history
- vaccination record
- physical examination findings
- laboratory reports
- imaging reports (including radiographic, ultrasonographic, CT, and MRI)
- provisional diagnosis
- treatment - medical and surgical
- drugs administered, prescribed and dispensed
- tissue examination reports
- final diagnosis
- necropsy findings, if pertinent.

In addition:

- Hospital inpatients require daily written progress reports.
- Signed medical and surgical consent and release forms should be included with the medical records.
- The record of the physical examination conducted should list all “systems” that should be examined, with a notation of normal, abnormal or not examined, and each abnormal finding should be explained.
- Medications administered – the record of medical treatment should include the name, strength, dose, date/time and route of administration for any medication administered to the animal in the facility.
- Medications prescribed or dispensed – the record of medical treatment should include the name, strength, dose, number/volume dispensed or prescribed, and number of refills ordered, if any.
- Surgery – the record of surgery should include a detailed description of anesthetic protocol; surgical procedure including location, incision shape, size, and depth; procedure; method and material used in closure; type of monitoring; and recovery notes.

- Upon discharge, the record should include a summary of the discharge instructions given to the client, and date of return for patient follow-up, suture removal and/or evaluation.

For further assistance in developing excellent patient records please review "Veterinary Medical Recordkeeping – A Comprehensive Guide" developed by the NYSVMS, available online at [www.nysvms.org](http://www.nysvms.org) under "Knowledgebase," or by calling 800-876-9867.

2. Vaccinations -- For any vaccine administered, the vaccine manufacturer and serial number should be recorded. Vaccine vial labels should be included in the medical record.
3. Paperless Medical records -- If you maintain medical records in a paperless format, a verifiable "lockout" must be part of the software used to prevent the possibility of records being altered. Software that tracks any changes made in the record after it's created is acceptable.
4. Medical Records Retention -- Medical records must be retained for a minimum of 3 years after the last visit. The medical record must be retained for a minimum of 5 years if it contains controlled substance use or dispensing information.

### **III. Examination Facilities**

- A. Examination Area or Room  
The examination room should be brightly lighted, neat, clean and free of objectionable odors. A convenient and ample-sized examination area or room with chairs is appreciated by clients.
- B. Equipment  
Diagnostic equipment for proper examination of patients is required. The basic equipment includes that which is necessary for safe handling of patients as well as instruments for minor surgery and diagnostic examination. Sterile equipment for injections, proper light, stethoscope, scale, restraint aids, thermometer, otoscope and ophthalmoscope should be readily available.

The examination room or area should be supplied with running water. Soap and disposable towels for hand washing should be readily available. Disinfectant solutions and disposable towels should be readily available for instrument and table cleaning. A radiographic view box is useful when discussing radiographic cases in the examination area. A container for medical waste must be readily available.

### **IV. Regulated Medical Waste - Syringes and Needles**

- A. Items from the veterinary hospital that contain pathogens infectious to humans are considered regulated medical waste, and must be handled as required by the

NYS Regulated Medical Waste Law and NYS Department of Health Rules and Regulations.

- B. Syringes and needles (“sharps”) are regulated medical waste, and must be handled as required by the NYS Regulated Medical Waste Law and NYS Department of Health Rules and Regulations.

- 1. Storage

- a. It is recommended that hypodermic syringes and needles be stored in a locked, secure place.

- b. Hypodermic syringes and needles not in reserve, not in main stocks, and not in use should be kept under suitable locked protection.

- 2. Disposal

- Disposal of hypodermic syringes and needles (sharps) should be done as required by the NYS Regulated Medical Waste Law, whether sharps are destroyed on premises or packaged for disposal by a permitted waste hauler. For further information see the Department of Health guidelines at:

- [www.health.state.ny.us/facilities/waste/#sharps](http://www.health.state.ny.us/facilities/waste/#sharps).

- C. Resterilized syringes and needles should not be used for the injection of biologicals. Catheters, syringes, and needles that are to be reused must be scrupulously cleaned and thoroughly rinsed prior to sterilization. Resterilized catheters, syringes, and needles should be in completely enclosed, individual cases or envelopes. Sterilization monitors should be enclosed and dated.

## V. Pharmacy

The veterinary hospital should maintain a pharmacy that is administered in accordance with federal and New York State Laws (See Appendix A – Veterinary Drugs). All pharmaceuticals and biologicals should be stored, transported and reconstituted in such manner that the patient receives full potential of the agent.

Food animal veterinarians are obligated to follow federal regulations and guidelines designed to keep drugs out of the food supply. There are two federal acts that provide guidelines for drug use in food animals:

1. AMDUCA (Animal Medicinal Drug Use Clarification Act) defines drug use, records and labeling for drugs used for food animal therapy. The regulations are very specific and are enforced.
2. PMO (Pasteurized Milk Ordinance -2007) defines drug storage, labeling and residue testing for dairy farms. This regulation is amended often, and practitioners need to refer to the most current document.

USDA administers the Food Animal Residue Avoidance and Depletion Program (FARAD) to assist livestock producers and veterinarians to use drugs and pesticides properly and

avoid drug, pesticide and environmental contaminant residue problems. The FARAD program provides guidance to veterinarians (and others) concerning drug withdrawal times for meat and milk if medications are used in an extra-label manner. Veterinarians and dairy farmers should consult with FARAD whenever extra-label use of a medication is being considered.

More information on these three food animal drug use restrictions is found in Appendix B.

A. Controlled Substances

All controlled substances must be received, handled, stored, labeled, administered, dispensed, documented and disposed of in accordance with New York State controlled substances law and regulations (see [www.health.state.ny.us/professionals/narcotic/laws\\_and\\_regulations.htm](http://www.health.state.ny.us/professionals/narcotic/laws_and_regulations.htm)), and federal law and regulations (see [www.deadiversion.usdoj.gov/21cfr/index.html](http://www.deadiversion.usdoj.gov/21cfr/index.html)). In addition, NYS regulations must be followed when you prescribe controlled substances, and records of controlled substances dispensed from your hospital must be reported to the state Bureau of Narcotics Enforcement as required by state regulations (see the information on "NYS Prescription Law" in the Knowledgebase on the NYSVMS website, [www.NYSVMS.org](http://www.NYSVMS.org)). A current DEA controlled substances registration certificate must be posted, but not in a public area.

Due to the serious nature with which offenses are viewed, and because of the high fines for violations, be sure you are in compliance with the following state and federal requirements:

1. Storage – controlled substances must be stored in a securely locked, substantially constructed cabinet. No other items can be stored with the controlled substances, including purchase records, prescription forms and usage logs. Access to the keys or combination should be restricted to a limited number of employees authorized to use controlled substances.
2. Recordkeeping – meticulous records must be maintained on the ordering, receipt, storage, administration, dispensing, and disposal of all controlled substances. Controlled substance invoices must be available for inspection by authorities.
3. Dispensing – controlled substances dispensed to clients must have an orange, specially-designed label affixed. Clear orange tape over the hospital label is permissible.
4. Destruction or Disposal – unwanted or out of date controlled substances must be destroyed or disposed in a manner approved by DEA and the NYS Bureau of Narcotic Enforcement. NYS now strongly recommends that controlled substances be returned to the manufacturer or distributor from whom they were purchased, or delivered to a "reverse distributor," a company approved by DEA and NYSDOH to receive controlled substances from DEA registrants and dispose of them. (See

additional information on "Disposal and Destruction of Controlled Substances" in the Knowledgebase on the NYSVMS website, [www.NYSVMS.org](http://www.NYSVMS.org).)

5. Record Retention – all controlled substance records (including the patient's medical records) must be retained for **five** (5) years.

6. Responsible Party – although controlled substance recordkeeping responsibilities are often delegated to a another veterinarian or a licensed veterinary technician, the DEA-licensed veterinarian will be held responsible for the accuracy of the controlled substance records. The DEA-licensed veterinarian should know all the federal rules for controlled substance use; a practitioner's manual is available on the DEA website at: [www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html).

B. Controlled Substances Records

1. Record of usage – a *Veterinary Controlled Drug Disposition Record* (controlled substance log) should be used to record the administration and dispensing of controlled substances in the facility. A separate log must be kept for each controlled substance, and must record the total amount of the drug in the facility after each use or after any amount is dispensed.

2. Purchase Records – records of controlled substance purchases should include a copy of the federal order form (DEA form 222), date of delivery, name and quantity of drugs, and the name, address and DEA registration number of the supplier of the drug. DEA regulations require that purchase records for Schedules I and II controlled substances be kept separate from records for Schedule III, IV and V controlled substances.

3. Inventory – a biennial inventory of all controlled substances must be completed by May 1 of every odd-numbered year or the date listed on the veterinarian's DEA registration. An inventory must always note whether it is taken at the beginning of the day or the end of the day. DEA recommends that in-house inventories be performed more frequently than bi-annually.

C. Euthanasia Drugs

Bottles of euthanasia drugs should be stored in a locked cabinet that meets the requirement for controlled substances, and separated from all other injectibles.

D. Out of Date Products

Out of date pharmaceuticals, biologicals and supplies should not be stocked or used. Out of date controlled substances must be disposed of as required by the NYS Bureau of Narcotic Enforcement (see Destruction or Disposal, above).

E. Medications and Safety

Prescription medications must be dispensed in child-resistant packaging and should be labeled with:

1. Client identification
2. Patient identification – name of animal and species
3. Identification of medication, including strength and quantity
4. Date dispensed
5. Instructions for use, including withdrawal time and precautionary information, if applicable
6. Necessary warning labels
7. Name of dispensing veterinarian; practice identification, including facility name, address, and telephone number
8. Expiration date, when applicable
9. Statement to appear on label: For Veterinary Use Only

If medications are dispensed in the manufacturer's original container, the manufacturer's instructions should be included.

