



U.S. Nuclear Regulatory Commission

Office of Nuclear Security and Incident Response

NSIR Temporary Staff Guidance

Temporary Staff Guidance No.: **TSG-NSIR-2020-01**

Temporary Staff Guidance Title: **COVID-19 RELATED EXEMPTIONS FROM NRC REGULATIONS – EMERGENCY PREPAREDNESS EXERCISES**

Effective Date: **September 11, 2020**

Approved By: **Kathryn Brock**

Date Approved: **September 11, 2020**

Primary Contact: **Don A. Johnson**
301-287-9230
don.johnson@nrc.gov

Responsible Organization: **NSIR/DPR/POB**

ADAMS Accession No.: **ML20196M030**



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***by e-mail**

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Temporary Staff Guidance - COVID-19 Related Exemptions from NRC Regulations

1. OBJECTIVE

This temporary staff guidance (TSG) document provides staff guidance for the timely disposition of requests for exemption from the biennial onsite emergency preparedness (EP) exercises required by Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities,” to Part 50, “Domestic Licensing of Production and Utilization Facilities,” to Title 10, “Energy,” of the *Code of Federal Regulations* (10 CFR), Section IV.F.2.b, and offsite exercises required by Appendix E, Section IV.F.2.c and deferral of those exercises from calendar year (CY) 2020 to CY 2021. In addition, this TSG provides guidance for the timely disposition of requests to defer the offsite biennial EP exercises from CY 2020 to CY 2022. Also, licensees may need to seek an exemption for exercises required to be demonstrated during the 8-year exercise cycle, if applicable, in Appendix E, Section IV.F.2.d and Section IV.F.2.j. To facilitate timely and consistent application of this TSG in the staff’s review of and response to these exemption and deferral requests, the enclosures to this TSG include a review checklist and response templates.

This TSG provides the staff with expectations and flexibilities that supplement the typical exemption review processes described in Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-103, “Exemptions from NRC Regulations” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19155A121), as supplemented by TSG-DORL-2020-02, “COVID-19 Related Exemptions from NRC Regulations” (ADAMS Accession No. ML20101F039). These expectations and flexibilities are intended to enhance NSIR’s efficiency in responding to the needs of licensees and the public during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE). Exemption requests for offsite exercises would allow State and local governments to continue to focus their essential response efforts on the COVID-19 PHE.

Specific objectives of this TSG include the following:

- Maintain reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at a nuclear power plant;
- Promote consistency in the processing of COVID-19 PHE related exemptions from onsite and offsite biennial exercise requirements by providing the NSIR staff with a framework for the review process;
- Increase awareness that exemption requests for biennial exercises required to be conducted in CY 2020 must be approved before December 31, 2020, to preclude noncompliance with the applicable regulation(s);
- Improve the effectiveness of the expedited review by providing response letter templates for:
 - Submittals that request the deferral of onsite and/or offsite biennial exercises from CY 2020 to CY 2021;

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- Submittals that request the deferral of offsite biennial exercises from CY 2020 to CY 2022 through a request for a one-time exemption from the biennial exercise requirement in Appendix E, Section IV.F.2.c.; and
- Improve internal and external communications.

This TSG is to be used for COVID-19 PHE related exemption requests for regulations associated with CY 2020 biennial EP exercises and/or those associated with exercises required to be demonstrated during the 8-year exercise cycle, if applicable, in Appendix E, Section IV.F.2.d and Section IV.F.2.j. Depending on the duration of the PHE, this TSG may be used to support EP exercise exemption requests beyond CY 2022. The submittal and response templates are based upon Appendix E, Section IV.F.2.b and/or 2.c. If the exemption request is for Appendix E, Section IV.F.2.d or 2.j, then the appropriate template should be adjusted accordingly by the staff.

TSG-DORL-2020-02, Section 3.4, “Work Schedule,” states, in part, “Each COVID-19 exemption should be temporary (e.g., an expiration date of 90 days after the PHE ends or December 31, 2020, whichever occurs first).” For biennial exercise exemptions, exemptions that are approved under this process would be in effect until the performance of the onsite and/or offsite biennial exercise, as applicable. The remaining parts of Section 3.4 continue to apply for biennial exercise exemptions.

2. **BACKGROUND**

On January 31, 2020, the U.S. Department of Health and Human Services declared a PHE for the United States to aid the nation’s healthcare community in responding to COVID-19. On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization. As discussed during a public meeting held on March 20, 2020, with nuclear industry representatives and members of the public, this is an unprecedented time for our country, the U.S. Nuclear Regulatory Commission (NRC), and its regulated entities. A summary of this meeting is available at ADAMS Accession No. ML20093F120.

Regulatory Issue Summary (RIS) 2006-003, “Guidance on Requesting an Exemption from Biennial Emergency Preparedness Exercise Requirements” (ADAMS Accession No. ML053390039), provides guidance for nuclear power reactor licensees. Further, a joint NRC and Federal Emergency Management Agency (FEMA) memorandum, “Guidance for Postponement of REP Exercises Due to the COVID-19 Outbreak,” dated March 27, 2020 (ADAMS Accession Number ML20085F705), provides additional information on postponement of biennial exercises within CY 2020.

