

COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership
FROM: COGR Staff
SUBJECT: Winter 2009 Update

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1. COGR Comments on DOE Laboratory Technology Transfer Practices; Comment Deadline Extended

As reported in our recent Holiday Update, the Department of Energy (DOE) asked for public comment on a series of questions concerning technology practices at DOE laboratories (Federal Register; 11/26/08; page 72036). In response, COGR submitted comments to DOE on January 26, 2009.

The COGR comment letter noted that while the ability to partner with DOE laboratories is an important priority for many of our member institutions, challenges in these relationships are of significant concern to the university community. It noted the “take it or leave it” attitude of some DOE facilities with regard to their willingness to modify the terms of the Standard DOE “Work for Others” Agreement. DOE mandates use of this Agreement for access to DOD facilities or collaborators. The letter cited a number of problems with the terms of the Standard

Agreement, which is commonly used by COGR member institutions in situations where DOE laboratories are functioning as subcontractors under federally funded research projects. These include indemnity provisions, patent rights, subaward issues, advance funding requirements and reserved government rights. Similar problems exist with standard DOE Cooperative Research and Development Agreements (CRADAs). We recommended that when collaborating with a university, DOE adopt the Federal Demonstration Partnership's (FDP) Research Subaward Agreement. We also suggested that DOE review other agency model User Agreements and CRADAs, which typically are shorter and simpler than DOE's.

A copy of the COGR comment letter is posted on our website. We submitted our comments on the original due date; however, on that day DOE announced a 60-day extension of the public comment period (Federal Register; 1/26/09; p. 4418) to 3/26/09. We encourage COGR member institutions to consider submitting their own comments to DOE. Both DOE and institutions would benefit by simplifying the current cumbersome DOE procedures and practices.

2. Government Further Delays Implementation of E-Verify

On January 14, 2009 we notified the COGR membership that implementation of the E-Verify employment eligibility requirement for federal contracts had been postponed to February 20, 2009. This requirement was discussed in last October's COGR Meeting Report. It would require use of E-Verify for all university employees assigned to federal contracts over \$100,000 and subcontracts over \$3,000.

On January 27, 2009 the US Chamber of Commerce announced that the federal government had agreed to further delay until May 21, 2009 implementation of E-Verify. The delay subsequently was announced in the Federal Register on January 30 (page 5621). A lawsuit challenging the rule has been filed by a number of business groups. The initial delay was the result of negotiations associated with the lawsuit. According to the Chamber of Commerce announcement, hearings in the court case have been suspended pending the new Administration's review of the rule. See <http://counsel.cua.edu/fedlaw/Ina1952.cfm#may21>.

3. DOD Issues Rule Expanding Whistleblower Protection for DOD Contracts

On January 15, 2009 the Department of Defense (DOD) issued an interim rule (FR 1/15/09; page 2410) amending the Defense Federal Acquisition Regulation Supplement (DFARS) to expand whistleblower protections for contractor employees. The DFARS rule expands the types of information to which the protections apply; the categories of government officials to whom information may be disclosed; establishes time periods for agency or Inspector General (IG) action on a complaint; establishes a right of action in federal district court for employees who have exhausted their administrative remedies; and adds a contract clause (DFARS 252.203-7002) requiring contractors to inform employees in writing of their whistleblower rights and protections.

The DFARS rule was mandated by the DOD '08 and '09 Authorization Acts. It goes beyond the Federal Acquisition Regulation (FAR) provisions (FAR 3.9) which provide for complaints to be filed with agency IGs for reprisals against employees who have disclosed "whistleblower" information to Congress, agency officials, or the Justice Department. The interim DOD rule was effective immediately; public comments for consideration in developing the final rule are due March 16. At this time COGR does not expect to submit comments.

4. Series of Executive Orders Published on Federal Contracting

Three Executive Orders (EOs) on federal contracting were published in the Federal Register on February 4, 2009. The one of most note is Executive Order 13496 (1/30/09; FR 2/4/09; page 6107) on “Notification of Employee Rights Under Federal Labor Laws.” This requires federal contractors to post notices of employee rights under federal labor laws to collective bargaining, freedom of association, self-bargaining, and designation of their own representatives for negotiating terms of employment. The requirement also applies to all subcontracts. The Secretary of Labor is to prescribe the size, form and content of the notice within 120 days. The Secretary also is empowered to provide exemptions and impose remedies. The EO revokes prior Executive Order 13201, which required federal contractors to post a notice stating that employees could not be required to join a union and could withhold any portion of their union dues not related to collective bargaining, contract administration or grievance adjustment.

The other Executive Orders disallow costs of any activities undertaken to persuade employees not to engage in collective bargaining (EO 13494; FR 2/4/09; page 6099); and provide for a right of first refusal of employment for qualified employees of a predecessor service contractor when a successor contract or subcontract is awarded (EO 13495; FR 2/4/09; page 6103). There are a number of exclusions and agencies can exempt particular contracts in the latter EO. The EO revokes Executive Order 13204, which revoked a Clinton Administration Executive Order (EO 12933) which also provided for a right of first refusal.