If medications are dispensed in other than the manufacturer's original container, the container should be equipped with a child resistant cap unless a non-child resistant cap is requested by the client. Further information regarding child-resistant containers is available at:

<http://www.cpsc.gov/CPSCPUB/PUBS/5104.html>.

F. Compounding Medications.

Be fully aware of the legal risks inherent in prescribing any drug compounded in-house or by a compounding pharmacy. Trademarked or generic drugs must be used if available. A compounded drug may be ordered for a single patient only, and cannot be stockpiled in the veterinary hospital for other uses.

G. References.

1. The Animal & Veterinary section of the US Food and Drug Administration website: [www.fda.gov/AnimalVeterinary/default.htm](http://www.fda.gov/AnimalVeterinary/default.htm)
2. FDA Veterinarian Newsletter: [www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/default.htm](http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/default.htm)
3. Information on veterinary biologics in the Animal Health section of the USDA website: [www.aphis.usda.gov/animal\\_health/vet\\_biologics/](http://www.aphis.usda.gov/animal_health/vet_biologics/)
4. For further guidance on dairy farm drug labeling and storage, refer to Appendix B of these standards

## VI. Clinical Pathology Laboratory

- A. Clinical pathology may be provided in the hospital or through the use of outside laboratories. Results of life-dependent procedures should be available within twenty-four (24) hours following sample collection. Instrumentation for tests performed on premises must be adequate. The monthly use of standardized test samples for evaluation of laboratory accuracy is recommended. The same sample from one patient should be tested in-house and at a reference laboratory (split sample) at least once yearly to monitor and verify the accuracy of an in-house laboratory. Use an accredited outside laboratory to ensure accurate results.

- B. Clinical pathology services should include the following:
  - 1. Hematology and Serology
  - 2. Analysis of body fluids, feces and urine
  - 3. Microbiology, culturing and antibiotic sensitivity
  - 4. Parasitological examination
  - 5. Cytology/Histopathology
  - 6. Necropsy
- C. Specimen Log  
A continuous sequential record of laboratory specimens is recommended.

## **VII. Imaging Department**

### **Veterinary Radiographic Installations**

- A. Equipment and Use  
All radiographic installations should meet the applicable provisions of the NY Sanitary Code, found in Section 225 of the Public Health Law, and the DOH regulations in 10 NYCRR. In Part 16 of the regulations (Ionizing Radiation) Sections 16.50–16.52 are generally applicable; Section 16.54 applies specifically to veterinary installations (see [www.health.state.ny.us/environmental/radiological/radon/radioactive\\_material\\_licensing/docs/part16.pdf](http://www.health.state.ny.us/environmental/radiological/radon/radioactive_material_licensing/docs/part16.pdf) for a copy of the regulations).
  - 1. Fixed Radiographic Installations
    - a. Equipment
      - i. Should be of diagnostic type.
      - ii. Collimating devices should be used.
      - iii. Exposed x-ray films should show substantial evidence of cutoff.
      - iv. Timer should terminate exposure at a pre-set time. The exposure switch should be of the dead man type and should be so arranged that it cannot be operated outside a shielded area.
    - b. Structural Shielding  
Control apparatus for the radiographic equipment should be located in an adjacent room or in a fixed booth within the same room provided such a booth is composed of radiation shielding to a minimum height of seven feet.
    - c. Conditions for Operation of Equipment
      - i. Only persons required for the x-ray procedure should be in the x-ray room during the exposure.
      - ii. When an animal patient must be held in position during exposure, mechanical, supporting or restraining devices should be used.

- iii. Occupationally exposed individuals should hold animal patients or films ONLY WHEN CLINICALLY NECESSARY under EXTREME CONDITIONS. Such individuals should wear protective gloves having at least 0.5mm lead equivalent, a protective apron of at least 0.25mm lead equivalent, and should keep all parts of the body out of the useful beam.
- iv. The exposure of any individual who holds animals should be monitored (Film Badge Service).  
During Exposure: PREGNANT WOMEN AND INDIVIDUALS UNDER 18-YEARS OF AGE SHALL NOT HOLD ANIMAL PATIENTS OR FILM UNDER ANY CONDITION. Pregnant women and individuals under 18 years should not be in range of radiation emissions at any time.
- v. The owner may never be permitted to hold the animal during the x-ray exposure.

2. Portable or Mobile Radiographic Installations

All of the above requirements apply with the following exception: A dead man type of exposure switch shall be provided with a cord sufficiently long so that the operator can stand at least six feet from the animal patient, the x-ray tube, and the useful beam.

B. Film Quality

Exposed films should be of diagnostic quality. Measuring calipers should be available to accurately determine the thickness of the part being radiographed. Various devices to position patients should be available. A technique chart should be mounted near the x-ray control panel.

C. Film Identification

All films should be permanently identified with the name of the facility, the patient's owner's name, patient identification, the date, and the film file number. There should be various lead characters available to help identify positioning attitudes (e.g. R, L, VD, DV).

D. Location

It is desirable to have a room devoted solely to radiology; however, the room may serve other purposes provided it is not the aseptic surgery operating room.

E. Posting Equipment Registration

A State of New York Department of Health Certificate of Registration for Radiographic Installations must be conspicuously posted. The Department may accept, in lieu of registration with the Department, registration with the New York City Department of Health and Mental Hygiene.

F. Safety Equipment

- 1. The following protective accessories must used if an employee is manually restraining an animal for a radiograph:
  - a. Lead aprons in sound condition.

- b. Lead gloves or mitts in sound condition.
    - c. Lead lined walls and/or lead lined control booth.
  2. Film Badge Service. The DOH regulations require that all employees of a facility with a radiographic installation wear a film badge if they can be expected to receive an annual dose of radiation in excess of levels set forth in the regulations (see section 16.11 and 16.6). Employees assisting in radiology should wear film badges when radiographs are being taken. Film badges should be worn on or near the collar. If the radiographic case load is high, it is recommended that all employees wear film badges during all hours of employment.
  3. The following protective accessories are highly recommended for any employee assisting with radiographs:
    - a. Lead collars protecting the thyroid.
    - b. Lead impregnated glasses.
  4. Film badge records should be retained until DOH authorizes disposition of the records. These records must be retained even if the veterinary practice closes or removes its radiographic equipment.
  5. Employees shall be advised annually, in writing, of the employee's exposure to radiation as shown in the records maintained in the veterinary practice.
  6. Reference: see [www.health.state.ny.us/environmental/radiological/radiation\\_safety\\_guides/](http://www.health.state.ny.us/environmental/radiological/radiation_safety_guides/) for the NYSDOH recommendations for a radiation safety quality assurance program.
- G. Film Filing

The maintenance of a radiology log is recommended to facilitate prompt retrieval of case information. Films are part of the veterinary medical record, and must be retained for a minimum of three (3) years from the date the animal was last seen or five (5) years if the medical record shows the use or dispensing of controlled substances.
- H. X-Ray Film Developing Room
  1. The developing room should be clean, lightproof and adequately ventilated.
  2. Regardless of developing technique, a protocol should be in place that allows for the production of diagnostic images.
  3. Automatic film processors should be operated in a manner prescribed in appropriate instruction manuals.
- I. Disposal of Radiologic Fluids
  1. Radiologic fluid is considered hazardous waste by the NYS Department of Environmental Conservation, and must be disposed of in accordance with their regulations.
  2. If the facility is on a private sewage system, the material should not be put down the drain unless the septic system is permitted by DEC to handle this type of waste.
  3. If the veterinary facility is connected to a public wastewater system, the solid waste management authority should be contacted to determine if the amount and type of material in your radiologic waste fluid can be processed through their system.

4. A facility can contract with a hazardous waste hauler (such as a regulated medical waste hauler) to take the material and dispose of it properly. A company that services the equipment is often permitted to transport and dispose of this material.

### **Digital radiology**

The basic principles of radiation safety, image identification and image quality as established for film/screen technology shall apply to digital radiology installations. However, the technology that underlies digital radiology has some unique requirements.

- A. The original digital image must be stored in the dicom format.
- B. The veterinary facility must have the equipment that allows for manipulation of the image to improve diagnostic quality, conversion of the digital images to a non-dicom format such as JPEG to allow for ease of viewing.
- C. All digital images shall be available for review as needed on premises or remotely through transfer via the internet or other means of transferring electronic data.

### **Ultrasound**

- A. All ultrasound studies should be recorded on a medium that will not allow the raw data to be altered.
- B. All ultrasound studies shall be recorded on a medium that will allow for a full review of the study; static images may be obtained to supplement the recording but static images are not acceptable as the only validation of the study.
- C. All ultrasound studies shall be identified with:
  - Owner's name
  - Patient's name and/or ID number
  - Facility name
  - Date
- D. All ultrasound studies shall be available for review as needed on premises or remotely through transfer via the internet or other means of transferring electronic data.
- E. All ultrasound equipment must allow the examiner to:
  1. Obtain B mode images
  2. Obtain M mode images
  3. Label images
  4. Measure structures
  5. Record the study on a dynamic electronic medium

6. Match transducer frequency, depth of penetration and resolution appropriately for the patient and organ system/s of interest.

See Appendix C for general guidelines for digital and ultrasound imaging.

The facility is encouraged to have a representative sample of all imaging modalities used in the practice (radiographs, digital radiographs, and ultrasound studies) reviewed by a board certified radiologist once a year to obtain an independent opinion about image quality and technique.

## **VIII. Surgery Department**

### **A. Surgical Suite**

The surgical suite should be isolated from the non-surgical activities of the veterinary facility by a self-closing, self-latching, tightly fitting door that is kept closed during surgical procedures. Positive pressure ventilation or a separate ventilation system is recommended.

