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

July 24, 2020

Mr. Don Moul
Executive Vice President, Nuclear
Division and Chief Nuclear Officer
Florida Power & Light Company
Mail Stop: NT3/JW
15430 Endeavor Drive
Jupiter, FL 33478

SUBJECT: DUANE ARNOLD ENERGY CENTER – APPROVAL OF EXEMPTION FROM CERTAIN REQUIREMENTS OF 10 CFR PART 26, "FITNESS FOR DUTY PROGRAMS" (EPID L-2020-LLE-0079 [COVID-19])

Dear Mr. Moul:

The U.S. Nuclear Regulatory Commission (NRC, the Commission) approves the below temporary exemption from certain requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs," for the Duane Arnold Energy Center (DAEC). This action is in response to the application submitted by NextEra Energy Duane Arnold, LLC (NEDA, the licensee) dated May 21, 2020 (non-publicly available, withheld under 10 CFR 2.390), as superseded and replaced by letter dated June 15, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML20142A192 and ML20167A262, respectively), that requested a temporary exemption for DAEC from 10 CFR 26.119(a), 26.165(b)(5), 26.169(a), 26.185(d)(3), 26.185(p), and 26.189(c). In the application, the licensee described the controls that it would implement at DAEC to maintain the effectiveness of its fitness for duty (FFD) program during the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE).

On January 31, 2020, the U.S. Department of Health and Human Services (HHS) declared a COVID-19 PHE for the United States. Subsequently, the Centers for Disease Control and Prevention issued recommendations (e.g., social distancing, limiting assemblies, etc.) to limit the spread of COVID-19. On April 21, 2020, HHS renewed the COVID-19 PHE effective April 26, 2020.

In the June 15, 2020, application, the licensee stated the following for each requirement from which it is requesting exemption:

- NEDA will develop an exemption policy that delineates when and how NEDA would invoke exemption from the requirements and who has the authority to approve the invocation.

- NEDA will continue to adhere to current requirements until such time as those requirements cannot be met.

- NEDA will place the actual exemption, if exercised, into its corrective action program for tracking and track specific cases within the FFD program.

- NEDA will resume compliance with the current requirements as soon as practicable.

- This exemption will remain in effect until no later than 90 days after the COVID-19 PHE has ended or December 31, 2020, whichever occurs first.

Exemption from Certain 10 CFR Part 26 Requirements and NRC Safety Assessment

10 CFR 26.119, "Determining 'shy' bladder"

The requirements in 10 CFR 26.119(a) state:

> When a donor has not provided a specimen of at least 30 mL [milliliter] within the 3 hours permitted for urine collection, FFD program personnel shall direct the donor to obtain, within 5 business days, an evaluation from a licensed physician who is acceptable to the MRO [Medical Review Officer] and has expertise in the medical issues raised by the donor's failure to provide a sufficient specimen. The MRO may perform this evaluation if the MRO has the appropriate expertise.

The purpose of a timely evaluation of the donor by a licensed physician is to determine if the donor has a medical condition that precluded the provision of a sufficient amount of urine. If a medical condition is identified, the MRO could request the collection of an alternative specimen, such as oral fluid or blood, to complete the drug testing. If no medical condition is identified, the donor would be determined to have subverted the testing process by refusing to provide a urine specimen for testing. The timely completion of the evaluation is critical in instances when the donor is in work status.

For 10 CFR 26.119(a), the licensee requested that the 5 business days requirement to obtain a medical evaluation be extended an additional 10 calendar days due to the COVID-19 PHE. NEDA stated:

- If licensed physicians are unavailable due to [medical] practices being shut down or seeing patients on a limited basis, five (5) business days will not be enough time to meet this requirement.

- Individuals are able to utilize personal physicians as the NEDA MRO does not perform these evaluations. Results are reviewed by the MRO and[,] as needed, discussed with the individuals' physician for the final FFD decision.

The NRC finds NEDA's basis for exemption from this requirement to be reasonable. Medical professionals may be unavailable or have limited staffing as a result of the COVID-19 PHE, thereby preventing an individual from meeting with a medical doctor in the required timeframe to obtain a medical evaluation. Under the current requirements, if an individual is unable to obtain a medical evaluation within 5 business days, the licensee would make a subversion attempt determination for a refusal to provide a specimen for testing and the individual would be permanently denied authorization under 10 CFR 26.75, "Sanctions." Affording the individual additional time to complete the medical evaluation could prevent such a punitive outcome that could be due solely to circumstances beyond the individual's control. Further, if an individual in

a work status is unable to provide a specimen, 10 CFR 26.77(b)(3) requires the licensee or other entity to withdraw authorization until the "questionable condition" is resolved. The additional 10 calendar days bounds the time in which the licensee must administratively disposition this testing event.

