How to Pass an IACUC inspection… and other Important Inspections your IACUC won't tell you.

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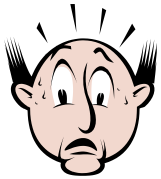
The who, what, when, and where's of animal research inspections

- Who… does the inspections
- What …to expect during an inspection
- Where...inspections occur
- When … these inspections take place

WHO inspects and WHEN?

- WF IACUC
  - Every six months in spring (Announced) and fall (Unannounced)
- WF Oversight and Outreach
  - Post-Approval Monitoring
- Others
  - USDA



    - Whenever they want!
      - Routine annual and For-cause - ?
  - AAALAC

    - Every 3 years
      - Next is early 2014

WHERE are inspections done?

Depends on the inspector

- WF IACUC
  - All housing, procedural and support areas, including labs
  - Space managed by Animal Resources Program & Investigators
- Oversight & Outreach
  - Individual research labs
- USDA, APHIS
  - USDA-regulated species only
- AAALAC
  - All housing, procedural and support areas, including some labs

What to expect at IACUC inspections?

- The group: 2 IACUC members, 1 veterinarian, 1 IACUC staff member
- The inspectors will want to look at all space where
  - Housing and husbandry areas
  - Live animal work is done
  - Surgery is performed
  - Euthanasia is done

Best ways to interact with inspectors…

- Smile and Breath

- Be friendly
- Answer questions concisely

- Don’t offer more than is asked

- Say ‘I don’t know’ if you don’t
  - ‘but I know who to ask!’
  - ‘but I know where to find it!’

Surgery and Procedures: Facilities

Surgical areas

- USDA-regulated

  (Non-rodent) animal surgeries must be done in dedicated surgical suite.
- Rodent surgery areas can be multi-use. However, during surgery…
- Keep surgery areas clean, clutter free and disinfected. Clean before and after each use.
- 70% ethanol or Novasan on surfaces, then create sterile field
- Need: Materials to remove hair from the surgical site.

Area for Minor Procedures

Inspection Details

Clean and uncluttered space to perform minor procedures.

Aseptic instruments and technique, as well as appropriate PPE.

Records of anesthetic use & adequate monitoring during recovery from anesthesia.

Materials to remove hair from the surgical site.

Materials for anesthesia/analgesia should be labeled and within expiration dates.

Refer to Policy 13: http://infinet.wfubmc.edu/depts/ord/acuc_policy/

Area for Terminal Procedures

Inspection Details

Clean and uncluttered space to perform terminal procedures.

Materials to remove hair from the surgical site.

Clean but not necessarily aseptic instruments and technique. Gloves for the surgeon.

Appropriate materials for anesthesia and analgesia, as well as, records of use. Anesthetics and analgesics cannot be expired for use in terminal procedures; however, the USDA allows for the use of other expired compounds in terminal procedures performed in regulated species.

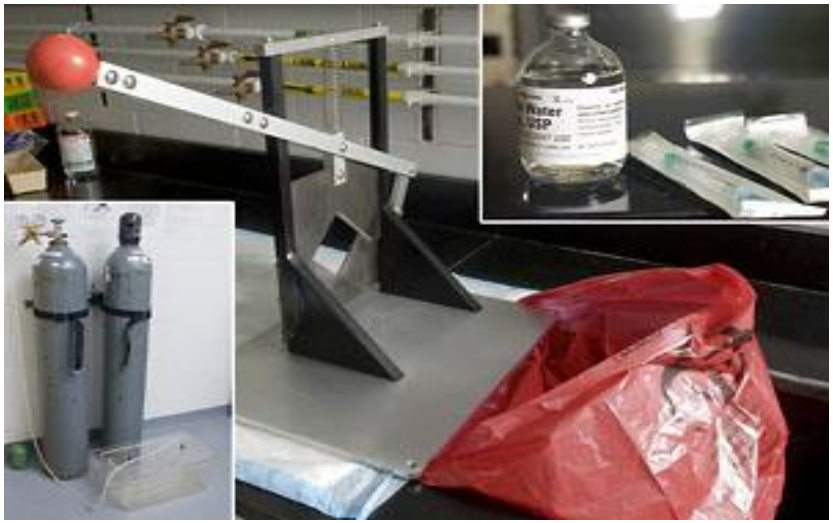
Surgery-related

- Gas Tanks secure
- Vaporizers serviced annually
- Scavenge anesthetic gases and record canister weights.
- Use approved sharps containers

Autoclave monitoring

- During regular use, autoclaves must be tested weekly with a biological monitor. Biological control tests must be conducted monthly.
- For intermittent use, test with biological monitor and control when reinitiating use.
- Temperature-sensitive tape must be applied to all packs.
- Sterile instruments must be dated at autoclaving and can be used for one year from the date.
- Contact ARP – 713-7394 for more information and a copy of the SOP

Euthanasia



Inspection Details

Materials for approved methods of euthanasia.