### **B. Surgical Equipment**

1. Essential equipment to be used in aseptic surgical procedures must be sterilized. There are several accepted methods of sterilization:

- a. Steam sterilization
- b. Dry heat sterilization
- c. Gas sterilization
- d. Chemical sterilization

For further information on sterilization and disinfecting procedures see Appendix D.

2. Every surgical pack should be dated, and if not used within the appropriate time frame, should be resterilized. (See "double-wrapped muslin" in Appendix D.)

### **C. Surgical Attire**

1. Surgeons and participating surgical assistants must wear properly prepared attire during aseptic surgical procedures, which will include gowns, gloves, caps and masks. Sterilized towels and drapes should be available.

2. Observers of aseptic surgery should wear cap, mask, and clean gown.

### **D. Sterilization indicators**

You should monitor the sterilization process you use to ensure that it is effective. Indicators should be contained within and on the surface of the surgical pack. There are several monitoring techniques available. (See "sterilizer operation" in Appendix D.)

- E. **Surgical Patient Preparation Area**  
To reduce the danger of contamination from dust, hair and skin debris, preoperative preparation must be done outside the aseptic surgery operating room. The surgical patient preparation area may be in a separate room, ward or it may be a portion of a multipurpose room. It cannot be in the aseptic surgery operating room. The area should be well-maintained, spacious, neat, clean, odor free and well-lighted.
- F. **Surgeon's Scrub Area**  
The surgeon's scrub area should be a room isolated from the non-surgical activities of the facility. The surgeon's scrub area may not be part of a multipurpose room and may not be in the aseptic surgery operating room, but should be in close proximity to it. The surgeon's scrub area should be neat, clean, odor free, well-maintained and brightly lighted.
- G. **Aseptic Surgery Operating Room**
1. **Small Animal Facility**  
The aseptic surgery operating room in a small animal facility must be a single purpose room for the performance of all aseptic surgical procedures and must be scrupulously clean. The aseptic surgery operating room cannot, under any circumstances, be used for any procedure other than aseptic surgery. The door to the aseptic surgery operating room should be closed during surgery. Positive pressure ventilation is recommended. Optimal lighting is essential.
  2. **Large Animal Facility**  
The aseptic surgery operating room in a large animal facility should be a single purpose room for the performance of all aseptic surgical procedures and must be exceptionally clean. Optimal lighting is essential.
  3. **The operating room must include the following:**
    - surgical lamp
    - instrument table
    - gas scavenger system (must meet OSHA rules and regulations)
    - operating table (stainless steel)
    - O<sub>2</sub> supply
    - emergency lighting
    - emergency medications
    - gas anesthesia machine
    - waste receptacle
  4. **Other items that are highly recommended include:**
    - respiratory monitor
    - suction equipment
    - intravenous fluid stand
    - esophageal stethoscope (not L.A.)
    - pulse oximeter

- automatic respirator
- cardiac monitor
- wall clock with sweep second hand
- wall mounted radiograph view box
- supplemental heat for intra-op patients; circulating water systems are recommended

5. Items not used for surgery should not be in the surgical operating room. Surgically related items, in limited amounts, may be stored in the aseptic surgery operating room.

6. Disposal of sharps and infectious medical waste from surgery must be done in accordance with NYSDOH regulations.  
(see [www.health.state.ny.us/facilities/waste/](http://www.health.state.ny.us/facilities/waste/))

H. Surgical Patient Recovery Area

The surgical patient recovery area may be a separate room or may be part of a medical/surgical ward. The recovery area or room must be located where the patient can be readily and closely observed until appropriate protective reflexes have returned, but should not be located in the aseptic surgery operating room. Supplemental heat for post-op and critical care patients should be available. The anesthetized patient must be constantly observed during the recovery period with an endotracheal tube in place until the swallowing reflex has been re-established.

I. Surgery Log

The maintenance of a surgery log is recommended. The log may be used as the anesthetic administration record. These logs are part of your veterinary medical records, and retention times mandated for medical records must be followed.

J. Laser Equipment

**Laser Safety for a Class IV Laser**

1. The veterinarian should understand basic safety information concerning the use of a laser if one is used in the veterinary practice.

2. Information on the safe use of lasers can be found in standards documents Z136.1 and Z136.3, available for purchase from the American National Standards Institute ([www.ansi.org](http://www.ansi.org)); also available through the Laser Institute ([www.laserinstitute.org](http://www.laserinstitute.org)). The ANSI guidelines are cited by OSHA as the best resource for information about using lasers safely. We strongly recommend that the user read these two ANSI standards before using a laser in clinical practice.

3. Safety courses in laser use are conducted by the Laser Institute and the schedule can be found on their website.

4. Using the information from the ANSI guidelines, a practice should develop protocols for laser use in the facility. The protocols should address procedures to guard against the specific hazards associated with laser use, including:

- Eye hazards
- Skin hazards
- Smoke plume hazards
- Fire hazards
- Gas embolisms
- Electrical and facility hazards

**IX. Dental Standards**

- A. All dental procedures should be performed under general anesthesia with endotracheal intubation, using cuffed and appropriately sized endotracheal tubes.
- B. Veterinarians and LVTs performing dental procedures should wear protective equipment (eye protection, masks and gloves).
- C. Dental services should include prophylaxis (scaling and polishing).
- D. A thorough oral cavity examination should be performed by a licensed veterinarian.
- E. Dental radiography is strongly recommended, especially when extractions are performed. Extractions are considered to be surgery, which must be performed by a veterinarian.
- F. Appropriate dental instruments should be available (ultrasonic or similar scaler, sharpened curettes and hand scalers) and a dental polisher (electric, compressor or gas driven low speed handpiece) should be employed after scaling. Single use, disposable prophy cups should be utilized.
- G. Instruments used should either be single use or sterilized after each use.
- H. The medical record must document the condition of the dentition and oral cavity, and should be maintained and updated with each procedure.
- I. Dental procedures should be performed in an area away from other practice activities to minimize the exposure of staff and other patients to infectious aerosolized material.
- J. Pain control (combination of regional analgesia and medical) should be provided, where appropriate.
- K. Documented home care instructions should be provided to clients at discharge.

**X. Treatment Area**

- A. The treatment area should be brightly lit, well-maintained, clean, neat and odor free. In a small animal facility, it is advisable to have a gas anesthesia machine that is limited to treatment room use.
- B. The treatment area should be of sufficient size to allow uncongested traffic through the area as well as adequate space for veterinarian, assistants and patients, all of whom may be in the area at the same time. An exhaust fan in the treatment area is advisable.
- C. The treatment room cannot be used as an aseptic surgery operating room.

**XI. Patient Housing Area**

- A. The patient's comfort and welfare must always be of primary importance. Sufficient staff must be available to ensure adequate nursing and handling of the patient. The patient housing area should be an appropriate environment for the recuperating patient, for the staff performing their duties and for visiting owners.

Animal compartments (e.g. cages, pens, stanchions and stalls) must be structurally sound and in good repair. They must be large enough to permit the patient to stand up, turn around and lie down in a fully stretched out position, even when compartment accoutrements are in place. They should be maintained in good structural condition to ensure that the animal patient cannot escape, and that it will be safe from injury inside.

Construction and design of the animal compartments should facilitate cleaning, sanitizing, and should prevent animal-to-animal contact. Surfaces should have an impervious finish that will not permit fluids to be absorbed, and that can be thoroughly and repeatedly cleaned and disinfected without retaining odors.

If the housing compartment is constructed of metal strands, the construction must not allow the animal's feet to pass through any opening in the floor. The flooring should not sag or bend substantially between structural supports.

The patient housing area must be a clean, neat, orderly area that is well-maintained, free of objectionable odors, and vermin free. The housing area should be ventilated at all times to provide for the health and well-being of the animal patients, with ventilation from windows, vents, fans or air conditioners that minimizes drafts, odors and moisture condensation. This area must be kept at a comfortable temperature for the animal patients, consistent with a temperature that aids their health and well-being. The patient housing area should be provided with adequate lighting sufficient to allow for good observation of the patient's condition, routine inspection of the housing, and adequate cleaning.

The housing area should be cleaned periodically; excess water, excretions and waste material should be removed during cleaning. Cleaning of housing enclosures with sterilizing agents or agents toxic to animals should not be done while the animal remains inside the enclosure.

Fresh water should be available to animal patients, as appropriate, provided in a clean and sanitary manner.

- B. Nursing supervision of the patients, night and day, must be consistent with their physical condition.
- C. Hospitalized patients should wear identification bands or tags. The I.D. bands or tags should have sufficient information included to accurately identify the patient. Each cage, stall or pen should have an IDENTIFICATION TAG imprinted with owner's name, animal's name and precautions to be observed. Any animal scheduled for euthanasia must have a distinctive identification tag on the cage that indicates the animal is to be euthanized.

## **XII. Exercise Area**

### **A. Small Animal Facility**

1. Exercise areas should be large enough to be accommodate any patient. The areas should be constructed to:

- a. prevent direct animal-to-animal contact
- b. be well-drained -- pitched sufficiently to dry rapidly
- c. be impervious to urine
- d. prevent inadvertent escape

2. A ratio of one exercise area for every 6-10 compartments is acceptable.

3. In lieu of exercise areas, walking of individual patients on a leash outdoors is acceptable. If exercise is provided in this manner, sufficient ward staff must be available to walk patients for a period long enough to accomplish evacuation. In most cases a minimum of two (2) exercise periods in a twenty-four (24) hour period is necessary. The exercise area must be kept clean and sanitary. Animal waste must be removed between patients.

4. Intensive efforts should be made to eliminate odors through the use of ventilation, hot water, sanitizing and disinfection.