On May 14, 2020, the NRC provided letters to the Nuclear Energy Institute, Entergy Nuclear, and Florida Power & Light Company, “U.S. Nuclear Regulatory Commission Planned Actions Related to Emergency Preparedness Biennial Exercise Requirements for All Licensees During the Coronavirus Disease 2019 Public Health Emergency” (ADAMS Accession No. ML20123A003). On September 2, 2020, the NRC issued an addendum to this letter (ADAMS Accession No. ML20223A152). This TSG supplements both the letter and its addendum.

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On June 23, 2020, the NRC held a public meeting to discuss potential biennial exercise exemption requests. A summary of this meeting is available at ADAMS Accession No. ML20198M514.

3. BASIC REQUIREMENTS

3.1 Basic Process

Refer to Enclosure 1, “Biennial Exercise Exemption Request Roadmap,” for a basic flow path to be considered for the review and disposition of biennial exercise exemption requests. Timely and effective communication between the licensee and NRC staff (NRR Project Managers (PM) and NSIR staff) is important to expedite the review of the request. In addition, it is important that the licensee effectively communicates and coordinates biennial exercises with applicable offsite response organizations (OROs), the applicable FEMA Regional Radiological Emergency Preparedness (REP) staff, and the applicable NRC Regional EP staff as appropriate for the specific regulation(s) applicable to the exemption request.

To allow for expedited consideration of the temporary exemption request to reschedule the onsite and/or offsite biennial exercise from CY 2020 to CY 2021, licensees should endeavor to reschedule the biennial exercise within 35 months of when it was performed in CY 2018. Licensees that cannot meet this target should coordinate with the appropriate NRC Region regarding the rescheduling of selected elements of the EP Baseline Program Inspection during CY 2020 to ensure that the licensee’s EP Program is effectively maintained. This would provide support to the justification for an exemption beyond 35 months.

By design, the requirement for the onsite biennial exercise is separate and distinct from the requirement for the offsite biennial exercise, even though they are typically performed simultaneously. Therefore, for the CY 2020 biennial exercise, licensees have the option of (1) seeking exemption for both requirements; (2) only seeking an exemption for the onsite biennial exercise, or (3) only seeking an exemption for the offsite biennial exercise.

The NRC is responsible for determining reasonable assurance in accordance with 10 CFR Part 50 and Appendix E to 10 CFR Part 50. This TSG only addresses exemptions from requirements of 10 CFR Part 50, Appendix E, and does not address 44 CFR Part 350, “Review and Approval of State and Local Radiological Emergency Plans and Preparedness.”

Licensees should also evaluate the impact that the proposed exemption would have on their 8-year exercise cycle plan to ensure the completion of various required performance activities, such as those required in Appendix E, Sections IV.F.2.d (ingestion pathway) and IV.F.2.j (varied scenario content elements). If necessary, an exemption may be considered for these requirements, in addition to the biennial exercise requirements, which would necessitate a postponement of these requirements.

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3.2 Expected Exemption Package Content

When requested by the licensee through the NRR PM, NSIR staff will support any pre-submittal conference calls or meetings related to proposed biennial EP exercise exemption requests. The NRC and licensee will discuss package content such that the licensee has a clear understanding of what information should be part of the exemption request submittal to support a timely review of the request.

3.3 Technical Review Guidance

Granting a licensee's request for exemption from the onsite and/or offsite biennial exercise requirement would demonstrate that the NRC maintains reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the nuclear power plant. In the statement of considerations for the final rule that established the standards to be applied when considering whether to grant exemptions from regulations in 10 CFR Part 50 ("Specific Exemptions; Clarification of Standards, Final Rule," 50 FR 50764, dated December 12, 1985), the Commission stated:

While compliance with all NRC regulations provides reasonable assurance of adequate protection of the public health and safety, the converse is not correct, that failure to comply with one regulation or another is an indication of the absence of adequate protection, at least in a situation where the Commission has reviewed the noncompliance and found that it does not pose an "undue risk" to the public health and safety. Furthermore, the Commission has never defined the concept of "defense-in-depth" to preclude the granting of an exemption from a regulation as long as the applicable exemption criteria are met. In fact, the Commission has recognized that its regulations may provide for the possibility of exemptions when an appropriately high level of safety is in fact achieved and the public interest is served.

The technical review of the exemption requests consists of an evaluation and determination that the licensee and/or OROs are adequately prepared to implement their respective emergency plan in the event of a declared radiological emergency.

To facilitate the timely and consistent review of biennial exercise exemption requests, the reviewer should use the checklist provided in Enclosure 2, "Technical Review Checklist," to support their technical review of the exemption request.

**Temporary Staff Guidance – COVID-19 Related
Exemptions from NRC Regulations – Radiological Emergency Preparedness Exercises**

