DISCUSSIONS DURING TELECONFERENCE

LICENSEE-PROPOSED EXEMPTION TO TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* PART 26, "FITNESS-FOR-DUTY PROGRAMS"

SUMMARY

The licensee expects that its safety analysis supporting the request for exemption will justify the use of oral fluid as a biological test matrix. Part of the licensee's justification will be that oral fluid provides reasonable assurance that the drug testing program required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness-for-Duty Programs," will remain or be more effective when compared to the use of urine as a biological test matrix. This assurance may be based on the licensee's continuing ability to meet the section 26.23, "Performance objectives," described in this appendix. The licensee also stated that the use of oral fluid as the biological test matrix could enhance some elements of drug testing, such as prevention of subversion attempts.

The U.S. Nuclear Regulatory Commission's (NRC) staff noted that enhancements to 10 CFR Part 26 implementation can also improve the assurance that individuals subject to 10 CFR Part 26 are trustworthy and reliable. This occurs because oral fluid testing is better at preventing subversion attempts and identifying contemporaneous substance use and abuse which is more of an indicator of impairment. This enhanced effectiveness not only contributes to the section 26.23, performance objectives, but to the high assurance program objective of the section 73.56, "Personnel access authorization requirements for nuclear power plants," under 10 CFR Part 73, "Physical Protection of Plants and Materials."

The scope of this licensee-proposed exemption request would be a first-ever submission to the NRC. The following information was discussed during the teleconference. Documentation of this discussion is for knowledge management and demonstrates NRC staff commitment to, and execution of the regulatory strategies presented in the NRC's 2018-2022 Strategic Plan.

NRC'S STRATEGIC PLAN

As stated in the Strategic Plan, public engagement, openness, and clarity are important aspects of effective and good regulation. The NRC staff processing of this licensee-proposed request will be consistent with the NRC's Safety and Security Strategy 1 to enhance the NRC's regulatory programs using information gained from domestic operating experience and advances in science and technology; Safety Strategy 2 to risk-inform the current regulatory framework in response to advances in science and technology to focus on the most safety significant issues by ensuring, in part, that the regulations are up-to-date and contribute to defense-in-depth; and Safety Strategy 3 to enhance the efficiency of licensing activities to maintain both quality and timeliness by improving transparency, reducing unnecessary regulatory burden, and engaging in pre-application activities to provide timely feedback and information. Security Strategy 4 is also applicable because this strategy directs the NRC staff to proactively identify, assess, and address, in part, vulnerabilities and security risks – the occurrence of subversion attempts within the commercial nuclear industry is indicative of an identified possible vulnerability associated with the effectiveness of the 10 CFR part 26 drug testing program. The security strategy also facilitates, in part, the evaluation of operational experience and internal hazards, such as an insider mitigation program (paragraph 73.55(b)(9)).

TELECONFERENCE ATTENDEES

The below-listed individuals and their affiliations participated in the teleconference:

Paul Harris, NRC	Nick DePietro, First Energy
Brian Zaleski, NRC	Johnny Rogers, Dominion
Silas Kennedy, NRC	Maude Hall, South Texas Project
Nick Duffy, Exelon	Roger Aguilera, South Texas Project
Aaron Enloe, Ameren	Dolly Adams, Exelon
Mike Hagland, Ameren	Bob Kelm, Nuclear Energy Institute
Bill Graven, Ameren	Richard Mogavero, Nuclear Energy Institute
Hannah Gingrich, Exelon	

DISCLAIMER

The information in this memo is provided as a public service and solely for informational purposes and is not, nor should be deemed as, an official NRC position, opinion or guidance, or "a written interpretation by the General Counsel" under 10 CFR 26.7, on any matter to which the information may relate. The opinions, representations, positions, interpretations, guidance or recommendations which may be expressed by the NRC technical staff in this memo are those of solely the NRC technical staff and do not necessarily represent the same for the NRC. Accordingly, the fact that the information was obtained through the NRC technical staff will not have a precedential effect in any legal or regulatory proceeding.

DISCUSSION ITEMS

A. Process

1. Exemption Requirements. There are two exemption requirements applicable to this licensee submission: section 26.9, "Specific exemptions," and section 50.12, "Specific exemptions." As a matter of routine, the NRC staff will work with the NRC's Office of the General Counsel (OGC) and the Office of Nuclear Reactor Regulation (NRR) to ascertain the regulatory process and inform the licensee. This information is important to inform the licensee-planned schedule.

   Item 1: Signature Authority

   The NRR director has signature authority for a section 50.12, "Specific exemptions." If the director does not have signature authority for a section 26.9-based exemption, then the licensee's submission would require Commission approval.