### **B. Large Animal Facility**

Exercise areas in a large animal facility may be minimal, providing the housing compartment provides enough room for the animal to turn around and lie down.

### **C. Animal Enclosures**

All yards, runs, corrals, pens, paddocks, alleys, chutes, stanchions and ramps should be neat, well-maintained, well-drained, escape proof and free of offensive odors and vermin.

### **XIII. Library**

The library should be capable of providing pertinent information to serve the needs of the veterinary staff. Library resources must be current. The use of DVDs, computer resources and online information (such as VIN) should be encouraged.

### **XIV. Storage Areas**

- A. Storage areas, basements, attics and outbuildings should be uncluttered and vermin free. Flammable items, compressed gases and volatile agents should be stored in a proper manner.
  - Flammable items should not be stored within the facility unless adequate fire safety precautions are observed.
  - Compressed gases should be cradled or chained to a wall.
  - Volatile agents should be stored in an area vented to the exterior.
- B. Closed storage should be provided for housekeeping supplies and equipment. The area above the small animal compartments, if used for storage, should have doors.
- C. The feed and bedding storage area in a large animal facility should be orderly, dry and vermin free. Precautions should be taken to guard against fire when flammable items such as hay and straw are stored.

### **XV. Mortuary**

The mortuary should be clean and odor free. Companion animal cadavers should be stored under refrigeration until the owner decides on the method of disposal and completes the required pet disposal form. The use of plastic body bags is essential. Cadaver disposal should be accomplished in a manner that is acceptable to owners and complies with state and local laws. Any individual involved in the disposal of an animal's body must continue to act with respect toward that animal.

### **XVI. Toilet Facilities**

Toilet facilities should be clean, properly equipped, odor free and lockable. Facilities should be available to both staff and clients.

## **XVII. Professional Apparel**

- A. Apparel of the veterinarians and staff members should be professionally appropriate, neat and clean.
- B. Identifying badges indicating name and title should be worn by all staff. The title should indicate which staff members are licensed veterinary professionals. The use of name tags permits the client to identify staff members.

## **XVIII. Emergency Service**

While an animal hospital or animal clinic need not be open to the public at all times, information on obtaining veterinary service in emergency situations must always be available. Emergency service may be provided in various ways, but that information should be easily available to the client with an emergency, through a telephone answering message and a posted sign (see Interior of Facility, I.B.2, page 3.).

## **XIX. Safety**

- A. Fire
  - 1. Every facility should develop a fire evacuation plan, which should include:
    - Procedures for notifying employees and other persons of a fire or other emergency
    - Procedure for notifying the fire department and/or other emergency response organization
    - Identification of emergency exit or escape routes
    - Procedures to be followed for employees who must remain to operate critical equipment before evacuating
    - Procedures for evacuating any animals in the facility at the time of the emergency
    - Procedures for accounting for employees and other occupants after evacuation has been completed
    - Identification of persons responsible for overseeing emergency evacuation
  - 2. Procedures to follow in case of fire should be conspicuously posted and should be clearly understood by the staff.
  - 3. Exits must be marked by an approved exit sign readily visible from any direction. Exit signs must be illuminated. Fire exits may not be locked from the outside, or with a keyed lock; fire exits must be accessible at all times and cannot be blocked.

4. Fire drills should be scheduled on a regular basis, and should be designed in cooperation with the local fire department. Frequency of fire drills depends on the type and size of the building; consult your local fire department for guidance.
  5. Portable fire extinguishers should be located in conspicuous locations where they will be readily accessible and immediately available for use. Consult your local fire department or the building code enforcement officials for assistance in choosing an appropriate fire extinguisher and in determining how many should be present in the facility. Fire extinguishers should be inspected and recharged annually or in accordance with the manufacturer's instructions.
  6. A fire alarm and detection system must be installed. The type of alarm system required will depend on the age and type of construction of the building. Consult your local fire department or the building code enforcement officials for assistance in choosing an appropriate fire or smoke alarm system and in determining how many should be installed in the facility. Alarms should be connected to an external power source and should be capable of sending an alarm directly to the fire department if no one is in the building at the time of a fire emergency.
  7. Certain types of construction may require the installation of an automatic sprinkler system connected to the fire detection system. Consult your local fire department or the building code enforcement officials to determine whether you should install a sprinkler system.
  8. The local fire department should be asked to conduct an annual fire prevention evaluation of the facility.
- B. Theft and Burglary
1. There are many valuable items in a veterinary practice that make theft a distinct possibility. The local law enforcement officers should be encouraged to watch the facility during the hours no one is in attendance.
  2. Burglar alarms and other security systems should be considered. If there are controlled substances present on the premises, DEA may require that you install a burglar alarm or monitoring system for the entire facility or for the area where controlled substances are kept.
  3. Theft of any controlled substances must be reported to DEA (use DEA form 106 - Report of Theft or Loss of Controlled Substances) and the NYS Bureau of Narcotic Enforcement (use DOH form 2094 - [www.health.state.ny.us/forms/doh-2094.pdf](http://www.health.state.ny.us/forms/doh-2094.pdf)) within one day. Theft of any official NYS prescription form must also be reported to the NYS Bureau of Narcotic Enforcement. Any burglary should be reported to the police.
- C. Emergency Telephone Numbers

Appropriate telephone numbers for the following should be conspicuously posted at the outside line phones in the facility:

- Police Department
- Ambulance/Rescue
- Fire Department
- Poison Control Centers (human and animal)
- Utilities (gas, electric, water)

D. Hazards

The following items commonly found in a veterinary facility may be considered hazardous to employees in the facility:

- ionizing radiation
- lasers
- flammable and combustible liquids
- chemotherapy drugs
- other drugs
- pathogens contagious to humans
- "sharps" – needles and syringes

OSHA Standards should be observed to minimize hazardous conditions in the facility.

1. Hazardous Materials Training Program

A hazardous materials training program should be implemented to ensure compliance with Federal requirements. Programs for veterinary facilities have been developed by:

- a. American Animal Hospital Association  
[www.aahanet.org](http://www.aahanet.org)
- b. AVMA Professional Liability Insurance Trust  
[www.avmaplit.com](http://www.avmaplit.com)
- c. SafetyVet  
[www.safetyvet.com](http://www.safetyvet.com)

These programs are designed to meet federal "Right to Know" requirements for employee training on hazardous materials. Federal law requires that veterinarians must:

- inform their employees of the dangers of hazardous substances used in the practice;
- train employees in proper procedures for their storing, handling, mixing, and disposal; and
- document training provided to employees.

2. OSHA Requirements – Chemicals on Premises

- a. Hazard Communication Plan (HCP) (See Appendix E for an example or consult [www.safetyvet.com/osha/chemplan.htm](http://www.safetyvet.com/osha/chemplan.htm) for assistance in writing your own HCP). The Hazard Communication Program is the written plan dealing with chemicals that are present

in the workplace. The HCP is meant to be a reference manual for employees, and must contain details on labeling requirements, safety procedures to be followed, dissemination of emergency information and staff training. The HCP must list the specific chemicals used in the veterinary practice that are considered hazardous by OSHA.

- b. Material Safety Data Sheets (MSDS)
  - 1. You must have an MSDS for each hazardous material in the building.
  - 2. There must be one individual designated to update and maintain the MSDSs.
  
- c. Labeling
  - 1. The HCP explains the labeling system used in the clinics.
  - 2. A designated person ensures that hospital containers are properly labeled.
    - a. Legible labels
    - b. Contents, Hazardous Warnings and any dilutions made.
  
- d. Staff Training
  - 1. The HCP describes the format of the training to be done.
  - 2. The HCP describes all elements of the training; i.e. HCP, MSDS, etc.
  - 3. A qualified person is designated to conduct the training.
  - 4. Records are kept of employee training.
  - 5. New employees are promptly trained.
  - 6. Biomedical waste handling is covered in training program.
  - 7. Program explains the use and location of personal protective equipment and clothing.
  - 8. Instruction provided on use and location of fire extinguishers.
  - 9. Fire-extinguisher dates should be checked by a designated person.
  - 10. A system of reporting job-related accidents should be in place.
  - 11. A person should be designated to handle non-routine hazardous tasks.
  
- e. Miscellaneous
  - 1. A central area should be maintained for posting OSHA information.
  - 2. Hospital floor plans should be posted throughout the building to assist in evacuation.
  - 3. A fire emergency evacuation plan should be posted.
  - 4. Emergency telephone numbers should be posted in readily-available areas.
  - 5. A first aid and a hazardous spill kit should be maintained.
  - 6. Exits and non-exits should be labeled.
  - 7. Fuse boxes (circuit breakers) should be labeled.

8. Human consumption items should be kept in separate containers from hospital materials.
9. Containers and refrigerators that contain biomedical materials should be marked with HAZARDOUS labels.
10. An eye-wash station should be strategically located and all employees trained in its use.

- E. **Veterinary Facility Emergency Policy**  
Every veterinary practice should have an established protocol for the various types of emergencies that may occur over time. Seeing that this task is done will eliminate confusion and ensure that the appropriate measures are taken in an emergency.
- F. **Emergency Lighting**  
The veterinary facility must be equipped with battery-powered emergency lighting. The lighting should be of sufficient strength to permit a person with poor vision to find building exits safely. You may consider utilizing a generator that will provide lighting and other electrical power in case of an emergency.