5. NAS Issues “Fortress America” Report

On January 8 2009 the National Academy of Sciences (NAS) Committee on Science, Security and Prosperity in a Changing World issued its report “Beyond “Fortress America”: National Security Controls on Science and Technology in a Globalized World.” The Report bluntly declares that many federal regulations governing sharing of information and products with citizens of other countries are “harming the nation’s security and its economic prosperity. This system was designed for a world that no longer exists, and it needs to be replaced.”

The report focuses mostly on export controls. It finds that many current controls weaken U.S. innovation and competitiveness while not protecting national security. The technology base that supports our national security now also supports the high tech sector of the civilian economy. The current list-based export control systems are unwieldy, slow, difficult to administer rationally, and are overly proscriptive. The failure of the executive and legislative branches of government to come to agreement either internally or with each other on dual use export control policy has led to vulnerabilities in both our national security and economic competitiveness. U.S. restrictions provide a road map for foreign competitors as to investments in technology, while visa and deemed export controls have made U.S. universities less attractive to foreign researchers and helped drive knowledge intensive jobs overseas. U.S. national security and economic prosperity depend on full global engagement in science and technology. The U.S. needs to change to a philosophy of openness.

The report calls for “sunsetting” all items on the export control lists that are controlled unilaterally by the U.S., with strict criteria for determining whether any items remaining on the list would present a substantial risk to national security if removed, with an annual review. The report recommends creation of an economic competitiveness exemption from export controls

that eliminates controls on dual use items when they are available without restriction in open markets outside the U.S. It also recommends establishment of a new coordinating center for export controls to coordinate all interactions with export license applicants and expedite agency processing, and establishment of an independent export license appeals panel. Finally, the report contains a set of recommendations on the visa process. According to the report, all the recommended changes can be accomplished by Executive Order.

The report is notable for its hard hitting tone. The committee includes a number of individuals with impeccable national security credentials. The co-chairs are General Brent Scowcroft, President and Founder of The Scowcroft Group and former National Security Advisor to Presidents Ford and George H.W. Bush; and John L. Hennessy, President of Stanford University. We understand that committee members have briefed a large number of representatives of both the executive and legislative branches on the report findings and recommendations, including members of the new Administration. There may be some question as to whether all the recommendations can be accomplished by Executive Order as claimed. Also establishment of two new administrative entities as recommended might serve only to add additional bureaucracy to the process. However, the report's basic findings are consistent with other recent groups such as the Commerce Deemed Export Advisory Committee and the NAS Committee on a New Government-University Partnership for Science and Security (see COGR February 2008 Update). Hopefully this consistent set of reports from such high level committees eventually will lead to export control reform. The "Fortress America" report is available at <http://www.nap.edu>.

6. NIH/NIAID Issues RFP With Determination of Exceptional Circumstances

On October 15, 2008 NIH/NIAID issued an RFP (NIH-NIAID-DMID-AI2008041) for "Animal Models of Infectious Diseases" (https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=634ec47a3c14483c87b29440e54d5eb6&_cvview=0). The RFP contains a Determination of Exceptional Circumstances (DEC) to restrict the contractor's rights to subject inventions. Specifically the contractor will be required to assign to the government or to a collaborating party designated by the government all rights in subject inventions. The RFP also contains a notice of deviation from normal contractor data rights under the Federal Acquisition Regulations (FAR) to restrict the contractor's right to data produced under the contract. The RFP also requires IP options to be offered to third party material providers both for research use and commercialization for any invention made with the use of the provider's materials, which conflicts with the DEC (it is not clear how the contractor can comply with this requirement if they do not have rights). This requirement also extends to subcontracts for materials evaluation. In the event of failure to reach agreement with a single provider on the terms of an exclusive commercial license (multiple providers are to be granted co-exclusive commercial licenses), the contractor will be required not to offer a third party better terms for a six month period. Subject inventions for purposes of this requirement include those "whether patentable or not." The RFP also contains information security (FISMA) requirements including background checks and training. The proposal due date recently was extended to February 24.

In addition to the DEC issues, of particular concern are the expansion of subject inventions, the reach through requirements for materials that conflict with NIH's own policies, and the substantial expansion of data controls and IT security. The publication restrictions and the requirement for national security checks for contractor personnel may trigger export control

requirements and the need for technology control plans. We understand that a number of institutions have decided not to respond to the RFP because of these issues. While the RFP was not called to our attention in time to meet the initial 30-day comment period, COGR has contacted NIH about these concerns and plans to follow up with written comments.

7. COGR Discusses Bayh-Dole March-In Rights with GAO

COGR was contacted by the Government Accountability Office (GAO), which is conducting a review of march-in rights under the Bayh-Dole Act. The review is pursuant to GAO's mandate to conduct a review of Bayh-Dole implementation at least every five years. The GAO review is focused on three questions: 1) What policies and procedures have DOD, DOE, NASA and NIH established to determine whether march-in rights under the Bayh-Dole Act should be exercised? 2) To what extent have these agencies exercised march-in rights under the Act? 3) What barriers, if any, have these agencies encountered in the exercise of march-in rights?

