

to shares of Common Stock should be passed through to the accounts of Participants.

29. The Applicant states that the requested exemption is protective of the rights of Participants and beneficiaries because they had the opportunity, at their own discretion, to participate in the Offering on the same terms as every other Shareholder. The Applicant stresses that Participants and their beneficiaries had no obligation to exercise their Rights, and in fact could not exercise their Rights if the Subscription Price was below the Closing Price on January 14, 2011 (any Rights not exercised by the Participants simply expired). The Applicant states that the terms of the Offering were described to the Participants in clearly written communications, namely the 401(k) Participant Instructions and the 401(k) Participant Election Form, and that the decision by Participants to exercise Rights held in their Plan Accounts of the Participants in the Offering was strictly voluntary. Finally, the Applicant notes that neither TIB nor any of the Plan fiduciaries placed any pressure on Participants to exercise their Rights in the

**P** : In addition to providing written comments, interested parties are invited to attend the public workshop on May 15th. The workshop will include presentations from key government officials, industry, and experts on standards and conformity assessment issues, and time will be allotted for participant input and discussions. There is no registration fee for the workshop.

**To gain access to the NIST campus, located at 100 Bureau Drive in Gaithersburg, MD 20899, all participants must register in advance no later than 5 p.m. EST on May 8, 2012. Non-U.S. citizens must register no later than May 1, 2012. There will be no onsite registration. To register online, visit the "Register Now" link on the conference web site at [http://www.nist.gov/standards/2012/05/08/](#).**

**ADDRESSES:** All comments should be submitted via [http://www.nist.gov/standards/2012/05/08/](#)

or faxed at 202-395-5167. Please submit comments only and include your name, company name (if any), and cite "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" in all correspondence. All comments received will be posted, without change or redaction, to [http://www.nist.gov/standards/2012/05/08/](#), so commenters should not include information they do not wish to be posted (e.g., personal or confidential business information).

**FOR FURTHER INFORMATION CONTACT:** Jasmeet Seehra, Office of Information and Regulatory Affairs, at [http://www.nist.gov/standards/2012/05/08/](#).

**SUPPLEMENTARY INFORMATION:** In the "National Technology Transfer and Advancement Act of 1995" (Pub L. 104-113; hereinafter "the NTAA"), Congress stated that Federal agencies "shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities," except when an agency determines that such use "is inconsistent with applicable law or otherwise impractical." As amended by Section 1115 of Public Law 107-107, Section 12(d) provides that:

(d) **UTILIZATION OF CONSENSUS TECHNICAL STANDARDS BY FEDERAL AGENCIES; REPORTS.—**

(1) **IN GENERAL.—**Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry

out policy objectives or activities determined by the agencies and departments.

(2) **CONSULTATION; PARTICIPATION.—**In carrying out paragraph (1) of this subsection, Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards.

(3) **EXCEPTION.—**If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph.

(4) **EXPENSES OF GOVERNMENT PERSONNEL.—**Section 5946 of title 5, United States Code, shall not apply with respect to any activity of an employee of a Federal agency or department that is determined by the head of that agency or department as being an activity undertaken in carrying out this subsection.

(5) **DEFINITION OF TECHNICAL STANDARDS.—**As used in this subsection, the term "technical standards" means performance based or design-specific technical specifications and related management systems practices.

Section 12(d) is found as a "note" to 15 U.S.C. 272.

In response to the enactment of the NTAA, OMB prepared a proposed set

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<sup>1</sup> See [http://www.nist.gov/standards/2012/05/08/](#).

**Register** notice published on March 16, 2012 (77 FR 15719).

If OMB determines, based on the responses to the RFI, discussions at the workshops, and further consideration of the issues, that it would be useful to develop supplemental guidance for the Circular to address some or all of the issues raised, then OMB will publish a draft notice in the **Federal Register** at a subsequent date and request public comment.

In response to this RFI and at the workshop, OMB is interested in receiving input from interested stakeholders pertaining to one or more of the following issues relating to standards and conformity assessment, specifically with respect to how these issues may affect agencies engaged in rulemaking, procurement, and other activities.

119. Are Federal agencies generally following the guidance set out in the Circular and providing an adequate explanation of how they considered standards and conformity assessment-related issues in the preambles to rulemakings?

OMB A-119 does not establish a preference between consensus and non-consensus standards developed in the private sector. A limited set of foundational attributes of standardization activities are identified in the Circular, focusing on voluntary consensus standard activities. It may also be important to recognize the contributions of standardization activities that take place outside of the voluntary consensus process, in particular certain activities in emerging technology areas.

- What factors should agencies use in evaluating whether to use voluntary non-consensus standards in regulation, procurement solicitations, or other non-regulatory uses? OMB also invites comments on the respective roles of voluntary consensus standards vs. voluntary non-consensus standards for agency responsibilities in rulemaking, procurement, and other activities.

Circular A-119 directs the Secretary of Commerce to issue guidance to Federal agencies on conformity assessment. NIST issued such guidance in 2000 and plans to update the guidance.

