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Secretary
U.S. Nuclear Regulatory Commission
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Quest Diagnostics Comments on the Notice of Proposed Revisions to the NRC revision of Part 26 : Fitness for Duty Program

Attached are the comments of Quest Diagnostics Incorporated ("Quest Diagnostics") on the proposed revision to NRC Part 26: Fitness for Duty Program. (http://ruleforum.llnl.gov/cgi-bin/downloader/Part26_risk_lib/1054-0110.htm?st=risk) Quest Diagnostics - is the nation's leading provider of diagnostic testing, information and services, providing insights that enable healthcare professionals to make decisions that improve health. The company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is the leading provider of esoteric testing, including gene-based medical testing, and provides advanced information technology solutions to improve patient care. Quest Diagnostics performs Federal workplace drug testing through our network of six SAMHSA-certified laboratories.

Our comments on the proposed guidelines are organized by Section number as they are enumerated in the proposed regulations

For further clarification on any issue or comment cited above, please do not hesitate to contact me directly at 610-454-4173.

Respectfully Submitted,

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SECY-02

SECTION	CURRENT LANGUAGE	PROPOSED CHANGE
Subpart A Administrative Provisions		
Section 26.5 Definitions		
Confirmed positive test result	"means a non-negative test result that demonstrates that an individual has used drugs or alcohol in violation of the requirements of this part. For drugs, a confirmed positive test result is determined by the Medical Review Officer (MRO) after verification of the analytical result. For alcohol, a confirmed positive test result is based upon a confirmatory test results from an evidential breath testing device without MRO verification of the test result.	The definition does not include positive adulterants that may demonstrate that an individual has adulterated their specimen. We recommend the following addition:" For the presence of adulterants, a confirmed positive test result is determined by the MRO after verification of the analytical result."
Control	"means a urine sample used to monitor the status of an analysis"	We recommend that the word urine be deleted from this definition consistent with the definition of Quality control sample which appears later on.
Subpart B – Program Elements		
Section 26.31 Drug and alcohol testing		
D(ii)(D) other analytes	When conducting additional testing based on dilute sample, may request lab to test "at the confirmatory assay's LOD but only if the initial test suggests the presence of a drug or metabolite within 35% of the established cutoff concentration"	At the recent NRC meeting, some attendees (non-technical) wanted to drop this. We strongly support this approach but would change wording to "within 70% of cutoff" which is currently being done. This percentage provides cost savings for the utilities.
Section 26.41 Audits and corrective action		
(c)(2) HHS inspection records	However, the licensees and other entity shall review the HHS certification inspection records and reports to identify any areas in which the licensee or other entity uses services that the HHS certification inspection did not address.	Conceptually, we agree that the HHS inspection report needs to be reviewed at the audit but would like to see some limits on the scope of the inspection report reviews. "Records and reports" seems to be a broad category. We recommend the following:

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		Review of HHS **inspection records and reports** shall be reviewed during the audit process, however such review shall be limited in scope to the most recent HHS inspection report and laboratory response thereto, immediately preceding the audit, to identify any areas in which the HHS certified laboratory uses services that the HHS certification inspection did not include as part of the routine HHS certification program. Inspectors shall not be permitted to generate or remove copies of any and all laboratory documentation from the premises, including but not limited to HHS audit reports and/or related documentation.
(d) Contracts	Licensee's and other entities' contracts with C/Vs and HHS-certified laboratories must reserve the right to audit the C/V, the C/V's subcontractors providing FFD program services, and the HHS-certified laboratories at any time, including at unannounced times, as well as to obtain all information and documentation that is reasonably relevant to the audits.	1. Unannounced audits at any time is not reasonable given the other inspections, client tours, scheduled department meetings and off-site requirements for testimony that are required of labs and their staff. 2. We have issues with taking documents off –site. We support a review of data during the audit but do not support removal of documents from the laboratory. We also would require that the inspectors follow internal lab polices and procedures, which shall include the signing of a confidentiality or non-disclosure agreement prior

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		to the inspection. We recommend the following re-write: "Contracts "must reserve the right to audit..HHS certified labs (published in the Federal Register) upon providing at least thirty (30) days prior written notice of such audit to the Director of Laboratory Operations, The audit shall be conducted during normal business hours of the laboratory and shall not last longer than forty-eight hours in duration. Contracts shall have the right during such audit to review any and all information and documentation that is material and relevant to the audit. The contract will permit the inspectors to review any relevant and material information and documentation on site, including but not limited to review of any documents pertaining to the certified laboratory HHS inspections. Contracts shall not permit the inspectors to produce copies of or remove any documents, including audit inspection reports from the premises of the laboratory. Inspectors shall abide by all applicable internal policies and procedures of the laboratory, while on-site at the laboratory including but not limited to any and all confidentiality requirements."

