

SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

RELATED TO EXEMPTION AND AMENDMENT NO. 49

TO THE COMBINED LICENSE NOS. NFP-93 AND NFP-94

SOUTH CAROLINA ELECTRIC & GAS COMPANY

SOUTH CAROLINA PUBLIC SERVICE AUTHORITY

VIRGIL C. SUMMER NUCLEAR STATION UNITS 2 AND 3

DOCKET NOS. 52-027 AND 52-028

1.0 INTRODUCTION

By letter dated June 30, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15181A470), South Carolina Electric & Gas Company on behalf of the South Carolina Public Service Authority (both hereafter called the licensee) requested that the U.S. Nuclear Regulatory Commission (NRC) amend the combined licenses (COLs) for Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, COL Numbers NPF-93 and NPF-94, respectively.

The proposed amendment requests changes to Tier 1 material included in Appendix C of each of the VCSNS Units 2 and 3 COLs. The proposed amendment also provides changes to the Tier 2 material in the Updated Final Safety Analysis Report (UFSAR). The proposed amendment would allow changes to correct errors and promote consistency with the UFSAR Tier 2 information.

The licensee has also requested an exemption from Tier 1 of the generic Design Control Document (DCD)<sup>1</sup> of the Design Certification for the Advanced Passive 1000 (AP1000). This

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<sup>1</sup> While the licensee describes the requested exemption as being from Section III.B of 10 CFR Part 52, Appendix D, the entirety of the exemption pertains to proposed departures from Tier 1 information in the generic DCD. In the remainder of this evaluation, the NRC will refer to the exemption as an exemption from Tier 1 information to match the language of Section VIII.A.4 of 10 CFR Part 52, Appendix D, which specifically governs the granting of exemptions from Tier 1 information.

exemption would allow a departure from elements of the certification information in Tier 1 of the DCD incorporated by reference into the COL under Title 10, *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Appendix D, "Design Certification Rule for the AP1000 Design," Section III.B.

This license amendment request (LAR) 15-03 revises Tier 1 information in COL Appendix C and Tier 2 information in the UFSAR (Tier 1 Figure 2.2.5-1, Tier 2 Table 3I.6-3, and Tier 2 Figure 6.4-2).

In order to modify the plant-specific DCD, Tier 1 information, the NRC must find the licensee's exemption request included in its submittal for the LAR acceptable. The staff's review of the exemption request as well as the LAR is included in this safety evaluation.

## 2.0 REGULATORY EVALUATION

10 CFR Part 50, Appendix A, General Design Criterion (GDC) 4 requires that structures, systems, and components be designed to accommodate the effects of and to be compatible with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents, including loss-of-coolant accidents. These structures, systems, and components shall be appropriately protected against the dynamic effects, including the effects of missiles, pipe whipping, and discharging fluids, that may result from equipment failures and from events and conditions outside the nuclear power unit. However, dynamic effects associated with postulated pipe ruptures in nuclear power units may be excluded from the design basis when analyses reviewed and approved by the Commission demonstrate that the probability of fluid system piping rupture is extremely low under conditions consistent with the design basis for the piping.

10 CFR Part 50, Appendix A, GDC 19 requires, among other things, that a control room shall be provided from which actions can be taken to operate the nuclear power unit safely under normal conditions and to maintain it in a safe condition under accident conditions, including loss-of-coolant accidents.

10 CFR 50.34(f)(2)(xxviii) requires, among other things, an evaluation of potential pathways for radioactivity and radiation that may lead to control room habitability problems under accident conditions resulting in an accident source term release and make necessary provisions to preclude such problems.

NUREG-0737 TMI Action Plan Item III.D.3.4 requires that licensees shall assure that control room operators will be adequately protected against the effects of accidental release of toxic and radioactive gases and that the nuclear power plant can be safely operated or shut down under design basis accident conditions.

10 CFR Part 52, Appendix D, Section VIII.A.4 states that exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 10 CFR 52.98(f). It also states that the Commission will deny such a request if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

10 CFR Part 52, Appendix D, Section VIII.B.5.a requires, among other things, that an applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2\* information, or Technical Specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section.

10 CFR 52.63(b)(1) allows the licensee who references a design certification rule to request NRC approval for an exemption from one or more elements of the certification information. The Commission may only grant such a request if it determines that the exemption will comply with the requirements of 10 CFR 52.7, which in turn points to the requirements listed in 10 CFR 50.12 for specific exemptions, and if the special circumstances present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. Therefore, any exemption from the Tier 1 information certified by Appendix D to 10 CFR Part 52 must meet the requirements of 10 CFR 50.12, 52.7, and 52.63(b)(1).