10 CFR 26.165, "Testing split specimens and retesting single specimens"

The requirements in 10 CFR 26.165(b)(5) state:

> As soon as reasonably practical and not more than 1 business day following the day of the donor's request, as permitted in paragraph (b)(3) or (b)(4) of this section, the MRO shall ensure that the HHS-certified laboratory forwards an aliquot of a single specimen, or that the HHS-certified laboratory (or licensee testing facility, as appropriate) forwards Bottle B of a split specimen, to a second HHS-certified laboratory that did not test the specimen in Bottle A.

The purpose of the 1 business day shipping requirement is to ensure that the first laboratory sends the donor's specimen to the second laboratory in a timely manner so that retesting can be conducted to verify the accuracy of the initial laboratory's confirmatory positive, adulterated, or substituted test result. The timely shipment of the specimen to a second HHS-certified laboratory ensures that an inaccurate test result can be identified and any adverse consequence to the donor can be remedied under 10 CFR 26.185(n)(3) or (n)(4). A donor can only request specimen retesting if the MRO determines that a FFD drug testing violation has occurred, which would result in the donor's authorization being terminated or denied under 10 CFR 26.75.

For 10 CFR 26.165(b)(5), the licensee requested that the 1 business day requirement be extended to 3 business days due to the COVID-19 PHE. NEDA stated:

- If a laboratory's business operations are affected by COVID-19 and staffing is limited, one (1) business day may not be enough [time] for the lab to have the appropriate personnel go to the lab and forward Bottle B to the lab of the donor's choice.

The NRC finds NEDA's basis for exemption from this requirement to be reasonable because the COVID-19 PHE could affect the staff levels at an HHS-certified laboratory, which could limit the ability to ship the specimen to the second laboratory in a timely manner. Additionally, the MRO may be unable to make his or her notification to the HHS-certified laboratory, which could limit the ability to ship the specimen to the second laboratory in a timely manner. The requested 3 business days limit continues to protect the donor by minimizing the delay in shipping the specimen for confirmatory drug testing by a second HHS-certified laboratory.

10 CFR 26.169, "Reporting Results"

The requirements in 10 CFR 26.169(a) state:

> The HHS-certified laboratory shall report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen from the licensee or other entity. Before reporting any test result to the MRO, the laboratory's certifying scientist shall certify the result as correct. The report must identify the substances for which testing was performed; the results of the validity

and drug tests; the cutoff levels for each; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory.

The purpose of the 5 business days result reporting requirement is to ensure the timely completion of testing, which is especially important in instances when an individual is in work status and tests positive for a drug or is identified as having potentially subverted the testing process (i.e., adulterated, substituted, or invalid test result). Upon receipt of the test result, the MRO would review the result and contact the donor. A delay in receipt of a test result for an individual without access to the structures, systems, and components of a commercial nuclear power reactor facility poses no risk to regulated activities. However, such a delay would prevent the licensee or other entity from granting FFD authorization under 10 CFR 26.65 because the licensee must be in receipt of negative pre-access drug and alcohol test result under 10 CFR 26.65 in order to grant FFD authorization under Part 26. These Part 26 authorization requirements are distinct from those under 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants." A licensee needs to satisfy both the Part 26 and 73 authorization requirements before an individual may have unescorted access to the protected area. As stated in the Statement of Considerations for the Part 26 Final Rule (73 FR 16971; March 31, 2008), the requirements in "Part 26 and the access authorization requirements [in 10 CFR 73.56(h)(4)] each contain provisions that require establishing the trustworthiness and reliability of personnel before granting unescorted access to the protected areas of nuclear power plants."

For 10 CFR 26.169(a), the licensee requested that the laboratory be allowed to "test as soon as reasonably practical," instead of the 5 business days requirement, due to the COVID-19 PHE. NEDA stated:

- HHS certified laboratories are already required to have contingency plans available[;] this request is for circumstances beyond our control.

- If a laboratory's business operations are affected by COVID-19 and staffing is limited, five (5) business days may not [provide enough time] for the lab to have the appropriate personnel go to the lab for completing the testing process and comply with this requirement.

- In the event the test is for a For-Cause or Follow-Up testing, the individual's site access badge will be placed on hold.

