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NIST invited comments on Special Publication 2000-1: *The ABC's of Conformity Assessment* on January 12, 2018. The American Nuclear Society's Risk-informed, Performance-based Principles and Policy Committee (RP3C) reviewed the document and provides the following proposed changes to the document:

RP3C requests that the text of Special Publication 2000-1 be modified to reflect the following starting with Line 237. It is expected that editorial alterations may be required such as for the reference provided.

"Standards used in conformity assessment should not impede innovation. When possible, standards should be performance based, describing how a product is supposed to function, rather than how the product is to be designed (OMB, 2016). The US Nuclear Regulatory Commission has published guidance on this subject (NUREG/BR-0303, "Guidance for Performance-Based Regulation). For example, a performance standard for water pipe might set requirements for the pressure per unit area that a pipe must withstand, along with a test method to determine if a pipe sample meets the requirement. The performance standard ideally also indicates the functional purposes that are to be accomplished by the pipe. It could serve as the barrier to release of radioactive material, or it may simply convey water from one location to another. In an even simpler scenario, it may merely serve to equalize pressure between two points in a system. Manufacturers should be free to choose any product design, material, and manufacturing process as long as the pipe can perform in the specified manner. On the other hand, a standard that requires that a pipe be made of a given gage of copper and have a given diameter as a design standard may unnecessarily restrict options and impede innovation. Manufacturers trying to comply with such as standard should be free to make the pipe out of material that will deliver the outcome consistent with the functional purposes to be achieved.

While a performance standard better provides for innovation, it can be more complicated to specify, implement, and assess for conformity. The complication could be mitigated by treating specification of a requirement and establishing the test methods and protocols for conformity assessment within an integrated system. Experience with performance based approaches has shown that effective implementation of such a system requires consideration of the margin between the nominal performance and the level at which performance would be deemed unacceptable. The importance of testing and monitoring becomes evident when one considers that one may allude to a desired level of performance, but until one has operationalized the conformity assessment, it may not be possible to know what real performance to expect.

Standards used in conformity assessment should also be chosen so that they specify all essential characteristics of a product necessary for achieving the objective of the conformity assessment activity. For example, if confidence of the electrical safety of a coffee pot is the objective, a standard that covers only the electrical safety of the coffee pot's cord and does not cover the pot's heating element would not meet the objective. In the water pipe example, the objective of preventing unintended release of radioactivity requires consideration of a more comprehensive set of performance factors than merely allowing water to flow from one location to another. Knowing what aspects of the product will be evaluated in a conformity assessment process and whether there are other aspects that might impact quality, safety, or performance allows the user of the conformity assessment data to evaluate the data's significance."

Please acknowledge receipt of this comment. Please contact the undersigned if there are any questions.

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Risk-informed Performance-based Principles and Policy Committee
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