

# Orange Peel Newsletter

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## Upcoming Meetings

- 5/22-25/05  
District 8 Meeting
- 7/21/05  
Arizona Branch Board Meeting  
Tucson, AZ
- 8/8-12/05  
Association of Avian Vets Conference  
Monterey, CA
- 8/17-20/05  
American Society of Primatologists Meeting  
Portland
- 8/18-19/05  
Lab Animal Welfare Training Exchange (LAWTE) Conference  
San Diego
- 9/05  
SCAW sponsored IACUC Advanced  
Davis, CA
- 9/22-24/05  
American Association of Bovine Practitioners Meeting  
Salt Lake City, UT
- 10/15-19/06  
National AALAS Meeting  
Salt Lake City, UT

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## President's Message

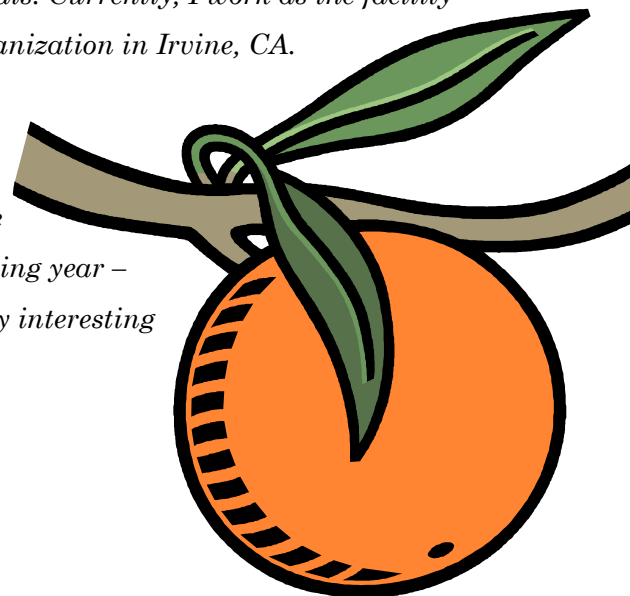
*For those of us who work in laboratory animal science, it is impossible to miss how important the work we do is to the world at large. All we have to do is pick up a newspaper or turn on the television, and there are the stories: Questions about NSAIDs continue to surface. The fiftieth anniversary of the polio vaccine is celebrated. Silicone breast implants are rejected and approved in the same week.*

*For the most part, the media leave out the role that animal science plays in virtually all major health stories. But when we read those stories, we know.*

*Because I recognize the importance of the often unsung work animal scientists do, I am excited to be the incoming president of OCB-AALAS. My interest in animal science spans back to high school, where I raised cows and pigs as member of Future Farmers of America at Westminster High School. I pursued this interest to Cal Poly San Luis Obispo, which is where I first participated in research using animals. Currently, I work as the facility manager for a contract research organization in Irvine, CA.*

*OCB-AALAS is the perfect way for those of us in this field to learn more and get to know each other. The coming year – and it's April already! – brings many interesting events to OC AALAS.*

**Sherri Decker**  
President  
Orange County AALAS



# USA PATRIOT Act: What Does It Mean to Us Now?

By Leta Eng, BS RLATG, Montana State University

In the April, 2003 (Vol. 8, No. 2) issue of TechTalk, I wrote about the eventual impact of the implementation of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 and its cousin, the Public Health Security and Bioterrorism Act of 2002 on animal research facilities. These two acts were developed to operate in concert to minimize the risk to public health and provide security against an act of terrorism using biological agents. At that time, there were many gray areas concerning the execution of the requirements of the act, and what impact these would have for animal research facilities working with select agents. Since that time, many facilities have implemented the changes required by the acts and some of the gray has become more black and white. One of the questions most frequently asked in the beginning was, "Will the Department of Justice (DOJ) really issue security clearances for everybody working with these agents?" In spite of the skepticism voiced by many of us, the answer is yes. The DOJ has been very efficient in processing security clearances in a timely fashion. The exceptions have been, as was in my case, the submission of substandard fingerprints. These applications are returned, but even with a delay of this nature, clearances have generally been granted within six weeks. Site inspections are also taking place at registered facilities. The Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) publish lists of regulated or "select agents." The inspecting agency will depend on the list on which the select agent appears. Overlap agents (those listed by both the HHS and USDA) can be inspected by either agency. Since the two acts have become law, our facility has been inspected **twice by agents of the Center for Disease (CDC)** to insure compliance.

The first site inspection was a learning experience for our institution. With one under our belt, it became more clear to us that we were actually dealing with two separate issues—our protocols for working with Bio safety Level (BSL) 2 and 3 organisms in general and the level of security for the select agents. Facilities that have been dealing with BSL 2 and BSL 3 agents prior to the acts becoming law will already have the appropriate biohazard practices in place, leaving the security issues to be dealt with to ensure compliance.

The criteria used for inspecting the entity or facility to determine compliance with established biosafety recommendations are based on the *Biosafety in Microbiological and Biomedical Laboratories*, 4th edition. A checklist has been developed that guides the entity's Responsible Official (RO), as well as the inspection team through the process of a site inspection. As with most federal regulations, the key is accurate and extensive documentation; have these records available for the site inspection team. In addition to the usual quality control documentation (autoclave monitoring, cage wash monitoring, etc.),

facilities are also required to maintain a log of individuals entering the areas where select agents are used or stored.

The security requirements used during a site inspection are specified by the Public Health Security and Bioterrorism Act of 2002. Compliance with the act requires that entry doors to the areas where select agents are stored or used, such as research labs and animal rooms, are secured with a key lock, card key, or proximity reader.

All entering the area must log the time of entry and exit. Personnel not cleared to work with all the select agents in use in an area must be accompanied by an individual that has received clearance. Along with the DOJ security clearance, individuals must also be registered with the RO of the facility to work with the specific select agents. For example, if there are two different select agents used in the same room, as is the case in many animal facilities, all personnel entering that room must be cleared to work with both agents, even if they are actually only working with one.

Clearance and registration are specific to the entity or facility, as well. For example, if an agent is produced in a private lab, but is used in animals in another, unrelated facility, personnel working in both facilities must have two separate clearances—one for working in the lab, and one for working in the animal facility. This means two separate DOJ investigations must be done for the same person and they must be registered with both facilities in order to produce, transport, and work with the agent.

This leads to the subject of transporting select agents. In order to transfer a select agent from one entity to another, approval to transfer the agent must be granted from the CDC for agents listed under the HHS Select Agents List, or APHIS for agents listed under the USDA Select Agents List.

o overlap agents, either the CDC or APHIS can be contacted.

he transport process requires multiple levels of approval and verification at each step, and records of the transaction must be kept for three years. The time it takes to complete this process varies greatly. On average, it will take at least two weeks and may require more time depending on the conditions surrounding the shipment (response times of the ROs, distance the package has to travel, etc.). Keeping this process in mind, it is wise to plan ahead for such transfers and schedule experiments involving select agents appropriately.

Despite the fact that key components of the USA PATRIOT Act expired on December 31, 2004 and renewal is pending, the sections which addressed the bioterrorism threat are not included in the "sunset" expiration. It appears the new regulations are here to stay and the best way to ensure compliance is to educate yourself and your staff.

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