Response to Public Comments on Draft Regulatory Guide DG-1363 "Setpoints for Safety-Related Instrumentation" Proposed Revision 4 of Regulatory Guide (RG) 1.105

On August 14, 2020, the NRC published a notice in the *Federal Register* (85 FR 49685) that Draft Regulatory Guide, DG-1363 (Proposed Revision 4 of RG 1.105), was available for public comment. The public comment period ended on September 14, 2020. The NRC received comments from the organizations listed below. The NRC has combined the comments and NRC staff responses in the following table.

Comments were received from the following:

1. Anonymous
   Agencywide Document and Management System (ADAMS) Accession No. ML20234A197

2. Anonymous
   ADAMS Accession No. ML20234A198

3. Anonymous
   ADAMS Accession No. ML20234A200

4. Anonymous
   ADAMS Accession No. ML20234A202

5. Anonymous
   ADAMS Accession No. ML20234A204

6. Anonymous
   ADAMS Accession No. ML20234A697

7. Anonymous
   ADAMS Accession No. ML20240A256

8. Anonymous
   ADAMS Accession No. ML20240A257

9. Anonymous
   ADAMS Accession No. ML20240A259

10. Anonymous
    ADAMS Accession No. ML20240A260

11. Anonymous
    ADAMS Accession No. ML20241A164

12. Anonymous
    ADAMS Accession No. ML20245E263

13. Anonymous
    ADAMS Accession No. ML20245E265

14. Mendy Maxey
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16. Anonymous
ADAMS Accession No. ML20246G653

17. Anonymous
ADAMS Accession No. ML20247J618

18. Anonymous
ADAMS Accession No. ML20253A004

19. Anonymous
ADAMS Accession No. ML20253A229

20. Anonymous
ADAMS Accession No. ML20253A231

21. Anonymous
ADAMS Accession No. ML20254A107

22. Anonymous
ADAMS Accession No. ML20255A303

23. Anonymous
ADAMS Accession No. ML20261H514

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Commenter	Section of DG-1363	Specific Comments (These are the full comments as provided in each submission)	NRC Resolution
1. Anonymous	General	The public review and comment period for this matter was shortened from the normal 60 days to 30 days. The rationale for this change given was the assertion that the NRC has previously interacted with stakeholders on related industry and NRC guidance and the proposed revision endorses ANSI/ISA 67.04.01-2018 without any exceptions or clarifications. There have not been a public meeting on this matter since August 2014 on DG-1141 so many of those who have commented on the previous draft regulatory guide are at a disadvantage first to become aware of this notice and then to review the new version and prepare appropriate comments. The staff has had sufficient time since December 2018 when ISA Standard 67.04.01-	The NRC staff disagrees with this comment. The NRC does not normally hold public meetings for the proposed revisions to Regulatory Guide updates. An explanation of the transition from DG-1141 to DG-1363 is provided in detail within the *Federal Register* notice for this proposed revision issued on August 8, 2020 (85 FR 49685). The International Society of Automation (ISA) Standards Development

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		2018 was issued to conduct a public meeting to gather feedback from other stakeholders who have similar systems and components which perform safety-critical functions.	Organization (SDO) follows the American National Standards Institute (ANSI) endorsed process for developing standards, which includes opportunities for the public to submit comments to the standards organization(s) during the development of the draft standard. Further, because the NRC is endorsing this consensus ANSI/ISA 67.04.01-2018, "Setpoints for Nuclear Safety Related Instrumentation," without any exceptions, the 30 day comment period was deemed appropriate. The NRC staff made no changes to DG-1363 as a result of this comment.
2. Anonymous	General	Obsolescence of systems and components, and market conditions, is incentivizing nuclear power plant (NPP) owners to upgrade outdated analog Instrumentation and Control (I&C) systems with digital technology. Most U.S. operating plants have extended their license to 60 years (potential extension to 80 years), so replacing outdated 1960s-70s technology is unavoidable. Digital components (e.g., I/O modules, software) may introduce new errors into the measurement due to digital technology. The regulatory analysis of the draft regulatory guide states that the revision would incorporate the latest information in setpoint determination. However, the draft regulatory guide does not address Quantization Error which may be introduced due to digital upgrade changes in NPPs. The process by which an analog signal (sampled and held at a constant value), is approximated to a set of values meant to represent the signal and dependent on number of bits used to represent the signal. The analog signal and its digital representation after	The NRC staff partially agrees with this comment with respect to the need for digital technology to be used along with its associated uncertainties and that DG-1363 does not address quantization error. However, the ANSI/ISA 67.04.01-2018 standard is technology inclusive and provides the bounding requirements and attributes one needs to analyze while evaluating uncertainties. DG-1363 endorses this standard and Section 4.4 of the standard states that all sources of uncertainties need to be addressed. Section B.2.2.8 of DG-1363 also identifies that additional information for determining total loop uncertainties may be found in the ISA Recommended

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		quantization is the Quantization Error (Rounding/Round off and Truncation/Truncating errors).	Practice (RP) document ISA-RP67.04.02-2010, "Methodologies for the Determination of Setpoints for Nuclear Safety Related Instrumentation," which implements the set of requirements specified in the standard. The identification and treatment of digital processing-related channel uncertainties are covered in depth within Section 6.2.9 and Annex H of ISA-RP67.04.02-2010. In addition, ISA periodically reviews their recommended practices to look for needed revisions. However, as stated in DG-1363, the NRC staff does not endorse any version of ISA RP67.04.02, but the staff believes those versions contain useful information. The NRC staff made no changes to DG-1363 as a result of this comment.
3. Anonymous	Section C	The endorsed standard (i.e., ISA 67.04.01-2018) contains a figure that is misleading (i.e., Figure 1, "Relation between setpoint parameters") which should be clarified in the RG. Typically, the accident analysis presumes a particular protective action is initiated at a particular process parameter value (i.e., the analytical limit) and takes an assumed amount of time to achieve the protective action. The accident analysis then determines the most extreme values that all the process parameters reach; these extreme values are then compared to the associated safety limits. That is, the process parameter that initiates the protective action (e.g., primary coolant temperature) generally is not the same process parameter that has an associated safety limit; that is, the safety limits (typically listed in the technical	The NRC staff disagrees with this comment. Both the safety limit and analytical limit are established by a safety analysis outside the scope of ISA 67.04.01-2018. The safety limit and the analytical limit in Figure 1 are only provided for illustrative purposes as a reference point. The NRC staff made no changes to DG-1363 as a result of this comment.