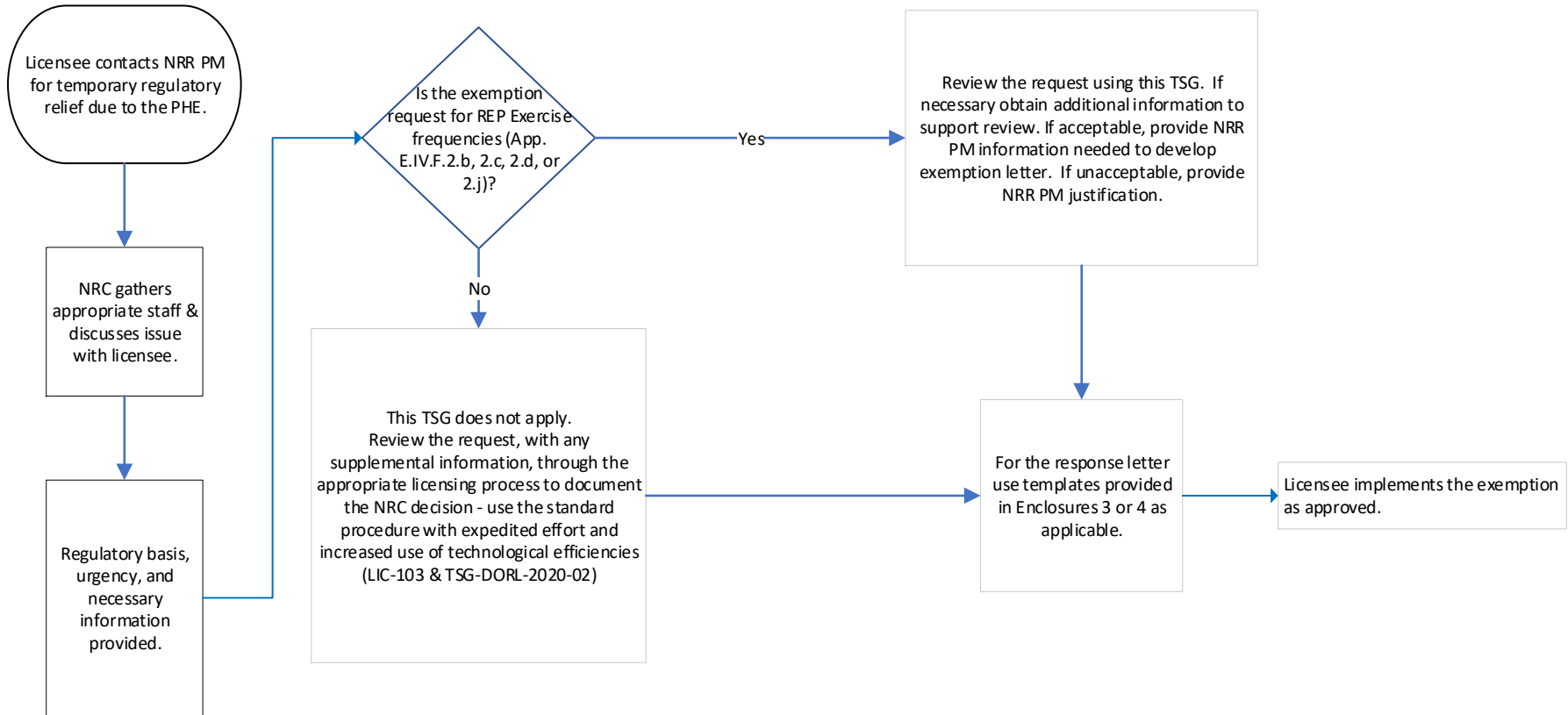
3.4 Coordination with NRR PM

NRR Office Instruction LIC-103 and NRR TSG-DORL-2020-02 provide guidance and direction for the processing of the exemption request. NSIR staff should use NSIR TSG-2020-01 to support the technical review of the request, and LIC-103, as supplemented by TSG-DORL-2020-02, for the regulatory process to use for the exemption request as directed by the applicable NRR PM. The following enclosures provide response letter templates:

- Enclosure 3, “Response Template – Exemption Request for 10 CFR Part 50, Appendix E, Sections IV.F.2.b and/or 2.c to CY 2021.”
- Enclosure 4, “Response Template – Exemption Request for 10 CFR Part 50, Appendix E, Section IV.F.2.c to CY 2022.”

Enclosure 1

Biennial Exercise Exemption Request Roadmap



Enclosure 2

Technical Review Checklist

- Identifies exercise requirement(s) (Appendix E, Sections IV.F.2.b, 2.c, 2.d, and/or 2.j).
- Provides an impact statement for the effect on the 8-year inspection cycle if the exemption is for 2.d and/or 2.j.
- Provides regulatory basis for exemption (10 CFR 50.12).

{Per 10 CFR 50.12(a)(2), the NRC will not consider granting an exemption unless special circumstances are present. Under 10 CFR 50.12(a)(2)(v), special circumstances include when the exemption would provide only temporary relief from the applicable regulation and the licensee has made good faith efforts to comply with the regulation. The requested exemption to not conduct the biennial exercise in CY 2020 would provide only temporary relief from the applicable regulation.}
- Provides last biennial exercise date (CY 2018).
- Provides justification to support that the licensee has made a reasonable effort to reschedule the onsite and/or the offsite biennial exercise date within CY 2020 but was unsuccessful. Note that the inability of the OROs to participate is not adequate justification for an exemption from the onsite exercise requirement.
- Provides proposed biennial exercise date, if the exemption request is to reschedule the CY 2020 exercise to CY 2021.
- If the exemption request is to reschedule the CY 2020 exercise to CY2021, and the proposed exercise date is more than 35 months from the CY 2018 biennial exercise date, provides a CY 2020 date for when an EP Baseline Program Inspection should be performed. Includes a statement that this date was coordinated with the Regional EP inspectors (reference "Inspection Guidance During Transition From COVID-19 Mandatory Telework," dated May 28, 2020 (ADAMS Accession No. ML20141L766)).
- If the exemption request is for the CY 2020 offsite biennial exercise requirement in Appendix E, Section IV.F.2.c, such that the next exercise is to be performed no later than the end of CY 2022, includes the following:
 - a statement that a reasonable effort was made to reschedule the exercise during CY 2020, but was unsuccessful;
 - a statement from responsible OROs that they are in agreement with the licensee's exemption request and that they are committed to maintaining their radiological emergency plans; and
 - a statement from responsible OROs that they are not impacted in a manner that would adversely affect their ability to maintain response capability to support emergency response activities to actual nuclear power plant radiological emergencies.
- Provides a statement that the next biennial exercise date, for both onsite and offsite exercises, will continue to be in even years.