The NRC finds NEDA's basis for exemption from this requirement to be reasonable because the COVID-19 PHE could adversely affect the licensee's HHS-certified laboratory such that laboratory staff is unable to perform testing or the facility is closed, which would prevent the processing of specimens within 5 business days. Also, if the laboratory needs to implement its contingency plan (which is required by HHS's National Laboratory Certification Program) and transfers specimens to a second HHS-certified laboratory to complete testing, the licensee would have no control over when the specimens would be shipped and tested at the second laboratory. However, the importance of the 5 business days requirement necessitates conditioning this exemption on a maximum time limit instead of the NEDA-proposed "as soon as reasonably practicable" limit. The NRC established a maximum time limit of 12 business days to report test results, which would accommodate the shipping (2 days) and testing (5 days) of specimens at the second HHS-certified laboratory. The licensee mitigates the potential risk

associated with testing delays for potential impairment or credible use of illegal drugs (i.e., for-cause testing) and for verification of an individual's continued abstinence from substance abuse (i.e., follow-up testing) by administratively withdrawing the individual's authorization until a verified test result is received from the MRO. In addition, an individual applying for authorization (i.e., pre-access testing) could not be granted authorization until negative test results were received and reviewed by the MRO.

10 CFR 26.185, "Determining a fitness-for-duty policy violation"

The requirements in 10 CFR 26.185(d)(3) state:

> (d) *Donor unavailability*. The MRO may determine that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in the following three circumstances:
>
> …
>
> (3) The MRO, after making all reasonable efforts and documenting the dates and time of those efforts, has been unable to contact the donor. Reasonable efforts include, at a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the donor at the day and evening telephone numbers listed on the custody-and-control form.

The purpose of a timely MRO discussion with the donor is to afford the donor the opportunity to provide a legitimate medical explanation (e.g., prescription medication use) for a test result, which otherwise would be determined to be an FFD drug testing policy violation. The timely discussion with the donor is especially important if an individual is in a work status.

For 10 CFR 26.185(d)(3), the licensee requested that the 24-hour requirement be extended to 72 hours due to the COVID-19 PHE. NEDA stated:

- If it is a pre-access test[,] for example, the MRO may have difficulty in reaching the donor if the donor is sequestered where they are unreachable.

- The two (2) additional days will allow for greater flexibility in reaching the donor in an effort to ensure all avenues have been exhausted in reaching the donor.

- If the test results are for an individual currently badged (e.g., random test, etc.) … NEDA will continue to adhere to the current requirements for maintaining Unescorted Access Authorization/Unescorted Access (UAA/UA).

The NRC finds NEDA's basis for exemption from this requirement to be reasonable because the COVID-19 PHE could adversely impact the MRO's ability to contact a donor within the required 24-hour period. Affording the MRO two additional days to attempt to contact a donor in a non-work status to discuss a test result may prevent the licensee from issuing an unnecessary FFD policy violation to the individual, which would prevent unnecessary burden on the individual and the licensee if the individual is able to provide a legitimate medical explanation for the test result.

The requirements in 10 CFR 26.185(p) state:

> *Time to complete MRO review*. The MRO shall complete his or her review of positive, adulterated, substituted, and invalid test results and, in instances when the MRO determines that there is no legitimate medical explanation for the test result(s), notify the licensee's or other entity's designated representative within 10 business days of an initial positive, adulterated, substituted, or invalid test result. The MRO shall notify the licensee or other entity of the results of his or her review in writing and in a manner designed to ensure the confidentiality of the information.

The purpose of the timely review of a laboratory test result by the MRO and notification to the licensee's or other entity's designated representative of the test result determination is especially important if an individual is in a work status and tests positive for a drug or is identified as having potentially subverted the testing process (i.e., adulterated, substituted, or invalid test result). Completing a timely review of a potential FFD drug testing policy violation is critical to ensuring that an individual identified as using an impairing substance or subverting the testing process is denied authorization and removed from the protected area of the commercial power reactor. A delay in the MRO review of the test results for an individual without access authorization poses no risk to regulated activities but would prevent the licensee or other entity from making an access authorization determination.

For 10 CFR 26.185(p), the licensee requested that the 10 business days requirement be extended to 15 business days due to the COVID-19 PHE. NEDA stated:

- If the MRO was unable to reach the donor in accordance with 10 CFR 26.185(d)(3) as seen above (requesting new total of three (3) days), this will have a direct impact upon this requirement.

- NEDA will continue to adhere to current requirements, especially for those maintaining UAA/UA and for those covered by the FFD program.

