



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 19, 2021

Mr. Terry J. Brown  
Site Vice President  
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SUBJECT: DAVIS-BESSE NUCLEAR POWER STATION, UNIT NO. 1 – TEMPORARY  
EXEMPTION FROM CERTAIN BIENNIAL EMERGENCY PREPAREDNESS  
EXERCISE REQUIREMENTS OF 10 CFR PART 50, APPENDIX E,  
SECTION IV.F (EPID L-2021-LLE-0018 [COVID-19])

Dear Mr. Brown:

The U.S. Nuclear Regulatory Commission (NRC, the Commission) has approved a temporary exemption from specific requirements in Appendix E to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Section IV.F.2.c, for the Davis-Besse Nuclear Power Station, Unit No. 1 (DBNPS). This action is in response to the Energy Harbor Nuclear Corp. (EHNC, the licensee) letter dated March 15, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21074A367), that requested a one-time exemption for DBNPS to exclude the participation of the offsite response organizations (OROs) in the biennial emergency preparedness (EP) exercise for calendar year (CY) 2021.

EHNC holds Renewed Facility Operating License No. NPF-3, which authorizes operation of DBNPS. This license is subject to the rules, regulations, and orders of the Commission. The facility consists of a pressurized-water reactor located in Ottawa County, Ohio.

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 prevent the spread of COVID-19.<sup>1</sup>

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

In its March 15, 2021, application, the licensee provided the following information:

- The requested exemption to exclude the OROs from participation in the CY 2021 biennial EP exercise supports the continued implementation of isolation activities (e.g., social distancing, group size limitations, and self-quarantining) to protect required ORO personnel in response to the COVID-19 pandemic. These activities are needed to ensure that supporting State and local government personnel are isolated from the COVID-19 virus and remain capable of executing the emergency response functions, as described in the DBNPS emergency plan, as well as other non-nuclear health and safety functions for the benefit of the public.
- The CY 2021 biennial EP exercise with ORO participants is scheduled for May 4, 2021. The continued threat of COVID-19 spread has resulted in the inability to safely conduct the offsite biennial EP exercise. Representatives of the OROs, including the State of Ohio, Ottawa County, and Lucas County, have communicated to EHNC that they have concerns with supporting the biennial EP exercise and maintaining protection of their staff during the current COVID-19 pandemic. Based on these concerns, the needed response to the pandemic, and the uncertainty of the future in this matter, the need to seek a one-time exemption regarding the OROs participation in the CY 2021 exercise was determined to be the most appropriate response. The OROs continue to maintain readiness to respond to an actual radiological emergency at DBNPS.
- The last biennial EP exercise with ORO participation was conducted on April 16, 2019. Since that time, DBNPS has conducted numerous drills, exercises, and other training activities that have exercised its emergency response strategies, in coordination with offsite authorities, including the following:
  - DBNPS integrated drills with partial ORO participation on September 17, 2019; October 15, 2019; October 6, 2020; and February 23, 2021.
  - Federal Emergency Management Agency (FEMA) evaluated medical services (MS-1) on October 22, 2019, with the Jerusalem Township Fire Department and St. Charles Hospital, and November 17, 2020, with Carroll Township and Promedica Hospital.
- EHNC expects to continue to conduct drills, exercises, and other training activities that exercise the emergency response strategies. State and local authorities are expected to participate to the extent practical while also complying with the CDC recommendations limit the spread of COVID-19.
- EHNC has made a reasonable effort to reschedule the exercise during CY 2021 but was unsuccessful. EHNC has determined that it is not feasible to schedule the exercise in 2021 due to uncertainty of COVID-19 isolation actions. Further complicating the matter is that Emergency Operations Centers (EOCs) in Ottawa and Lucas counties are being used during this current PHE for distribution of personal protective equipment to frontline workers in hospitals, fire and emergency medical services, law enforcement, and healthcare agencies. Additionally, the Lucas County EOC has been activated since March 13, 2020, and is currently serving as the physical workspace for individuals supporting COVID-19 response, with many additional individuals supporting the EOC

virtually. Many of the agencies and partners that are directly engaged in the COVID-19 response, are the same that support the Lucas County EOC during radiological exercises.

- The OROs have indicated agreement with this exemption request. The OROs have also indicated they will maintain their current radiological emergency plans and remain able to respond to an emergency during the pandemic. The exemption from participation in the exercise does not obviate the ability to respond should an actual nuclear power plant radiological emergency occur.
- The next biennial exercise is expected to occur in May 2023 (continuing with the original schedule and remaining in odd years) and be coordinated with the applicable OROs, the applicable NRC region, and the applicable FEMA region. Therefore, the next performance of the exercise would be no later than the end of CY 2023.

Enclosure B to the application provides a letter from the Ohio Department of Public Safety supporting the licensee's exemption request. This letter states, in part, that the State of Ohio, Ottawa County, and Lucas County "are fully prepared to continue to participate virtually in all available integrated drills as these afford us the opportunity to continue to practice our dose assessment skills, executive coordination and leadership, and communication within the virtual platform. The State of Ohio, Ottawa and Lucas County remain prepared to respond to actual events at our nuclear power plants." Enclosures C and D to the application provides letters from Ottawa and Lucas Counties, respectively, which affirm that these counties are prepared to respond to events and emergencies at the DBNPS and support the licensee's exemption request.