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		specifications) are very few, and are often not directly measurable by sensors (i.e., they are calculated). Therefore, the analytical limit and the associated safety limit are generally on two different process parameters. An explanation superior to this one should be included in the RG.	
4. Anonymous 5. Anonymous	General	For analog to digital system upgrades the analog signals received by digital processor; filtered, digitized, manipulated, converted back into analog form, filtered again, sent out for safety-related purposes. The associated filter component reduces aliasing noise introduced by signal frequencies high relative to fixed sampling rate and the amplitude of signal is held long enough to permit conversion to a digital word. For a sampling rate higher than twice analog signal bandwidth, then the sampled signal is a good representation of analog input signal. Analog signals containing frequencies too high versus the sampling rate, aliasing uncertainty will be introduced. Either anti-aliasing band limiting filters should be used to minimize aliasing uncertainty or this error should be accounted for in setpoint calculations. The draft regulatory guide should address this type of error. For analogy to digital upgrades in aging nuclear power plants the analog to digital converter (A/D Converter) is a source of errors associated with digital technology. For example, (1) Digitizing Uncertainty – associated with A/D Converters such that sampled signal amplitude at that time divided into a finite number of levels, digital word n bits long. The lower the numbers of bits, the greater the digitizing uncertainty; (2) Linearity Error -maximum deviation of the A/D converter from ideal to the actual; and (3) Gain Error - deviation between full scale actual change in input signal and output of the A/D converter. The draft regulatory guide should address these types of errors.	The NRC staff disagrees with these three comments because ISA 67.04.01-2018 and DG-1363 are not intended to address any particular type of error. The identification and treatment of digital processing-related channel uncertainties are covered in depth within Section 6.2.9 and Annex H of the ISA-RP 67.04.02-2010, and Section B.2.2.8 of DG-1363 identifies that additional information may be found in the ISA RP. In general, all uncertainties, including digital uncertainties, within a instrument channel need to be addressed when establishing safety-related instrument setpoints. In addition, ISA periodically reviews their recommended practices to look for needed revisions. However, as stated in DG-1363, the NRC staff does not endorse any version of ISA RP67.04.02, but the staff believes those versions contain useful information. The NRC staff made no changes to DG-1363 as a result of this comment.

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6. Anonymous		Analog signal approximated to a quantization level value higher than the original analog signal Truncation Error: Analog signal above the nearest quantization level is dropped. Usually the main source of error in numerical integration or solution of differential equations. Errors can be amplified as they propagate through a computation: (1) Loss of precision in displayed or monitored parameter, and (2) Cause oscillation in closed loop control systems; control error (difference between measured value and control setpoint) inaccurately represented and output signal either set too high or too low, depending on the error. Overflow Error: Result of a computation that cannot be held in the accumulator. It may result in wraparound error. Such type errors have been implicated in two high-visibility rocket accidents: (1) Failure of U.S. Patriot missile to intercept Iraqi-launched Scud missile during Gulf War, and (2) Failure of Ariane 5 launch vehicle during maiden flight. Indicating Reading Error: Error applied to accuracy when reading analog and digital indications in an instrument loop or on M&TE. The draft regulatory guide should address these types of errors.	
7. Anonymous		DG-1141, the predecessor to the subject draft regulatory guide DG-1363, defined a random variable as follows: Trippoint = {Measured Setpoint} + {unknown errors] Trippoint is the value of the process variable at which a channel actually does trip under operating conditions (including design basis condition). Figure 2, Trippoint Probability Distribution, of DG-1141 depicts an Actual Trippoint (ATP) distribution intended to show the importance of separating the limiting setpoint from the analytical limit (AL) by an amount not less than the total loop uncertainty (TLU). The industry standard, American National Standard Institute (ANSI)/ International Society of Automation	The NRC staff disagrees with this comment. The exclusion of total loop uncertainty (TLU) in DG-1141 was associated with a particular set of circumstances that are explained within DG-1141 and not always applicable. Section 4.4 of ANSI/ISA 67.04.01-2018 states, "The TLU shall account for the effects of all applicable design-basis events and the following process instrument uncertainties unless they were included in the determination of the analytical limit, considering as a minimum." Therefore, the concerns raised in the comment with respect to

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		(ISA) 67.04.01-2018, Setpoints for Nuclear Safety-Related Instrumentation, being endorsed by DG-1363 does not define a random variable equivalent to ATP. The subject standard in Section 4.4 stipulates that the Limiting Trip Setpoint (LTSP) for a trip or actuation on an increasing process would be LTSP = AL - TLU The subject standard states that the data used to calculate the TLU should be obtained from appropriate sources, which may include any of the following: operating experience, equipment qualification tests, equipment specifications, engineering analysis, laboratory tests, and engineering drawings. TLU cited in the subject standard should account for the effects of all applicable design-basis events and process instrument uncertainties unless they are included in the determination of the analytical limit. In contrast, per Figure 2 of DG-1141, TLU is characterized as Bias and Random factors. Further, Section C of DG-1141 utilizes the ATP variable to determine the staff regulatory positions. For example, one regulatory position in Section C.8.d states: As used to determine the limiting setpoint, the TLU does not need to include setting tolerance. If the setting tolerance is included in the TLU but is not to be included in the determination of the limiting setpoint, then, for the purpose of determining the limiting setpoint, the setting tolerance should be removed The subject standard includes the setting tolerance in the determination of the TLU. Given that the regulatory analysis for DG-1363 commits to address the technical issues related to the issuance of DG-1141, the draft regulatory guide should disposition the staff's position on ATP.	DG-1141 are adequately addressed in the revised standard. In addition, the NRC (as a voting member of the ISA Nuclear Standards Committee) was aware that the ISA SDO considered the proposed guidance that was contained in DG-1141 and addressed those criteria considered to be relevant in the revision to ANSI/ISA 67.04.01-2018. The NRC staff made no changes to DG-1363 as a result of this comment.