**XX. Mobile Practice**

- A. Veterinarians operating a mobile veterinary practice or providing mobile services onsite at the client's location are subject to the same laws and regulations as those practicing from a fixed location.
- B. **Vehicles used in a mobile practice**
1. Vehicles should be well maintained. The exterior of the vehicle must be clean and in good repair. The interior must be orderly.
  2. Refrigeration must be provided for products requiring a controlled temperature.
  3. A medical waste receptacle and a sharps container should be available for use.
  4. Stored water should be available if water is not available at the site of the call.
  5. Disinfectant should be available for washing boots unless plastic disposable boots are used on calls. Disease control dictates that footwear be clean upon entering and leaving each farm, stable, kennel or residence.
  6. An adequate supply of clean clothing should be available.
  7. The vehicle should carry instruments, sterile supplies and medication adequate to resolve the majority of practice occurrences.
  8. Controlled substances carried in the vehicle must be locked in a container affixed to the frame of the vehicle, and the vehicle itself must be locked whenever controlled substances are in that locked container.
  9. Adequate emergency lighting should be carried.
  10. Personal Protective Equipment should be carried.

## Appendix A: Veterinary Drugs

Title 21, Code of Federal Regulations, Part 201.105, concerning the sale of veterinary prescription drugs, contains specific provisions which limit the dispensing of certain drugs intended for use by veterinarians.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

Section 502(f)(l) of the Food, Drug and Cosmetic Act - requires the labeling of drugs, including veterinary drugs, bear adequate directions for use.

[http://www.fda.gov/ora/compliance\\_ref/cpg/cpgvet/cpg608-500.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg608-500.html)

In the clinic, veterinary prescription drugs should be stored separately from over-the-counter drugs, and be easily distinguishable to the professional and para-professional staff. Drugs should be stored under conditions set forth by the manufacturer. Veterinary prescription drugs should not be openly displayed or promoted for sale to the public. All drugs should be examined periodically to ensure cleanliness and current dating.

Veterinary drugs for which adequate directions for use cannot be prepared, and which therefore cannot be safely used except by or under the supervision of a veterinarian, must bear on their label the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." Occasionally, animal drugs may bear a label statement such as "Sold only to licensed veterinarians." Such a statement has no basis in law but is intended to reflect the sales policy of the manufacturer or distributor.

Sale or dispensing, making shipment or otherwise making available for use in animal(s) to the lay person of an animal drug whose label bears this "caution" legend may be used only by or on the bona-fide order of a duly licensed veterinarian. Such sale of a prescription legend drug must come about as a result of a proper doctor/client/patient relationship which cannot normally be established merely through letter or telephone communication between a veterinarian and a layman.

Conviction of a first offense is a misdemeanor; conviction of a second offense is a felony that could lead to a fine of \$250,000 and one year in prison on each count. Conviction of a felony could lead to revocation of a license to practice veterinary medicine.

### **According to interpretation of the FDA, a veterinarian/client/patient relationship exists when:**

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian;
2. The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This

means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) and/or by medically appropriate and timely visits to the premises where the animal(s) is kept;

3. The practicing veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage in event of adverse reactions or failures of the regimen of therapy.

### **FEDERAL LEGEND DRUGS**

There are about 1,500 veterinary prescription drugs, all have health hazard potential. Keep in mind: any drug bearing the legend "**Caution: Federal Law restricts this drug to use by or on the order of a licensed veterinarian**" is covered by the law.

For a complete list of veterinary drugs and their manufacturers see the 2002 online Green Book at the FDA website center for Veterinary Medicine:

<http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847>

## **Appendix B: Veterinary Drug Use in Food Animals**

- **Animal Medicinal Drug Use Clarification Act (AMDUCA)**
- **Pasteurized Milk Ordinance (PMO)**
- **Food Animal Residue Avoidance and Depletion Program (FARAD)**

# **Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA): Extra-label Drug Use in Veterinary Medicine**

*by Gillian Comyn, D.V.M., M.P.H., D.A.C.V.P.M.*

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### ***Introduction***

Since 1994, when Congress passed the **Animal Medicinal Drug Use Clarification Act** of 1994 (AMDUCA), veterinarians in the U.S. have enjoyed legitimate extra-label use (ELU) privileges. Veterinarians can safeguard ELU privileges by following AMDUCA, and by educating clients (particularly food animal producers) on AMDUCA and prudent drug use principles. This article outlines key points of AMDUCA in plain language.

### ***Animal Medicinal Drug Use Clarification Act***

Extra-label drug use (ELU) refers to the use of an approved drug in a manner that is not in accordance with the approved label directions. ELU of new animal drugs was considered illegal and permitted only as a matter of enforcement discretion until the passing of AMDUCA. AMDUCA amended the Federal Food, Drug, and Cosmetic Act (the Act), legalizing extra-label drug use by and under the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and became effective in 1996 when implementing regulations (21 CFR Part 530) were published.

AMDUCA allows veterinarians to prescribe extra-label uses of certain approved animal drugs and approved human drugs for animals under specified conditions.

### ***The key components and conditions of AMDUCA are as follows:***

- Veterinarian-Client-Patient Relationship (VCPR)
- General Conditions for Extra-Label Use Under AMDUCA
- Conditions for Extra-Label Use in Food Animals
- Compounding Under AMDUCA
- Prohibitions Under AMDUCA

### ***Veterinarian-Client-Patient Relationship (VCPR)***

The regulation defines a valid veterinarian-client-patient relationship as one in which:

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

***General Conditions for Extra-Label Drug Use Under AMDUCA***

1. There is no animal drug approved for the intended use;
2. Or, there is an animal drug approved for the intended use, but the approved drug is not in the required dosage form or concentration;
3. Or, the approved drug has been found to be clinically ineffective when used as labeled;
4. Or, if the intended use is in a non-food animal, an approved human drug can be used even if an approved animal drug is available.
5. In food animals, use of approved human drugs is not permitted if (an) approved animal drug(s) can be used.
6. **RECORDKEEPING:** The veterinarian must maintain records with animal identification (in food animal practices, on a group, herd, flock, or per-client basis). The records have to include: established name of the drug and its active ingredient, or if formulated from more than one ingredient, established name of each ingredient; condition treated; species of the treated animal(s); dosage administered; treatment duration; number of animals treated; and withdrawal, withholding, or discard time(s), for meat, milk, eggs, or any food from the animals treated. The veterinarian must keep these records for 2 years or as required by Federal or State law, whichever is greater. The records must be available at any reasonable times to FDA designated personnel, for copying and verifying.
7. **LABELING:** The label on a drug dispensed for ELU, whether by a veterinarian or dispensed by a pharmacist on the order of a veterinarian, must have the following information: name and address of the prescribing veterinarian (and the pharmacy if dispensed this way). Also, the labeling must have on it the following:
  - animal identification (individual for companion animals, or group or pen if food animal),
  - indication (what condition is the drug being used to treat),
  - number of animals treated (in the case of food animals),
  - dosage, route, and duration of treatment,
  - withdrawal intervals, and,
  - any cautionary statements (for example: not for use in horses intended for food).
8. AMDUCA does not allow extra-label drug use in animal feeds.
9. AMDUCA does not permit veterinarians, or pharmacists, to compound unapproved finished new animal drug products from bulk drugs

***Conditions for Extra-Label Use in Food Animals***

1. Before prescribing or dispensing an approved new animal or human drug for an extra-label use in food animals, the veterinarian must:
  - make a careful diagnosis and evaluation of the conditions for which the drug is to be used;
  - provide an estimated, scientifically-based, withdrawal interval for the milk, meat, eggs, or other edible products from the treated animal (this information may be obtained by the veterinarian in context of a VCPR from among other sources, scientific literature, academia, or the Food Animal Residue Avoidance Databank (FARAD)<sup>2</sup> ;
  - make sure that the identity of the treated animal or animals is maintained;
  - take measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extra-label treatment.
2. When considering extra-label use of an approved human drug in food animals:
  - the veterinarian must have medical rationale for the use;
  - the veterinarian may not use an approved human drug if an animal drug approved for use in food-producing animals can be used instead for the particular ELU; and
  - if scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.

***Compounding Under AMDUCA***

FDA defines compounding as the manipulation of drugs to obtain products that differ from the starting materials in an approved dosage form drug. Under AMDUCA, compounding is considered to be extra-label drug use, and must be done from approved finished dosage form human or animal drugs only. Like any extra-label use, compounded drugs should not be used if an approved drug can be used at its approved dose and dosage form. AMDUCA does not permit veterinarians, or pharmacists, to compound unapproved finished new animal drug products from bulk drugs. Unless conditions set forth in 21 CFR 530.13(b) are met, the compounding of a new animal drug from an approved human or animal drug results in an adulterated new animal drug.

***Conditions for Compounding***

1. all relevant portions of the regulation have been complied with;
2. there is no approved new animal or approved new human drug that when used as labeled or in the available dosage form and concentration, will properly treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;
3. the compounding is performed by a licensed pharmacist upon the order of a veterinarian or by a veterinarian within the scope of their professional practice;
4. adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;

5. the scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and
6. all relevant State laws relating to the compounding of drugs for use in animals are followed.

### ***Prohibited Drug Uses Under AMDUCA***

As described above, AMDUCA allows FDA to place limits on certain extra-label drug uses in animals. These limits include prohibitions of certain extra-label uses. Though The Act provides a stepwise procedure leading to a prohibition, the Agency does not have to take all the steps before prohibiting an extra label use if it finds that the extra-label drug use “presents a risk”.

When assessing the risk from an extra-label drug use, the Agency may inspect a veterinarian’s records. The purpose of the inspection is to document the extent and nature of the extra-label use, not for enforcement reasons. The Agency provides informal public notice when it makes such a finding. If the Agency finds that an extra-label drug use presents a risk, or a required analytical method has not been developed, the Agency may prohibit the use. Any new prohibition ordered by the Agency will be published in the Federal Register, with a ninety-day delayed effective date and a sixty-day comment period. The order will be effective in ninety days, unless it is revoked or modified, or the comment period is extended. When a prohibition or any other important regulatory change is codified, the notice is posted immediately on the CVM web site and disseminated through printed media (FDA Veterinarian, veterinary and trade journals and other sources).