   Item 2: Section 50.12, "Specific Exemptions"

   The NRR director will not consider granting an exemption under section 50.12 unless, in part, the 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 a special circumstance is present. Special circumstances are listed in paragraph 50.12(a)(2).

Item 3: Part 51, “Environmental Protection Regulations for Domestic Licensing and related Regulatory Functions”

The NRC staff may need to prepare an environmental assessment (EA) for the licensee-proposed exemption. Section 51.21, “Criteria for and identification of licensing and regulatory actions requiring environmental assessments,” requires that an EA be written for certain licensing and rulemaking activities, including exemptions. paragraph 51.35(b) requires that the EA be published in the *Federal Register* prior to issuing the exemption. The EA will be prepared unless section 51.20 requires a full Environmental Impact Statement, or the activity is identified in paragraph 51.22(c) as a categorical exclusion.

2. Points of Contact.

   Lee (John) Klos, licensing project manager for the Callaway site, will have licensing project management lead. NRR will be the licensing authority for this licensee-proposed action.

   Paul Harris, senior program manager for fitness-for-duty (FFD) programs, drug and alcohol, will have the technical lead, write the safety evaluation, and provide project management support.

3. Written Communications. The section 50.4 and section 26.11, written communication requirements are applicable to this licensee submission. The licensee may consider copying the submission to the NRC’s Office of Nuclear Security and Incident Response (NSIR), Division of Physical and Cyber Security Policy, Fuel Cycle and Transportation Security Branch, to effectuate a time receipt review.

4. Proprietary information. The licensee exemption request should be marked for an NRC staff review pursuant to section 2.390, “Public inspections, exemptions, requests for withholding.”

5. Internal Procedures. The NRR and NSIR staffs will follow NRR Office Instructions: LIC-101, “License Amendment Review Process”; LIC-102,” Relief Request Reviews”; LIC-103, “Exemptions from NRC Regulation”; LIC-109, “Acceptance Review Procedures”; LIC-203, “Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues”; as informed by legal counsel. Office Instructions LIC-101, LIC-102 and LIC-109 are available for review in the NRC’s Agencywide Documents Access and Management System (ADAMS) at accession nos. ML16061A451, ML091380595, and ML16144A521, respectively. Office Instruction LIC-103 is not available for public review.

6. Fee Billable. The NRC staff review, requests for information, approval, concurrence, and any other NRC staff work activities directly associated with the processing of this licensee request will be fee billable in accordance with 10 CFR Part 171, section 170.21, “Schedule of Fees,” full cost reimbursement, based on professional staff time of $263 per hour, as amended and detailed in section 170.20, “Average cost per professional staff-hour.” Cost planning currently includes the following individuals and positions:

Lee (John) Klos, licensing project manager, Callaway site
Lisa Regner, back-up licensing project manager, Callaway site
Paula Blechman, licensing assistant
Paul Harris, FFD program lead
Brian Zaleski, FFD program specialist
NSIR and NRR managers
OGC

7. Contracted Support. Contract support for this activity is not planned or expected.

8. *Federal Register* Publication. If the licensee-proposed exemption is approved by the NRC, this regulatory action will be posted in the *Federal Register* by the NRC's Office of the Chief Information Officer, Rules and Directives Branch.

9. NRC Review and Approval Schedule. The NRC staff schedule considerations will be highly dependent on the adequacy of the licensee submission, competing NRC staff priorities, and implementation of the exemption review process. The following is provided for guidance only and it presents a very aggressive schedule to contribute to the licensee's desire to implement the proposed exemption prior to their February 2019, refueling/maintenance outage.

1 - 3 days	NRC receipt and docketing of the licensee-proposed exemption.
2 weeks	Completion of the acceptance review.
30 days	NRC technical staff receipt and technical review. This schedule assumes that the licensee's initial submission passes the NRC staff receipt inspection to commence a regulatory review.
45 days	Development of an NRC request for additional information, receipt of a licensee response, and NRC staff re-assessment.
90 days	*Federal Register* posting of the EA, paragraph 51.35(b).
15 days	NRC OGC legal review.
30 days	Resolution of legal comments, revision and formatting of the Safety Evaluation Report, letter to the licensee, and publication of the NRC's determination in the *Federal Register.*

10. Public Meetings. Within the preliminary planning schedule described above, the NRC staff may consider the conduct of one or more public meetings (face-to-face, teleconference, or Go-to-Meeting®) to solicit public input. Public input on an exemption request is not a requirement, but is it a hallmark of a good regulator, and public input will inform NRC staff determinations and considerations.

11. NRC Inspector Training. The licensee's proposed exemption request may require the NRC to train or inform its inspectors for the new drug testing methodology to be implemented at the Callaway site. The NRC may also need to revise its inspection procedure.

