

**From:** [Harris, Paul](#)  
**To:** [Caltabiano, Debra](#)  
**Cc:** [Zaleski, Brian](#); [Smith, Will](#); [SEARS, RUSSELL L \(RSEARS1@entergy.com\)](#)  
**Subject:** Oral fluid testing - MRO Determination of Dialysis  
**Date:** Tuesday, September 27, 2016 8:51:00 AM

---

Hi Debbie,

Under the provisions of 26.31(d)(5)(i) if an individual has a medical condition that makes the collection of urine difficult, the MRO may authorize an alternative evaluation process, tailored to the individual case, to meet the requirements of Part 26 for drug and alcohol testing. The alternative process must include measures to prevent subversion and achieve results that are comparable to those produced by urinalysis for drugs. This provision would cover a medical determination that the individual cannot provide a sufficient urine sample due to an existing medical condition – based on your discussion below and Dr. Wolf's determination, you have made this medical determination. For recordkeeping, Dr. Wolf may desire to document his determination.

Note that the above provision states "achieve results that are comparable to those produced by urinalysis for drugs." If oral fluid testing is proposed by your MRO, Quest, as well as other HHS-certified labs, have collection, specimen validity testing, initial cutoffs, and confirmatory cutoffs for the 26.31(d)(1) panel of drugs (excluding alcohol) to be tested using oral fluid as the test matrix. You may wish to confirm that your HHS-certified lab has laboratory reviewed, evaluated, and approved processes and procedures for oral fluid testing of the Part 26 panel of drugs.

Recently, HHS proposed for public review their proposed Guidelines for federal drug testing programs. Although these Guidelines are not yet "approved" by HHS, HHS has preliminarily determined that oral fluid testing pursuant to the proposed oral fluid guidelines is commensurate with that of urine testing – meaning that a federal agency may use either urine or oral fluid as the test matrix for the panel of drugs to be tested. These proposed guidelines have received independent expert and laboratory reviews prior to publication of the draft Guideline. On May 15, 2015, HHS announced (80 FR 28053) that it plans to issue mandatory guidelines for OF testing; the proposed Guidelines can be found on HHS/SAMHSA website. Note that immunoassay screening using a point-of-collection-testing device for oral fluid currently would not achieve results that are comparable to those produced by urinalysis for drugs – therefore, your MRO should consider an oral fluid collection device that facilitates laboratory-based validity, initial, and confirmatory testing.

We also acknowledge that HHS-certified laboratories are not yet certified for oral fluid testing. This situation is no different than if a 26.31(d)(5)(ii) blood specimen was used for drug testing for a hospital-based post-event test.

R,  
Paul

*Paul Harris*

**U.S. Nuclear Regulatory Commission / Office of Nuclear Security and Incident Response**  
**Division of Security Policy / Security Programs Support Branch**  
**Senior Program Manager, Fitness for Duty Programs, Drugs and Alcohol**

|  E-mail: [Paul.Harris@NRC.gov](mailto:Paul.Harris@NRC.gov) |  Office: (301) 287-9294 |  Fax: (301) 287-9347 |  Cell: (240) 498-9691

The information in this response 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 responding to an inquiry are solely the NRC technical staff's 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.

---

**From:** Caltabiano, Debra [mailto:DCaltab@entergy.com]

**Sent:** Monday, September 26, 2016 3:54 PM

**To:** Harris, Paul <Paul.Harris@nrc.gov>

**Subject:** [External\_Sender] Oral fluid testing

Paul, Our MRO, Dr. Ivan Wolf, spoke to you a couple months ago about an individual that works at JAF that we have documentation that he cannot provide a sufficient urine sample due to dialysis. He also does not have good vein access due to the dialysis. Dr. Ivan Wolf said that you instructed him that it would be at his discretion. He said that the two of you spoke and that you both agreed that oral sample testing would be the best way to collect this individual. Russell Sears from Grand Gulf is telling me that I should get something in writing from you stating such as oral fluid testing is not an NRC acceptable method. I have spoken to Quest Lab and was going to order the supplies until Russell brought this up. Can you verify/concur that you were in agreement with Dr. Ivan Wolf to do oral fluid testing for this individual? Thank you.

Debbie Caltabiano

*Debra J. Caltabiano*

Access FFD Coordinator

James A. FitzPatrick Nuclear Power Plant

Phone: 315-349-6412

**In the spring, at the end of the day, you should smell like dirt."**

“ -- Margaret Atwood,  
Canadian writer

***Life is bristling with thorns, and I know no other remedy than to cultivate one's garden.***

Voltaire,  
writer and philosopher