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.c, require, in part, offsite emergency plans to be exercised biennially with full participation by each ORO having a role under the radiological response plan. No new accident precursors are created by allowing the licensee to conduct the biennial EP exercise at DBNPS in CY 2021 without the participation of the OROs. Thus, the probability and consequences of postulated accidents are not increased. In addition, the requested one-time exemption from a biennial EP exercise requirement 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.

The application states that the special circumstances in 10 CFR 50.12(a)(2)(iv) and (v) are present. In accordance with 10 CFR 50.12(a)(2)(iv), special circumstances are present whenever "[t]he exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption." The

licensee stated: “Offsite organizations are currently dealing with COVID-19 in their daily duties. Participation in the biennial exercise presents a potential health risk for those concerned, who may become exposed to COVID-19. Through this exposure, they could become unable to perform their duties during a real-life emergency.” In addition, Ottawa and Lucas Counties have indicated that participation in the exercise may interfere with their ongoing response to the COVID-19 PHE.

The NRC staff recognizes that the biennial EP exercise presents concerns regarding potential health risks due to the COVID-19 PHE for the OROs. This may result in ORO personnel being exposed to the virus, which could negatively impact the OROs’ ability to respond to a real-life emergency. In addition, the NRC staff recognizes that, for some OROs, participation in the exercise may interfere with their ongoing response to the COVID-19 PHE. Therefore, granting the requested exemption from the 10 CFR Part 50, Appendix E, Section IV.F.2.c, requirement for offsite participation in the CY 2021 biennial EP exercise for DBNPS would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the granting of the exemption. Therefore, the NRC staff finds that the special circumstances of 10 CFR 50.12(a)(2)(iv) are present.

In accordance with 10 CFR 50.12(a)(2)(v), special circumstances are present whenever “[t]he 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 application indicates that the State of Ohio, Ottawa County, and Lucas County have informed EHNC that they have concerns with supporting the CY 2021 biennial EP exercise and maintaining protection of their staff during the current COVID-19 pandemic. In addition, Ottawa and Lucas Counties have indicated that participation in the exercise may interfere with their ongoing response to the COVID-19 PHE. The licensee states that it has made a reasonable effort to reschedule the exercise but has been unsuccessful. The licensee also determined that it is not feasible to schedule the exercise in CY 2021 due to uncertainty of COVID-19 isolation actions. The requested exemption would only apply to the CY 2021 biennial EP exercise at DBNPS, so the next performance of the exercise with full ORO participation would be no later than the end of CY 2023. Based on this information, the NRC staff determined that granting the exemption would only provide temporary relief from the applicable regulation and that the licensee has made good faith efforts to comply with the regulation. Therefore, the NRC staff finds that the special circumstances of 10 CFR 50.12(a)(2)(v) are present.

In addition, under 10 CFR 50.12(a)(2)(ii), special circumstances are present whenever “[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 regulations in 10 CFR Part 50, Appendix E, Section IV.F.2.c, require 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 2021, 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.<sup>2</sup> 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 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.<sup>3</sup> FEMA has 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 safety of the public in a radiological emergency during the COVID-19 PHE.<sup>4</sup> 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,<sup>5</sup> FEMA has alternative means of conducting these assessments.

Based on the above, granting EHNC's request for exemption from the 10 CFR Part 50, Appendix E, Section IV.F.2.c, requirement for offsite biennial exercises in CY 2021, with the next performance of the exercise to be no later than the end of CY 2023, would allow State, county, 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 2021 or CY 2022. 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, county, and local OROs 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 next offsite biennial EP exercise to occur in CY 2023, and the special circumstances of 10 CFR 50.12(a)(2)(v) are present.

The 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

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<sup>2</sup> COVID-19 Resources for State Leaders, *Executive Orders – By State*, accessed August 12, 2020, <https://web.csg.org/covid19/executive-orders/>

<sup>3</sup> "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.

<sup>4</sup> FEMA Preparedness Assessments, ADAMS Accession Nos. ML20164A275, ML20174A603, ML20141L795, ML20170B043, ML20170B171, ML20167A175, ML20164A038, ML20154K696, ML20154K617, ML20150A110, and ML20162A056.

<sup>5</sup> 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](https://www.fema.gov/media-library-data/1577108409695-4e49a0a56c8c62695dcc301272a1eda7/FEMA_REP_Program_Manual_Dec_2019.pdf)

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 DBNPS. 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 to exempt DBNPS from the requirements for full ORO participation in its offsite biennial EP exercise required during CY 2021 under 10 CFR Part 50, Appendix E, Section IV.F.2.c. This exemption expires on December 31, 2023, or when the offsite biennial EP exercise is performed in CY 2023, whichever occurs first.

T. Brown

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If you have any questions, please contact the DBNPS project manager, Blake A. Purnell, at 301-415-1380 or via e-mail at [Blake.Purnell@nrc.gov](mailto:Blake.Purnell@nrc.gov).

Sincerely

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

Docket No. 50-346

cc: Listserv

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EXEMPTION FROM CERTAIN BIENNIAL EMERGENCY PREPAREDNESS  
EXERCISE REQUIREMENTS OF 10 CFR PART 50, APPENDIX E,  
SECTION IV.F (EPID L-2021-LLE-0018 [COVID-19]) DATED APRIL 19, 2021

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