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8. Anonymous		Advanced sensors and portable devices which interconnect with internet of things (IoT) and industrial IoT (IIoT) devices can improve nuclear power plant operation, maintenance, decommissioning and data storage. Big data technology offers a better understanding of system and equipment performance by remote monitoring and data collection. The use of artificial intelligence technology to analyze real-time data could inform the decision-making process related to preventive maintenance and plant operations (e.g. manual and automatic response). These innovations which may reduce plant operating costs for an industry beset by economic drivers to become more competitive in order to continue to stay in business may also introduce new cyber security attack surfaces associated with the setpoint control of nuclear safety-related instrumentation. Since one of the purposes of Regulatory Guide 1.105 is to ensure that the nuclear safety-related instrumentation protect nuclear power plant safety and remain within the appropriate analytical limits, the draft regulatory guide revision should not be silent on potential safety issues arising from a cybersecurity threat. The draft regulatory guide revision should reference Regulatory Guide 5.71, Cyber Security Programs for Nuclear Facilities, and the staff should seek future opportunities to address safety issues from cyber security threats in future regulatory guidance documents.	Although the NRC staff agrees that digital technology and interconnectivity are increasing in use, the NRC staff disagrees with the recommendation of this comment as it relates to Cybersecurity guidance. Cybersecurity considerations and RG 5.71 are outside the scope of DG-1363. The scope of regulations and requirements applicable to DG-1363 are contained within Section A of DG-1363. In contrast, cybersecurity regulations and requirements are contained in 10 CFR 73.54, "Protection of digital computer and communication systems and networks," and RG 5.71.would not be an appropriate related guidance to list in DG-1363. The NRC staff made no changes to DG-1363 as a result of this comment.
9. Anonymous		DG-1141 defines a new term Deviation (or Setpoint Deviation) as the amount of change in a setpoint during the interval between scheduled setpoint assessments (i.e., the difference between the as-found value and the previous as-left value). The Deviation is used as described in B.5.1 to evaluate the acceptability of the asfound setpoint.	During the development of DG-1363, the staff considered and addressed technical issues and public comments related to the issuance of DG-1141. In addition, as discussed in the August 14, 2020 *Federal Register* notice, the NRC staff elected not to finalize DG-1141 as a

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		The industry standard, American National Standard Institute (ANSI)/ International Society of Automation (ISA) 67.04.01-2018, Setpoints for Nuclear Safety-Related Instrumentation, being endorsed by DG-1363 does not define any term like Deviation but uses the previously determined as-found tolerance to evaluate the asfound setpoint. According to the Staff Positions C.7.a and C.7.d(2) restated below the as-found tolerance may need to be recalculated depending on any change to uncertainty components: C.7.a The limiting value for acceptable setpoint deviation the as-found tolerance, should be computed in the setpoint uncertainty analysis. C.7.d(2) The as-found tolerance should include only those uncertainty components which are applicable to the as-found value measurement at the time the measurement is taken. In addition, Figure 1 Note 3 cited below also adds uncertainty in the evaluation of as-fund setpoints: Note 3 Section C.7c of this RG addresses the acceptability of occasional deviation in excess of the as-found tolerance (+AFT), provided that the deviations are neither too large nor too frequent. Section C.7e (3) of thisRG recommends that the deviation should be deemed excessive if the as-found value (AsF) of the setpoint is less conservative than the allowable value (AV) regardless of whether or not the as-found tolerance is exceeded and whether or not the occurrence of this condition is chronic. The industry standard methodology to evaluate as-found setpoint for acceptable performance provides more clarity and predictability in terms of implementation but DG-1363 does not withdraw the staff position on the use of the deviation methodology issued in DG-1141.	revision to RG 1.105 and chose instead to evaluate the ANSI/ISA 67.04.01-2018 standard for endorsement. When the NRC issued DG-1363 as a replacement for DG-1141, the draft staff positions in DG-1141 were replaced by the draft staff positions in DG-1363. As a result of public comments and concerns raised regarding DG-1141, the ISA Standards Committee opted to revise the standard considering all of the issues raised during the development of the 2018 revision to the standard. Therefore, the NRC initiated a review of the 2018 version of the standard while considering the previous concerns raised with DG 1141, which resulted in the issuance of DG-1363 and the endorsement of ANSI/ISA 67.04.01-2018. The NRC staff made no changes to DG-1363 as a result of this comment.

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		Given that the approach in DG-1141 is significantly different from that utilized by the subject industry standard is the deviation methodology replaced with the endorsement stated in Section C.1 of DG-1363?	
10. Anonymous		Given the introduction of software in the digital systems and components now being used in the replacement of analog instrumentation and control (I&C) equipment in operating nuclear power plants and being designed for the advanced and new reactors neither DG-1363 or the industry standard, American National Standard Institute (ANSI)/ International Society of Automation (ISA) 67.04.01-2018, Setpoints for Nuclear Safety-Related Instrumentation, being endorsed by DG-1363 adequately addresses the safety issues associated with todays technology. SECY-18-0090, Plan for Addressing Potential Common Cause Failure in Digital Instrumentation and Controls, identified that SRM-SECY-93-087 provided flexibility for the treatment of digital common cause failures in digital I&C systems through the regulatory tools available to the NRC staff. One of those tools is the issuance of regulatory guides to provide one acceptable method for licensees and applicants to meet the agencys regulations. In addition to the potential to introduce new common cause failure modes, software allows highly complex systems to be created and the potential for unintended ad unexpected interactions among components. The more interactions between system components and the more complex the functional design, the more the opportunities for unintended effects and consequently, the more opportunities for unsafe control actions that can lead to hazards.	The NRC staff disagrees with the recommendation of this comment. DG-1363 does not need to reference other regulatory guidance regarding the use of software or the effects of common cause failure in digital I&C since those concerns are considered to be outside the scope of DG-1363. The scope of DG-1363 is to establish and maintain limiting safety system settings (LSSS). Hazards that may result in a common cause failure would be considered only if it affects total loop uncertainty determination. The NRC made no changes to DG-1363 as a result of this comment.