In-date pharmaceuticals for euthanasia.

If carbon dioxide is used, then death must be confirmed by secondary method.

Guillotine and/or scissors must be sharp and well maintained

Surgery and Procedures: Recordkeeping

Recordkeeping

- Records should be complete, legible and accessible.
- Keep records for
  - Surgery/procedures: intra-operative, post-procedural monitoring and care
  - All animals must be monitored every 15 minutes during operative procedures (intra-operative).
    - Exception if minor procedures of less than one hour.
  - Record of drug use: drug, time, dose in a form that is understandable. DO NOT BACKLOG OR FORELOG.
  - Regulation/restriction of food/fluid

Proper post procedural monitoring

- …**of animals should occur every 30 minutes throughout stage 4 of recovery**, 6-10 hours throughout stage 3, and then daily.
- **Keep records...**
- WFU Policy: **Recovery from anesthetic**
  - Stage 4, un- or semi-conscious, monitor every 30 minutes;
  - Stage 3, sternal recumbant, monitor every 6-10 hours;
  - Stage 2, ambulatory but residual effects of procedure, monitor daily;
  - Stage 1, Sutures in place, monitor daily, Remove wound clips or skin sutures after 10-14 days;
  - Stage 0, Normal, close-out post-op surgical record with final statement about animals disposition.
- WFU Policy: **Pain**
  - Pain score must be recorded at monitoring point at stages 3 to 1.
  - III. Post-Surgical Chart and Pain Scoring System: http://infinet.wfubmc.edu/depts/ord/acuc_policy/

Drugs: Recordkeeping

Expired drugs and supplies

- Identify and properly dispose of outdated drugs, fluids and supplies, including suture material and gloves.
- Expired materials can be used for terminal procedures, <u>except</u> anesthetic agents and analgesics.
- Expired materials must be labeled as expired and stored separately.
- NOTE: If just one lab in the entire school is found with an expired drug it is a violation. A repeat violation carries a stiffer penalty, even if it occurs in a different lab.

Controlled drug

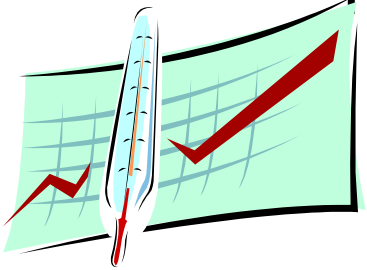
- **Store** behind at least two locks, e.g., room door and lock box.
- **Disposal**
  - often must be done in the presence of DEA. Contact DEA office for guidance at each occurrence.
  - ARP cannot dispense controlled drugs, e.g., ketamine, pentobarbital.
- **Records** of use must be complete, including Drug name, Lot/ID number, amount, personnel.
- EH&S website has forms – contact EH&S
  - http://www.wakehealth.edu/ehs/forms/

Housing and Husbandry

Animals should be checked daily

- Check all animals daily, including holidays and weekends, and keep records.
- Correct records NOT!

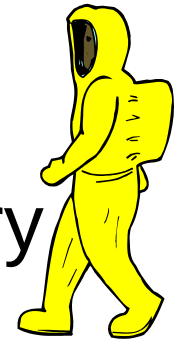
- Record room temperature in housing areas daily.



Sanitation

- Clean and sanitize animal housing areas, surgeries, surfaces and equipment regularly.
- For satellite housing, it is a best practice to post a cleaning/sanitation schedule and record dates done.

Personal protective equipment (PPE) use



- PPE is your last defense against work place hazards. Wear uniforms, scrubs or laboratory coats as indicated.
- These clothes should not be worn in public places. Do not wear gloves in elevators.
- Eye protection is required for nonhuman primates users. Eye glasses are not acceptable as PPE.

