

**REGULATORY COMPLIANCE INSPECTIONS THAT ENABLE SAFE CONDUCT of LABORATORY RESEARCH at the  
UNIVERSITY of MINNESOTA**

2013 Update	Required	Required by whom	Conducted by	Frequency	Risk Recalibration Assessment
<b>ANIMAL PROGRAM INSPECTIONS</b>					
<b>IACUC Semiannual Inspections</b> - All housing facilities and surgery sites for university owned animals	YES	OLAW, PHS, USDA, AAALAC	IACUC Members, IACUC Compliance Staff	2x/yr	Frequency and scope is federally mandated.
<b>IACUC Office Post Approval Monitoring</b> - All PIs utilizing research animals (with some exclusions, e.g. teaching, Ag, client owned animals, fisheries, wildlife, etc.)	YES	PHS/OLAW	IACUC Members, IACUC Compliance Staff	annual or biannual	Recalibrated in 2012 such that labs that meet certain criteria are inspected every 2 years instead of every year
<b>Investigator Managed Housing Area inspections</b> - Twin Cities Campus PIs housing animals outside of RAR (with some exclusions, e.g. client owned, fisheries, Ag, etc.)	YES	IACUC	RAR Veterinarians	monthly or quarterly	Recalibrated in 2012 such that IMHAs that meet certain criteria are inspected quarterly instead of monthly
<b>LAB SAFETY INSPECTIONS</b>					
<b>Controlled Substance Audits</b> - DEA Registrants perform annual inventory and submit to DEHS. DEHS performs inspections of labs authorized to use controlled substances. (see Administrative Policy at: <a href="http://www.policy.umn.edu/Policies/Research/CONTROLLEDSUBSTANCE.html">http://www.policy.umn.edu/Policies/Research/CONTROLLEDSUBSTANCE.html</a> )	YES	DEHS	DEHS	Annually	DEHS is assuming responsibility for the program during 2013. All labs to be inspected during the first year. Those without issues would be skipped the second year. Those with issues will be revisited the same year.
<b>Biosafety Lab Inspections</b> - Laboratories which use or store biohazardous materials are inspected. The primary focus of this inspection is handling of biohazardous materials, however, Research Safety staff accompany the Biosafety staff on these inspections as part of the College of Veterinary Medicine (CVM) pilot in an effort to reduce the number of DEHS inspections per lab.	YES	NIH, DEHS	DEHS Biosafety Officer (BSL3) and Biosafety Specialists	annual	New self-inspection/audit process being piloted in CVM for eventual use campus wide. Combination of research safety & biosafety. Labs with no issues would be audited every 2 years.

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<b>LAB SAFETY INSPECTIONS (cont'd)</b>					
<b>Radiation Safety Audit of X-ray equipment and users</b> - All aspects of ionizing radiation-producing equipment use are audited including inventory, training and quality assurance program compliance.	YES	MDH	Health physicist or DEHS radiation safety staff	annual or biennial	Frequency and scope is mandated by MN rule.
<b>Radiation Safety Compliance Audit: Radioactive material users</b> - All aspects of radioactive material use are audited including inventory, training and waste management. Annual audits have been determined by the All University Radiation Protection Committee (AURPC) to be an effective mechanism for assessing compliance with MDH-Radiation requirements, and are written into the University's radiation license.	YES	DEHS, MDH	Health physicist or DEHS radiation safety staff	annual	The audit is recorded in the Isotrack Management System so lab staff will have the results immediately. All violations with their supporting documentation as well as the responses are also recorded in Isotrack and are available for review at any time.
<b>Radiation Safety Routine Survey</b> - Radiation Protection staff monitor designated work areas for radiation contamination. Periodic surveys of all radiation users have been determined by the All University Radiation Protection Committee (AURPC) to be an effective mechanism for assessing compliance with MDH-Radiation requirements, and are written into the University's radiation license.	YES	DEHS, MDH	DEHS radiation safety staff or students	bi-annual	The survey requirements done by RPD are based on the isotopes and activities used. The usual schedule is twice a year. These surveys are recorded in Isotrack and will be available for review by the lab staff at any time.
<b>EXTERNAL INSPECTIONS</b>					
AAALAC	YES	UMN	AAALAC Site Visitors	triennial	AAALAC Accreditation requirements must be met by a triennial thorough site visit.
Consultants (IACUC, pre-AAALAC, NIH, private consulting groups, etc.)	NO	OVPR, IACUC, UMN departments	External Consultants	varies	Consultant visits are important informational tools but frequency has been reduced from annual to triennial.

<b>NONCOMPLIANT FINDINGS FROM INSPECTIONS MAY IMPACT:</b>					
Research Funding					
Individual and Institutional Reputation					
Fines may be levied for violations					
Approval for use of animals, controlled substances, radioactive or biological materials, etc. may be withheld or suspended during periods of noncompliance					

### **Glossary of Terms**

**DEA Registrant** - A University employee delegated by his/her department head to hold DEA registration and is responsible for ordering, storing, using and disposing of controlled substances in his or her unit

**Permit holder for radioactive materials** - The principal investigator or lab manager named as the applicant on a radioactive materials use permit.

### **Acronyms**

AAALAC - Association for the Assessment and Accreditation of Laboratory Animal Care, Intl. ([www.aaalac.org](http://www.aaalac.org))

AHC - Academic Health Center

AURPC - All University Radiation Protection Committee

BSL - Biosafety Lab

CVM - College of Veterinary Medicine

DEA - Drug Enforcement Administration

DEHS - Department of Environmental Health & Safety ([www.dehs.umn.edu/](http://www.dehs.umn.edu/)) 612-626-6002

EPA - Environmental Protection Agency

IACUC - Institutional Animal Care and Use Committee ([www.research.umn.edu/iacuc/](http://www.research.umn.edu/iacuc/))

MDH - Minnesota Department of Health ([www.health.state.mn.us/](http://www.health.state.mn.us/))

NIH - National Institutes of Health

OHS - Occupational Health and Safety

OLAW - Office of Laboratory Animal Welfare at NIH ([grants.nih.gov/grants/olaw/olaw.htm](http://grants.nih.gov/grants/olaw/olaw.htm))

OVPR - Office of the Vice President for Research

PHS - Public Health Service (Policy on Humane Care and Use of Laboratory Animals ([grants.nih.gov/grants/olaw/references/phspol.htm](http://grants.nih.gov/grants/olaw/references/phspol.htm)))

RAR - Research Animal Resources