In conjunction with NIST's efforts to update its conformity assessment guidance, should a supplement to Circular A-119 be issued to set out relevant principles on conformity assessment? If so, what issues should be addressed in such a supplement? The following are among the topics that could be considered:

- Factors agencies should use in selecting the appropriate conformity assessment procedure, including product/sector specific issues and the level of risk of non-fulfillment of legitimate regulatory, procurement, or other mission-related objectives;
- Guidance for regulatory agencies on compliance with relevant international obligations pertaining to conformity assessment and accreditation activities;
- Factors agencies should consider in determining whether to recognize the results of conformity assessment and accreditation activities conducted by private sector bodies in support of regulation;
- Non-regulatory uses of standards (including vendor conformity for purposes of response to procurement solicitations); and
- Ensuring that agencies consider how to minimize conformity assessment costs and delays for businesses, especially small and medium sized enterprises, subject to statutory and budgetary constraints and the ability of agencies to fulfill their legitimate regulatory, procurement, or other mission-related objectives.

Standards themselves are considered to be intellectual property and are typically copyrighted by the standards developing bodies that administer the process by which specific standards are developed and used for procurement, or other mission-related objectives. Standards themselves are considered to be intellectual property and are typically copyrighted by the standards developing bodies that administer the process by which specific standards are developed and used for procurement, or other mission-related objectives.

during rulemaking and during the effective period of the regulation while respecting the copyright associated with the standard?

- What are the best practices for incorporating standards by reference in regulation while respecting the copyright associated with the standard?

Standards developing bodies, including not-for-profit organizations, use a variety of cost-recovery models as part of their overall way of doing business. OMB believes that it may be helpful for the purposes of the Circular and for the evaluation of costs and benefits of significant regulatory actions pursuant to Executive Orders 12866 and 13563 for Federal agencies to have a basic understanding of the costs associated with the development of private sector standards, in addition to the purchase costs of standards. Similarly, agencies and the public should have an understanding of the overall resources and costs that would be involved if Federal agencies were to develop government-unique standards. Both of these can be elements in determining when it is practical or impractical to incorporate a voluntary standard into regulation or otherwise adopt a standard in the course of carrying out an agency's mission, as compared to developing a government-unique standard.

- What resource and other costs are involved in the development and revision of voluntary standards?
- What economic and other factors should agencies take into consideration when determining that the use of a voluntary standard is practical for regulatory or other mission purposes?
- How often do standards-developing bodies review and subsequently update standards? If standards are already incorporated by reference in regulations, do such bodies have mechanisms in place for alerting the relevant agencies and the public, especially in regard to the significance of the changes in the standards?

Federal agencies have adopted various methods of using standards as a basis for regulation. They have also developed different approaches to updating standards that have been referenced or incorporated in regulations.

- Should OMB set out best practices on how to reference/incorporate standards (or the relevant parts) in regulation? If so, what are the best means for doing so? Are the best means of reference/incorporation context-specific? Are there instances where incorporating a standard or part thereof

into a regulation is preferable to referencing a standard in regulation (or vice versa)?

- Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised? If so, what updating practices have worked well and which ones have not?

OMB recognizes that changes in technology and the need for innovation can result in the updating of private sector standards in a turn-around time of two years or even less. Where such standards are already incorporated into regulations, these changes can suggest a need to update the relevant regulations as well and, in some cases, can result in a need for regulated entities to purchase the newly updated standards on a fairly routine basis. In addition to the costs associated with the continuing purchase of such standards, rapid update cycles may make it difficult for the regulated public to understand the nature and significance of the changing regulations.

- Is there a role for OMB in providing guidance on how Federal agencies can best manage the need for relevant regulations in the face of changing standards?

- How should agencies determine the cost-effectiveness of issuing updated regulations in response to updated standards?

- Do agencies consult sufficiently with private sector standards bodies when considering the update of regulations that incorporate voluntary standards, especially when such standards may be updated on a regular basis?

OMB recognizes that, in some instances, it may be best, in terms of economic activity, if a regulation or procurement solicitation sets out a requirement that can be met by more than one standard and more than one conformity assessment procedure. In some cases, however, allowing the use of more than one standard or conformity assessment procedure may not be possible or meet the regulatory or procurement objective. For example, doing so may be precluded by statute, and an alternate standard or conformity assessment procedure may not provide an equivalent level of protection as the standard or conformity assessment procedure selected by the regulator.

- Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity

with regulatory requirements or solicitation provisions?

- Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or the use of an alternate conformity assessment procedure as adequate to fulfilling U.S. requirements, should OMB provide guidance to agencies on how to consider such requests?

#### Other Developments

- Have there been any developments internationally—including but not limited to U.S. regulatory cooperation initiatives—since the publication of Circular A-119 that OMB should take into account in developing a possible supplement to the Circular?

- Does the significant role played by consortia today in standards development in some technology areas have any bearing on (or specific implications for) Federal participation?

- Are there other issues not set out above that OMB might usefully seek to address in a supplement?

Cass Sunstein,

[FR Doc. 2012-7602 Filed 3-29-12; 8:45 am]

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#### MILLENNIUM CHALLENGE CORPORATION

[MCC 12-04]

#### Report on Countries That Are Candidates for Millennium Challenge Account Eligibility in Fiscal Year 2012 and Countries That Would Be Candidates but for Legal Prohibitions

AGENCY: Millennium Challenge

<sup>1</sup> The changes to the Act enacted in the Appropriations Act only apply to the FY 2012 selection process. The relevant language would need to be included in next year's appropriations