We met with the GAO representatives on February 4. We made the point that universities closely monitor the performance of their licensees in achieving commercialization, through performance milestones in license agreements, progress reports, etc. The very low volume of march-ins is an indication that universities are effectively performing this function. We also noted that universities can and do terminate licenses for non-performance. We stressed the potentially chilling effect on the ability to commercialize federally-funded inventions were the government to begin to actively exercise march-in rights. With regard to the possibility of government-initiated march-ins, we noted that the legislative history of Bayh-Dole indicated an expectation that march-ins would be initiated by third parties (as has been the case with the 3 NIH march-ins to date). It is not clear what criteria the government would use or what circumstances would be appropriate for government-initiated march-ins. We also pointed out that agencies are not staffed to assume greatly increased responsibilities in this area.

GAO asked about eliminating march-in rights entirely. We responded that we are generally supportive of reducing compliance burdens on our member institutions. However, march-in rights may provide leverage with regard to assuring commercialization, and they have a very long history (when the government waived title to contractors pre-Bayh-Dole, usually the waiver was contingent on march-in rights).

A considerable part of the discussion focused on the lack of strong government policy oversight over agency administration of Bayh-Dole (We subsequently furnished GAO with a copy of the 2007 joint COGR/AUTM letter to the Commerce Department about this issue). We provided examples of where strong central oversight might be helpful (NIH genomic invention policies, the VA's unique interpretation of its rights to inventions notwithstanding Bayh-Dole). The GAO representatives raised the possibility of a principles statement for licensing of federally-funded inventions; we mentioned the 9 Points statement (which they just had obtained). We also indicated that if such a statement were developed, it should be done at a central government level with strong stakeholder input, and not agency-by-agency.

There was some discussion of the NIH research tools policy; we noted that COGR had heavily interacted with NIH in the development of that policy. They asked about its degree of acceptance by universities; we expressed the view that for the most part the policy was well-accepted. There also was discussion of exclusive vs. non-exclusive licensing; we indicated that because of the need for private investment for commercial development a significant portion of

university licenses (probably at least half) are exclusive; however, non-exclusive licenses are possible. We directed them to the discussion of this point in the 9 Points document.

We also discussed the original purposes and objectives of Bayh-Dole in terms of economic development, not revenue-raising for universities. We also made the point that a large part of the success of Bayh-Dole was due to its flexibility. We suggested that GAO should be careful to avoid prescriptive recommendations with regard to Bayh-Dole guidance. We also suggested that GAO should consider reporting burdens both for institutions and federal agencies in any recommendations for increased reporting on federally funded inventions.

The discussion was very collegial. Our sense was that GAO is seeking to develop recommendations that will be helpful and not damaging to university tech transfer. They expect to have a draft report by June and a final report by the end of July.

8. Discussions Continue with NAS Committee on University IP Management

We have discussed the activities of this Committee in COGR Meeting Reports and Updates over the past year. The Committee will meet again on February 17-18, immediately prior to the COGR meeting. Our information is that the morning session on the 17th is likely to be open, but the remainder of the meeting will be closed for the committee to focus on its preliminary recommendations. These will address the areas discussed in the 6 panel sessions at the November 2008 meeting (see (http://www7.nationalacademies.org/stl/University_Property.html)).

We have continued to be in close contact with the responsible NAS staff. The committee has commissioned a number of small studies, including the relationship between the structure of tech transfer offices and the AUTM survey results; comparison of federally-funded research results with non-federal funding and licensing arrangements for different technologies based on 5 years worth of data from a large university system; specific company data on collaborations with universities; and a legal primer on statutes, regulations and case law at both federal and state levels that impact university tech transfer. These studies will be presented in closed session at the February meeting.

In our discussions with NAS we have talked about the need to recognize distinctions between tech transfer offices and the overall responsibilities for economic development at universities, and how universities increasingly are under pressure to show economic impacts. While the committee appears to have a clear interest in possible structural issues with tech transfer at universities, we cautioned that issues of university structure and economic impact need to be approached carefully and from a broad perspective. We also have expressed concerns about any calls for additional government oversight and the need to carefully consider the motivations of the critics of university tech transfer. Challenges faced by smaller institutions in licensing technologies particularly in economically depressed areas also seem of interest to the committee, with the possibility of suggesting clearinghouses or contracting out of tech transfer functions in such cases.

The current thinking is that the report may suggest revisiting the intent of the Bayh-Dole Act and the current federal implementation, but not call for any changes in the statute itself. The lack of federal policy oversight might be addressed, which is a concern that we strongly share. We will continue to closely follow and report on developments.

9. Draft HHS/SACGHS Report Expected to be Released Shortly

We discussed the forthcoming draft report of the HHS Secretary's Advisory Committee on Genetics, Health and Society (SAGHS) in the COGR Holiday 2008 Update. We understand the report may be issued shortly. It will discuss a range of policy options with regard to the patenting and licensing of genomic inventions and related issues such as how research agencies should handle data related to genetic IP. Plans are for the public comment period on the Report to last until April. We anticipate that COGR and many individual universities may wish to provide comments.

The report potentially will have significant implications for university technology transfer. The discussion at the Thursday morning session with the NIH Office of Technology Transfer (OTT) at the upcoming COGR February meeting may focus to a large extent on the report if it is available. Even if not, the SACGHS has discussed issues such as the applicability of the NIH research tools policy to genetic diagnostics and current licensing practices that OTT may wish to discuss with COGR members.

