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May 11, 2015

Mr. Mark A. Satorius  
Executive Director for Operations  
U.S. Nuclear Regulatory Commission  
Mail Stop 016E15  
11555 Rockville Pike  
Rockville, MD 20852-2738

**Subject:** Use of Qualitative Factors in Regulatory Decision Making

**Project Number:** 689

Dear Mr. Satorius

I am writing to express concern regarding the NRC staff's use of qualitative information (i.e., "qualitative factors") in regulatory and backfitting analyses.<sup>1</sup> Specifically, the industry is concerned because the staff continues to use qualitative information to support particular regulatory outcomes – even though such outcomes cannot be justified using available and relevant quantitative information.

As you are aware, concern over the use of qualitative information played a significant role in the Commission's decision to assess filtration strategies via rulemaking, rather than by order.<sup>2</sup> In response to the staff requirements memorandum providing direction on SECY-12-0157, the staff prepared a notation vote paper addressing the use of qualitative information to support agency decision making.<sup>3</sup> In that paper, the staff proposed changes to the agency's guidance on the use of qualitative factors, with the goal of achieving "greater transparency and consistency of NRC decisions."<sup>4</sup>

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<sup>1</sup> References to regulatory analyses and the regulatory analysis process in this letter should be read to include backfitting analyses that are performed pursuant to the guidance contained in NUREG/BR-0058.

<sup>2</sup> See Commission Voting Record SECY-12-0157, "Consideration of Additional Requirements for Containment Venting Systems for Boiling Water Reactors with Mark I and Mark II Containments," March 19, 2013.

<sup>3</sup> "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," SECY-14-0087, Aug. 14, 2014.

<sup>4</sup> *Id.* at 2.

Although approving revision of the agency's guidance to achieve these objectives, the Commission cautioned that it was not authorizing "an expansion of the consideration of qualitative factors" and that the revised guidance "should continue to encourage quantifying costs to the extent possible and use qualitative factors to inform decision making in limited cases, when quantitative analyses are not possible or practical."<sup>5</sup> Despite this express caution, and the history of Commission concern regarding the use of qualitative information,<sup>6</sup> it appears the staff is continuing to use qualitative information to support regulatory decisions despite available quantitative information indicating that such decisions are not justified. A recent example of such use of qualitative information can be found in the pre-decisional draft regulatory analysis supporting imposition of Severe Accident Mitigation Guidelines (SAMGs) as part of the broader mitigation of beyond-design-basis event (MBDBE) rulemaking.<sup>7</sup> A description of industry's concerns regarding the staff's use of qualitative information to support imposition of a SAMG requirement in the MBDBE rulemaking is provided in the attachment to this letter.

This use of qualitative factors presents several fundamental problems. First, reliance on qualitative information to overcome, rather than supplement in the absence of, quantitative information is contrary to the Commission's recent direction that regulatory decisions should be informed by qualitative factors "in limited cases, when quantitative analyses are not possible or practical (i.e., due to a lack of methodologies or data)."<sup>8</sup> The Commission provided this direction in order "[t]o ensure that qualitative factors are used in a judicious and disciplined manner."<sup>9</sup> Further, an outcome-focused use of qualitative information facilitates the potential misuse of the regulatory analysis process as a means to justify regulatory decisions that, in reality, have already been made. It has long been recognized that regulatory analyses "should not be used

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<sup>5</sup> Staff Requirements – SECY-14-0087 – "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," March 4, 2015.

<sup>6</sup> As Commission Svinicki pointed out in her vote on SECY-12-0157, Commission concern regarding the use of qualitative information to support regulatory decision making is not limited to the post-Fukushima era. See "Commissioner Svinicki's Comments on SECY-12-0157 Consideration of Additional Requirements for Containment Venting Systems for Boiling Water Reactors with Mark I and Mark II Containments," at 2 (quoting Commissioner Edward McGaffigan's vote joining a Commission majority disapproving the issues for public comment of the proposed Shutdown Rule, SECY-97-0168, Oct. 7, 1997).