Enclosure 2

Technical Review Checklist

- Provides a statement that the licensee conducted drills, exercises, and other training activities that exercised its emergency response strategies, in coordination with offsite authorities, since the previous biennial exercise.

Enclosure 3

Response Template: Exemption Request for 10 CFR Part 50, Appendix E Sections IV.F.2.b and/or 2.c to CY 2021

[Addressee]

SUBJECT: [PLANT NAME, UNIT(S)] – TEMPORARY EXEMPTION FROM
REQUIREMENTS OF 10 CFR PART 50, APPENDIX E, SECTION[S] [IV.F.2.B
AND/OR IV.F.2.C] (EPID XXXXX)

The U.S. Nuclear Regulatory Commission has approved the enclosed exemption from specific requirements of Appendix E to Title 10 of the *Code of Federal Regulations* Part 50, Section[s] [IV.F.2.b and/or IV.F.2.c], for [Plant Name, Unit(s)]. This action is in response to your application dated XXXXX, as supplemented by letter(s) dated XXXXX (Agencywide Documents Access and Management System Accession Nos. XXXXXX and XXXXX, respectively), that requested [subject matter].

<INSERT: company name> (the licensee) holds <INSERT: Renewed, if applicable> Facility Operating License No. <INSERT: NPF- or DPR- ,with the license number(s)>, which authorizes operation of <INSERT: Plant Name>, <INSERT: Unit or Units, with unit number(s)>. <INSERT: This license is/These licenses are> subject to the rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission).

The facility consists of a <INSERT: boiling- or pressurized-, as applicable> water reactor located in <INSERT: county name> County in <INSERT: State>.

By letter dated <INSERT: date>, <INSERT: name of licensee> submitted a request for temporary exemption from Appendix E to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Section(s) IV.F.<INSERT: 2.b and/or 2.c as specific to the exemption request> regarding the performance of its biennial emergency preparedness (EP) exercise.

The requirements in 10 CFR Part 50, Appendix E, Section IV.F.2.b state, in part:

Each licensee at each site shall conduct a subsequent exercise of its onsite emergency plan every 2 years. ... The exercise may be included in the full participation biennial exercise required by paragraph 2.c of this section.

The requirements in 10 CFR Part 50, Appendix E, Section IV.F.2.c state, in part:

Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the radiological response plan.

In Appendix E to 10 CFR Part 50, the NRC defines the term “full participation,” when used in conjunction with emergency preparedness exercises for a particular site, to mean appropriate offsite local and State authorities and licensee personnel physically and actively take part in testing their integrated capability to adequately assess and respond to an accident at a commercial nuclear power plant. Full participation includes testing major observable portions of the onsite and offsite emergency plans and mobilization of State, local, and licensee personnel and other resources in sufficient numbers to verify the capability to respond to the accident scenario. While desirable, full participation exercises are not required (i.e., exercises required

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Response Template: Exemption Request for 10 CFR Part 50, Appendix E Sections IV.F.2.b and/or 2.c to CY 2021

by 10 CFR Part 50, Appendix E, Sections IV.F.2.b and 2.c are not required to be performed simultaneously).

On January 31, 2020, the U.S. Department of Health and Human Services declared a public health emergency (PHE) for the United States to aid the nation's healthcare community in responding to the Coronavirus Disease 2019 (COVID-19). Subsequently, the Centers for Disease Control and Prevention (CDC) issued recommendations (e.g., social distancing, limiting assemblies) in an attempt to limit the spread of COVID-19.¹

In your application, you provided the following information:

- <INSERT: specific basis/justification from exemption request>
- The threat of COVID-19 spread has resulted in the inability to safely conduct the biennial EP exercise that was scheduled for <INSERT: exercise date>, 2020 due to implementation of isolation activities (e.g., social distancing, group size limitations, self-quarantining, etc.). In addition, the State of <INSERT: applicable State and affected offsite response organizations (OROs)> informed the licensee that they were no longer able to support the biennial EP exercise in the interest of protecting State and local staff, and Federal evaluators. The OROs continue to maintain readiness to respond to an actual radiological emergency at <INSERT: site name>.
- This one-time schedular exemption to allow for the conduct of the biennial EP exercise in calendar year (CY) 2021 supports continued implementation of the isolation activities (e.g., social distancing, group size limitations, self-quarantining, etc.) to protect required emergency response organization (ERO) and ORO personnel in response to the COVID-19 PHE.
- The last biennial EP exercise was conducted on <INSERT: date>, 2018. Since that time, the licensee has conducted numerous drills, exercises, and other training activities that have exercised its emergency response strategies. State officials participated in the following:
 - <INSERT: dates where OROs participated, fully or in part, if provided. Alternatively, provide a statement that the OROs and licensee frequently participate in joint exercises of various EP Program elements to ensure that readiness is maintained>;
- The licensee will continue to conduct drills, exercises, and other training activities that exercise its emergency response strategies. The State and local authorities are expected to participate to the extent practical while also complying with the CDC recommendations to limit the spread of COVID-19.
- The licensee made a reasonable effort to reschedule the biennial EP exercise during 2020 but was unsuccessful. <INSERT: additional information from exemption request>
- The date of the rescheduled biennial EP exercise falls within 35 months from the month

¹ CDC, "How to Protect Yourself and Others," April 18, 2020 (ADAMS Accession No. ML20125A069).