10. Biosafety and Biosecurity and the Life Sciences

On February 5, 2009, the National Research Council (NRC) and American Association for the Advancement of Science (AAAS) released the results of their collaborative "Survey of Attitudes and Actions on Dual Use Research in the Life Sciences." This survey addresses the issues that lie at the core of the National Science Advisory Board for Biosafety's (NSABB) Proposed Oversight Framework for Dual Use Research. The NSABB proposed framework builds on the investigator's recognition and reporting of the potential that his/her work involves dual use life science research of concern. In the hearings and deliberations held by the NSABB, panelist and participants have questioned how aware the research community is of this issue and how an oversight mechanism that relies on investigator awareness should be developed and whether it would be effective.

The respondents to the NRC/AAAS survey demonstrated awareness of the issue but NRC/AAAS believe investigators would benefit from additional resources to help limit the risk of misuse. NRC/AAAS cautioned the community about the limitations of the survey. The reported results are based on responses from 1,500+ AAAS members who work in the life sciences. The survey, conducted between August-October 2007, found that 87% of the respondents believe that principal investigators should be responsible for the initial evaluation of dual use potential and urged that any oversight mechanism be developed by the scientific community itself. Of note, the survey revealed that 15% of the respondents had already taken action based on their concerns for potential misuse. These actions included ending collaborations with foreign investigators, changing their research area or not conducting certain types of research and, in some cases, editing or modifying research manuscripts to avoid potential misuse of the scientific results. The report is available from the National Academies (www.nap.edu)

DOD-based Biosecurity Working Group - The issues concerning biosafety and biosecurity continue to gain the attention of the federal agencies. One of the last Executive Orders signed by George Bush established a Working Group on Strengthening the Biosecurity of the US based in the Department of Defense (DOD). Signed on January 9, 2009, the Working Group, co-chaired by DOD and the Department of Health and Human Services (HHS) is charged to review the efficiency and effectiveness of Federal

and nonfederal facilities that work with select agents and toxins. Unlike the NSABB, this Working Group will look more at the management of the facilities including personnel security.

NSABB December Meeting - But the issue of personnel security or assurance was the principal topic of discussion by the NSABB in December. When it met on December 10, 2008 to continue its consideration of the management of dual use research of concern, most of the NSABB meeting focused on current Personnel Reliability Programs (read “background checks”) and whether these would be useful models for dual use research. NSABB members were appropriately concerned that implementing current personnel reliability models like those used under the Centers for Disease Control’s Select Agent & Toxin regulations or by the Department of the Army would be difficult and likely inappropriate in managing dual use research activities conducted by universities and other academic research organizations.

Transfederal Biosafety Task Force - Even as the members of the NSABB gathered for their meeting, the Transfederal Task Force on Optimizing Biosafety Oversight met on December 8 and 9 to consider mechanisms for the oversight of public and private research involving infectious agents. The Task Force was announced by HHS during testimony at a House Energy and Commerce Committee Subcommittee on Oversight and Investigations in October 2007. This Task Force was formed in part as a response to the 2007 GAO report on the Oversight of BSL-3 and BSL-4 laboratories. The report found that no one federal agency knows the total number of high containment laboratories in the U.S and no one agency is responsible for determining the aggregate risks associated with these laboratories. The Task Force’s goal is to identify strategies for addressing public concerns with the management of these high containment facilities. Some mechanisms under consideration include mandatory Federal standards, centralization of Federal authority, certification of biosafety officers, and, unfortunately, accreditation of institutions.

Senate Hearing on WMD - These meetings proceeded a December 11, 2008 hearing of the Senate Homeland Security and Governmental Affairs Committee focused on *World at Risk: A Report from the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism*. In the report, the Commission predicts a terror attack somewhere in the world by 2013. The attack would use weapons of mass destruction, most likely biological agents, because they are more readily available than nuclear materials and are subject to fewer controls. Among the Commission's findings was that biological weapons pose a very real threat because of the global proliferation of legitimate biotechnology research and expertise. Following the hearing, Senators Joseph Lieberman (ID-CT) and Susan Collins (R-ME) announced they would draft legislation to tighten oversight of high containment laboratories.

OSTP Action - During the NSABB meeting, Diane DiEuliis, Assistant Director of the Life Sciences Division in Office of Science and Technology Policy (OSTP) provided an update on the Federal response to the NSABB proposed oversight framework for dual use research. She noted that the OSTP would be taking up the proposal within the Biotechnology Subcommittee of OSTP’s Committee on Science. Acknowledging that it was difficult to assign policy issues during the Presidential transition, the Subcommittee would begin consideration and likely return to NSABB with questions. She observed that

the proposed framework provided only the briefest description of the oversight roles and responsibilities of institutions and noted the relative absence of a description of how the oversight would work on the federal side. As with many items on the Federal agenda, consideration of the NSABB will likely be delayed until the consideration of John Holdren's nomination for the position of Assistant to the President for Science and Technology and Director, Office of Science and Technology Policy.

