NOTES
ICSP and ICSP/ANSI-GMF Meeting
Herbert Hoover Building
Room 6029 - Commerce Department Headquarters
1 - 5 pm
February 2, 2011
Washington DC

GMF Chair: Mr. Greg Saunders, DoD *ICSP Chair: Gordon Gillerman, NIST*

Participants:

Agencies
Michael Case, NRC
Colin Church, CPSC
Michael Fitzmaurice, HHS
Bill Hamilton, DOL, OSHA
Carol Herman, DHHS/FDA
Heidi Hijikata, ITA
Tim Klein, DOT
Mary McKiel, EPA
Oksana Pozda, GPO
Greg Saunders, DoD
Mary Saunders, ITA
Peter Shebell, DHS

NIST
George Arnold, NIST
Lisa Carnahan, NIST
Mary Jo DiBernardo, NIST

NIST (cont.)
Mary Donaldson, NIST
Gordon Gillerman, NIST
Pat Harris, NIST
Ileana Martinez, NIST
Erik Puskar, NIST
Nathalie Rioux, NIST

ANSI
Scott Cooper

Via Telecon
Anne Caldas, ANSI
Kathleen Baden, GSA
Ajit Jilla, NIST
Jennifer Moffat, GSA
Erin Morris, USDA
James Sorace, HHS
Carlos Pena, FDA
Donald Zink, FDA

ICSP Meeting

Welcome, introductions, changes to the agenda – Chair

The FDA Food Safety Modernization Act (FSMA) Implementation – FDA, Donald Zink, Center for Food Safety and Applied Nutrition, FDA
FSMA, which was signed into law on January 4th, 2011, is historic legislation which grants FDA new power, including the power to issue recalls, access records and suspend firms from importing. The FDA is still working through the implications of the new legislation. The new Act holds food suppliers accountable for preventing food borne illnesses, encourages prevention, and enhances partnerships with state regulatory agencies, and contains provisions for import safety. There is a requirement for FDA to establish science based standards for the safe production, packaging and harvesting of produce. These areas of the Act are challenging because the science needs further development. The FDA must develop a scheme for the accreditation of third party food testing laboratories as well as determine what foods will require testing to which standards.

Import safety under the Act is improved. Importers may rely on third parties to certify if foods meet US requirements, and the same safety requirements will apply to both domestic and imported foods. .

The FDA may deny product entry to certain firms and impose mandatory certification for certain foods. There will be increased reliance on inspections and there will be an increase in inspection capacity at the state and local level.

As part of the implementation of FSMA, FDA will promulgate 50 new rules along with guidance documents and reports within three years, a tight time line. (For additional information about the implementation of FSMA, visit: http://www.fda.gov/Food/FoodSafety/FSMA/default.htm).

EPA - Impact on food costs? FDA has not performed a detailed analysis of the possible impact on food costs. A large portion of the food industry is already engaged in preventive controls – for them the new Act will be only a refinement; the small producers may be challenged.

DOT- How is safe food transportation covered? A proposed rule on this topic is required within a year.

NIST - Mentioned that NIST and the ICSP members are available to provide support and that CPSC has been developing some similar requirements. NIST will provide some contacts to FDA at CPSC regarding the laboratory accreditation scheme.

HHS – ARHQ – Suggested coordinating with USDA to develop common terminology, requirements and penalties in the food area. FDA has a history of working with USDA's FSIS and AMS on regulatory drafts and hopes to continue doing so.

NTTAA Reports Status – Mary Donaldson, NIST
Most agencies have finished submitting their drafts to the FY2010 NTTAA report. Twenty one have, with only six agencies outstanding. Please send in your report to NIST in the next week at https://standards.gov/NTTAA/agency/index.cfm?fuseaction=home.login. Your promptness would be appreciated. Call Mary Donaldson (301-975-6197) if you need help.

Smart Grid Update – George Arnold, NIST (301-974-5627, George.arnold@nist.gov)
Topics covered in presentation included smart grid, government's role in developing standards including NIST's involvement, and recent developments moving standards into regulation. There were 28 different SDOs along with 22 categories of stakeholders involved in the standards development process. A report is available on the NIST website. The Federal Energy Regulatory Commission (FERC) held a Technical Conference on Smart Grid Interoperability Standards on January 31, 2011 to help inform the Commission of whether there was sufficient consensus within the stakeholder community on the initial set of standards. If so, FERC can move forward on adoption as directed by the Energy Independence and Security Act of 2007 EISA. Although the participants from industry on the panels were full participants in the standards development process, the panel did not affirm consensus. When asked how best to move forward, they recommended that NIST and FERC set up a new process in a few months. This is not a situation where it's feasible for FERC to adopt individual standards. Until the issue of how to achieve consensus is resolved, FERC cannot move forward.