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Response Template: Exemption Request for 10 CFR Part 50, Appendix E Sections IV.F.2.b and/or 2.c to CY 2021

of the previously evaluated biennial EP exercise conducted on <INSERT: date>, 2018. This exemption would defer the CY 2020 biennial EP exercise to CY 2021. Future biennial EP exercises would continue to be held in even-numbered years.

- <This is the alternative language if the requested date is more than 35 months from the last biennial exercise.> The date of the rescheduled biennial EP exercise is greater than 35 months from the month of the previously evaluated biennial EP exercise conducted on <INSERT: date>, 2018. The staff confirmed that the licensee's EP Program is adequately prepared by inspecting the EP Program using various selected elements of the Reactor Oversight Program EP Inspection Procedures. This exemption would defer the CY 2020 biennial EP exercise to CY 2021. Future biennial EP exercises would continue to be held in even-numbered years.

Pursuant to 10 CFR 50.12, "Specific exemptions," the NRC may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when (1) the exemptions are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security; and (2) special circumstances are present.

The NRC staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Therefore, the NRC staff finds that the requested exemption is authorized by law.

The regulations in 10 CFR Part 50, Appendix E, Section IV.F.2.b <and/or Section IV.F.2.c> concern requirements for licensees to conduct biennial EP exercises at their facilities. No new accident precursors are created by allowing the licensee to postpone the biennial EP exercise from CY 2020 until CY 2021. Thus, the probability and consequences of postulated accidents are not increased. In addition, the requested exemption for a one-time change to the biennial EP exercise schedule has no relation to security issues. Therefore, the NRC staff finds that the requested exemption will not present an undue risk to the public health and safety and is consistent with the common defense and security.

Special circumstances, per 10 CFR 50.12, that apply to the requested exemption include:

- a. 10 CFR 50.12(a)(2)(ii): "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 regulation in 10 CFR Part 50, Appendix E, Section, IV.F.2.b requires licensees to conduct an exercise of their site emergency plan biennially. Further, the regulation in 10 CFR Part 50, Appendix E, Section IV.F.2.c requires offsite plans for each site to be exercised biennially with full participation by each offsite authority having a role under the plan. The underlying purpose of these requirements is to ensure that the emergency organization personnel are familiar with their duties and to identify and correct any weaknesses that may exist in the licensee's EP Program. The underlying purpose of Section IV.F.2.c is also to test and maintain interfaces among affected State and local authorities and the licensee. The licensee stated that it has conducted training drills exercising the principal functional areas of emergency response since the last evaluated

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Response Template: Exemption Request for 10 CFR Part 50, Appendix E Sections IV.F.2.b and/or 2.c to CY 2021

biennial EP exercise and has activated all onsite emergency response facilities during those drills with State participation. Based on the above, the NRC staff finds that the underlying purposes of these regulations are met by the licensee having conducted these preparedness activities and establishing an acceptable tentative date for the rescheduled biennial EP exercise of <INSERT: date>, 2021. <Add any other pertinent information from the exemption request; it may be necessary to reword this section depending on the specific request being made, i.e., Section 2.b and/or 2.c, individually or together.>

- b. 10 CFR 50.12(a)(2)(v): “The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation.”

{For exemption from Appendix E, Section IV.F.2.b (onsite) state the following:}
{licensee} has determined that the originally scheduled exercise date does not support continued implementation of the isolation activities (e.g., social distancing, group size limitations, self-quarantining, etc.) to protect required ERO personnel in response to the ongoing COVID-19 PHE. These activities are needed to ensure that ERO personnel are isolated from COVID-19 and remain capable of executing the functions of the ERO, as described in the *{site}* Emergency Plan. A tentative date of <INSERT: date> has been proposed.

{For exemption to Appendix E, Section IV.F.2.c (offsite) state the following:}
The State of <INSERT: applicable States> informed the licensee that they were no longer able to support the originally scheduled biennial EP exercise in the interest of protecting State and local staff, and Federal evaluators. During discussions among the licensee, State, and local officials, and the NRC and FEMA Regions, the parties concluded that scheduling the exercise in CY 2020 would not be feasible due to conflicts, such as <INSERT: conflicts documented in request.> They agreed to a tentative date of <INSERT: date>, 2021.

<Document applicable alignment with FEMA specific to the requested exemption. Email is acceptable.>

Therefore, the NRC staff finds that the requested exemption to conduct the biennial EP exercise in CY 2021 instead of CY 2020 would provide only temporary relief from the applicable regulation and that the licensee has made good faith efforts to comply with the regulation.

Based on the above, the NRC staff finds that the special circumstances of 10 CFR 50.12(a)(2)(ii) and 10 CFR 50.12(a)(2)(v) are present.