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		If there are regulatory guides which can provide adequate guidance to licensees and applicants on the use of software in digital I&C then DG-1363 should reference these documents.	
11. Anonymous		The adoption of Figure 1 of ANSI/ISA 67,04,01-2018 to illustrate the setpoint relationship for nuclear safetyrelated setpoints is a welcomed clarification and disposition over Figure 1 in DG-1141. Some of the key differences are 1. Figure 1 of DG-1141 does not identify the discretionary margin typically included to maintain conservativism between the Limiting Trip Setpoint (LTSP or LSP) and the Nominal Trip Setpoint (NTSP or NSP). Note also that the Setting Tolerance (ST) is included in Total Loop Uncertainty (TLU) per the industry standard whereas DG-1141 associates ST with the NSP. 2. Figure 1 of DG-1141 depicts an anticipated excursions band which is not defined in the document nor is its applicability to the NRC regulations discussed for the reader. 3. Figure 1 of the subject industry standard includes the Safety Limit is defined in 10 CFR 50.36(c)(1)(i)(A). 4. Figure 1 of the subject industry standard indicates that the as-found tolerance (AFT) is a probabilistic band taken as a maximum value above and below the desired output such that the as-left value can quickly be assessed as acceptable or not during the calibration of an instrument or instrumentation channel. The staff is commended for providing a clear depiction of the relative position and relationship of the various setpoints.	The NRC staff agrees with the comment. The NRC staff made no changes to DG-1363 as a result of this comment.
12. Anonymous		NRC Safety Evaluation dated 10/14/16 (ADAMS Accession No. ML16256A788) which was issued after Westinghouse comments on DG-1141 [Letter from Mr. James A. Gresham, Manager Regulatory	Westinghouse representatives participated in the ISA committee for the 2018 revision to the standard and their

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		Compliance Westinghouse to Ms. Cindy Bladey, NRC dated 10/1/2014] stated that The NRC staff has found that WCAP-17503 WCAP-17504-P/NP, Westinghouse Generic Setpoint Methodology are acceptable for referring in licensing applicationswith the proper documentation. The subject Westinghouse Letter cited WCAP-17504 in their comments on DG-1141. The regulatory analysis for DG-1363 stated that the draft regulatory guide would consider and address technical issues and public comments related to the issuance of DG-1141. Given the significant staff involvement with WCAP-17504 was there a reconciliation document issued on the Westinghouse comments on DG-1141?	concerns related to LSSS were discussed and addressed while preparing the final version of ANSI/ISA 67.04.01-2018 and no reconciliation document was created for the Westinghouse comments on DG-1141. During the development of DG-1363, the staff considered and addressed technical issues and public comments related to the issuance of DG-1141. In addition, as discussed in the August 14, 2020 *Federal Register* notice, the NRC staff elected not to finalize DG-1141 as a revision to RG 1.105 and chose instead to evaluate the ANSI/ISA 67.04.01-2018 standard for endorsement and issued DG-1363 as a replacement for DG-1141. As a result of public comments and concerns raised regarding DG-1141, the ISA Standards Committee opted to revise the standard considering all of the issues raised during the development of the 2018 revision to the standard. Therefore, the NRC initiated a review of the 2018 version of the standard while considering the previous concerns raised with DG 1141, which resulted in the issuance of DG-1363 and the endorsement of ANSI/ISA 67.04.01-2018.

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			The NRC staff made no changes to DG-1363 as a result of this comment.
13. Anonymous		NuScale Power LLC Letter dated September 30, 2014 provided 26 comments on DG-1141. Although most comments seem applicable to DG-1141 Comments # 1, 19, 23 and 25 seems to be applicable to the current scope of DG-1363. The points raised by NuScale regarding a) the expansive treatment of small instrument errors with little safety significance; b) use of two-sided statistical approach effectively establishing a 97.5% probability which may increase plant trip/transient probability; c) NRC expectations regarding bounding values for environmental testing required for digital I&C equipment per RG 1.209; and d) consistency with Standard Review Plan (NUREG-0800) and draft Branch Technical Position (BTP) 7-12. The draft regulatory guide should address these technical issues previously raised by NuScale on DG-1141.	The NRC staff disagrees with the recommendation in this comment. As a result of public comments and concerns raised regarding DG-1141, the ISA Standards Committee opted to revise the standard considering all of the issues raised during the development of the 2018 revision to the standard. Therefore, the NRC initiated a review of the 2018 version of the standard while considering the previous concerns raised with DG 1141, which resulted in the issuance of DG-1363 and the endorsement of ANSI/ISA 67.04.01-2018. The NRC staff made no changes to DG-1363 as a result of this comment.
14. Mendy Maxey	General	NRC -2020-0171 .Thanks BG MD Maxey- West	The NRC staff did not consider this comment within the scope of DG-1363. The NRC staff made no changes to DG-1363 as a result of this comment.
15. Mendy Maxey	General	NRC -2020-0171 .Thanks BG MD Maxey- West	The NRC staff did not consider this comment within the scope of DG-1363. The NRC staff made no changes to DG-1363 as a result of this comment.
16. Anonymous	General	6 out of 8 documents in Section A authored by Mr. Paul J. Rebstock. Non-Concurring Employee for NCP-2020-004, Non-concurrence on DG-1363 (RG 1.105) Setpoints for Safety-Related Instrumentation (NRC Form 757), listed as references are not available to members of the public in the NRC ADAMS database.	The NRC staff will make these documents publicly available. The NRC staff made no changes to DG-1363 as a result of this comment.