10 CFR 52.98 (c)(1) states that changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule.

10 CFR 52.98 (c)(2) states that changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in 10 CFR part 50, unless they also involve changes to or noncompliance with information within the scope of the referenced design certification rule. In these cases, the applicable provisions of this section and the design certification rule apply.

10 CFR 52.98(f) states that any modification to, addition to, or deletion from the terms and conditions of a COL, including any modification to, addition to, or deletion from the inspections, tests, analyses, or related acceptance criteria (ITAAC) contained in the license is a proposed amendment to the license. Appendix C of COLs NPF-91 and NPF-92 contain information which the licensee is proposing to modify. Therefore, the proposed changes require a license amendment.

### 3.0 TECHNICAL EVALUATION

#### 3.1 EVALUATION OF EXEMPTION

##### INTRODUCTION

The regulations in Section III.B of Appendix D to 10 CFR Part 52 require a holder of a COL referencing Appendix D to 10 CFR Part 52 to incorporate by reference and comply with the requirements of Appendix D, including certified information in Tier 1 of the generic AP1000 DCD.

As defined in Section II of Appendix D to 10 CFR Part 52, Tier 1 information includes ITAAC and design descriptions, among other things. Therefore, a licensee referencing Appendix D incorporates by reference all Tier 1 information contained in the generic DCD. The Tier 1 ITAAC and the design descriptions, along with the plant-specific ITAAC, were included in Appendix C of the COL at its issuance. The proposed amendment would allow various changes to correct errors in Tier 1 and Tier 2 and promote consistency with the UFSAR Tier 2 information. The proposed changes impact Tier 1 and Tier 2 of the Plant-Specific DCD and

Appendix C of the COL. An exemption is needed because Section VIII.A.4 of Appendix D to 10 CFR Part 52 requires a licensee to obtain an exemption to change the Tier 1 information of the generic AP1000 DCD in the plant-specific Tier 1.

In summary, the end result of this exemption would be that the licensee can implement modifications to Tier 1 information described and justified in LAR 15-03 if and only if the NRC approves LAR 15-03. This is a permanent exemption limited in scope to the particular Tier 1 information specified.

As stated in Section VIII.A.4 of Appendix D to 10 CFR Part 52, an exemption from Tier 1 information is governed by the requirements of 10 CFR 52.63(b)(1) and 52.98(f). Additionally, the Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. Pursuant to 10 CFR 52.63(b)(1), the Commission may, upon application by an applicant or licensee referencing a certified design, grant exemptions from one or more elements of the certification information, so long as the criteria given in 10 CFR 52.7 are met, and that the special circumstances as defined by 10 CFR 50.12 outweigh any potential decrease in safety due to reduced standardization.

Pursuant to 10 CFR 52.7, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 52. 10 CFR 52.7 further states that the Commission's consideration will be governed by 10 CFR 50.12, "Specific exemptions," which states that an exemption may be granted when the exemptions are: (1) authorized by law, will not present an undue risk to public health and safety, and are consistent with the common defense and security; and (2) special circumstances are present. 10 CFR 50.12(a)(2) lists six special circumstances for which an exemption may be granted. It is necessary for one of these special circumstances to be present in order for NRC to consider granting an exemption request. The licensee stated that the requested exemption meets the special circumstances of 10 CFR 50.12(a)(2)(ii). That subsection defines special circumstances as when "[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule." The staff's analysis of each of these findings is presented below.

### 3.1.1 AUTHORIZED BY LAW

This exemption would allow the licensee to implement a revision to Tier 1, Figure 2.2.5-1 in the DCD. This is a permanent exemption limited in scope to particular Tier 1 information, and subsequent changes to Tier 1, Figures 2.2.5-1; or any other Tier 1 information, would be subject to the exemption process specified in Section VIII.A.4 of Appendix D to 10 CFR Part 52. As stated above, 10 CFR Part 52, Appendix D, Section VIII.A.4 allows the NRC to grant exemptions from one or more elements of the Tier 1 information. The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, as required by 10 CFR 50.12(a)(1), the exemption is authorized by law.