Summary of the Discussion:
The initial set of smart grid standards were developed by the SDO's and achieved consensus within the standards development processes of the organizations. The standards under consideration are some of the most mature and are in use. The complaints aired by the FERC conference panelists centered on the committee processes and the technical quality of the standards particularly in the area of cyber-security. It's is challenging to balance participation and technical quality of working groups. A lot of the resistance from industry is related to lack of support of regulation in this area. EISA mandates sufficient consensus for FERC to make rules – however 'consensus' is not defined. There was discussion of possible areas to explore such as market incentives and regulation at local level, the need to move forward in order to support the electric vehicle infrastructure, what some states are

doing, and the use of microgrids overseas. Most notably, this model of standards development breaks new ground and will serve as a framework for tackling other cross cutting infrastructure development.

ISO MANAGEMENT SYSTEMS STANDARDS ALIGNMENT – POSITION LETTER FROM ICSP, NIST – Mary Donaldson, NIST

Donaldson – At our last meeting we talked a bit about the consideration by the Technical Management Board (TMB) of ISO to mandate common elements such as mandatory text for management systems standards (MMS). The ICSP is concerned that the TMB Joint Technical Committee may implement a process that would not be compatible with the US consensus driven process. We have drafted a letter from the ICSP expressing these concerns to the Joint Technical Committee and requested consideration to issue their recommendations as guidance only and not to mandate common language to the extent that it would compromise the consensus method of developing standards. We've circulated (to the ICSP) a draft letter addressed to Steve Cornish, the US representative on the TMB, expressing the ICSP concerns. The letter supports the current US position, and is aimed to provide additional support to the US representative. Please review the draft and submit comments by 2/9/2011 as our input is due by 2/11/2011 in order to make it available for the next TMB meeting scheduled for 2/24/2011.

Discussion - Since some of these standards are not adopted, but are used as ISO, why would national adoption be an issue? For ANSs it may violate the ANSI Essential Requirements for due process conditions. In addition, if the US government is considering a consensus standard, there may be concerns in adopting standards whose consensus can be drawn into question. There is a school of thought that consensus should come from within the technical committee developing the standard. It was also brought up that there may be some trend towards mandating contents of ISO standards. Within the expanded ISO community there is some support to advocate to the TMB to make the Sustainability Guide mandatory. Similar to what is happening with MSS, Ileana Martinez provided a brief update on experiences with the ISO Conformity Assessment Committee (CASCO) standards and the use of common language in first drafts. There is a lot of controversy on how immutable is the language to be adopted. While it is noted that the working group can change the language if necessary, in practice they have found that such flexibility depends on the convener of the workgroup. In general it has been positive to have at the beginning some commonality in the language on topics that reoccur with the ability given to working groups to change the language if necessary.

OBSERVER PARTICIPATION ON ICSP – Gordon Gillerman, NIST

Throughout the federal government there are individuals who are very knowledgeable of standards but are not the official Standards Executive or Representatives for their agencies and may be able to contribute to and benefit from the ICSP. Unofficially this is happening now. There was a discussion of whether or not there was a need to expand this practice or somehow formalize it. There was the expression that this would be the call of the standards executive and participation should be worked out through them. It was also recommended that participation not include contractors.

UPDATE ON SUBCOMMITTEE ON STANDARDS (SOS) ACTIVITIES – Ajit Jillavenkatesa, NIST

On January 25, 2011 a Roundtable was held to elicit feedback from industry to the SOS's Federal Register Notice. Aneesh Chopra, (Federal CTO) highlighted the need to hear from industry about the SOS's Request for Information (RFI) at a high level perspective. CTOs from several industries participated in the roundtable. This initial Roundtable provided a narrow focus of views and issues related to mainly the IT sector. About 200 attended the roundtable, with many more viewing the webcast.

With regards to the RFI, the deadline for comments was extended 90 days to 3/7/11

Discussion – There will likely be additional interaction with the private sector. Standards.gov is a repository for information from the SOS

(http://standards.gov/standards_gov/nstcsubcommitteeonstandards.cfm) including a link to the roundtable webcast and documents related to the RFI. The comments are available now http://standards.gov/standards_gov/mastercomments030711.cfm.