B. NRC Acceptance Criteria and Sufficiency Items

The NRC staff presented the following acceptance criteria and sufficiency items to the licensee regarding their proposed exemption:

1. Will the licensee's proposal, if approved, provide reasonable assurance that the licensee's FFD program will continue to meet the paragraphs 26.23(a)-(d) performance objectives?
2. Will the exemption be authorized by law, paragraph 50.12(a)(1)?
3. Will the exemption not present an undue risk to the public health and safety, paragraph 50.12(a)(1)?
4. Will the exemption be consistent with the common defense and security, paragraph 50.12(a)(1)?
5. Are special circumstances associated with the exemption present, paragraph 50.12(a)(2)?
6. Does a categorical exclusion associated with the environmental review exist, paragraph 51.22(c)?

C. Licensee's Safety Analysis

The NRC staff and licensee discussed the following considerations. The 10 CFR Part 26 sections are provided for reference only.

1. U.S. Department of Health and Human Services' (HHS) Guidelines. Safety analyses (i.e., the licensee's technical evaluation) typically includes references to technical or scientific studies, evaluations, codes, and standards to help justify the licensee-proposed exemption. The NRC staff uses the HHS Mandatory Guidelines for Federal Workplace Drug Testing (HHS Guidelines) as part of its scientific and technical basis for 10 CFR Part 26 requirements and will use the guidelines to inform its decision on the licensee-proposed exemption. As such, licensee-proposed deviations from the HHS oral guidelines will need to be assessed by the NRC staff. If the final guidelines have not been issued in time for its use in the licensee submission, the NRC staff will need to ascertain whether the licensee provided a mitigating strategy (e.g., a comparative analysis, pilot program, etc.) to justify its use of the draft guidelines, non-certified drug-testing laboratories, and what would be considered by the licensee when the final guidelines are issued. The NRC staff provides the following hypothetical examples of possible deviations: (1) a licensee proposal not to use the HHS-proposed expanded opioid panel; (2) a licensee proposal not to use an HHS-certified laboratory because the HHS has not yet issued its final oral fluid guidelines, or has not yet completed its certification of laboratories using oral fluid as a biological test matrix; and (3) a licensee proposal to deviate from the HHS-proposed quality assurance and blind performance test guidance.

2. Technical Information. Safety analyses typically provide information of sufficient detail to enable the NRC staff to make an independent assessment regarding the acceptability of the proposed exemption.

3. Completeness of Information. Information provided in safety analyses is complete and technical references are provided. A promise or commitment to provide additional information needed to justify a sufficiency item would challenge the NRC's staff acceptance review.

4. Sufficiency Items. Sufficient justification of sufficiency items is considered necessary for the NRC staff to complete its acceptance review. If a sufficiency item is not addressed, initiation of the NRC staff review may not be possible.

5. Longevity of the Licensee-Proposed Exemption. Although an NRC-approved exemption is not issued with an expiration date, typically an exemption will be superseded by another action. For example, the licensee could determine that the exemption is no longer needed, because site conditions have changed warranting revocation of the exemption, or the licensee could petition the Commission for rulemaking to address the exempted requirements and to propose additional regulatory enhancements (such as the possibility of point-of-collection-testing) to further improve 10 CFR Part 26 implementation and possibly reduce costs. Safety analyses typically describe the licensee's long-term plans regarding implementation of the exemption.

6. Risk Assessment. Safety analyses typically include a quantitative and/or qualitative risk assessment of the licensee-proposed exemption. This information helps risk-inform NRC decision-making consistent with Commission direction on the use of risk information in regulatory decisions. This assessment could delineate any site staffing and technical/professional disciplines differences between normal reactor operations and a maintenance/refueling outage, since the employment type percentages will change, thereby potentially changing the testing results. A quantitative risk assessment could use site-specific and industry-wide drug testing performance data, or that obtained from the conduct of oral fluid testing pursuant to paragraph 26.31(d)(5), "Medical conditions." A qualitative risk assessment could ascertain whether it is reasonable that risk consequences are lower, equivalent, or higher than that associated with using urine as the test matrix.

7. Site Conditions. Safety analyses typically include a general description of expected or necessary changes to site conditions resulting from implementation of the exemption. For this licensee-proposed exemption, these descriptions could include any licensee-proposed changes to policy and procedures (section 26.27); training (section 26.29); and audits, corrective actions, and contracts (section 26.41).

8. Collector and Medical Review Officer (MRO) Training and Qualifications. Safety analyses typically assess whether the proposed exemption has an impact on individuals who perform duties and responsibilities associated with the proposed exemption. This discussion would include, for example, the specific training and qualification requirements for the collector (section 26.85) and MRO (section 26.183). Section 26.183 also establishes duties and responsibilities for the MRO staff.