### 3.1.2 NO UNDUE RISK TO PUBLIC HEALTH AND SAFETY

The underlying purpose of Appendix D to 10 CFR 52 is to ensure that the licensee will construct and operate the plant based on the approved information found in the DCD incorporated by reference into the licensee's licensing basis. The changes do not add, delete, or modify systems or equipment as described in Tier 1 of the AP1000 DCD. These changes will not

impact the ability of the structures to perform their design function. Because the changes will not alter the operation of any plant equipment or systems, these changes do not present an undue risk from existing equipment or systems. These changes do not add any new equipment or system interfaces to the current plant design. The description changes do not introduce any new industrial, chemical, or radiological hazards that would represent a public health or safety risk, nor do they modify or remove any design or operational controls or safeguards intended to mitigate any existing on-site hazards. Furthermore, the proposed changes would not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that would result in significant fuel cladding failures. Accordingly, these changes do not present an undue risk from any new equipment or systems. Therefore, as required by 10 CFR 50.12(a)(1), the staff finds that there is no undue risk public health and safety.

### 3.1.3 CONSISTENT WITH COMMON DEFENSE AND SECURITY

The proposed exemption would allow changes to correct inconsistencies between existing design and corresponding descriptions in Tier 2 and Tier 1 including corresponding description in Appendix C of the COLs regarding the Main Control Room Emergency Habitability System (VES) configuration, safety classifications and equipment safety designation in elements of the plant-specific DCD. This is a permanent exemption limited in scope to particular Tier 1, Figure 2.2.5-1 information; or any other Tier 1 information would be subject to the exemption process in Section VIII.A.4 of Appendix D to 10 CFR Part 52. The change does not alter or impede the design, function, or operation of any plant structures, systems or components (SSCs) associated with the facility's physical or cyber security, and therefore does not affect any plant equipment that is necessary to maintain a safe and secure plant status. In addition, the changes have no impact on plant security or safeguards. Therefore, as required by 10 CFR 50.12(a)(1), the staff finds that the common defense and security is not impacted by this exemption.

### 3.1.4 SPECIAL CIRCUMSTANCES

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of the Tier 1 information is to ensure that the licensee will safely construct and operate the plant based on the certified information found in the AP1000 DCD, which was incorporated by reference into the licensee's licensing basis. The proposed changes to the Main Control Room Emergency Habitability System (VES) correct inconsistencies between corresponding descriptions in Tier 2 and Tier 1 including corresponding description in Appendix C of the COLs regarding configuration, safety classifications and equipment safety designation in elements of the plant-specific DCD. These changes will enable the licensee to safely construct and operate the AP1000 facility consistent with the design certified by the NRC, by clarifying the information mentioned above found in Tier 1, Figure 2.2.5-1 of the DCD.

Special circumstances are present in the particular circumstances discussed in LAR 15-03 because the application of the specified Tier 1 information does not serve the underlying purpose of the rule. The proposed change implements changes to the American Society of Mechanical Engineers (ASME) safety classification, equipment orientation, addition and removal, and identification of the number of emergency air storage tanks. This exemption request and associated revisions to Figure 2.2.5-1 demonstrate that the applicable regulatory requirements will continue to be met. Consequently, the safety impact that may result from any

reduction in standardization is minimized, since the proposed design change does not result in a reduction in the level of safety. Therefore, the staff finds that the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of an exemption from the Tier 1 information exist.

### 3.1.5 SPECIAL CIRCUMSTANCES OUTWEIGH REDUCED STANDARDIZATION

This exemption would allow the implementation of revising Tier 1, Figure 2.2.5-1 in the DCD proposed in the LAR. The design functions of the systems associated with this request will continue to be maintained because the associated revisions to Figure 2.2.5-1 demonstrate that the applicable regulatory requirements will continue to be met. Consequently, the safety impact that may result from any reduction in standardization is minimized, since the proposed design change does not result in a reduction in the level of safety. Based on this, as required by 10 CFR Part 52.63(b)(1), the staff finds that the special circumstances outweigh the effects the departure has on the standardization of the AP1000 design.

### 3.1.6 NO SIGNIFICANT REDUCTION IN SAFETY

This exemption would allow the implementation of changes to Tier 1, Figure 2.2.5-1 in the DCD proposed in the LAR. The exemption request proposes to depart from the certified design by revising information on the ASME safety classification, equipment orientation, adding and removing equipment, and identification of the number of emergency air storage tanks. The changes for consistency will not impact the functional capabilities of these components. The proposed changes will not adversely affect the ability of the SSCs to perform their design functions and the level of safety provided by the SSCs is unchanged; therefore, as required by 10 CFR Part 52, Appendix D, Section VIII.A.4, the staff finds that granting the exemption would not result in a significant decrease in the level of safety otherwise provided by the design.