11. DHS CFATS Next Steps – Site Visits

On the subject of security, members of the Department of Homeland Security (DHS) staff met with representatives of the higher education community to update the community on their progress implementing the Chemical Facilities Anti-Terrorism Standards (CFATS) regulations. As you will recall, the CFATS regulations with its Appendix A list of Chemicals of Interest were finalized in November 2007 with the publication of the final list of Chemicals. At that time, all research institutions inventoried their chemicals to determine whether it held the named chemicals in the quantity, concentrations, and/or in the manner listed in Appendix A. If the campus held chemicals of interest that meet DHS' thresholds, the rule requires (and still requires) submission of the Department's Top-Screen for each facility. If the institution determined that it had no chemical inventory that exceeded the Top Screen thresholds then it did not need to proceed further and the process is finished.

Top Screen Reviews - In the January 9, 2009 meeting, DHS said that of the 35,000 submitted Top Screens, approximately 380 were received from colleges and universities and of that number, 180 institutions were "screened out" and required no further action. Of the remaining, most (112) are in the lowest Tier 4, 56 institutions were in Tier 3, 30 in Tier 2 and 5/6 in Tier 1, the highest tier requiring the greatest level of security. DHS expressed surprise at the low number of institutions submitting Top Screens and worried that sufficient outreach had occurred to make the community aware of the requirements. We assured DHS that the associations had been aggressive in educating our community and we were not surprised at the low number of institutions reporting. We reminded DHS of our initial assessment that institutions used small quantities of materials, dispersed widely across the campuses and that a reasonable determination of a "facility" (that physical space that would contain chemicals that needed controls, e.g., a building or complex of buildings) would drop many institutions out of the process.

Outlier Site Visits - Because of DHS' unease about the community's response, they have decided to conduct a pilot program of site visits. The sites will be institutions they believe should have submitted a Top Screen but didn't. Focused first in New York and New Jersey, DHS will identify institutions by looking for those with research programs similar to programs at institutions that did submit Top Screens. DHS will consult with local and state authorities like state environmental agencies or other agencies that regulate chemicals or waste, to determine which institutions may be holding chemicals of interest in regulated quantities. Once DHS has identified these "outliers" they will visit the campus to determine why a Top Screen was not submitted – based on a lack of knowledge or a thorough inventory and determination.

We reminded DHS of the provisions in the regulations that allowed institutions flexibility in "defining the boundaries of their facility" and permitting, "if appropriate, [the institution] to submit a Top-Screen on a building-by-building basis or a campus-wide

basis.” DHS is committed to these visits but DHS was invited by a campus represented at the meeting to visit early in the process to help DHS understand how campuses approached the question of defining a facility and how they conduct and manage their chemical holdings. This New Jersey institution will serve as a very good model for DHS to visit and may temper the Department’s concerns.

SVA and ASP Issues - The purpose of the meeting was to discuss the next steps (after the Top Screen) including the filing of a Security Vulnerability Assessment (SVA) by the 200 tiered institutions and how the use of an Alternative Security Plan (ASP) could be utilized by the institutions. DHS agreed to participate in an online “conversation” with representatives of the higher education community led by our colleagues in the Campus Safety Health Environmental Management Association (CSHEMA) to clarify the Risk-Based Performance Standards recently released by DHS. The goal will be to successfully integrate the Performance Standards into an Alternative Security Plan that is flexible enough to be used as a template by institutions.

We will keep the membership informed of this effort by CSHEMA and invite members who are contacted by DHS for a site visit to let us know (cblum@co.gr.edu).

12. **Regulatory Review Reviewed**

There has been significant public reporting on a number of Executive Orders (EO) signed by President Obama as he entered office, notably the closure of the Guantanamo (Cuba) Detention Facilities, the revocation of the Mexico City Policy and Assistance for Voluntary Population Planning limitations, and the required Ethics Commitments by Executive Branch Personnel and Pay Freeze for senior members of the White House staff.

There have been other important Executive Orders issued of particular importance to the federally regulated communities including research institutions. We want to alert COGR members to some of the less-reported but equally important EOs issued since January 20, 2009 (See also Item 4. above on **Series of Executive Orders on Contracting.**)

Delay in New Regulations - We begin with a January 20, 2009 memorandum from Chief of Staff Rahm Emanuel to the federal agencies and departments. In a process similar to that used by earlier Presidents, the departments and agencies were directed not to issue proposed or final regulations until the regulation has been reviewed and approved by a agency or department head appointed or designated by the President “after noon on January 20, 2009” – the new President. In addition to not issuing new regulations, Emanuel asked the departments and agencies to consider extending for 60 days the effective dates of regulations published in the Federal Register but not yet effective. Thus, the effective date for the implementation of E-Verify, the employment verification system, has been delayed to March. Of note, for the published-but-not-yet effective regulations, Emanuel directs the agencies to reopen the comment period for 30 days. Any comments that raise “substantial questions of law or policy,” must be reported to OMB and the agency is expected to “take appropriate further action.” There are exceptions to this directive for emergencies – national security, public health, etc – and for regulations that have a statutory or judicial deadline.

A January 21, 2009 memorandum from Peter Orszag, new Director of the Office of Management and Budget (OMB), offered criteria for agency and department heads to use in their consideration of postponing the effective date and, if appropriate, reopening the rulemaking process. These criteria include the adequacy of the original rulemaking procedures and consideration of objections, the reasonableness of legal considerations including the authority to issue the rule, the transparency of the process including interested parties access to facts and data the agency used, and “whether the rule found adequate support in the rulemaking record.”