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		Package containing all cited ADAMS documents: ML20006f031 Response Document (RD) (from 9Mar2016 concurrence pkg) ML15335a085 (ML19317D837 includes notes) Draft Regulatory Guide 1.105r4 (from 9Mar2016 concurrence pkg) ML15135a255 (ML19317d838 includes tracking to RD commitments) 95/95 and SSS --- ML19239a261 Can the above documents be made publically available to clearly understand the safety and/or regulatory concerns of the Non-Concurring Employee?	
17. Anonymous	DG Section C, subsection 2.2.3	During the Advisory Committee for Reactor Safeguards (ACRS) Meeting held on November 21, 2019, one ACRS Member asked why the Electric Power Research Institute (EPRI) which has studied instrument drift for years could not share that data with the NRC staff to help address the decades-long concerns on this issue. The EPRI representative stated that non-disclosure agreements prevented the sharing of the raw data with the NRC staff. Revision 1 of Regulatory Guide (RG) 1.105 noted in the Discussion Section that Abnormal Occurrence Reports submitted by operating utilities between January 1972 and June 1973 record the most frequent abnormal occurrence as the drift of the protective instrument setpoint outside the limits specified in the technical specifications. In Section 2.2.3 (Evaluation of the Allowance for Drift) of DG-1363, the NRC staff provided additional direction beyond what is stated in ANSI/ISA 67.04.01-2018 with the following statements: As described in the footnote in Section 4.6 of the standard, when determining the magnitude of drift to be included when establishing the AFT, licensees should estimate on the low side so as not to	The NRC staff disagrees with this comment. The staff believes that the standard is not deficient in the manner stated by the commenter. The purpose of the standard is not to specify what data to use but rather to identify appropriate attributes of the instrument channel performance when determining the TLU. The instrument performance data used to determine the TLU is not within the scope of this RG. In addition, the staff finds that the footnote in Section 4.6 of ANSI/ISA 67.04.01-2018 is acceptable for clarifying the guidance in the standard and the staff's endorsement of the standard in Section C of DG-1363 does not need any clarifications. However, to avoid confusion, the staff made the following edits to DG-1363 and replaced some of the current

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		potentially mask the ability to detect a degrading instrument during a required surveillance. In addition, when establishing an appropriate allowance for total loop uncertainty between the analytical limit and the limiting trip setpoint, licensees should estimate drift on the high side so as to ensure adequate margin for instrument channel performance in achieving the safety objectives. These statements imply that the subject standard is deficient in some manner. Why not identify this additional direction in Section C as a regulatory position to clarify the staffs intent? Given that instrument drift is just another random uncertainty why not provide acceptable ways of handling this uncertainty as provided using probabilistic risk assessment techniques (i.e., RG 1.174)?	language in DG Section B.2.2.3. with the exact language from the Section 4.6 footnote of the standard, stated as follows: "Here, estimates of "more conservative" performance test acceptance criteria are those that result in acceptance tolerances that tend to be on the smaller side, so as not to mask any adverse performance. For estimates of TLU, more conservative estimates of total uncertainty are those that tend to be on the larger side, so as not to underestimate the required minimal allowance for instrument channel performance uncertainty between the analytical limit and the limiting trip setpoint."
18. Anonymous	DG-1363 Section B, subsection 2.2.2	While it is not clear why the NRC staff chose in Section 2.2.2, Adequacy of the Allowance for Channel Uncertainties between the Limiting Trip Setpoint and the Analytical Limit, of DG-1363 to paraphrase portions of ANSI/ISA 67.04.01-2018 there is the potential for this section to cause confusion. The ISA Standard 4.4 states If there is not sufficient data to justify a statistical estimate but Section 2.2.2 states for cases in which the sample population is not large enough to support a usable statistical estimate Section 2.2.2 omits noting that drift and reference accuracy should not be among those uncertainty terms which may have insufficient data to estimate the confidence level (see ISA Standard Section 4.4, page 19). In describing the ISA Standard, Section 2.2.2 states that the result of the combination represents a value of the random uncertainty	The NRC staff agrees with this comment. The language in DG-1363 Section B.2.2.2 is consistent with the language in ANSI/ISA 67.04.01-2018. However, to avoid any confusion, the staff has replaced the second sentence of the second paragraph in Section B.2.2.2, and replaced it with the following text from Section 4.4 of the ISA standard: "If there is not sufficient data to justify a statistical estimate of the uncertainty tolerance interval at the 95/95 level, then a bounding uncertainty term shall be

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		performance of the instrument channel at a 95-percent probability at a 95-percent confidence level versus the clearer statement in the ISA Standard that The result of the combination shall be a value that represents the performance of the instrumentation with a 95% probability at a 95% confidence level,	determined, and the basis for determining the bounds of the uncertainty shall be documented. The bounding estimates shall be treated as a 95/95 term in the uncertainty analysis."
19. Anonymous	General	NRC should seize this transformational opportunity to use DG-1363 to define the content of the information that new/advanced reactor applicants and operating reactor licensees need to submit in order to adequately address instrumentation uncertainties. In the past there have been a range of outcomes centered on the proper communication and understanding of the instrument uncertainties for a change to the licensing basis of a nuclear power plant. For example, one outcome involving good communication of the uncertainties pertained to the measurement uncertainty recapture (MUR) power uprates program as described in Regulatory Information Summary 2002-03, Guidance on the Conduct of Measurement Uncertainty Recapture Power Update Applications. Several licensee applications utilized the NRC approved the Caldon Ultrasonic Inc. (Caldon)), the leading edge flow meter (LEFM) CheckPlus System, [ER-80P with ER-157P design] to increase their maximum power up to 1.7% depending on being able to adequately accounted for all instrumentation uncertainties in the reactor thermal power measurement uncertainty calculations. Specifically, from the earliest to later application the following nuclear power plants (% power increase approved) utilized the guidance provided by the NRC staff for the above ultrasonic flowmeter design: Waterford (1.5); Sequoyah (1.3); Grand Gulf (1.7); H. B. Robinson (1.7); Peach Bottom (1.62=>1.66); Point Beach (1.4); D. C. Cook (1.66/1.7); River Bend (1.7); Seabrook (1.7) Crystal River (1.7); Vogtle (1.7); Cooper (1.62); David-Besse (1.63); Calvert Cliffs (1.38); North Anna (1.6); Prairie Island (1.64); LaSalle County (1.65); Surry (1.6); Limerick (1.65); Shearon Harris (1.66); McGuire (1.7); Braidwood	The NRC staff agrees with the conclusion of this comment. However, licensees are only required to comply with the requirements in their licensing basis and any new reactor applicants are encouraged to follow the latest NRC guidance. In addition, the ANSI/ISA 67.04.01-2018 standard endorsed in DG-1363 is applicable to the establishment and maintenance of LSSS as addressed in 10 CFR 50.36. The discussion presented in the comment deals with operational issues of plants within their licensed condition and does not relate to LSSS. The NRC staff made no changes to the DG-1363 as a result of this comment.

