

OFFICE OF MANAGEMENT AND BUDGET

U.S.-Canada Regulatory Cooperation Council Stakeholder Request for Comment Summer 2013

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice.

In recognition of the integrated nature of the Canadian and U.S. economies, the role of free and open trade in encouraging jobs and growth, and the benefits of increased regulatory alignment, President Obama and Prime Minister Harper announced the Canada-U.S. Regulatory Cooperation Council (RCC) in February 2011.

In December 2011, the Canadian and U.S. governments launched the initial RCC Joint Action Plan and identified specific issues where there was bi-national willingness to work together to seek greater cooperation in our regulatory approaches. A detailed work plan was developed for each of the twenty-nine (29) Joint Action Plan initiatives including specific milestones, consideration for more systemic changes, and a commitment to stakeholder engagement. We have made important progress to date, and we continue our work to implement these work plans.

At this time, the Canadian and the U.S. Governments invite public views on progress to-date and how best to address regulatory divergence between our two governments moving forward. In particular, we invite comment on certain issues/sectors that should be considered for future cooperation, including proposals to align regulatory systems, streamline bilateral cooperation, and improve stakeholder engagement.

Canada and the United States intend to identify opportunities for greater cooperation that, if undertaken in a systemic way, would secure greater alignment between our countries' regulatory systems. These collaborative mechanisms are aimed at bringing Canadian and U.S. regulatory agencies together in a more comprehensive way around the planning and coordination of work across our regulatory systems.

With the recognition that increased regulatory cooperation in no way diminishes the sovereignty of either the United States or Canada or the ability of either country to carry out its regulatory functions according to its domestic, legal policy and international commitments, one potential way to advance collaboration is enhanced

cooperative arrangements between Canadian and U.S. regulatory agencies.

These cooperative arrangements could provide the framework for high-level commitment to pursue further alignment of our regulatory systems, such as identifying work-sharing opportunities, common programs, and a greater reliance on work performed under either system. These arrangements may also include opportunities for long-term and annual planning so that routine regulatory work and system advancements could be considered together.

In any approach to strengthening cooperation, regulators would have the key role in securing and implementing these arrangements between Canadian and U.S. agencies. Stakeholder input is instrumental in providing practical recommendations for future alignment opportunities, clarifying priorities, and assisting in possible pilot projects.

Below are some key areas where we believe stakeholder insights would be most helpful, though we certainly welcome input beyond these areas:

- Ideas on the appropriate role for stakeholders, and how stakeholders can best engage with Canadian and U.S. regulators on regulatory cooperation opportunities and Action Plan implementation.
- Recommendations on how to augment standards cooperation between our respective countries—both public and private sector—to support and build on the RCC work.
- Recommendations on how to institutionalize regulatory cooperation between our two countries.
- Opinions on moving forward on the next phase of Canada-U.S. regulatory cooperation through mechanisms such as agency-to-agency cooperative arrangements. We welcome ideas on how to advance them where they already exist and create them where they are non-existent.
- Detail on measurable benefits for industry, government, and/or consumers that can be quantified and shared, which occurred as a direct result of a current RCC initiative.
- Particular sectors or issues for which the RCC should consider further regulatory alignment, including emerging technologies (such as nanotechnology) that are not yet regulated. Where possible, please provide:
 - a description of the issue or unnecessary difference as well as the potential alignment opportunity;
 - the relevant regulatory agencies;
 - the relevant regulatory and/or statutory provisions for each jurisdiction (or an indication that such

provisions do not yet exist in one or both jurisdictions);

- an assessment of the net benefits of enhanced regulatory alignment (i.e. quantified costs and benefits, and the time period over which they would accrue); and
- possible regulatory cooperation best practices that should be considered for removing unnecessary differences or duplicative practices.

Please provide your responses by Friday, October 11, 2013. Comments are welcomed through Regulations.gov (search by keywords: "Regulatory Cooperation Council" or Docket ID#: OMB-2013-0004), and the Canada Gazette. Written submissions can also be sent to the United States via *International-OIRA@omb.eop.gov* and to Canada via *RCC-CCR@pco-bcp.gc.ca*.

Your detailed input will help the RCC Secretariat and Government Agencies in finalizing implementation of the current work plans and in establishing systemic structures to strengthen regulatory cooperation efforts. We plan to explore the input we receive, and provide next steps by the end of the calendar year.

For more information on the RCC, please visit www.trade.gov/rcc and www.actionplan.gc.ca/rcc.

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US-Canada Regulatory Cooperation Council

SUPPLEMENTARY INFORMATION

The United States and Canada enjoy the largest bilateral trading relationship in the world and almost 9,000 km (5,600 miles) of common border. We have a shared focus on: the importance of protecting health, safety, and the environment; mature and highly effective regulatory systems; and a long history of regulatory cooperation at the bi-national and international levels. This relationship represents both a strong starting point and clear motivation for deepening regulatory cooperation.