Regulatory Review Memo and EO - On January 30, 2009, President Obama issued a memorandum to the departments and agencies calling for a revisiting of the regulatory review process. Acknowledging that much has been learned about the process since the principles and processes were established in President Clinton’s September 1993 EO 12866, Regulatory Planning and Review, President Obama has asked the Director of OMB, Peter Orszag, to produce within 100 days (April 30, 2009) recommendations for a new Executive Order on regulatory review. Obama outlines questions to be addressed – transparency, public participation, cost-benefit analysis, the role of behavioral sciences in regulatory review, etc – and encourages consultation with all regulatory agencies, as appropriate.

The same day – January 30, 2009 – President Obama issued EO 13497 revoking EO 13258 (February 2002) and EO 13422 (January 2007) which had made modifications to the original 1993 EO 12866, Regulatory Planning and Review. These two revoked EOs had made some minor procedural changes – eliminating the role of the Vice President as principal advisor to the President on policy planning and review and shifting these responsibilities, in most cases, to the Director of OMB – and a change of greater significance to the regulated communities.

Unfortunately, EO 13422 of January 2007 had added the review of significant guidance documents to the planning and review process, a review which had the potential of benefiting the regulated community. In November 2005, OMB issued a draft of a Bulletin for federal agencies outlining “Agency Good Guidance Practices.” COGR commended OMB for proposing a more uniform approach to the development, issuance and use of guidance and endorsed the admonition that guidance documents should avoid “mandatory language.” COGR asked OMB to reconsider the focus on economically significant guidance versus significant guidance with regard to agency responses to comments. Nonetheless, the OMB Good Guidance Practices has provided COGR and others with another tool to use to assess proposed and draft guidance issued by agencies.

EO 13422 incorporated the guidance into the regulatory review process bringing the same considerations of significant economic impact, inconsistency with other agency actions, altering the budgetary impact of grants, etc., and raising novel legal or policy questions to the review of guidance documents. In the short term, agencies will not be required to bring significant guidance documents to OMB for review.

Transparency & Open Government EO - Finally, on January 21, 2009, President Obama issued a memorandum to all department and agency heads addressing Transparency and Open Government. In order to achieve a system of transparency, public participation and collaboration in government, the President directs the Chief

Technology Officer (CTO) to develop recommendations for an Open Government Directive. Within 120 days, the CTO with OMB and the General Services Administration will identify specific actions agencies should take to provide more information and more opportunities for participation in governing to the public and greater cooperation between the federal agencies and nonprofit organizations, business and individuals in the private sector.

COGR will monitor the progress on these initiatives and report to the membership as recommendations emerge concerning open government and regulatory review. (See Item 4. above on **Series of Executive Orders on Contracting.**)

13. Open Skies – Finally OPEN

On January 15, 2009, the General Services Administration (GSA) issued the final rule covering the use of Open Skies agreements provisions which allows federally supported travelers (including grantees and contractors) to use non-US carriers in some cases. As the GSA Federal Travel Office notes on its website (www.gsa.gov – following the links through Policies and Regulations to the Federal Travel Regulations [FTR]) generally federally supported travelers are required by "Fly America Act" to use U.S. flag air carrier service. "However, an exception to this requirement is transportation provided under a bilateral or multilateral air transportation agreement to which the United States Government and the government of a foreign country are parties, and which the Department of Transportation has determined meets the requirements of the Fly America Act." There are currently three Open Skies agreements – with the European Union, Australia and Switzerland. As we noted in earlier Updates, there are limitations to the use of non-US carriers under an Open Skies agreement notably that the current Open Skies agreements do not apply to Department of Defense supported activities and the prohibition against non-US carriers if a City Pairs agreement exists. More information on the Open Skies agreements and the City-Pair limitations is available on the GSA website, under Travel.

14. IRB Registration Required

On January 15, 2009 the Department of Health and Human Services (HHS) Office for Human Research Protections and the Food and Drug Administration finalized their respective requirements for the registration of Institutional Review Boards (IRBs). First proposed in 2004, the final rules require any IRB designated by an institution in its Federalwide Assurance (FWA) to register with HHS. In addition to the name, postal and electronic address and phone number for the operating institution and contact person, the registration requires the approximate numbers of all active protocols, HHS-supported protocols and the number of full-time equivalent IRB staff. This rule is effective on July 14, 2009 to allow OHRP and the FDA to complete the development and approval of the electronic registration system. Those institutions holding a FWA have registered their IRBs so this rule adds only new elements to that registration process. The rule for OHRP and the FDA appeared in the January 15, 2009 Federal Register.

15. National Science Board – Draft Report on Cost Sharing

The National Science Board (NSB) has made available as a Draft for Public Comment, "Investing in the Future: NSF Cost Sharing Policies for a Robust Federal Research Enterprise". The report is available at: <http://www.nsf.gov/nsb/committees/cs/index.jsp>

As we reported in the COGR Holiday Report (December 22, 2008), we have been actively engaged since the NSB began its review of NSF cost sharing policies in late 2007. In the Holiday Report, we described in detail the background behind the Draft Report, and included some of the anticipated recommendations. Now that the Draft Report is available, we can confirm that the report is consistent with recommendations that we expected.