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		(1.63); Fermi (1.64); Catawba (1.7); Columbia (1.66);and Hope Creek (1.62). The guidance provided in RIS 2002-03 and Regulatory Guide 1.105, Revision 3 was used by the NRC staff and licensees for these completed licensing actions. In another example. in 2006, LaSalle County Nuclear Power Plant was denied its licensee amendment request to revise Technical Specification (TS) 3.7.3, Ultimate Heat Sink [UHS], to increase the temperature limit of the cooling water supplied to the plant from the core standby cooling system pond (i.e., UHS) from 100 degrees Fahrenheit to 101.5 degrees Fahrenheit. The licensee proposed to reduce the temperature measurement uncertainty by replacing the existing thermocouples with higher precision temperature measuring equipment. The NRC Safety Evaluation (Agencywide Document and Management System (ADAMS) Accession No. ML062760617), concluded that the licensee had not shown that the instrumentation is sufficiently accurate to justify the requested reduction in margin and provided adequate assurance that anticipated measurement errors would not exceed the margin between the proposed TS limit and the temperature assumed in the plant safety analyses. It should be noted that current TS 3.7.3 for LaSalle County Nuclear Power Plant does reflect an increase temperature limit from 100 degrees Fahrenheit to 101.25 degrees Fahrenheit. Therefore, it would benefit both new and advanced reactor applicants and operating reactor licensees to obtain informed guidance from the NRC staff on how to address instrumentation uncertainties in their future submittals.	
20. Anonymous		As noted below there is a more stringent regulatory requirement in the reactor area (i.e., guidance document) than the nuclear materials area (i.e., NRC regulation) proposed for licensees and applicants by DG-1141, although Regulatory Guide 1.105, Revision 3 stipulates the	The NRC staff agrees in part with this comment in that the criteria specified in 10 CFR 50.68 forms the basis for the 95-95 criteria for setpoints. This criteria is applied to each instrument loop

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		same 95 percent probability, 95 percent confidence level criteria as specified in 10 CFR 50.68. Background Section of NRC Information Notice 2011-03, Nonconservative Criticality Safety Analyses for Fuel Storage, states the following: Paragraph 50.68(b)(4) of 10 CFR 50.68, Criticality Accident Requirements, requires the following: If no credit for soluble boron is taken, the k-effective of the spent fuel storage racks loaded with fuel of the maximum fuel assembly reactivity must not exceed 0.95, at a 95 percent probability, 95 percent confidence level, if flooded with unborated water. If credit is taken for soluble boron, the k-effective of the spent fuel storage racks loaded with fuel of the maximum fuel assembly reactivity must not exceed 0.95, at a 95 percent probability, 95 percent confidence level, if flooded with borated water, and the k-effective must remain below 1.0 subcritical), at a 95 percent probability, 95 percent confidence level, if flooded with unborated water. NUREG/CR-6698, Guide for Validation of Nuclear Criticality Safety Calculational Methodology, January 2001 (Agencywide Document and Management System (ADAMS) Accession No. ML050250061), provides guidance on determining the bias uncertainty for Monte Carlo codes. The primary NRC staff guidance regarding the depletion uncertainty is an internal NRC memorandum from L. Kopp to T. Collins, Guidance on the Regulatory Requirements for Criticality Analysis of Fuel Storage at Light-Water Reactor Power Plants, dated August 19, 1998 (ADAMS Accession No. ML003728001) (Kopp Letter). The Kopp Letter is referenced by virtually all spent fuel pool criticality license amendment requests submitted since its issuance.	independently. Therefore, the use of redundant channels in combination with the 95% probability and 95% confidence level provides a reasonable assurance of adequate protection relating to bounding uncertainties. However, the NRC staff disagrees with the comment with respect to the associated non-concurrence NCP-2020-004 (ADAMS Accession No. ML20181A524). The non-concurrence was dispositioned using the NRC's established policies and procedures located in Management Directive 10.158, "NRC Non-Concurrence Process," (ADAMS Accession No. ML18073A296). NCP-2020-004 concluded that no changes to DG-1363 were required due to the non-concurrence. Further, the NRC cannot use a guidance document to change a regulation, as the commenter suggests by saying the NRC staff should "make the safety case for a more stringent requirement than what is in place for 10 CFR 50.68." The NRC staff made no changes to DG-1363 as a result of this comment.