## 3.2 TECHNICAL EVALUATION OF PROPOSED CHANGES

The information presented by the licensee in this LAR was evaluated by NRC staff for its completeness, quality, and clarity. No new technical review of the designated changes proposed to be modified by this LAR was required or performed. This is because the changes to Tier 1 Figure 2.2.5-1 of Appendix C of the COL, are derived from Tier 2 information, and this Tier 2 information was reviewed during the evaluation of the AP1000 DCD and then incorporated by reference into SCE&G's COL application for VCSNS Units 2 and 3. In addition, the changes made to Tier 2 Table 3I.6-3 and Tier 2 Figure 6.4-2 are the result of inconsistencies with existing design descriptions in the UFSAR Tier 2 information. As part of this license amendment, VCSNS did not request any changes to design information; it merely requested changes to how the design information was described in Appendix C of the COLs and in Tier 1 and Tier 2 of the DCD. The following paragraphs describe the staff's approach to review the LAR. The licensee stated in its application that it was identical to VEGP Units 3 and 4.

The staff reviewed and found the proposed changes were identical and, therefore, determined that the changes do not affect any of the information used or cited in the NRC's safety findings as documented in either the AP1000 DCD Final Safety Evaluation Report (FSER) or the VCSNS Units 2 and 3 COL FSER. The proposed changes to Tier 1 Figure 2.2.5-1, Tier 2 Table 3I.6-3, and Tier 2 Figure 6.4-2 are to correct inconsistencies or errors. There are no changes to the design, functional capabilities, method for performing a function, design analysis, safety analysis, or UFSAR Tier 2 information involved. Thus, the requested Tier 1 and Tier 2 changes

do not affect any design functions. The proposed changes do not involve a change to the method of evaluation for establishing design bases or safety analyses. Tests, experiments and procedures described in the licensing basis were not changed by these departures.

- *Change to MCR Air Filtration Line Eductor Orientation*

Tier 2 Section 6.4.2.3 describes the MCR air filtration line eductor as a passive component that is designed to use the MCR emergency habitability system (VES) bottled air supply to create a vacuum to draw air from the MCR through the air filtration unit and then into the MCR. However, Tier 1 Figure 2.2.5-1 and Tier 2 Figure 6.4-2 (Sheet 2) incorrectly show the eductor reversed from the intended orientation. The proposed change will fix the inconsistency by changing the orientation to have the emergency air storage tanks connected to the motive air inlet of the eductor and the MCR air inlet connected to the suction tap of the eductor.

The staff verified that the proposed change to Tier 1 Figure 2.2.5-1 and Tier 2 Figure 6.4-2 (Sheet 2), to correct the orientation of the educator, accurately reflects the Tier 2 information described in Tier 2 Section 6.4.2.3. These changes do not involve a physical change to the plant or changes to the original design function of the plant. The staff reviewed the updated information, and confirmed that it provides consistency between Tier 1 and Tier 2.

- *Addition of Air Bank Fill/Vent Header with Air Tank Fill/Vent Isolation Valves*

Tier 1 Figure 2.2.5-1 does not include a header with isolation valves for the VES emergency air storage tanks design as shown in Tier 2 Figure 6.4-2 (Sheet 1). The proposed change will add the air bank fill / vent header with a safety-related air tank fill/vent isolation valve at each of the four air banks to Tier 1 Figure 2.2.5-1. In addition, the proposed change will move the ASME Code classification transition to immediately upstream of the safety-related air tank fill / vent isolation valves.

The staff verified that the proposed change to Tier 1 Figure 2.2.5-1, to correct the missing header with isolation valves, accurately reflects the Tier 2 information shown in Tier 2 Figure 6.4-2 (Sheet 2). These changes do not involve a physical change to the plant or changes to the original design function of the plant. The staff reviewed the updated information, and confirmed that it provides consistency between Tier 1 and Tier 2.

- *Change in Safety Classification of Refill Line Isolation Valve*

Tier 2 Figure 6.4-2 (Sheet 1) shows the refill line isolation valve (VES-PLV038) as nonsafety-related. However, Tier 1 Figure 2.2.5-1 and Tier 2 Table 3I.6-3 incorrectly show the refill line isolation valve (VES-PLV038) as safety-related. The proposed change will designate the refill line isolation valve as nonsafety-related.

The staff verified that the proposed change to Tier 1 Figure 2.2.5-1 and Tier 2 Table 3I.6-3, to correct the safety classification of the refill line isolation valve (VES-PLV038), accurately reflects the Tier 2 information shown in Tier 2 Figure 6.4-2 (Sheet 1). These changes do not involve a physical change to the plant or changes to the original design function of the plant. The staff reviewed the updated information, and confirmed that it provides consistency between Tier 1 and Tier 2.