COGR and others in the research community provided important feedback to the NSB, and from the COGR perspective, the NSB followed through with a thoughtful and important statement addressing cost sharing policy at NSF. The report creates a positive and productive framework with the potential to transform how we view cost sharing. We encourage you to read the report, and below are several of the highlights:

- The primary recommendations are found on page 2: “In this report, the National Science Board (Board) prescribes a set of recommendations with two primary objectives: (1) to allow, but narrowly circumscribe, the application of mandatory cost sharing requirements in NSF programs in which such cost sharing is foundational to achieving programmatic goals, and (2) to prohibit voluntary committed cost sharing in NSF proposals and thus eliminate post-award tracking and reporting requirements.” COGR believes that since voluntary cost sharing will no longer be applicable and can not play a role in the NSF merit review process, any audit initiatives associated with voluntary cost sharing effectively should disappear.
- In total, the NSB makes 9 recommendations. Recommendation 6 addresses the prohibition of voluntary cost sharing in a detailed discussion. Recommendation 6 can be found on pages 10 through 12 of the report.
- Recommendation 6 also suggests that the Facilities, Equipment, and Other Resources (FER) section of NSF proposals be used to allow institutions to more fully describe resources available to the project. This would not include cost commitments, but rather would allow for the opportunity to expand on the important elements of the institution's research infrastructure and the strategic vision related to its research enterprise.
- Pages 13 and 14 contain other recommendations, a notable one being: “The Board understands the fundamental intent of the administrative rate reimbursement cap – to ensure that the majority of research funding supports direct research effort, rather than administrative costs – but also concurs with the general view of the research community that the current 26 percent reimbursement cap requires re-evaluation.”
- Note, there is no statement in the report that states grant applications will be rejected if they contain a financial commitment of voluntary cost sharing. Instead, the emphasis is on education and a change in culture, with the understanding that a policy change will require an adjustment period.

Upon a final release of the Final Report, a revised policy would be applicable to NSF only. However, and as one NSB board member commented at a public meeting last December, implementing a policy where voluntary cost sharing is prohibited across all federal agencies would be the next logical step. Of course, that would require active engagement with other funding agencies, OMB, OSTP, and other stakeholders. COGR will stay focused on all developments related to this issue.

Comments on the Draft Report are due Monday, February 16, 2009. While COGR expects to respond, the emphasis of our response may be in the form of an endorsement of the recommendations. However, if you have ideas or insights, please feel free to share them with COGR staff.

16. NSF Survey of R&D Expenditures – New Format for the FY2010 Survey

The National Science Foundation (NSF) Division of Science Resources Statistics (SRS) has spent the past several years doing extensive fact-finding and meeting with focus groups in an effort to redesign the annual survey on R&D Expenditures. COGR participated in two of these meetings, and engaged with SRS staff on a number of other occasions.

SRS conducted 15 site visits last year to obtain general input for research institutions, and is now embarking on a pilot test at 40 institutions to utilize the new survey format for the FY2009 survey. The expectation is that the revised survey format will be used by all institutions for the FY2010 survey that will be initiated in November 2010. In addition, SRS expects to contact all institutions of the changes in Fall 2009.

Note, the survey format that is being presented is still considered a draft version, and SRS is very open and interested in constructive input. To date, some of the COGR membership has shared their concerns, including topics such as what would be the most appropriate reporting of research at affiliated organizations, as well as the more general concern related to the additional burden that may occur due to new reporting categories and data elements.

As we have started to share your feedback with SRS, SRS has emphasized with us that this phase of the redesign presents the opportunity for institutions to voice their concerns. If you are interested in discussing more, contact David Kennedy at dkennedy@cogr.edu. We can address both the substance of the new survey format and contact information for personnel at the NSF SRS can be provided.

17. Update on Costing Issues from the Holiday Report

In COGR's Holiday Report (December 22, 2008), we reported on some of the immediate items that will be relevant to the Costing Committee in early 2009. Four of the five are repeated. The fifth item from the Holiday Report, "The Economic Crisis and Research Finances", is addressed above as an introduction to the Thursday General Session. Also note, "VA-University Joint Appointments and Effort Reporting" includes updated information.

DOD F&A Cap and the GAO Study on Indirect Costs. In the October Meeting report, we reported on our meeting with Government Accountability Office (GAO). We expect to be in contact with the GAO during the first quarter of 2009, and will keep the membership updated on the status of the GAO Study.

NSF Salary Policy Revision. In the October Meeting report, we also included an analysis on the revised NSF Salary Policy. We concluded that section of the report by stating that we expect there will be situations that require further clarification. COGR is prepared to work with the membership and the NSF to identify these situations and challenges, and when appropriate, provide guidance and clarification to the community. We are very interested in

hearing feedback from the membership, but we also encourage you to contact NSF in that they are responsible for implementing the policy. All new and revised policies in the January 2009 Proposal and Award Policies and Procedures Guide are effective for proposals with a due date on or after January 5, 2009. Also see:

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf091

VA-University Joint Appointments and Effort Reporting - UPDATED. Last week we completed Draft Version 3. We will use this version as the version to share with selected Federal officials, prior to releasing a final version. The paper has evolved into an issues-oriented paper on “Faculty Appointments at Academic Medical Centers”. VA-University joint appointments, and related issues with compensation and effort commitments, are still the primary focus. As has been our policy the past several months, COGR can share with you a confidential draft version of the paper.