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		Regarding the depletion uncertainty, the Kopp Letter states the following: A reactivity uncertainty due to uncertainty in the fuel depletion calculations should be developed and combined with other calculational uncertainties. In the absence of any other determination of the depletion uncertainty, an uncertainty equal to 5 percent of the reactivity decrement to the burnup of interest is an acceptable assumption. Although DG-1363 through the endorsement of ANSI/ISA 67.04.01-2018 returned to the Revision 3 criteria for probability and confidence level sought for instrumentation performance, the associated Non-Concurrence statement by a NRC Senior Instrumentation & Control Engineer indicates the desire for a more stringent requirement. Section 2 of DG-1363 should either make the safety case for a more stringent requirement than what is in place for 10 CFR 50.68, Criticality Accident Requirements, or discuss the acceptability of the 5 percent uncertainty.	
21. Anonymous	DG-1363 Section C, subsection 2.2.6	In DG-1363, Section 2.2.6, Graded Approach Based on Safety Significance, there is the following statement: The NRC staff has not identified a specific position on the appropriate technical methodology to be used when establishing setpoints for nonlimiting safety system setting-related instrument channels. However, the Staff Position in Interim Staff Guidance (ISG) DI&C-ISG-03, Task Working Group #3: Review of New Reactor Digital Instrumentation and Control Probabilistic Risk Assessments, Revision 0 (Initial Issue for Use) which utilize a risk-informed approach to review digital instrumentation and controls systems and components identifies any attributes that warrant additional	The NRC staff disagrees with this comment. ANSI/ISA 67.04.01-2018 is a deterministic standard for establishing and maintaining LSSS for compliance with 10 CFR 50.36 requirements. 10 CFR 50.36 does not have any provisions for risk informing the LSSS determination. Although the risk-informed approaches in ISG DI&C-ISG-03 and draft BTP 7-19, Revision 8, are available, these approaches are not within the scope of DG-1363.

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		regulatory attention and whether there are highlevel, risk-significant problems, including the existence of risk outliers. Therefore, DI&C-ISG-03 should be referenced as an acceptable guidance document to assist applicants and licensees in the development their own design-specific safety significant graded approach. In addition, the Draft Branch Technical Position (BTP) 7-19, Guidance for Evaluation of Potential Common Cause Failure Due to Latent Software Defects in Digital Instrumentation and Control Systems, Revision 8, June 2020, introduced a graded risk-informed approach which could also assist applicants and licensees in developing a graded approach for setpoints. The existence of ISG DI&C-ISG-03 and draft BTP 7-19, Revision 8, seem to contradict the above mentioned statement that there is no applicable staff position.	The NRC staff made no changes to DG-1363 as a result of this comment.
22. Anonymous		Excerpts from the comment submitted by Mr. Jerald Head on October 8, 2014 for General Electric Hitachi (GEH) [Agencywide Document and Management System (ADAMS) Accession No. ML14283A501] are cited below. The draft regulatory guide should address the technical issues previously raised by GEH on DG-1141. GEH COMMENT The Draft DG-1141 appears to impose a requirement of 97.5% probability of single channel trip before the AL is reached. This is inconsistent with the current and previous revisions of RG 1.105 (Revision 3 and earlier) which clearly define the requirement of trip before AL is reached to be 95% probability. The previous 95% probability requirement is the basis of the licensed GEH safety analyses, and the basis of the NRCapproved GEH setpoint methodology (Reference 2). The GEH safety analysis application methodologies use the same 95/95 definition. This is evidenced by a letter from the NRC to GE (Reference 3) which states, in part, "This procedure provides for a statistical determination of the pressurization transient CPR/ICPR	The NRC staff disagrees with this comment. GEH representatives participated in the ISA committee for the 2018 revision to the standard and their concerns related to LSSS were discussed and addressed while preparing the final version of ANSI/ISA 67.04.01-2018. In addition, as discussed in the August 14, 2020 *Federal Register* notice, the NRC staff elected not to finalize DG-1141 as a revision to RG 1.105 and chose instead to evaluate the ANSI/ISA 67.04.01-2018 standard for endorsement and issued DG-1363 as a replacement for DG-1141. As a result of public comments and concerns raised regarding DG-1141, the ISA Standards Committee opted to revise the standard considering all of the issues raised during the development of the 2018 revision to the standard.

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		such that there is a 95% probability with 95% confidence (95/95) that the event will not cause the critical power ratio to fall below the MCPR Fuel Cladding Integrity Safety Limit." Thus, 95% is the non-exceedance %/probability. GEH has consistently used this 95/95=95% non-exceedance definition in analysis of Anticipated Operational Occurrences. The 97.5% probability is a different definition of 95% probability/95% confidence level from that already being applied by the NRC. Note also that basing the setpoint on the 97.5% probability criterion instead of the 95% probability criterion could also decrease the margin between the setpoint and the normal operating limit (OL), and that would result in an undesirable increase in the spurious trip probability. These calculations show that basing the LSP on the 97.5% probability criterion rather than the historical 95% probability criterion results in an insignificant increase in probability of tripping before the AL is reached, but could lead to a significant detrimental increase in spurious trip probability. Moreover, the licensed GEH safety analyses are based on LSPs that meet the 95% probability criterion, so no increase in trip probability is required from the safety point of view. The 97.5% probability criterion is the consequence of using "two-sided" statistics, whereas using "singlesided" statistics would correctly locate the setpoint such that it meets the historical 95% probability requirement for not exceeding the AL. Note that the NRC's statistical handbook (Reference 4,NUREG-1475 Rev 1,"Applying Statistics") indicates that use of single-sided statistics is appropriate for the usual case where the variable approaches a safety related setpoint, or limit, in one direction from the safe side (see description of Critical Power Ratio in example 9.4 of Reference 4. and see Section 9.13 of Reference 4 for a description of how to determine with high confidence the upper limit of the population	Therefore, the NRC initiated a review of the 2018 version of the standard while considering the previous concerns raised with DG 1141, which resulted in the issuance of DG-1363 and the endorsement of ANSI/ISA 67.04.01-2018. The NRC staff made no changes to the DG-1363 as a result of this comment.