The NRC finds NEDA's basis for exemption from this requirement to be reasonable because the COVID-19 PHE may prevent the MRO from completing the review of a donor's test results within 10 business days. The additional 5 business days does not present an increase in risk to public health and safety or the common defense and security because the exemption is limited to the test result reviews for individuals not performing any job functions covered under 10 CFR Part 26. The NRC also understands that NEDA will continue to adhere to the 10 business days requirement for individuals maintaining UAA/UA, meaning that NEDA will not apply the exemption to these individuals.

<u>10 CFR 26.189, "Determination of fitness"</u>

The requirements in 10 CFR 26.189(c) state:

> A determination of fitness that is conducted for-cause (i.e., because of observed behavior or a physical condition) must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used.

The purpose of a face-to-face determination of fitness conducted for-cause is to ensure that the qualified professional can evaluate the specific fitness issue(s) presented by the individual. The individual's physiological (e.g., balance, body temperature, skin color, odor) and/or psychological issue(s) may not be detectable if the determination is conducted remotely by video or telephone. A for-cause determination of fitness is only performed when an individual's behavior or physical condition indicates possible impairment from substance abuse or the licensee or other entity received credible information that an individual is engaging in substance abuse, as defined in 10 CFR 26.5, "Definitions."

For 10 CFR 26.189(c), the licensee requested the use of an electronic means in lieu of performing a face-to-face fitness determination. The requirement for a face-to-face evaluation may be overly restrictive due to the COVID-19 PHE because licensed professionals may be unavailable due to medical practices being shut down, may refuse in-person visits, or may be seeing individuals on a limited basis. NEDA stated:

- FFD staff trained in Behavior Observation will relay the individual's condition to the licensed professional conducting the evaluation for a first-hand observation. This will ensure the licensed professional has all the available information in making the evaluation decision.

The NRC finds NEDA's basis for exemption from this requirement to be reasonable because the COVID-19 PHE could prevent the licensed professional who would perform the determination of fitness from conducting a face-to-face evaluation with the individual. A face-to-face determination of fitness is important due to the necessity to evaluate possible impairment from substance abuse and the performance of appropriate drug and/or alcohol testing, if warranted, as required under 10 CFR 26.77(b) ("If an individual appears to be impaired or the individual's fitness is questionable…, the licensee or other entity shall take immediate action to prevent the individual from performing the duties that require him or her to be subject to [management actions and sanctions]"). The proposed NEDA approach is consistent with a technical study performed by the Pacific Northwest National Laboratory for the NRC.[1] The study stated that "it is generally agreed that the in-person, face-to-face presence of a practitioner is necessary in certain medical situations and that exclusive telemedicine is not a good fit for all medical interactions. … In a for-cause determination that is based on a physical condition or observed behavior, accurate perception and assessment of nonverbal cues (e.g., those provided by body or breath odor, posture, and muscle tone) may be important to the expert practitioner's ability to make an accurate diagnosis (Zeng and Lin 2012). … With regard to for-cause determinations of fitness, where there is a significant degree of urgency, it is possible that a qualified expert will not be available within a reasonable commuting distance or in time to observe a behavior or physical condition, which may be transitory. In such circumstances, it may be beneficial to allow an appropriate expert practitioner to conduct the for-cause DOF [determination of fitness] using electronic communications as a consultant to a local 'host' practitioner who is physically present with the patient." This "host practitioner" is analogous to the NEDA statement that "FFD staff trained in Behavior Observation will relay the individual's condition to the licensed professional conducting the evaluation for a first-hand observation."

[1] "The Use of Electronic Communications to Perform Determinations of Fitness" (PNNL-26695), KM Branch and EP Kennedy, Pacific Northwest National Laboratory, Department of Energy, August 2017; ADAMS Accession No. ML18081A607.

Conditions

The temporary exemption from the above requirements is governed by the licensee controls stated above and the following conditions:

1. NEDA stated that it will develop an exemption policy that delineates when and how exemptions would be invoked and who has the authority to approve the invocation of the exemptions. This control is conditioned on NEDA: applying the exemption to all individuals subject to the FFD program, except that the exemptions from 10 CFR 26.185(d)(3) and (p) will not apply in the cases of individuals currently badged and maintaining UAA/UA; providing summary documentation of these management actions in its annual FFD performance report (10 CFR 26.717(b)(8)); and issuing interim licensee guidance that describes:

    a) The process, limitations, roles, and responsibilities of the "FFD staff trained in Behavioral Observation" that would assist the licensed practitioner conducting the 10 CFR 26.189(c) for-cause determination of fitness assessment electronically. Additionally, the NRC finds that NEDA's use of "FFD staff" means the staff designated under 10 CFR 26.4(g) as FFD program personnel. The FFD program personnel designation is needed given the possible disclosure of medical information by the donor during the discussion with the licensed clinician (10 CFR 26.37, "Protection of information").