NRC approval of the requested exemption is categorically excluded under 10 CFR 51.22(c)(25) and there are no extraordinary circumstances present that would preclude reliance on this exclusion. The NRC staff determined, per 10 CFR 51.22(c)(25)(vi)(E), that the requirements from which the exemption is sought involve education, training, experience, qualification, requalification, or other employment suitability requirements. The NRC staff also determined that approval of this exemption involves no significant hazards consideration because it does not authorize any physical changes to the facility or any of its safety systems, change any of the

Enclosure 3

Response Template: Exemption Request for 10 CFR Part 50, Appendix E Sections IV.F.2.b and/or 2.c to CY 2021

assumptions or limits used in the licensee's safety analyses, or introduce any new failure modes. There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite because this exemption does not affect any effluent release limits as provided in the licensee's technical specifications or by the regulations in 10 CFR Part 20, "Standards for Protection Against Radiation." There is no significant increase in individual or cumulative public or occupational radiation exposure because this exemption does not affect limits on the release of any radioactive material, or the limits provided in 10 CFR Part 20 for radiation exposure to workers or members of the public. There is no significant construction impact because this exemption does not involve any changes to a construction permit. There is no significant increase in the potential for or consequences from radiological accidents because the exemption does not alter any of the assumptions or limits in the licensee's safety analysis. In addition, the NRC staff determined that there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of the requested exemption.

Granting the requested exemption does not impact NRC findings of reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at <INSERT: site name>. In the statement of considerations for the standards to be applied when considering whether to grant exemptions ("Specific Exemptions; Clarification of Standards, Final Rule," 50 FR 50764, dated December 12, 1985), the Commission stated:

While compliance with all NRC regulations provides reasonable assurance of adequate protection of the public health and safety, the converse is not correct, that failure to comply with one regulation or another is an indication of the absence of adequate protection, at least in a situation where the Commission has reviewed the noncompliance and found that it does not pose an "undue risk" to the public health and safety. Furthermore, the Commission has never defined the concept of "defense-in-depth" to preclude the granting of an exemption from a regulation as long as the applicable exemption criteria are met. In fact, the Commission has recognized that its regulations may provide for the possibility of exemptions when an appropriately high level of safety is in fact achieved and the public interest is served.

The NRC staff has determined that in accordance with 10 CFR 50.12, the requested exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security; and that special circumstances are present. Therefore, the NRC hereby grants the licensee's request for a one-time schedular exemption from the requirements for the biennial EP exercise in 10 CFR Part 50, Appendix E, Sections IV.F.2.b <and/or IV.F.2.c>.

This exemption expires on <If request is for a date that is not more than 35 months from the last biennial EP exercise, then the expiration date should be the month in CY 2021 that is 35 months after the last biennial EP exercise. If the request is for a date that is more than 35 months from the last biennial EP exercise, then the expiration date should be December 31, 2021.>

If you have any questions, please contact the NRR project manager, <INSERT: name and contact information>.

Enclosure 3

**Response Template: Exemption Request for 10 CFR Part 50, Appendix E
Sections IV.F.2.b and/or 2.c to CY 2021**

Sincerely,

Craig G. Erlanger, Director
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. xx-xxxx

cc: Listserv

Enclosure 4

Response Template: Exemption Request for 10 CFR Part 50, Appendix E Section IV.F.2.c to CY 2022

[Addressee]

SUBJECT: [PLANT NAME, UNIT(S)] – TEMPORARY EXEMPTION FROM REQUIREMENTS OF 10 CFR PART 50, APPENDIX E, SECTION[S] [IV.F.2.B AND/OR IV.F.2.C] (EPID XXXXX)

The U.S. Nuclear Regulatory Commission has approved the enclosed exemption from specific requirements of Appendix E to Title 10 of the *Code of Federal Regulations* Part 50, Section[s] [IV.F.2.b and/or IV.F.2.c], for [Plant Name, Unit(s)]. This action is in response to your application dated XXXXX, as supplemented by letter(s) dated XXXXX (Agencywide Documents Access and Management System Accession Nos. XXXXXX and XXXXX, respectively), that requested [subject matter].

<INSERT: Company Name> (the licensee) holds <INSERT: Renewed, if applicable> Facility Operating License No. <INSERT: NPF- or DPR- , with the license number(s)>, which authorizes operation of <INSERT: Plant Name>, <INSERT: Unit or Units, with unit number(s)>. <INSERT: This license is/These licenses are> subject to the rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission).

The facility consists of a <INSERT: boiling- or pressurized-, as applicable> water reactor located in <INSERT: county name> County in <INSERT: State>.

By letter dated <INSERT: date>, <INSERT: name of licensee> submitted a request for temporary exemption from Appendix E to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Section IV.F.2.c regarding the performance of the CY 2020 biennial emergency preparedness (EP) exercise for responsible offsite response organizations (OROs).

The requirements in 10 CFR Part 50, Appendix E, Section IV.F.2.c state, in part:

Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the radiological response plan.

On January 31, 2020, the U.S. Department of Health and Human Services declared a public health emergency (PHE) for the United States to aid the nation's healthcare community in responding to the Coronavirus Disease 2019 (COVID-19). Subsequently, the Centers for Disease Control and Prevention (CDC) issued recommendations (e.g., social distancing, limiting assemblies) in an attempt to limit the spread of COVID-19.²

In your application, you provided the following information:

- <INSERT: specific basis/justification from exemption request>.
- The threat of COVID-19 spread has resulted in the inability to safely conduct the offsite

² CDC, "How to Protect Yourself and Others," April 18, 2020 (ADAMS Accession No. ML20125A069).

