

Minutes*

**Senate Research Committee
Monday, March 10, 2003
1:15 - 3:00
238A Morrill Hall**

Present: Gary Balas (chair), Gerry Baldrige, Victor Bloomfield, Kathleen Conklin, James Cotter, Steve Gantt, Paul Johnson, James Luby, Sharon Neet, Mark Paller, Thomas Schumacher, Charles Spetland, Charles Stech, Barbara VanDrasek, Michael Volna

Absent: Melissa Anderson, Sharon Danes, Robin Dittman, Sabine Fritz, Yev Garif, David Hamilton, Katherine Klink, Phillip Larsen, Scott McConnell, James Orf, Ted Powell, Virginia Seybold, Mehul Vora

Guests: Edward Wink (Sponsored Projects Administration), Winnifred Schumi (Oversight Analysis and Reporting); Craig Moody (Interim Director, Environmental Health and Safety), Jim Lauer (University Biosafety Officer)

Other:

[In these minutes: (1) Sponsored Financial Reporting issues; (2) "select substances" regulations and oversight]

1. Sponsored Financial Reporting

Professor Balas convened the meeting at 1:15 and noted that Mr. Volna would talk about issues related to Sponsored Financial Reporting (SFR) that have been raised by faculty (such as sending invoices in a timely manner, checking the status of invoices, IX cross-charges, and (primarily a Sponsored Projects Administration issue) setting up subcontracts).

Mr. Volna distributed a handout outlining the issues that Professor Balas had raised and information about those issues. With respect to invoices and providing information to investigators, he explained that his office has installed a new \$1.3-million system to automate and improve the timeliness of reports and invoices. The system is one used in other auxiliary units. They have also adopted new policies and procedures to improve timeliness, accuracy, and completeness of reports. The new system will allow reports to be generated more quickly and accurately.

There is a "delicate dance" involved, however: they cannot get an invoice out quickly without the necessary information from the department and SPA so they need good and timely communication with those units. There is currently no backlog of invoices. Professor Balas suggested that in addition to talking with a department accountant, SFR also talk to the investigator if something has fallen behind. Is there any policy on when they involve the PI? They will do whatever a department wishes, Mr. Volna said; most want PIs (who do not understand the technical side of transactions) informed but ask that SFR

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate or Twin Cities Campus Assembly; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate or Assembly, the Administration, or the Board of Regents.

work with department staff. If PIs are to work with SFR, they need to understand transactions. PIs must also know when departments have been asked for information, Professor Balas responded; they have to be kept in the loop.

The Committee discussed the frequency of reports required by various agencies. One requires monthly reports, which is not usual for the University for federal contracts. Agencies also look at draw records; the Department of Defense will take the money back if it is not being spent. Contracts often require quarterly reports but program people typically want monthly reports, Mr. Wink reported. The University produces a large number of reports quarterly and monthly; NIH and NSF are relatively simple ones, Mr. Volna said. It produces even more reports for businesses and foundations, which tend to have a lot of reporting requirements.

Reporting lags are sometimes due to subcontractors, Professor Balas said; is there a way to structure contracts so subcontractors MUST pay two weeks before the University must pay? That is handled by SPA, Mr. Volna said, but his office would be glad to work with SPA to work out a system. If the University is the subcontractor, it will not have the full information for a month until about the 10th day after the end of the month, Mr. Wink said, and the University has told its subcontractors that it will take funds away if information is not provided. Mr. Volna said the University should look into accrual accounting, used in the private sector, so that liability accrues.

Another issue is lack of information about cross-charges and the lateness of some charges. Mr. Volna noted University policy that requires buyers on internal transactions must be charged within 45 days of the date of delivery or service; after that, a department has the right to refuse to pay. Many do not refuse because the unit providing the service or goods has a monopoly and a long-standing relationship, but some units are very good about paying and are responsive to customers (e.g., the bookstores). So he does not have to pay charges that are two years late, Professor Balas asked? He does not, Mr. Volna said; there are no charges to sponsored accounts after 12 months from the date the original charge was posted to CUFFS.