9. Oral Fluid Testing Methodology. Safety analyses typically include an analysis describing any proposed methodology associated with the exemption. For example, 10 CFR Part 26, Subpart E, "Collecting Specimens for Testing," describes currently acceptable methodologies for collecting urine specimens for drug testing; the collection of oral fluid would be a different methodology. Such a discussion could include, but not be limited to: collection site (section 26.87); preparation (sections 26.89 and 26.105); collection devices (section 26.91); collection (section 26.107); oral fluid quantity (section 26.109); acceptability (section 26.11); split specimen testing, if performed (section 26.113); storage and shipping (section 26.117); and inability to produce an adequate volume of specimen (section 26.119).

10. Worker Protections and Due Process Requirements. Safety analyses typically assess whether the proposed exemption has an impact on existing requirements. This discussion would include the protection of information (section 26.37), donor's privacy (paragraph 26.89(b)), and implementation of requirements that establish due process (e.g., section 26.39, paragraphs 26.53(c) and (h), 26.55(a)(1), 26.89(c), 26.165, 26.185(b) and (e), etc.) for individuals subject to testing.

11. Reasonable Equivalence of the Biological Testing Matrices. Safety analyses typically include an analysis that the proposed exemption provides assurance that is reasonably equivalent to that provided by the requirement. For this licensee-proposed exemption, assurance will be based on, in part, the licensee's ability to meet or exceed the section 26.23, "Performance objectives." Specifically, justification would be based on whether the use of oral fluid as a biological matrix for drug testing results in programmatic outcomes that are or are not reasonably equivalent to the use of urine as a biological matrix. For example, this assessment could assess: (1) any statement of consideration made by HHS regarding their proposed oral fluid guideline; (2) technical or scientific studies; (3) the target metabolites; (4) *windows of detection*; (5) initial and confirmatory cutoffs; (6) storage and transportation; (7) laboratory testing processes; (8) MRO; and (9) blind performance testing and quality assurance provisions. Although NRC staff acknowledges that complete equivalence does not exist, HHS issuance of oral fluid guidelines for the Federal workforce drug testing program provides assurance that both matrices are reasonably equivalent in assuring effective deterrence, detection of illicit drug use, and prevention of subversion attempts. As such, the oral fluid guidelines are an alternative drug testing methodology that accomplishes the same outcomes as using urine as a biological test matrix.

12. Pilot Program. Ameren described that they are considering the implementation of a voluntary pilot program to assess oral fluid testing at the Callaway site, for all employment types, and possibly all technical/professional disciplines. The licensee stated that results from the pilot program will be compared and contrasted to the licensee's normal urine testing program to inform their safety analysis. The details of this pilot program have not been completed at the time of the teleconference.

13. Advantages and Disadvantages of Oral Fluid Testing. Safety analyses typically include a description of the advantages and disadvantages associated with its proposed exemption. For this licensee-proposed exemption, some considerations include, but are not limited to: (1) the identification or prevention of subversion attempts; (2) the specimen collection process; (3) time away from duties and responsibilities necessary for safety and security; (4) status of licensee-contracted laboratories to conduct drug testing using oral fluid; (5) processes following an individual's inability to produce a sufficient volume of oral fluid required for test; (6) whether oral fluid drug testing results are more indicative of contemporaneous use of an impairing or illicit drug (this is important as oral fluid results correlates better to possible impairment); (7) privacy considerations, and (8) use of the currently approved Federal Control and Custody Form. The NRC staff is aware that commercial power reactor licensees have effectively used oral fluid as the biological test matrix under paragraph 26.31(d)(5), "Medical conditions," and that oral fluid testing is conducted in other industries.

14. Defense-in-Depth. Safety analyses typically describe the defense-in-depth considerations associated with the proposed exemption. Defense-in-depth

considerations associated with the 10 CFR Part 26 requirements include, but are not limited to: behavioral observation; conditions for testing; quality assurance; FFD program personnel integrity, training, and qualifications; the HHS National Laboratory Certification Program; and the authorization requirements described in 10 CFR Part 26, Subpart C, “Granting and Maintaining Authorization,” and section 73.56, ”Personnel access authorization requirements for nuclear power plants.”

15. Licensee Commitments and Licensing-basis Documentation. Safety analyses typically include a description of how the proposed exemption would change licensee commitments or licensing-basis documentation. For example, this licensee-proposed exemption could affect the licensee’s commitment to NRC’s Regulatory Guide 5.66, revision 2, “Access Authorization Program for Nuclear Power Plants” (ADAMS, accession no. ML112060028) and descriptions in its Final Safety Analysis Report.

16. Schedule. Safety analyses typically describe the licensee’s desired schedule for implementation.