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biennial EP exercise that was scheduled for <INSERT: exercise date>, 2020 due to implementation of isolation activities (e.g., social distancing, group size limitations, self-quarantining, etc.). In addition, the State of <INSERT: applicable State and affected local offsite response organizations (OROs)> informed the licensee that they were no longer able to support the biennial EP exercise in the interest of protecting State and local staff, and Federal evaluators. The OROs continue to maintain readiness to respond to an actual radiological emergency at <INSERT: site name>.

- This one-time schedular exemption to not conduct the offsite biennial EP exercise in calendar year (CY) 2020 supports continued implementation of the isolation activities (e.g., social distancing, group size limitations, self-quarantining, etc.) to protect required ORO personnel in response to the COVID-19 PHE.
- The last offsite biennial EP exercise was conducted on <INSERT: date>, 2018. Since that time, the licensee has conducted numerous drills, exercises, and other training activities that have exercised its emergency response strategies. State and local offsite response organizations participated in the following:
 - <INSERT: dates where OROs participated, fully or in part, if provided. Alternatively, provide a statement that the OROs and licensee frequently participate in joint exercises of various EP Program elements to ensure that readiness is maintained>.
- The licensee will continue to conduct drills, exercises, and other training activities that exercise its emergency response strategies. The State and local authorities are expected to participate to the extent practical while also complying with the CDC recommendations to limit the spread of COVID-19.
- The licensee made a reasonable effort to reschedule the biennial EP exercise during CY 2020 and CY 2021 but was unsuccessful. <INSERT: document what the licensee and applicable OROs did>.
- A statement from responsible OROs that they are in agreement with the licensee's exemption request and that they are committed to maintaining their radiological emergency plans.
- A statement from responsible OROs that they are not impacted in a manner that would adversely affect their ability to maintain response capability to support emergency response activities to actual nuclear power plant radiological emergencies.

Pursuant to 10 CFR 50.12, "Specific exemptions," the NRC may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when (1) the exemptions are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security; and (2) special circumstances are present.

The NRC staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities

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that would be authorized by the exemption. Therefore, the NRC staff finds that the requested exemption is authorized by law.

The regulations in 10 CFR Part 50, Appendix E, Section IV.F.2.c concern requirements for licensees to conduct biennial EP exercises at their facilities. No new accident precursors are created by allowing the licensee to postpone the biennial EP exercise from CY 2020 until CY 2022. Thus, the probability and consequences of postulated accidents are not increased. In addition, the requested exemption for a one-time change to the biennial EP exercise schedule has no relation to security issues. Therefore, the NRC staff finds that the requested exemption will not present an undue risk to the public health and safety and is consistent with the common defense and security.

Special circumstances, per 10 CFR 50.12, that apply to the requested exemption include:

- a. 10 CFR 50.12(a)(2)(ii): “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 regulation in 10 CFR Part 50, Appendix E, Section, IV.F.2.c requires offsite plans for each site to be exercised biennially with full participation by each offsite authority having a role under the plan. The underlying purpose of these requirements is to ensure that the emergency organization personnel are familiar with their duties and to identify and correct any weaknesses that may exist in the licensee’s EP Program. The underlying purpose of Section IV.F.2.c is also to test and maintain interfaces among affected State and local authorities and the licensee.

The NRC recognizes that even if a licensee were to be exempted from the requirement to conduct an offsite biennial exercise in CY 2020, in the event of an actual radiological emergency, offsite authorities would respond. Offsite authorities in all states are currently demonstrating response capabilities, including making decisions on protective actions for the public, in response to the COVID-19 PHE.³ Additionally, the NRC continues to monitor U.S. nuclear power plants to ensure that they operate safely during the COVID-19 PHE and that defense-in-depth is maintained to prevent accidents from happening and to mitigate their consequences.

The NRC has consulted with the Federal Emergency Management Agency (FEMA) on the readiness of OROs and the use of this information to inform the NRC decision to grant exemptions, per the NRC/FEMA Memorandum of Understanding.⁴ FEMA has recently performed assessments of all offsite emergency response plan capabilities and has concluded that offsite radiological EP remains adequate to provide reasonable assurance that appropriate measures can and will be taken to protect the health and

³ COVID-19 Resources for State Leaders, *Executive Orders – By State*, accessed August 12, 2020, <https://web.csg.org/covid19/executive-orders/>

⁴ “Memorandum of Understanding (MOU) Between the Department of Homeland Security / Federal Emergency Management Agency and Nuclear Regulatory Commission Regarding Radiological Response, Planning and Preparedness,” December 7, 2015, ADAMS Accession No. ML15344A371.

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safety of the public in a radiological emergency during the COVID-19 PHE.⁵ FEMA monitors response and preparedness capabilities of the OROs to ensure that the response to the current PHE does not adversely impact their ability to protect the public health and safety in the event of a radiological emergency at a commercial nuclear power plant. Exercises are just one of the many methods by which FEMA assesses and validates the adequacy of OROs' plans and ability to implement those plans. In accordance with current FEMA program guidance,⁶ FEMA has alternative means of conducting these assessments.