Are there problems with delays, Professor Balas asked? In some internal service organizations there are, Mr. Volna said. Some are not timely but more of the complaints are about a lack of appropriate documentation. A lot of the system interfaces are inadequate but there must adequate documentation to support the transaction in the event there is an audit.

Another issue is payments to individuals, Mr. Volna noted, and this was an issue that former President Yudof was also concerned about. They have put in place a process to identify small businesses and corporations and to pay them in one day. Any new vendor and the University must do a lot of reporting, to meet legal requirements, so they obtain the information to set up the one-day payments at the time a vendor begins doing business with the University. He said they did a study of the time it took for payment; it was about 17 days. He said he wants to know of any instance when a vendor is not paid for several months.

The most complex process is contracting for professional services, Mr. Volna said; Executive Vice President Maziar has asked his office to work on this issue and they hope to have something by summer that is on-line and that can shorten the process by half. There is a flow chart for contracting professional services and it looks like a wiring diagram, he remarked.

Professor Balas thanked Mr. Volna for his presentation.

2. Select Agents

Professor Balas now turned to Craig Moody, Interim Director of Environmental Health and Safety, and Jim Lauer, University Biosafety Officer, to lead a discussion of "select agents."

Mr. Moody began by telling the Committee that select agents include not only bio-organisms but also the toxins they produce. Certain biological agents and toxins have been identified by the federal government as of great concern should they be used by terrorists because they have the potential to pose a severe threat to human, animal, and plant health.

The first Select Agent regulation was the "Antiterrorism and Effective Death Penalty Act of 1996," which is what the University has been working with since it was adopted. The goal was to prevent terrorists from ordering select agents; the act contained a list of about 40 agents. The law required that universities and researchers register with the CDC before being authorized to receive any of the identified select agents. Until last year, no one at the University of Minnesota had received any of them.

After the events of 9/11 and the letters with anthrax, additional laws were enacted (the USA PATRIOT Act of 2001, the Public Health and Bioterrorism Preparedness Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002). The second of the acts, for example, required that all who possess biotoxins must notify the CDC by September, 2002 (which the University of Minnesota did). The University has no agricultural agents, so did not have to respond to the requirements of the agricultural bioterrorism act.

There are interim rules in place to implement the laws. The requirements include an updated list of select agents, new thresholds, a proviso that an institution must register even if merely possesses select agents, irrespective of whether it transfers or receives them, and how it uses them. Possession and storage is regulated; organizations must submit registration information to CDC that includes detailed facility information. The University's "Responsible Official" as well as researchers with access to select agents must be screened by the Department of Justice. A security plan is required. These are pretty extensive regulations, Mr. Moody commented. Is there a citizenship requirement, Professor Balas asked? One is not required to be a U.S. citizen, Mr. Moody said, but no one with access to select agents may come from a country that is involved in terrorism. Nor may a felon have such access.

After the letters with anthrax, there was discussion with Drs. Cerra and Maziar about inventorying the University's select agents. People were hired to conduct the inventory; they went through about 600-700 labs and had good cooperation. Was there anything unknown found or were there any surprises, Professor Conklin asked? There were a few, Mr. Lauer said--some botulism strains, for example. The information from the survey is in a secure database that is locked up at night, he said. They are developing an electronic reporting system for ongoing inventory management, Mr. Moody told the Committee, and it will be implemented during the second half of this year. PIs will be asked to provide information via the web to update the inventory.

Is there a problem with providing secure information via the web, Professor Balas asked? Does that not violate the spirit of having a secure and self-contained database? They believe they can keep it secure, Mr. Moody said; few people will have access to it. They also had to make choices: do they do a

physical inventory every year or identify areas of priority where restrictions are most likely to apply? They have opted for the second because it is more efficient.