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		standard deviation from the standard deviation obtained from a limited size sample).	
23. Anonymous		The NRC staff is commended on clarifying the mathematically incorrect assumptions in DG-1141. However, Section B should clarify whether the desired statistical objective for licenses and applicants is a tolerance interval rather than a confidence interval as requirements for safety-related instrument setpoints. (See https://www.graphpad.com/support/faq/the-distinction-between-confidence-intervals-prediction-intervalsand-tolerance-intervals/#:~:text=If%20you%20set%20the%20first,wider%20than%20a%20prediction%20interval)). The incorrect assumptions center on Figure 2 in DG-1141. For example, characterization of the as-found trip setpoint in terms of an error band reflects a deterministic not a probabilistic engineering expectation. Trip setpoint which is subject to the various random based uncertainties would be expected to be found within the total loop uncertainty as defined in the ISA Standard Section 4.4. Similarly, given the nonrandom terms in Equation 2 of the ISA Standard the assumption of a normal distribution is an incorrect one. Lastly, the notion that 21/2% probability can be assigned or allocated to one side or another of a distribution runs contrary to the laws of probability. On confidence intervals (https://en.wikipedia.org/wiki/Confidence_interval) A 95% confidence level does not mean that for a given realized interval there is a 95% probability that the population parameter lies within the interval (i.e., a 95% probability that the interval covers the population parameter). According to the strict frequentist interpretation, once an interval is calculated, this interval either covers the parameter value or it does not; it is no longer a matter of	The NRC staff disagrees with the comment. ANSI/ISA 67.04.01-2018 requires both (1) a statistical limit between the analytical limits and the LSSS and (2) a tolerance interval with endpoints determined at a 95% confidence level to encompass 95% probability distribution of interest. During the development of DG-1363, the staff considered and addressed technical issues and public comments related to the issuance of DG-1141. In addition, as discussed in the August 14, 2020 *Federal Register* notice, the NRC staff elected not to finalize DG-1141 as a revision to RG 1.105 and chose instead to evaluate the ANSI/ISA 67.04.01-2018 standard for endorsement and issued DG-1363 as a replacement for DG-1141. The relevant concerns associated with DG-1141 were adequately addressed by the ISA committee while preparing the final version of 2018 standard and which has been fully endorsed by the NRC in DG-1363. The NRC staff made no changes to DG-1363 as a result of this comment.

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		probability. The 95% probability relates to the reliability of the estimation procedure, not to a specific calculated interval. Neyman himself (the original proponent of confidence intervals) made this point in his original paper: "It will be noticed that in the above description, the probability statements refer to the problems of estimation with which the statistician will be concerned in the future. In fact, I have repeatedly stated that the frequency of correct results will tend to . Consider now the case when a sample is already drawn, and the calculations have given [particular limits]. Can we say that in this particular case the probability of the true value [falling between these limits] is equal to ? The answer is obviously in the negative. The parameter is an unknown constant, and no probability statement concerning its value may be made..." Deborah Mayo expands on this further as follows: "It must be stressed, however, that having seen the value [of the data], NeymanPearson theory never permits one to conclude that the specific confidence interval formed covers the true value of 0 with either (1)100% probability or (1)100% degree of confidence. Seidenfeld's remark seems rooted in a (not uncommon) desire for NeymanPearson confidence intervals to provide something which they cannot legitimately provide; namely, a measure of the degree of probability, belief, or support that an unknown parameter value lies in a specific interval. Following Savage (1962), the probability that a parameter lies in a specific interval may be referred to as a measure of final precision. While a measure of final precision may seem desirable, and while confidence levels are often (wrongly) interpreted as providing such a measure, no such interpretation is warranted. Admittedly, such a misinterpretation is encouraged by the word 'confidence'." A 95% confidence level does not mean that 95% of the sample data lie within the confidence interval.	

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		A confidence interval is not a definitive range of plausible values for the sample parameter, though it may be understood as an estimate of plausible values for the population parameter. A particular confidence level of 95% calculated from an experiment does not mean that there is a 95% probability of a sample parameter from a repeat of the experiment falling within this interval. Bottom Line: If the NRC expects licensees or applicants to meet a statistical limit with respect to the Analytical Limits in nuclear power plant technical specifications then a tolerance interval should be required rather than a confidence interval.	
24. Stephen J. Vaughn	B.1	ANSI/ISA S67.04-2018 should be ANSI/ISA S67.04.01-2018	The NRC staff agrees with this comment and made the editorial change to Section B.1 of DG-1363.
	B.2.1	First sentence. The term “anticipated conditions” is not commonly used and causes confusion. The term “accident conditions” is a more appropriate term because any of the non-normal conditions are not anticipated.	The NRC staff agrees in part with the comment. The term, “anticipated conditions,” is not the correct term to use. However, the staff does not agree that the correct term is “accident conditions.” The staff changed “anticipated conditions” in Section B.2.1 of DG-1363 to “design basis event conditions,” which encompasses both anticipated operational occurrences and postulated accidents, as opposed to just “accident conditions.” Therefore, Section B.2.1 of DG-1363 was updated to change “anticipated conditions” to “design basis event conditions.”
	B.2.2.1	Paragraph 3 reaffirms the NRC staff’s approval of Option B of TSTF-493, Revision 4 but there is no mention throughout the DG-1363 of Option A of TSTF-493, Revision 4.	Option A of Technical Specifications Task Force (TSTF) Traveler 493 is discussed in 75 FR 26294, “Notice of

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			Availability of Models for Plant-Specific Adoption of Technical Specifications Task Force Traveler TSTF-493, Revision 4, 'Clarify Application of Setpoint Methodology for LSSS Functions,'" dated May 11, 2010. The staff believes that Option A is not relevant to setpoint determination and is outside the scope of DG-1363. However, TSTF-493 Option B is intended to establish and maintain safety-related setpoints. The NRC staff made no changes to DG-1363 as a result of this comment.
	B.2.2.3	This section refers to "drift" as though is mentioned in the footnote under 4.6 of the standard; however the footnote in the standard only mentions "test acceptance criteria" and "TLU."	The NRC staff disagrees with this comment. The discussion in Section 4.6 of the standard adequately addresses consideration for drift. However, the footnote under Section 4.6 of the ANSI/ISA 67.04.01-2018 standard provides caution on appropriately calculating the drift value. The discussion in Section B.2.2.3 of DG-1363 and the footnote in Section 4.6 of the standard are both addressing the potential for masking any adverse performance. Refer to the response to comment 17 on the footnote in Section 4.6 of the standard and the change made to DG-1363 indicated there. No additional

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			changes were made to the DG-1363 as a result of this comment.
	B 2.2.5	The term "(Performance Acceptance Criteria)" should be "(Performance Test Acceptance Criteria)"	The NRC staff agrees with this comment and made the editorial change to Section B.2.2.5 of DG-1363.