### ***The Current List of Drugs Prohibited From Extra-Label Use (As listed in 21 CFR 530.41)***

These drugs (both animal and human), families of drugs, and substances are currently prohibited for extra-label uses in all food-producing animals, (including horses intended for human food):

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Dimetridazole
- Ipronidazole and other nitroimidazoles
- Furazolidone, Nitrofurazone, other nitrofurans
- Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxyypyridazine)
- Fluoroquinolones
- Glycopeptides (example Vancomycin)
- Phenybutazone in female dairy cattle 20 months of age or older

(Editor’s note: This list is complete as of press date, see related article FDA Order Prohibits Extra-Label Use of Phenybutazone.)

***Conclusion***

AMDUCA legalized extra-label use of approved animal and human drugs in animals when that use is under the supervision of a veterinarian and in accordance with FDA regulations. AMDUCA provided veterinarians with privileges comparable to those generally enjoyed by physicians. Veterinarians can protect these privileges by complying with AMDUCA, and understanding the permitted and prohibited extra-label drugs and uses (including compounding).

For more information on AMDUCA, other regulations and policies, and to request hard copies, please visit the CVM Home Page, and look under Quick Index. Notices of proposed rulemaking and final rules, such as additions to prohibited drug list, are announced by Federal Register notices and posted on the CVM Home Page and the FDA Dockets Advanced Publication Display website.

*Dr. Comyn is a Consumer Safety Officer in CVM's Division of Compliance.*

**MEDICAL RECORD REQUIREMENTS**

- Identify the animals, either as individuals or a group.
- Animal species treated.
- Numbers of animals treated.
- Conditions being treated.
- The established name of the drug and active ingredient.
- Dosage prescribed or used.
- Duration of treatment.
- Specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or animal-derived food.
- Keep records for 2 years. (NY State requires retention of treatment records at the farm and veterinarian for 3 years.)
- FDA may have access to these records to estimate risk to public health.

Additional information for food animal practitioners concerning compliance with AMDUCA is available at: <http://www.avma.org/reference/amduca/amduca1.asp> .

### **Pasteurized Milk Ordinance – 2007**

The Grade "A" Pasteurized Milk Ordinance (PMO), with Appendices, governs the production, storage, transportation and processing of fluid milk. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce.

ITEM 15r and Appendix N are of particular interest to dairy veterinarians as these sections deal with drug and chemical use, storage and labeling on the farm and residue testing. Practitioners have a responsibility to assist dairy farmers to properly label, use and store drugs on their dairy farms. Violations of any of these regulations could result in the loss of a farm's permit to sell Grade A milk and place the farm and/or veterinarian in jeopardy of regulatory action. Current drug labeling requirements for dairy farms indicated in the PMO are fully compatible with the labeling requirements outlined in AMDUCA. The most current version of the PMO is available at the website listed below.

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSModelDocuments/PasteurizedMilkOrdinance2007/default.htm>

### **Food Animal Residue Avoidance and Depletion Program (FARAD)**

FARAD is a computer-based decision support system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. The drugs and pesticides used in modern animal agriculture improve animal health and thereby promote more efficient and humane production.

FARAD expert-mediated assistance:

WEB ACCESS: <http://www.farad.org/>  
Call 1-888-USFARAD

**APPENDIX C: GUIDELINES FOR IMAGING IN THE VETERINARY PRACTICE. The following review of imaging in the veterinary practice will be performed during the VFAP evaluation to ensure that imaging is properly performed in the practice.**

**Digital Images**

Types of radiographic studies performed in the last six months that will be reviewed:

- Thorax –lateral and DV or VD –patient over 50 lbs; patient under 20 lbs.
- Abdomen-lateral and DV/VD-patient over 50 lbs; patient under 20 lbs.
- Pelvis-VD-patient over 50 lbs; patient under 20 lbs.
- Extremity-lateral and Cranial-caudal-any size patient.

Each image should be examined to assure that:

- It is appropriately labeled
- It is appropriately collimated
- There are no parts of any person visible in the primary beam, with or without protective garb
- The image quality is “good”

Overall considerations:

- How are images stored for each case
- How are images made available for external review
- How will the image be made available to the owner if the owner requires a copy, or for a second opinion

**Ultrasound Images**

Ultrasound images will be examined to assure that:

- Gain settings are properly adjusted
- Structures and lesions are accurately measured and labeled
- Images are recorded with clarity

Ultrasound equipment will be examined to ensure that the appropriate transducer frequency is used for different species:

- Dogs 5-10 mHz
- Cats 6-10 mHz

Ultrasound supplies should include:

- Clippers
- Ultrasound gel
- Positioning devices - foam V trough, echocardiogram table

Overall considerations:

- Are ultrasound studies matched with the medical record
- Are dynamic studies able to be copied and made available to the owner if the owner requires a copy, or for a second opinion

## **APPENDIX D: STERILIZATION AND DISINFECTION PROCEDURES**

The material in this section has been extracted from an article appearing in *Solvay Animal Health Inc. Veterinary Reports* authored by:

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Successful surgical intervention depends on the creation and maintenance of an aseptic environment. Sterilization and disinfection are techniques used to achieve this goal.

Sterilization is the destruction of all life. Consistent, absolute sterilization by any one process is now considered unattainable. Sterility is the 99.9999 probability that an item is not contaminated. Disinfection eliminates virtually all recognized pathogenic microorganisms, but not necessarily all microbial forms on inanimate objects.

### **STANDARDIZED STERILIZATION PROCEDURES**

Specific standardized procedures are necessary for the sterilization or disinfection of all supplies and equipment used in the operating room. A combination of skilled personnel, correct preliminary cleaning of the items to be sterilized, correct assembly and packaging of these items, an approved sterilizer, proper sterilizer loading, and adequate exposure of the items to the sterilizing agent are required to ensure sterilization. Proper packaging and loading of the sterilizer allow the direct contact of the items with the sterilizing agent. An adequate period of exposure provides for complete penetration of the load and ensures an acceptable margin of safety for sterilization.

Process-associated parameters include temperature, time, purity of the sterilizing agent and air, agent residue, penetration of the agent, and the capacity of the sterilizer.

### **METHODS OF STERILIZATION**

Sterilizing agents are either physical or chemical in nature. Selecting an agent depends on the material to be sterilized. Once an agent has been selected, the period the instrument is exposed to the agent is critical for achieving sterility.

**Physical Sterilization** -- The most common methods of physical sterilization are by thermal energy, radiation, and filtration.

**Thermal Sterilization** -- Moist and dry heat are the basic elements of thermal sterilization. Moist heat is either saturated steam or boiling water. Boiling water, however, is not considered a very good sterilizing agent because of its relatively low temperature at ambient pressure. Saturated steam under pressure is inexpensive and a very dependable medium for the destruction of all forms of microbial life.

**Dry heat** is relatively slow and requires higher temperatures for application. Dry heat, however, will penetrate materials (e.g., oils, petrolatum, and stoppered containers) that steam cannot permeate. The presence of moisture hastens coagulation of cellular proteins, with water acting as a catalyst for these reactions. The thermal death of cells is exponential and is always a function of the "time-temperature" relationship.

For sterilization to occur, steam must be heated to a required temperature and for a specified length of time. The steam must then penetrate every fiber and reach every surface of the item in the sterilizer. Wet sterilized packages are susceptible to recontamination as bacteria pass through damp wrapping materials. Therefore, most steam sterilizers include a drying phase.

No living organism can survive direct exposure to saturated steam at 250 deg. F (121 deg. C) for longer than 15 minutes. Shorter times of exposure may be used with higher temperatures. An effective time-temperature relationship must be maintained to achieve sterilization. In addition to the temperature within the chamber, exposure times for instruments are also dependent upon the size and content of the load.

Chamber air is the most detrimental factor to efficient steam sterilization. When air is trapped in the chamber or in wrapped items, the killing power of the steam is greatly reduced. Therefore, it is extremely important that all air is removed from the chamber and that the steam reaches the required temperature before sterilization can begin.

### **Preparation of Items for Steam Sterilization**

Instruments must be thoroughly cleaned before sterilization to minimize bioburden and remove any debris that can hinder the sterilization process. Instruments should be rinsed in cold water immediately after surgery and promptly cleaned. If exposed for some time before final cleaning, the instruments must be immersed in warm water with a detergent. Instruments can be cleaned either manually or with ultrasonic cleaning equipment.

Soft, bristled brushes and an effective detergent are necessary for the manual cleaning of surgical instruments. Special care should be taken to clean each instrument as it is almost impossible to remove all traces of debris from inaccessible areas (e.g., box locks, serrations). After cleaning, the instruments should be thoroughly rinsed and dried.

Ultrasonic equipment can thoroughly wash instrument areas that are inaccessible to other methods of cleaning.

### **Packaging Materials**

Packaging materials must cover items completely, provide an impermeable barrier against dust, microorganisms, and moisture, be resistant to damage when handled, permit penetration of the sterilizing agent, allow easy removal of the contents to a sterile field, and be economical and nontoxic. Acceptable packaging materials for steam sterilization include muslin, paper, polypropylene, and a combination of paper and polypropylene.

Muslin wraps are usually 140 threads per inch and are often of double thickness. Packages are wrapped in two layers (four thicknesses) to provide an adequate dust and microbial barrier. Muslin packages have a limited shelf life after sterilization—30 days maximum in closed cabinets and 21 days or less in open shelving.

Crepe paper is inexpensive and provides a long-term Barrier to contamination after sterilization. Crepe paper is disposable and its reuse is considered unsafe.

Polypropylene is the only plastic acceptable for steam sterilization. When used with paper, polypropylene is an excellent long-term barrier to microorganism penetration. Polypropylene also permits good visibility of package contents.