ICSP/GMF Meeting

THE PRESIDENT'S REGULATORY STRATEGY – POSSIBLE STANDARDS IMPLICATIONS – Tim Klein, DOT

Several standards concerns have come up recently within DOT including the public availability of standards and the proliferation of standards that cross over each other. The trucking industry, having many small operators, has brought up the "pay to play" issue regarding standards development, and would like DOT to examine alternative models to have standards made accessible DOT is looking for ideas on how other agencies approach this issue. Standards issues are now a big topic within DOT, particularly within the leadership and have gained more life because of the President's regulatory agenda.

Discussion – A number of agencies shared their experiences and discussed alternatives. HHS ARHQ negotiated to buy IP rights for medical vocabulary through the College of American Pathologies (CAP). Because their standards were mandated from the start, ARHQ wanted to provide access to anyone in US. Suggested that DOT find out from the SDO how much it would cost to make the standards accessible to a defined group. Concern was expressed that if this practice of negotiating access to standards became the norm, too large a percentage of SDO revenue would come from the government and the number of negotiations would greatly increase. CPSC has had standards made available by SDOs in read only format during the open comment period. DOT has standards accessible in their library to view. EPA has tried both approaches and has had problems with unscrupulous copying. DOT is under pressure to find a solution that provides access to standards as this is important for public safety and also fits into the competitive agenda atmosphere. With regards to standards incorporated by reference into regulations, EPA made the referenced part of the standard available for viewing in their library. At the next ICSP/GMF meeting, it is proposed to have a presentation from ANSI. Topics were originally envisioned to be on the various ways SDOs interact with government in standards development and the tools now available to allow participation without incurring travel costs. With regard to availability of standards, perhaps two different presentations would be appropriate – one on making standards available nationally, the other on access for large numbers of staff at governmental agencies.

DOT'S RESPONSE TO INQUIRY RE: NFPA 495 – Tim Klein, DOT

DOT received an inquiry from a party that was concerned about the contents of an NFPA standard. The party had carried its concerns through the ANSI process and did not prevail in its position. DOT is not able to intervene in this case, however if there are safety issues with a DOT rule, DOT can issue an emergency statute.

Discussion – EPA has faced a similar issue with regard to use of a chemical in an ASTM standard. The EPA technique requires use of a different chemical and was asked to intervene with the SDO. EPA's response was that it had no authority over the SDO but could provide assistance in providing the appropriate contact within the SDO. This issue can arise when technology advances beyond an older technology in a standard that is frozen into regulation. Agencies encountering inquiries on standards may contact ANSI and can also refer the party to ANSI to help with the issue.

DEVELOPMENT OF PRESENTATION MATERIALS WHICH ADDRESS FEDERAL USE OF AND PARTICIPATION IN THE DEVELOPMENT OF PRIVATE SECTOR STANDARDS – Greg Saunders, DoD

A joint ICSP-GMF task force was created to pull together a generic briefing on how and why the federal government uses voluntary standards. The briefing will be supplemented with agency specific

supporting documentation. Requests went out to agencies with a good response, but not all have provided input. Input can be in bullet or narrative form. The end result will be a succinct but well stated generic federal government briefing with the ability of customizing the presentation to the audience's needs. For example, if audience is more interested in regulatory standards, the presenter can add in regulatory examples; the same for trade, procurement, or an even narrower focus on something like energy. A link is provided to the set of questions. We hope to have 3-5 view graphs with bullets from each agency.

PROPOSED CHANGES TO THE ANSI ER (DUPLICATION) UPDATE – Anne Caldas, ANSI
The Essential Requirements (ER) are ANSI procedures that govern the American National Standards process and are approved and maintained by the Executive Standards Council (ExSC). The ExSC formed a task group to look at the issues of conflict and duplication and subsequently developed proposed revisions to the ANSI ER and the Operating Procedures of the ANSI Executive Standards Council which were announced for public comment. The proposed revisions provide some clarifications, a new definition for duplication, add details that define "good faith effort", introduce greater transparency with respect to PINS deliberation reports, offer a sample format to report the outcome of a PINS deliberation on duplication, and outlines the role of ExSC as a potential mediator of whether "good faith" efforts were used to address good faith efforts.