Ms. Schumi pointed out that the inventory should include instructional settings as well, those instances when instructors use select substances in teaching. There are two types of labs that are regulated, Mr. Moody said: research labs using select agents or toxins and clinical diagnostic labs that have the potential to isolate select agents in clinical samples. The research labs involved are a small subset of all research labs; people requiring access must be identified and certified by the Department of Justice as not "restricted." Lab security will include an entry/access log and an inventory and use log. There are only a handful of labs at the University that will need to comply with these requirements.

Clinical diagnostic labs receive samples for identification and may isolate select agents. The labs are exempt from registration requirements if they report any select agents immediately and destroy or transfer the agent according to CDC rules.

How intrusive will the Department of Justice process be, Professor Balas asked? Mr. Lauer said they do not know yet; the Department is developing forms. It may include fingerprinting. Mr. Wink said they will require a lot of personal information; not being "restricted" will be close to having clearance for classified information. There is no indication, Mr. Moody said, that there will be inquiries about people who USED TO work for the University. Mr. Baldrige said he was most concerned about the Orwellian surveillance aspects of the law. Mr. Moody said the federal laws are trying to fit a model to universities that does not work well. The University is trying to comply as best it is able, but this has been a hurry-up process with questions to come later.

Full compliance with the rules is expected by November 12, 2003. University requirements for research labs using, transferring, receiving, and destroying select agents are being drafted. Mr. Moody reviewed the timeline for risk assessment, security plans, and so on, in order that the University can meet the November deadline. The security plan presents some challenges because some labs are "open landscape" and permit potential access to select agents by a number of people. Labs may have to be creative or they may have to confine select agents to specific areas. If there are new grants that include select agents, they will have to look at how buildings are structured and where to put the agents. Will there be questions on grant forms about accepting select agents, Professor Balas asked? Mr. Wink said he would not want to see any proposals leave the University without knowing it could handle select agents.

These are only preliminary regulations, Mr. Lauer pointed out, and there has been a lot of comment and commotion about them. Some in the government may have thought that every lab had to have a level of security equal to that at CDC. He said he hopes that they realize they may have carried things too far. But there could be even more restrictions, Professor Neet observed, if it is discovered, for example, that there are biologic agents in Iraq. Mr. Lauer said that with some knowledge, a potential terrorist can get a number of things; there are other things (e.g., smallpox) that they could never get, so the question is the risk.

Professor Conklin noted that reporting is voluntary, which is acceptable, but that could mean individuals have select agents and not tell about them. Mr. Lauer said that individuals from his office went through all the labs, but if someone were determined to hide something, they could--they did not open and test every container. Professor Gantt said the system has to rely on good people cooperating.

The protection needs to be against others coming from the outside and stealing select agents, Professor Conklin agreed.

Mr. Moody reviewed the potential impact of the regulations. "Academics fear that government red tape will result in U.S. researchers choosing other areas for study while other countries continue to work with select agents. Scientists believe that valuable stock culture have been/will be destroyed in order to comply with regulations. Cost in time and money is significant for institutions supporting research involving select agents." These concerns come with a corresponding worry that there will be no gain in terms of stopping terrorism. The government can say it knows what is in a place and protect against someone walking in the door and taking select agents, and there is value to knowing what the University has and what is not necessary to retain.

Mr. Lauer said there is a lot of funding available for select agent research so the University will probably see more proposals. Questions raised include: "Have we gained any ground in preventing terrorism? Are there dangers to our freedoms when government regulations impact scientific inquiry? Will researchers who do select agent research be allowed to publish or will the information be classified?"

For more information, one can go to www.cdc.gov/od/sap, www.aphis.usda.gov, and www.aau.edu/research/science1.10.03.pdf.

Professor Balas thanked Messrs. Lauer and Moody for joining the meeting, and adjourned it at 2:40.

-- Gary Engstrand

University of Minnesota