USDA-CSREES F&A Limitations and Cost Sharing. COGR has closely followed the Cooperative State Research, Education, and Extension Service (CSREES) process and interpretation on the treatment of cost sharing specific to their competitive grant programs (also see COGR’s Fall and Summer 2008 Updates). We provided a formal response to CSREES in a letter dated September 30, 2008 (www.cogr.edu, see COGR home page, Recent COGR News, September 30, 2008). Our understanding is that CSREES is in the process of reviewing comment letters, and prior to finalizing any rule, they will work with their Office of General Counsel for legal clearance. We will keep the membership posted on any developments.

Audit and Office of Inspector General (OIG) Developments

2009 A-133 Compliance Supplement. The A-133 Compliance Supplement that will be applicable to your FY2009 audits should be available in March. We will keep the membership updated on this process.

Independent Internal Evaluation, J10b(2)(f) – Help Requested. In the Holiday Report we indicated we would like to share some “model policies” related to J10b(2)(f) with the membership. This initiative is based on the ongoing NSF OIG labor and effort audit program, and the consistent finding that institutions are not complying with this criterion. If you have an institutional policy that describes how your institution complies with this section of Circular A-21, please contact David Kennedy at dkennedy@cogr.edu.

Administrative and Clerical Audit, HHS Office of Inspector General. The HHS OIG Review of Administrative and Clerical Audit program has been ongoing for several years. The third of four anticipated audit reports was released this week. The first two reports contained no substantial findings or cost disallowances. The third report contains more significant findings than the first two, and the HHS OIG recommends the institution should:

- refund \$1,661,011 to the Federal Government and
- revise its policies as needed to comply with the requirements of OMB Circular A-21 and ensure consistent treatment of administrative and clerical costs.

The institution partially agreed with the first recommendation and disagreed with the second. For example, the institution questioned some of the sampling and extrapolation techniques used by the HHS OIG to arrive at the recommended refund amount. In addition, the HHS OIG stated “While the University’s policies and procedures were generally effective, some University employees did not always comply with them.” The institution worked closely with the HHS OIG throughout the process, and some disagreements still may be addressed in the audit resolution period. A copy of the audit report has been posted on the HHS OIG web site and can be found at: <http://www.oig.hhs.gov/oas/reports/region4/40501014.pdf>

18. Other Costing Discussions

Several other costing-related topics could be addressed during the Friday morning Committee Reports. The list includes:

New NIH Salary Limitation. Effective January 1, 2009, the Federal Executive Level I salary increased to \$196,700. While for FY09 NIH and many other federal agencies continue to operate under a Continuing Resolution (CR), the language from the FY08 NIH Appropriations Bill that limits salary charges on grants to the Executive Level I rate carries over to FY09 as part of the CR. Therefore, the new salary cap as of January 1 is \$196,700. The NIH Notice announcing this can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-037.html>

Prompt Payment Status by Federal Agencies. An institution reported to COGR that her institution was experiencing situations whereby it has been taking 120 to 180 days to be reimbursed on Federal awards. We will raise this issue Friday morning, but also contact COGR in advance if you have experienced something similar at your institution.

NASA – New Letter of Credit System. Several members have reported problems using NASA’s new letter of credit system. NASA implemented the new system to be in-line with the HHS Payment Management System, one of several payment systems all Federal agencies have the option to implement. However, there appears to be “growing pains” concerning consistency with account and ID numbers between the old and new systems. COGR has spoken with the contact person at NASA and can engage as appropriate.

NIH K Award Policy Update. The NIH released a Notice on January 21, 2009; NIH Policy Concerning Career Development (K) Awards: Leave, Temporary Adjustments to Percent Effort, and Part-Time Institutional Appointments (NOT-OD-09-036). The emphasis of the Notice is to specify allowable situations for reducing a recipient’s appointment status to part-time and to ensure that the recipient will return to full-time status (or at least return to 75-percent effort) as soon as possible. The Notice can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-036.html>

NIH SBIR/STTR and related F&A Policy Update. The NIH released a Notice on January 21, 2009; NIH Policy Change on Threshold for Negotiation of Facilities and Administrative (F&A)/Indirect Costs for Phase II SBIR/STTR Grants (NOT-OD-09-038). This may not be applicable directly to COGR institutions, but we have provided a summary for informational purposes. For an applicant that is a Small Business Concern (SBC), if the SBC did not have a currently effective negotiated F&A rate with a Federal agency, the applicant was to

propose an estimated F&A rate in the application. The new policy states requested F&A cost rates of 40 percent of total direct costs or less will require no further justification at the time of award, and F&A costs will be awarded at the requested rate. The prior threshold was 25 percent. SBCs with F&A rates greater than 40 percent will still need to be negotiated. The Notice can be found at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-038.html>

F&A Survey Update. Preliminary reports are available, upon request. Throughout the next few months, reports will be finalized and posted to the COGR web site. As we have reported in past reports, we expect to begin a project to create a new web-based F&A Survey interface. If you have comments or ideas for future directions of the survey, do not hesitate to contact David Kennedy at dkennedy@cogr.edu to discuss.