All public comments are posted on ANSI's site. Twenty-three public comments were received, The comments were widely ranging, with some having concerns that proposed strategic directions needed the Board of Directors to review; others feeling the changes are too onerous and would drive future standards groups away from the ANSI process; a few expressing support for the merits of the revisions; some offering mixed comments. The ICT (information and communication technology) community is particularly concerned about the possible anti-competitive effect of the proposed revisions.

The task group met to consider the comments and how to address them. It was decided to defer this task until after soliciting additional input during a May 2011 workshop that will address standards coordination. This is part of a larger effort partially funded by ANSI and NIST to improve access to standards information and update the NSSN database of current and pending standards. The workshop will cover the issues of conflict, duplication, and how this database may facilitate solutions through greater access to more information. (The workshop, "Standards Wars: Myth or Reality," is to be held on May 12 in Washington, DC - visit ww.ansi.org/standardswars for more information.)

After the workshop, the task group will look at comments and also consider the merits of engaging National Policy Committee if the proposed revisions are determined to be of a strategic nature. Any revisions approved by ANSI this year would appear in the 2012 edition of the relevant ANSI procedures.

HEALTH IT UPDATE – Lisa Carnahan, NIST
Slide presentation – NIST provided an update of activities in Health IT standards and certification. Due to a short time frame, HHS had to develop standards, test method and certification program in parallel. NIST was consulted, and devised the notion of a phased approach having an initial temporary program followed by a permanent one. The temporary program is being implemented now, with the permanent certification program in place by January 2012.

The temporary method uses a single testing and certification body with ISO management systems in place for assurance of confidence and repeatability. The process will help populate a certified health IT product list. There are six authorized test and certification bodies where health IT vendors can get their electronic health records (HER) systems certified. The rollout will be assisted by incentive payments from Medicaid and Medicare with potentially some disincentives for nonparticipation being phased in later.

This initiative may be a good case study of what to do and what works well when requirements come out rapidly and interactions between multiple agencies lead to very positive outcomes. HHS is putting together a "Standards Interoperability Framework" model to aid in the identification of gaps, test methods and to help move the development of standards forward.

NIST is working in two additional areas - Usability in health IT: standards are needed to ensure user centered designs. The other area is in medical devices – body implants and sensors requiring low level networking protocols, data standards, security, battery life. For example, NIST is looking into harnessing the energy from human motion to recharge batteries in implanted devices.

Discussion: There is a need to prevent mix up of patient data at the outset. FDA is aware of this and there will be universal ID elements within the devices.

In area of device security, managing security will take some thought – will need an unbreakable algorithm, but cannot have DC encryption as it would use up too much battery power. Transmissions require a short life/timeframe, which is different from car devices which require continuous connectivity. DOT is working on this area in cars.

ISO SUSTAINABILITY GUIDE UPDATE – Mary McKiel, EPA
The attached presentation provided an update on the progress of the development of a guide for use by ISO standards writers when incorporating sustainability elements into standards.

Discussion: The discussion began with a question regarding the meaning of "sustainability" in a standard. It's defined as not the life cycle of the standard, but the incorporation of elements within a standard that address the broad field of sustainability, particularly environmental, but may include social, economic, etc. ANSI has a virtual TAG to help inform the delegates. Members are welcome to join the virtual TAG. Mary McKiel is an alternate and Ed Penaro is the primary delegate from the US.

BRIEFING ON CONGRESSIONAL ACTIVITIES – Scott Cooper ANSI
Scott Cooper briefed on changes in the House Science Committee. He has met with Julia Jester who is the new chief of staff for the Technology & Innovation Subcommittee. The new House Technology & Innovation Subcommittee Chair is a freshman to Congress, Benjamin Quayle. It is likely that there will be oversight hearings particularly in areas such as regulatory initiatives, jobs and innovation, global competitiveness, and cybersecurity.

UPDATES FROM PARTICIPANTS - All
HHS US Health Information Knowledge Base (USHIK), a metadata registry of heath care data standards, is being extended with a re-competition of the contract.

NIST offers free training for federal agencies on standards and conformity assessment which includes a day long standards simulation exercise on how standards are created. The simulation is conducted by a contracted trainer. There are a few open workshops available until the end of this calendar year, so if anyone is considering the training for their agency, now is a good time to schedule it. Contact Mary Jo DiBernardo for more information (maryjo.dibernardo@nist.gov).

Reminder about NTTAA reports and input to the presentation material.

Next joint meeting will be around April 21 as part of the GMF meeting.

Adjourn