- *Deletion of Flow Control Orifices (Flow Restricting Orifices)*

Tier 2 Section 6.4.2.3 describes that the flow metering orifices are located downstream of the pressure regulating valve in the eductor and in the eductor bypass line and are designed to limit the flow rate of air delivered to the MCR. It also states that these flow metering orifices are sized to provide the required air flow rate to the MCR. However, Tier 1 Figure 2.2.5-1 and Tier 2 Figure 6.4-2 (Sheet 2) incorrectly show additional flow metering orifices downstream of the pressure regulating valves and upstream of the other flow metering orifices in the eductor and in the eductor bypass line. The proposed change will delete the additional flow metering orifices since the flow metering orifices in the eductor and in the eductor bypass line that are described in Tier 2 Section 6.4.2.3 are designed to provide the required air flow rate to the MCR.

The staff verified that the proposed change to Tier 1 Figure 2.2.5-1 and Tier 2 Figure 6.4-2 (Sheet 2), to delete the additional flow metering orifices, accurately reflects the Tier 2 information described in Tier 2 Section 6.4.2.3. These changes do not involve a physical change to the plant or changes to the original design function of the plant. The staff reviewed the updated information, and confirmed that it provides consistency between Tier 1 and Tier 2.

- *Change in Safety Classification and Designation of Emergency Air Storage Tanks*

Tier 2 Table 3.2-3 (Sheet 62 of 75 and Sheet 63 of 75) lists all 32 VES emergency air storage tanks as safety-related (AP1000 Class C and Seismic Category I). However, Tier 1 Figure 2.2.5-1 incorrectly shows the emergency air storage tanks as nonsafety-related. The proposed change will revise the classification of the emergency air storage tanks in Tier 1 Figure 2.2.5-1 to safety-related.

The staff verified that the proposed change to Tier 1 Figure 2.2.5-1, to revise the classification of the emergency air storage tanks, accurately reflects the Tier 2 information described in Tier 2 Table 3.2-3. These changes do not involve a physical change to the plant or changes to the original design function of the plant. The staff reviewed the updated information, and confirmed that it provides consistency between Tier 1 and Tier 2.

All of the above proposed changes do not represent any technical changes to the design, construction, or operation of the plant. No structure, system, component, design function, or analysis as described in the AP1000 certified design is affected.

#### 4.0 STATE CONSULTATION

In accordance with the Commission's regulations in 10 CFR 50.91(b)(2), the South Carolina State official was notified of the proposed issuance of the amendment. The State official had no comments.

#### 5.0 ENVIRONMENTAL CONSIDERATION

The amendment changes a requirement with respect to installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20. The NRC staff has determined that the amendment involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite, and that there is no



significant increase in individual or cumulative occupational radiation exposure. The Commission has previously issued a proposed finding that the amendment involves no significant hazards consideration, and there has been no public comment on such finding (80 FR 61476 (October 13, 2015)). Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

Because the exemption is necessary to allow the changes proposed in the license amendment, and because the exemption does not authorize any activities other than those proposed in the license amendment, the environmental consideration for the exemption is identical to that of the license amendment. Accordingly, the exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

## 6.0 CONCLUSION

The staff has determined that pursuant to Section VIII.A.4 of Appendix D to 10 CFR Part 52, the exemption (1) is authorized by law, (2) presents no undue risk to the public health and safety, (3) is consistent with the common defense and security, (4) presents special circumstances, (5) the special circumstances outweigh the potential decrease in safety due to reduced standardization, and (6) does not significantly reduce the level of safety at the licensee's facility. Therefore, the staff grants the licensee an exemption from the Tier 1 information specified by the licensee.

The staff has concluded, based on the considerations discussed in Section 3.2 and confirming that these changes do not change an analysis methodology, assumptions, or the design itself, that there is reasonable assurance that: (1) the health and safety of the public will not be endangered by operation in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public. Therefore, the staff finds the changes proposed in this license amendment acceptable.

## 7.0 REFERENCES

1. Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, Updated Final Safety Analysis Report (UFSAR), Revision 5, dated July 7, 2011 (ADAMS Accession No. ML11187A074).
2. AP1000 Design Control Document, Revision 19, dated June 13, 2012 (ADAMS Accession No. ML11171A500).
3. U.S. Nuclear Regulatory Commission, "Final Safety Evaluation Report Related to the Combined Licenses for Vogtle Electric Generating Plant, Units 3 and 4," Volume 1, NUREG-2124, dated September 30, 2012 (ADAMS Accession No. ML12271A045).
4. Final Safety Evaluation Report Related to Certification of the AP1000 Standard Plant Design, NUREG-1793, Supplement 2, dated August 5, 2011 (ADAMS Accession No. ML112061231).