Subpart D – Management Actions and Sanctions to be Imposed		
Section 26.75 Sanctions		
(h)(1) Methodology	Drugs for which action is taken should have been reported positive as the result of "GC/MS confirmatory test"	Since the proposed HHS regulations will allow the use of other for hyphenated mass spectrometry instrumentation during confirmatory testing, This section should be revised to include all methodology allowed by HHS guidelines and not restricted to GC/MS technology.
Subpart E – Collecting Specimens for Testing		
Section 26.113 Splitting the urine specimen		
(c) CCF	"shall use aliquots of the specimen contained in Bottle A for validity and drug testing, and store Bottle B and it's associated CCF in a secure manner"	The current OMB approved custody and control form does not have a split copy. Recommend that this section be modified to "shall use aliquots of the specimen contained in Bottle A for validity and drug testing, and store Bottle B in a secure manner"
Section 26.117 Preparing urine specimens for storage and shipping		
(e) CCF	"collector shall complete the CCF (or forms for both Bottle A and Bottle B)	Current CCF uses the same form for the A & B bottles
(i) Packaging	Requires a second tamper-evident shipping container that minimizes possibility of damage to the specimen during shipment (e.g. specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal	A provision needs to be included for a tamper evident bag placed into a shipping bag. The need for bulk insulated shipping containers is excessive and costly. Packing should dictated by the mode of transportation that will carry the specimens to the laboratory.

Subpart F – Licensee Testing Facilities		
Section 26.129 Assuring specimen security, COC and preservation		
(e) On-site tests sent to lab	"Urine specimens identified as non-negative at a licensee testing facility must be resealed with tamper-evident seal and shipped to an HHS-certified lab	As described there are potential Chain of Custody issues since the CCF would not adequately document actions taken during the on-site testing. We recommend that on-site drug and validity test be done on an aliquot from the specimen collection container and not on an aliquot from Bottle A.
(g) CCFs	"Original CCF is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated CCFs, must be placed in a second container	1. One CCF covers both Bottles A & B 2. See comments about chain of custody documentation in (e above) 3. See comments about packaging (26.117, (i))
Section 26. 133 Cutoff levels		
Levels	Coc Met is 300, Amps is 1000	The proposed HHS new regulations will change cocaine screening cutoff to 150 ng/mL and Amphetamines to 500 ng/mL. We recommend that a statement be included that permits the use of standard HHS cutoffs.
Subpart G – Labs Certified by the DHHS		
Section 26.153 Using certified labs		
(f)(4) employee access to info	In accordance with Sec. 503 of Pub. L. 100-71, any employee of a licensee or other entity who is the subject of a drug test shall, upon written request, have access to the laboratory's records related to his or her drug test and any records related to the results of any relevant certification, review, or revocation-of-certification proceedings and data package.	We recommend a re-write to: "Any employee of a licensee or other entity who is the direct subject of a drug test shall, upon written request granting specific authorization to the certified HHS laboratory to release the employee's drug testing records, the certified HHS laboratory must provide copies of the records pertaining to the employee's drug test, which shall be limited to the laboratory test report and data

		package. The certified HHS laboratory shall charge the employee for the cost, preparation and reproduction for copies of these records. Blanket releases by the employee to third parties are prohibited.

Section 26.159 Assuring specimen security, COC and preservation		
(f) send-outs	"If a specimen is to be transferred to a second HHS-certified lab, lab personnel shall ensure that the **original CCF** is packaged with its associated urine specimen bottle"	We recommend this to be changed to including a copy of the original CCF as follows: "If a specimen is to be transferred to a second HHS-certified lab, lab personnel shall ensure that a copy of **original CCF** is packaged with its associated urine specimen bottle"
Section 26.161 Cutoff levels for validity testing		
Entire section		We recommend that this section be aligned with the proposed guidelines published by HHS.
(i) new adulterants	If new adulterant detected, shall report finding in writing to NRC and HHS Division of Workplace Programs within 3 business days	It is not realistic to meet the requirement of notification within 3 business days.
Section 26.163 Cutoff levels for drugs		
(a)(1) Screen cutoffs	Coc metab 300; Amps 1000	These cutoffs are not consistent with proposed new guidelines by HHS. The cutoffs should be modified to 150 and 500 for cocaine and amphetamines respectively.

(a)(2) Dilutes	If specimen dilute, shall use analytical kits approved by the FDA that have the lowest concentration levels marketed for the technology(ies) being used to conduct initial testing of the specimen. The lab shall compare the responses of the dilute specimen . If the responses are within 35% of the cutoff, shall inform the MRO. At MRO's discretion, may test to LOD.	This approach is cumbersome and appears not to be a realistic approach. See section 26.31, where we suggested that if immunoreactivity detected within 70% of cutoff then LOD confirmatory testing should be done.
(b)(1) Confirm Cutoff	Coc metab 150; amps 500	Cutoffs should be changed to reflect the new proposed guidelines from HHS.
Section 26.165 Testing split specimens		
(a)(2) Test at HHS lab	If licensee lab result is non-negative, "then the HHS lab shall test the specimen in Bottle A"	Does not specify what testing the HHS certified lab should do (screen & confirm or confirm only?)
(f)(iv)	Refers to sections 26.297 & 26.299	Don't exist in current version