Packaging materials, with the exception of polypropylene, lose their effectiveness as contamination barriers when wet. Special care should be taken to prevent this from occurring after sterilization.

### **Packaging and Loading**

After being thoroughly cleaned and dried, surgical instruments should be arranged so that all surfaces will come in contact with the sterilizing agent.

Instrument packs should be prepared according to their intended use and placed in trays with perforated bottoms to facilitate steam penetration and to prevent the trapping of air. Complicated instruments must be disassembled and, if lubrication is necessary, a nontoxic water soluble lubricant should be used. Open containers or basins should be placed in the chamber open side down or horizontally. Sponges or drapes should not be packaged in basins. Freshly laundered and ironed linens must be fan folded or rolled loosely to provide the least possible resistance to steam penetration. The size of a linen pack should be limited to a maximum size of 12 inches by 12 inches by 20 inches and should not weigh more than 12 pounds. Linen should be placed into the autoclave in alternate vertical layers to minimize resistance to steam penetration.

### **Sterilizer Operation**

There are numerous time-temperature standards that have been established for the effective sterilization of materials. A safe minimum standard for exposure with unwrapped items is 15 minutes in saturated steam at 250 deg. F (121 deg. C). No item should be exposed for less time at this temperature. The type of material and the size of the pack are factors, especially in gravity displacement sterilizers. Wrapped instrument sets and large linen packs require longer heat-up times and exposure. Wrapped instrument sets should be sterilized for 30 minutes at 250 deg. F (121 deg. C).

Sterilization begins when the temperature in the exhaust line reaches the desired level. Following the sterilization cycle, all instrument and linen packs should be allowed to dry untouched for 20 to 60 minutes by partially opening the door of the autoclave. Wet wrappings are vulnerable to contamination. Because moisture can lead to microbial migration, drying packs should not be handled. Any pack that is wet when opened is to be considered contaminated.

Indicator Systems -- An indicator system shows that the minimal conditions for sterilization have been met. To monitor the effectiveness of an autoclave cycle, an indicator should be placed in the center of each pack. INDICATOR SYSTEMS DO NOT NECESSARILY PROVE THAT STERILIZATION HAS OCCURRED. These systems do not replace the monitoring of temperature, time and pressure. Indicator systems are not to be used as a replacement for the proper operation of a sterilizer, packaging, storage, or handling of items.

Many chemical indicators are paper strips impregnated with a chemical that undergoes a color change when a certain temperature is reached. Chemical indicators, however, do not provide the time of exposure.

Biologic indicators are preparations containing specific microorganisms that are resistant to a sterilization process. Biologic indicators are superior to chemical indicators and provide absolute proof that sterilization has occurred. All biologic indicators use an organism, rather than a natural contaminant, that is much more resistant to the sterilization process. The spore of *Bacillus stearotherophilus* is the most frequently used biologic indicator for steam sterilization.

(Sporicidal testing can be done through the Autoclave Testing Service (ATS), P.O. Box 1214 Valley Stream, NY 11582-1214. Tel. 203-325-3462. ATS supplies an ampoule or packet containing non-pathogenic spores. The ampoule is autoclaved along with the packs and is then returned by mail to ATS. The client is contacted with the results, which ATS documents.)

### **Sterile Pack Storage**

Packs that have been sterilized and dried should be stored in an area free of dust, dirt, and vermin. Packs can be safely stored in closed cabinets for longer periods because of less exposure to dust and contaminants. Sterile items should not be exposed to extremes in temperature or humidity. The date of sterilization and the expiration date should be marked on each pack.

**Double-wrapped muslin** items (four layers) and single-wrapped crepe paper items may be stored for 21 days on open shelves or 7 weeks in a closed cabinet before resterilization. The density of non-woven fabrics and plastic materials prolongs the shelf life of the sterilized pack. Tape-sealed packages wrapped in non-woven fabrics or plastic film can be stored for three to four months. Heat sealed items may be stored for six months to a year.

### **Chemical Sterilization**

For chemical sterilization, liquids or gaseous chemicals are used to sterilize materials that are sensitive to heat or moisture. Few, if any, liquid chemicals have the ability to sterilize. Ethylene oxide is the most commonly used agent for gas sterilization.

### **Sterilization with Ethylene Oxide**

Ethylene oxide is the most popular chemical agent used for gas sterilization. As a sterilant, ethylene oxide is capable of inactivating all microorganisms by replacing hydrogen atoms with hydroxyethyl groups. This alkylative reaction interferes with the metabolism of protein and the reproductive processes and results in cell death.

**CAUTION:** Use of ethylene oxide requires strict observance of OSHA regulations. There is risk to human health after exposure to the gas. Exposure also represents a potential reproductive hazard to both males and females. Personnel working in areas where ethylene oxide is used should have annual medical examinations.

## **Government Regulations**

The use and disposal of ethylene oxide is strictly regulated by state and federal governments. Because of the health concerns involved, it is very difficult for the average veterinary practice to use ethylene oxide safely.

## **Disinfection or Cold Sterilization**

A disinfectant is a substance, usually a chemical agent, that can destroy harmful bacteria or inanimate objects. Generally, disinfectants do not destroy bacterial spores, some viruses, or the tubercle bacillus. Cold sterilization is the practice of soaking instruments in disinfectant solutions.

Because disinfectants frequently do not kill bacterial spores or viruses, instruments introduced into the skin or mucous membranes should be sterilized. Only instruments that are used on unbroken skin or mucous membranes (i.e., dental instruments) can be cold sterilized. Sterilization with steam or ethylene oxide is always preferable for instruments that are used on the patient.

Most chemical disinfectants are in aqueous solution. These disinfectants should be pre-mixed and stored in properly labeled containers. Distilled water is recommended for dilution because the pH, calcium, and magnesium in tap water can inactivate disinfectants. All tap water contains *Pseudomonas* spp.

All instruments should be clean and dry before being placed in a disinfectant. The instruments should be completely submerged for the appropriate length of time, as recommended by the manufacturer, before being used.

## **Aldehydes**

- a) Formaldehyde, as a solution or gas, kills microorganisms by the coagulation of cell proteins. Formaldehyde is available in a 37 percent solution with water (formalin) and is effective against bacteria, spores, and viruses. Because formaldehyde is extremely irritating to tissues, this disinfectant must be rinsed from instruments with distilled water.
- b) Glutaraldehyde (activated, buffered 2% solution) kills microorganisms by the denaturation of protein. It is the method of choice for sterilizing heat-sensitive items if an ethylene oxide sterilizer is unavailable. Glutaraldehyde is also the liquid chemical of choice for lensed instruments because it will not damage the lenses or the cement on these instruments. Although glutaraldehyde is less irritating than formaldehyde, disinfected instruments should still be rinsed in sterile distilled water before use.
- c) Chlorhexidine -- Chlorhexidine, available in detergent, tincture, and aqueous formulations, is bactericidal at concentrations down to 100 ug/ml and is effective against both gram-positive and gram-negative organisms. This disinfectant, however, is inactive against bacterial spores at room temperature. Because Chlorhexidine is nonirritating, it is widely used as a surgical scrub. Chlorhexidine also possesses residual activity and its effectiveness increases after repeated use.

d) Iodine and Iodophors - This disinfectant has good bactericidal and viricidal activity. Tinctures of iodine are used primarily as antiseptics but are toxic to tissues at concentrations greater than 3.5 percent and will stain both tissue and fabric.

Iodophors are complexes of iodine and a carrier, such as quaternary ammonium compounds, detergents, and polyvinyl-pyrrolidone (povidone). This combination acts as a reservoir for the slow release of free iodine. Some iodophors are unstable in the presence of hard water, heat, or organic material. Generally, iodophors are reliable disinfectants if used according to manufacturers' recommendations. Both iodine and iodophors will corrode metal instruments that are disinfected for long periods.

**Quaternary Ammonium Compounds** - Quaternary ammonium compounds, including benzalkonium chloride and cetylpyridinium chloride, are surface-active agents that dissolve lipids in the cell membrane and affect cell permeability. These disinfectants are bactericidal, but have questionable efficacy against gram-negative organisms. Because quaternary ammonium compounds are inexpensive and are not toxic to tissue, these disinfectants are widely used.

## REFERENCES

Block SS: Disinfection, Sterilization and Preservation.  
Philadelphia, Lea & Febiger, 1983, pp 3-270.

Atkinson LJ, Kohn ML: Berry and Kohn's Introduction to Operating Room Technique. New York, McGraw-Hill, 1986, pp 122-143.

Perkins JJ: Principles of Sterilization and Health Sciences.  
Springfield, IL, Charles C. Thomas, 1969, pp 95-150, 193-264.

Slatter DH; Textbook of Small Animal Surgery.  
Philadelphia, WB Saunders Co, 1985, pp 261-269.

Title 29, Code of Federal Regulation Sec.1910.1047  
Ethylene Oxide, Occupational Safety and Health Administration.

**APPENDIX E: HAZARD COMMUNICATION PLAN**

**The following is an example of a Hazard Communication Plan.**

**HAZARD COMMUNICATION PLAN  
IN ACCORDANCE WITH OSHA 29 CFR 1910.1200**

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## **1.0 General:**

The following Hazard Communication Program (HAZCOM) has been established to insure compliance with all directives pertinent to Code of Federal Regulations (29 CFR 1910.1200). It is the intent of this program to provide all Employees with a reference guide to working with Hazardous Chemicals.

### **1.1 Location of Hazard Communication Plan**

The written Hazard Communication Plan is available for review by all employees at the following central location:

Office of the Director of Environmental Health & Safety.

Copies of the plan may be obtained from the above at the request of any supervisory personnel.