Regulatory cooperation is not about creating one regulatory system for Canada and the United States, nor does it mean that all regulatory work will be done in one country alone, or that it will always be done jointly. Instead, it is about working together where it is mutually beneficial for both countries. Lack of alignment, which can create unnecessary costs and unnecessary delays to trade, is generally not the product of fundamental differences in regulatory objectives. Instead, it is often simply the product of operating independently, without mechanisms to align our parallel regulatory systems.

Effective regulatory cooperation is about more than just regulations. It is possible that identical regulations could still contain duplicative requirements and verifications that hinder trade and increase costs. Regulatory cooperation must consider all facets of the regulatory system including regulatory policy, related programs and guidance, inspection and testing methods, and compliance and enforcement activities.

Work on the initial Regulatory Cooperation Council (RCC) Action Plan has helped to identify a number of areas where we believe deeper cooperation would generate significant benefit for regulated parties, citizens, and regulators. For example:

Standard Setting: aligning standards or sharing information concerning the standards development activities in which regulators will play an active role.

Product Reviews and Approvals: joint applications and aligned requirements, sharing in work to inform approvals.

Reliance on Outcomes of the Other Regulatory System: working together in advancing regulatory systems to achieve common outcomes, and then increasing reliance on the work conducted in the other jurisdiction.

Managing 3rd Country Import Risk: coordinating import programs and sharing information about third country technical requirements, increasing our reliance on assessment and inspection work done off-shore by the other country and at our external borders at the point of first entry into Canada or the United States.

Improving Confidence in Conformity Assessment: aligning conformity assessment practices, and reliance on international conformity assessment standards and acceptance mechanisms to achieve greater confidence in inspection and testing results.

The current range of authorities, policies, and administrative practices that support strong regulatory systems in the United States and Canada were developed in a much less integrated time. In order to maintain the strength of these systems and to meet the realities and expectations of Canadian and American citizens and industry, new and increased levels of cooperation must be considered. We therefore ask that comments and suggestions consider the full range of cooperation possibilities.

The objective is to make regulatory cooperation a cornerstone of an enhanced regulatory relationship between Canada and the United States, while leveraging the expertise and efforts of regulators in each country. We

welcome stakeholder input on considerations for ongoing alignment.

Howard A. Shelanski,

Administrator, Office of Information and Regulatory Affairs.

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NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-458; NRC-2013-0190]

Entergy Operations, Inc., River Bend Station, Unit 1; Exemption

1.0 Background

Entergy Operations Inc. (Entergy, the licensee) is the holder of Facility Operating License No. NPF-47, which authorizes operation of the River Bend Station, Unit 1 (RBS). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC) now or hereafter in effect.

The facility consists of a boiling-water reactor located in West Feliciana Parish, Louisiana.

2.0 Request/Action

Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors," requires that components which penetrate containment be periodically leak tested at the "P_a," defined as the "calculated peak containment internal pressure related to the design basis accident specified either in the technical specification or associated bases." In October 2011, Entergy was contacted by the NRC concerning the station's use of the appendix J definition of P_a. The NRC noted a conflict between Entergy's interpretation of that definition of P_a and the literal reading of the definition of P_a in the regulations. Entergy stated it was defining P_a based on the long-term calculated pressure peak for the containment as a whole and not on the short-term localized pressure spike in wetwell.

By letter dated August 23, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12241A250), Entergy submitted a request for an exemption from the definition of the P_a as stated in 10 CFR part 50, appendix J, and substitute an alternate definition. The value of P_a is determined by calculating the pressure response in containment over time after a main steam line break.

The original containment analysis for RBS had determined P_a to be 7.6 pounds per square inch gauge (psig). In July 1999, RBS submitted a license amendment request to increase the licensed thermal power of the station by 5 percent from 2,894 megawatts thermal (MWth) to 3,039 MWth. As part of the extended power uprate review, new calculations were performed and determined that a localized pressure spike in the wetwell occurs within a few seconds of the accident and with a pressure peak at 9.3 psig. However, the localized pressure in the wetwell quickly drops by several psig as the pressure equalizes throughout containment. This calculation also determined that the long-term peak containment pressure is 3.6 psig. To avoid a large number of procedure changes, which would be required if the value was changed, RBS elected to maintain P_a at the original (pre-extended power uprate) value of 7.6 psig, which is conservative to the calculated long-term peak value of 3.6 psig. The exemption would allow Entergy to continue to use the previously calculated value of 7.6 psig for P_a for RBS instead of the localized pressure spike in the wetwell calculated value of 9.3 psig.

The NRC staff has concluded that the use of the alternate definition for P_a meets the intent of 10 CFR part 50, appendix J because it provides testing of the primary containment parameters at a pressure that would exist throughout containment over the long term following a design basis accident.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. The staff accepts the licensee's determination that an exemption would be required to continue to use the alternate definition of P_a from that defined in 10 CFR part 50, appendix J.

The NRC staff examined the licensee's rationale to support the exemption request and concluded that the use the value of 7.6 psig for P_a would meet the underlying purpose of 10 CFR part 50, appendix J. Supporting the use of this alternate value is:

(1) The time for the pressure spike to occur and fall to equilibrium is 6 seconds, which is not sufficient time to release source terms from the core,