Feed and bedding storage

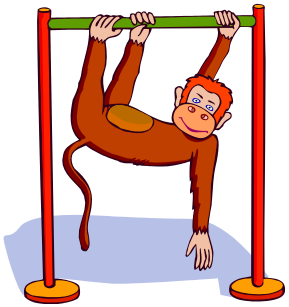
- Store bedding and feed on pallets away from the wall. Store opened bags of feed and bedding in vermin proof containers.
- Label containers with feed mill dates. Discard expired feed.
- Store feed or bedding away from chemicals and other contaminants.

Satellite housing

- House animals only in ARP Facilities or IACUC approved locations and for approved purposes and times.
- Greater than 12 consecutive hours is considered housing.
- Advantage of central housing is guaranteed environmental controls (temp, humidity, lighting, air exchanges) and infection/contamination/vermin controls.

Environmental Enrichment

- Expected for all species
- Special care for singly house animals, as documented in protocol
- Written SOPs for nonhuman primates



Last but not Least

NO FOOD OR DRINKS are allowed in lab spaces, surgery areas, and/or animal housing areas!

WAKE FOREST UNIVERSITY
SCHOOL of MEDICINE

IACUC SITE VISIT

Office of Research

Signed in as Colleen Bennett (username = cobennet)

Home Page | Admin Area | Site Visit List

Responsible Owner: [redacted]
Room: [redacted]
State: Completed
Date: 3/12/2009

Main | Site Visit | **Items**

If there are any items of non-compliance which need to be addressed, then click on the icon in the 'Actions' column. After entering your response then click the 'Save' button. Click on the 'Main' tab above which will show you the current status of this site visit.

	ACTIONS	AUDIT COMMENTS	CORRECT BY	REFERENCE
1.		Anesthetic scavenging canisters have not been weighed. They need to be weighed at each use and recorded on canister.	4/18/2009	Guide for the Care and Use of Laboratory Animals, NRC, 1996. Section: Physical Plant: Facilities for Aseptic Surgery

Office of Research Section	
Response Accepted:	Yes
Responsible Party's Section	
Action Taken:	Corrected
Comments:	anesthetic scavenging canisters have been weighed and marked on the canisters [redacted]
Completed On:	4/17/2009
Responded By:	[redacted]

Spring 2010
SUMMARY OF FACILITY INSPECTIONS

Definitions

- *Acceptable.* A room or area in which no deficiencies are noted.
- *A significant deficiency* is one that is or may be a threat to the health and safety of the animals (PHS Policy IV.B.3 and USDA 9 CFR 2.3 (c) (3)). In practice, the threat must be *immediate* to be considered significant.
- *A minor deficiency* is a small deviation for standards set by the US Dept. Agriculture, U.S. Dept Health and Human Service's (Public Health Service), Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), or WFU policy.

Findings for all facilities

- 514 rooms/spaces were visited.
- No *significant deficiencies* were found.
- 83.7% of space was in full compliance. One or more *minor deficiencies* were found in 84 of the 514 spaces inspected; or 16.3% of space.
- 120 *minor deficiencies* were noted total.

Spring 2010 Inspection
Top 4 Deficiencies

Comprised 78.3% of the issues

30% Procedure/surgical areas were cluttered.

75% of that (27 rooms) were areas that were dirty, dusty, needed cleaning

25% of that was rooms (9) with cardboard boxes on floor

29.2% Drugs: Expired drugs/materials & unlabelled drugs/containers were found.

36% of that was unlabelled drug/chemical containers (12 rooms)

36% of that was expired drugs (12 rooms)

25% of that was expired materials/supplies (9 rooms)

3% of that was improper storage of controlled drugs (2 rooms)

10% Waste was not properly disposed.

42% of that was waste not in appropriate containers (5 rooms)

33% of that was trash cans that need lids or emptied daily (4 rooms)

25% of that was overfilled sharps containers (3 rooms)

9% Walls, ceilings and floors need painting/repair (11 rooms)

Top Deficiencies as "Percent of Total Deficiencies" by Inspection

	Spring 2009	Fall 2009	Spring 2010	Fall 2010
Procedure/surgical areas, supply carts in animal rooms, etc. were cluttered	37	43	30	26
Drugs Unlabelled drug/chemical containers Expired drugs, materials Improper storage Drug logs not maintained	21	28	29	18
Waste Waste not in appropriate containers Trash cans need lids or emptied daily Sharps containers are full	10	13	10	16
Walls, ceiling & floors need repair/painting			9	
Anesthetic vaporizer not certified, not having appropriate exhaust system and/or not being used properly	11			