### **1.2 Designated Personnel**

The following personnel have been designated as responsible for updating and maintaining the hazard communication program, employee training, labeling, and ensuring that MSDS forms are obtained/maintained. (Refer to Chemical Hygiene Plan for specific reference to Laboratory supervision, management, and safety procedures).

#### **a. Hazard Communications Program:**

The Director of Environmental Health and Safety is the overall Hazard Communications coordinator. Department Hygiene Coordinators and Laboratory Supervisors are responsible for their respective areas.

Within laboratories, filing and maintenance of MSDS is the responsibility of the Laboratory Supervisor.

#### **b. Employee Training:**

Training will be conducted by Director of Environmental Health and Safety or designated EH&S personnel or supervisors as appropriate. After completion of initial training, it will be the responsibility of individual supervisors to provide on the job safety training to all newly hired personnel. When new chemicals or chemical products are introduced, additional training by supervisory personnel will be required.

When appropriate, external agencies may be contracted to conduct training as required.

#### **c. Labeling on Laboratory/Work Center Containers:**

It will be the responsibility of the supervisor of the laboratory or work center to insure proper labeling of containers. This is to be consistent with the information contained in the appropriate MSDS. NOTE: Common nomenclature must be stated on the label. Chemical symbols may be added, but common nomenclature is mandated by OSHA.

d. Labeling on Shipped Containers:

It will be the responsibility of central receiving to insure all boxes, containers, and cartons which are suspect of containing chemicals are appropriately labeled. Shipments that show damage/leak/or spill are to be refused.

e. Obtaining/Maintaining Material Safety Data Sheet (MSDS):

A central file of MSDS will be obtained by and maintained within the office of Environmental Health & Safety. Laboratories/Work Centers will receive MSDS appropriate to their work areas by written request from Environmental Health and Safety. Laboratory Supervisors will be responsible for the initiation of requests. They will also insure that appropriate files of MSDS are maintained in a central location within the laboratory. Work center supervisors will be responsible for providing access to a central file of appropriate MSDS within the work center.

f. Informing Contractors:

It will be the responsibility of Maintenance to inform contractors of the hazards in the work area on campus to which they are assigned. This is critical in any active Laboratory where chemicals/compressed gas are in use or stored. Contractors are to be informed of any restrictions involving use of compressed gasses, flame, or chemicals to be utilized by the contractor as part of the job.

### **1.3 Updating and Evaluating the HAZCOM Program:**

At least once per year, the Hazard Communication Program Coordinator (HCPC) will review and update the program. The HCPC will access the hazardous chemicals and materials in Laboratories and work areas with the assistance of the Lab Supervisors and Work Center Supervisors. The update will consist of each of the following elements of the HAZCOM program:

- a. Hazard assessment
- b. Assessment of applicable regulations
- c. Written plan(s)
- d. University Policies
- e. University Discipline/procedures
- f. Training
- g. Inspection Audits
- h. Designated employee accountability

### **2.0 Container Labels:**

Container Labels will be in accordance with current and accepted OSHA and NFPA Standards.

## **2.1 Materials Received:**

All containers received for use in each Laboratory or work site are to be properly and clearly marked in at least English with the following:

- Contents of container
- Hazard of the specific target organ
- Name and address of the Manufacturer

## **2.2. Materials Shipped:**

Any manufactured hazardous substance leaving the campus must be accompanied by the data listed in para. 2.1 of this document. In addition, if a material is shipped, an MSDS is to be included. Chemical waste will be shipped via a contracted vendor, in compliance with EPA, OSHA, and DOT regulations. Records will be maintained in the office of Environmental Health and Safety.

## **2.3 Missing Labels:**

Missing, defaced or illegible labels will be replaced immediately with clean, properly marked ones. Notices will be placed on bulletin boards that provide container labeling systems, and location of the HAZCOM program.

## **2.4 Portable Containers:**

Portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer are not required to be labeled. All other portable containers are to be labeled with the content and hazard of the specific target organ.

## **3.0 Material Safety Data Sheets:**

An MSDS for each hazardous chemical in the Laboratory or work center is to be maintained in a central location within the Laboratory, group of Laboratories, or work centers. They will be available for review by all employees during working hours.

### **3.1 Location:**

A master file of all MSDS will be kept within the office of Environmental Health and Safety. MSDSs obtained from Chemical Manufacturers or Distributors will be maintained in file cabinets by Manufacturer and will be cataloged by number assigned and in alphabetical/number sequence.

A work area/Lab specific MSDS file of that area's hazardous chemicals will be kept within a central location of the work area or Laboratory (*i.e.* Physical Plant/Environmental Services).

In addition to MSDSs obtained from manufacturer, employer utilizes the services of a computerized MSDS system from OHS (MSDS On Disk). This system has the capacity to cross reference by Chemical Name, Trade Name, CAS Number, OHS Number, and other reference factors. Work Centers or Laboratories requesting and MSDS will normally receive the MSDS provided via this system as they will normally be more detailed and scientifically specific than MSDS from the manufacturer. Further, MSDS provided via this system will contain CERCLA and NFPA ratings which may or may not be provided by manufacturer.

### **3.2 Hazard Determination:**

MSDSs will be requested for all incoming hazardous substances. Employer will rely on both furnished MSDS and those produced supplementally via OHS system.

### **3.3 MSDS INFORMATION:**

The designated person will ensure that all MSDS have complete information in each of the following categories:

- a. Identities used on label
- b. Chemical and Common Names
- c. Physical and chemical characteristics
- d. Physical Hazards
- e. Health Hazards
- f. Primary routes of entry
- g. Air exposure limits (PELs, TLVs)
- h. Carcinogenicity
- i. Precautions for safe handling
- j. Control Measures
- k. Emergency and first aid procedures
- l. Date of preparation of MSDS
- m. Name/address/phone number of MSDS preparer or distributor.

### **3.4 Missing MSDS:**

The office of Environmental Health and Safety will contact suppliers for any missing MSDS or missing MSDS category information. Contacts will be documented. If the requested information is not received within 30 days, the University may file a complaint with OSHA, or find a new supplier. Documentation of requests will be maintained.

## **4.0 Employee Information and Training:**

### **4.1 Initial Training:**

Prior to beginning work with hazardous chemicals, each employee will be required to attend a hazard communications training class. They will view a video presentation concerning

HAZCOM. Supervisors will ensure that new employees are trained, and that the training is documented.

#### **4.2 Retraining:**

Additional training will be conducted by supervisors when new chemicals are introduced into the work area. Retraining is not required if the new chemical contains hazard similar to previously existing chemicals for which training has already been conducted. Monthly safety meetings will be held and hazardous materials will be discussed.

#### **4.3 Record Keeping:**

The trainer or laboratory supervisor will require all employees attending the Hazard Communication Course to sign a sheet verifying their attendance.

#### **4.4 Training Format:**

Each employee attending the safety course will receive a lecture and Audio Visual Training. Training will include the following:

- a. The location and availability of the written Hazard Communication Program and MSDS.
- b. Training on the physical and health hazards of the chemicals in the work area.
- c. How to reduce or prevent exposure to these hazardous chemicals through proper work practices, engineering procedures, emergency procedures and personal protective equipment to be used.
- d. What the University has done to reduce or prevent the workers exposure to chemicals.
- e. Procedures to follow if they are exposed to chemicals.
- f. Methods and observations used to verify the presence or release of a hazardous chemical.
- g. Explanation of the details of the program, labeling, the MSDS, and how employees can obtain and use appropriate information.

#### **5.0 Hazardous Non-Routine Tasks:**

##### **5.1 Creighton University Policy:**

It is University policy that no employee or student will begin work or project or any non-routine task without first notifying the appropriate supervisor or instructor.

##### **5.2 Specific Training:**

Any non routine task will require specific training concerning the hazards associated with the task. This training will include information on:

--Specific Chemical Hazard

--Protective/safety measures that the employee can take.

--Measures that employer has taken to reduce hazards, to include, administrative controls, engineering controls, and personal protective equipment (PPE) required.

**5.3 Non-Routine Task:**

Due to the nature of research and education conducted on the premises, chemical use must be considered routine. Chemicals used by Physical Plant and Environmental Services are to be considered for use consistent with job requirements.

**6.0 Chemicals In Unlabeled Pipes:**

Prior to beginning any work on unlabeled pipes, employees shall contact Physical Plant Operations. Specific training regarding potential hazards and safety precautions must be conducted. Information for the piping system which identifies the location of all pipes and their contents must be available from the Physical Plant.

**6.1 Piping Contents:**

The following items may be contained within piping:

- Utility Gas Lines
- Electrical Conduit
- Water Pipe
- Acids
- Chemicals of any Nature

**7.0 Multi-Employer Work Sites:**

It is the responsibility of the designated individual within the Physical Plant to provide contractors and their employees with the information listed below. This information will be given to the contractor's employees prior to their entering the work site.

- a. Hazardous chemicals what they may be exposed to on the work site.
- b. Measures the employee may take to reduce the possible exposure
- c. Steps that the employer has taken to reduce the risks.
- d. MSDS for all hazardous chemicals are on file in the office of Environmental Health and Safety, or in the appropriate laboratory or work center.
- e. Procedures to follow if they are exposed.
- f. Location of the written plan is the office of Environmental Health and Safety.

**8.0 List of Hazardous Chemicals:**

Inventories of hazardous chemicals and materials used on the premises are located at the Office of Environmental Health and Safety. Due to the large inventory throughout the facilities, individual inventories per location are not attached.

**9.0 Policies:**

Policies set forth in this Hazard Communication Plan are to be adhered to by all employees and contractors working on the premises. Employees found to be knowingly violating the policies set forth will be subject to disciplinary actions, up to and including immediate termination.

Reviewed by:

Director of Environmental Health & Safety