Based on the above, granting requests for exemption from the 10 CFR Part 50, Appendix E, Section IV.F.2.c requirement for offsite biennial exercises in CY 2020, with the next performance of the exercise to be no later than the end of CY 2022, would allow State and local governments to continue to focus their essential response efforts on the COVID-19 PHE. This exemption would apply only to the requirements of 10 CFR Part 50, Appendix E, Section IV.F.2.c, and would not address 44 CFR Part 350. An exemption from Section IV.F.2.c would not prevent a State or local authority, at its discretion, from demonstrating key skills in drills and exercises for the 8-year exercise cycle or prevent a State or local authority from conducting the exercise in CY 2020 or CY 2021.

The licensee stated that it has conducted numerous drills, exercises, and other training activities that have exercised its emergency response strategies since the last evaluated biennial EP exercise and that State and local offsite response organizations have participated.

Therefore, the NRC staff finds that the underlying purposes of 10 CFR Part 50, Appendix E, Section, IV.F.2.c are met with the rescheduled offsite biennial EP exercise to occur in CY 2022.

- b. 10 CFR 50.12(a)(2)(v): "The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation."

The State of <INSERT: applicable States> informed the licensee that they were no longer able to support the originally scheduled biennial EP exercise in the interest of protecting State and local staff, and Federal evaluators. During discussions among the licensee, State, and local officials, and the NRC and FEMA Regions, the parties concluded that scheduling the exercise in CY 2020 or CY 2021 would not be feasible due to conflicts, such as <INSERT: conflicts documented in request.>

<Document applicable alignment with FEMA specific to the requested exemption. Email is acceptable.>

⁵ FEMA Preparedness Assessments, ADAMS Accession Nos. ML20164A275, ML20174A603, ML20141L795, ML20170B043, ML20170B171, ML20167A175, ML20164A038, ML20154K696, ML20154K617, ML20150A110, and ML20162A056.

⁶ Program Manual, Radiological Emergency Preparedness, FEMA P-1028, December 2019, accessed August 12, 2020, https://www.fema.gov/media-library-data/1577108409695-4e49a0a56c8c62695dcc301272a1eda7/FEMA_REP_Program_Manual_Dec_2019.pdf

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Therefore, granting the requested exemption from the 10 CFR Part 50, Appendix E, Section IV.F.2.c requirement for offsite biennial EP exercises in CY 2020, with the next performance of the exercise to be no later than the end of CY 2022, would provide only temporary relief from the applicable regulation and the licensee has made good faith efforts to comply with the regulation.

Based on the above, the NRC staff finds that the special circumstances of 10 CFR 50.12(a)(2)(ii) and 10 CFR 50.12(a)(2)(v) are present.

NRC approval of the requested exemption is categorically excluded under 10 CFR 51.22(c)(25) and there are no extraordinary circumstances present that would preclude reliance on this exclusion. The NRC staff determined, per 10 CFR 51.22(c)(25)(vi)(E), that the requirements from which the exemption is sought involve education, training, experience, qualification, requalification, or other employment suitability requirements. The NRC staff also determined that approval of this exemption involves no significant hazards consideration because it does not authorize any physical changes to the facility or any of its safety systems, change any of the assumptions or limits used in the facility licensee's safety analyses, or introduce any new failure modes. There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite because this exemption does not affect any effluent release limits as provided in the licensee's technical specifications or by the regulations in 10 CFR Part 20, "Standards for Protection Against Radiation." There is no significant increase in individual or cumulative public or occupational radiation exposure because this exemption does not affect limits on the release of any radioactive material, or the limits provided in 10 CFR Part 20 for radiation exposure to workers or members of the public. There is no significant construction impact because this exemption does not involve any changes to a construction permit. There is no significant increase in the potential for or consequences from radiological accidents because the exemption does not alter any of the assumptions or limits in the licensee's safety analysis. In addition, the NRC staff determined that there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of the requested exemption.

Granting the requested exemption does not impact NRC findings of reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at <INSERT: site name>. In the statement of considerations for the standards to be applied when considering whether to grant exemptions ("Specific Exemptions; Clarification of Standards, Final Rule," 50 FR 50764, dated December 12, 1985), the Commission stated:

While compliance with all NRC regulations provides reasonable assurance of adequate protection of the public health and safety, the converse is not correct, that failure to comply with one regulation or another is an indication of the absence of adequate protection, at least in a situation where the Commission has reviewed the noncompliance and found that it does not pose an "undue risk" to the public health and safety. Furthermore, the Commission has never defined the concept of "defense-in-depth" to preclude the granting of an exemption from a regulation as long as the applicable exemption criteria are met. In fact, the Commission has recognized that its regulations may provide for the possibility of exemptions when an appropriately high level of safety is in fact achieved and the public interest is served.

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The NRC staff has determined that in accordance with 10 CFR 50.12, the requested exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security; and that special circumstances are present. Therefore, the NRC hereby grants the licensee's request for a one-time schedular exemption from the requirements for the offsite biennial EP exercise in 10 CFR Part 50, Appendix E, Sections IV.F.2.c.

This exemption expires on December 31, 2022 or when the offsite biennial EP exercise is performed in CY 2022, whichever occurs first.

If you have any questions, please contact the NRR project manager, <**INSERT:** name and contact information>.

Sincerely,

Craig G. Erlanger, Director
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. xx-xxxx

cc: Listserv