<sup>7</sup> Draft Regulatory Analysis: Proposed Rulemaking to Address Mitigation Beyond-Design-Basis Events, ML15068A284, February 24, 2015 (pre-decisional) ("Draft Regulatory Analysis"). "*Despite the available risk information, the NRC proposes that SAMGs should be requirements based on qualitative reasons described in greater detail below.*" *Id.* at 69 (emphasis added).

<sup>8</sup> Staff Requirements – SECY-14-0087 – "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," March 4, 2015. Admittedly, the Draft Regulatory Analysis was developed prior to issuance of SRM-SECY-14-0087. However, the presentations and discussion at the April 30 "Commission Briefing on the Status of Lessons Learned from the Fukushima Dai-ichi Accident" indicated that the position taken in the pre-decisional draft regulatory basis has not been significantly modified.

<sup>9</sup> *Id.*

to produce *post hoc* rationalizations for decisions already made.”<sup>10</sup> The NRC’s guidance governing the development of regulatory analyses echoes this sentiment essentially verbatim, stating: “The [regulatory analysis] process is to be used neither to produce after-the-fact rationalizations to justify decisions already made, nor to unnecessarily delay regulatory actions.”<sup>11</sup>

Although the NRC has positioned the regulatory analysis process to facilitate informed decision making from a procedural standpoint,<sup>12</sup> misuse of qualitative information has the potential to undermine use of the process to ensure that the agency’s regulatory initiatives are appropriately safety-focused, cost-justified, and cost-effective when compared with reasonable alternatives. The Office of Management and Budget’s (OMB) Circular A-4 explains the preeminence of quantified estimates in regulatory analyses stating that “sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternative actions.”<sup>13</sup>

As OMB has explained, the regulatory analysis process “has an important democratic function; it promotes accountability and transparency and is a central part of open government.”<sup>14</sup> In the context of the NRC’s regulatory framework, regulatory analyses also serve an important “gatekeeping” function in the effort to address the cumulative impacts of regulation. That is, a meaningful regulatory analysis verifies that individual regulatory initiatives will yield tangible safety benefits and will be cost-beneficial, prior to imposition on licensees. In this way, properly performed regulatory analyses ensure that the risk prioritization process is applied to an appropriately scoped set of high-quality regulatory initiatives.

In sum, the NRC’s Principles of Good Regulation demand that the agency’s regulatory framework exhibit the attributes of Clarity, Efficiency, and Reliability. Appropriately limiting the use of qualitative factors in situations where relevant quantitative information exists will yield a more meaningful and objective regulatory analysis process. Such a process furthers the Principles of Good Regulation by ensuring that

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<sup>10</sup> Administrative Conference of the United States, *Recommendation 85-2, Agency Procedures for Performing Regulatory Analysis of Rules*, 50 Fed. Reg. 28,363, 28,364 (July 12, 1985).

<sup>11</sup> See *Regulatory Analysis Guidelines of the United States Nuclear Regulatory Commission*, NUREG/BR-0058, Rev. 4, at 4 (“The [regulatory analysis] process is to be used neither to produce after-the-fact rationalizations to justify decisions already made, nor to unnecessarily delay regulatory actions.”).

<sup>12</sup>For example, the NRC uses regulatory analysis to inform a wide variety of regulatory initiatives including “all mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees. . . . These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions, and standard technical specifications.” NUREG/BR-0058, at pg. 5. In addition, the NRC has incorporated the regulatory analysis process early in the rulemaking process to facilitate sound decision-making.

<sup>13</sup> Circular A-4, Sept. 2003, at 26.

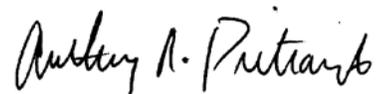
<sup>14</sup> *Regulatory Impact Analysis: A Primer*, at 2.

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regulatory initiatives are justified given the degree of risk reduction they achieve; cost-beneficial and cost-effective in situations where several reasonable alternatives are available; and readily understood by industry and other stakeholders.

Please feel free to contact me, if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Anthony R. Pietrangelo". The signature is written in a cursive, slightly slanted style.

Anthony R. Pietrangelo

c:     The Honorable Stephen Burns  
       The Honorable Kristine Svinicki  
       The Honorable William Ostendorff  
       The Honorable Jeff Baran  
       Michael Johnson, NRC DEDO  
       William Dean, NRC NRR