2. NEDA stated that it will place the actual exemption, if exercised, into its corrective action program for tracking and track specific cases within the FFD program. This control is conditioned on NEDA also documenting how or why the COVID-19 PHE required the implementation of the exemption and the date and time that the exemption was executed and exited for each specific occurrence.

3. NEDA stated that its control for the exemption from 10 CFR 26.169(a) would accomplish specimen testing "as soon as reasonably practical," instead of the 5 business days requirement. Approval of an exemption from 10 CFR 26.169(a) is conditioned upon replacement of "as soon as reasonably practicable" with completion of specimen testing within 12 business days after the first laboratory received the specimen from the licensee or other entity.

Approval of the Exemption

Pursuant to 10 CFR 26.9, "Specific exemptions," upon application of any interested person or on its own initiative, the Commission may grant such exemptions from the requirements of 10 CFR Part 26 as it determines are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest.

The NRC staff has reviewed the requested exemption and determined that it 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 NRC staff has reviewed the requested exemption and determined that it will not endanger life or property or the common defense and security. Consistent with the underlying purpose of the requirements in 10 CFR 26.119(a), 26.165(b)(5), 26.169(a), 26.185(d)(3), 26.185(p), and

26.189(c), the temporary exemption from these requirements will support the continued effectiveness of the FFD program during the COVID-19 PHE. For sections 26.119(a), 26.165(b)(5), 26.169(a), 26.185(d)(3), and 26.185(p), flexibility is afforded by permitting a reasonable increase in the time to complete a required activity. For section 26.189(c), flexibility is afforded by permitting the use of an alternative method to conduct a determination of fitness for-cause. The limited scope of the exemption from these requirements, relatively short duration of the exemption period, and NEDA controls and NRC conditions provide reasonable assurance that the licensee will continue to meet the FFD performance objectives described in 10 CFR 26.23, "Performance objectives." Therefore, the NRC staff finds that the requested exemption will not endanger life or property or the common defense and security.

The NRC staff has reviewed the requested exemption and determined that it is in the public interest. An FFD program under 10 CFR Part 26 provides reasonable assurance that individuals subject to the program are not under the influence of any substance or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties. The FFD program requirements from which the licensee requests exemption are process and administrative requirements that directly contribute to the effectiveness of the licensee's FFD program. The requested exemption is necessary, however, because a PHE was not considered during the 10 CFR Part 26 rulemakings in 1989 (54 FR 24468; June 7, 1989) and 2008 (73 FR 16966; March 31, 2008). Maintenance of a workforce during the COVID-19 PHE to safely and competently operate a commercial nuclear power reactor that generates electricity to supply the Nation's electrical infrastructure serves the public interest. Temporary exemption from specific FFD program process and administrative requirements, with the associated licensee controls and NRC conditions, will enable the licensee to maintain its workforce and continue to provide reasonable assurance that individuals can safely and competently perform assigned duties and responsibilities while also accounting for the COVID-19 PHE. Therefore, the NRC staff finds that the requested exemption is in the public interest.

Environmental Considerations

NRC approval of this exemption request is categorically excluded under 10 CFR 51.22(c)(25) and there are no special circumstances present that would preclude reliance on this exclusion. The NRC staff determined, per 10 CFR 51.22(c)(25)(vi)(I), that the requirements from which the exemption is sought are of an administrative nature. 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 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 the 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 the 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 the 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 this exemption request.

Conclusions

The NRC has determined that pursuant to 10 CFR 26.9, the requested exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the NRC hereby grants the licensee's request to exempt DAEC from the requirements in 10 CFR 26.119(a), 26.165(b)(5), 26.169(a), 26.185(d)(3), 26.185(p), and 26.189(c), as controlled and conditioned as discussed above. The exemption is effective upon issuance until 90 days after the COVID-19 PHE is ended or until December 31, 2020, whichever occurs first.

If you have any questions, please contact the plant project manager, Scott P. Wall, at 301-415-2855 or Scott.Wall@nrc.gov.

Sincerely,

Craig G. Erlanger

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Date: 2020.07.24 10:43:26 -04'00'

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

Docket No. 50-331

cc: Listserv

SUBJECT: DUANE ARNOLD ENERGY CENTER – APPROVAL OF EXEMPTION FROM CERTAIN REQUIREMENTS OF 10 CFR PART 26, "FITNESS FOR DUTY PROGRAMS" (EPID L-2020-LLE-0079 [COVID-19]) DATED JULY 24, 2020

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