

From: FFDProgram Resource
Sent: Friday, October 05, 2012 3:29 PM
To: barbara.j.rowland@questdiagnostics.com
Subject: Response to your inquiry to the U.S. Nuclear Regulatory Commission

Ms. Rowland

Thank you for your inquiry. Title 10 of the *Code of Federal Regulations* (10 CFR) 26.153(c), specifies that an HHS-certified laboratory “may not subcontract and shall perform all work with its own personnel and equipment unless otherwise authorized by the licensee or other entity.” Temporary employees, provided that they are employed by the HHS-certified laboratory and not by another organization or entity, would not be considered subcontractors under this section of the regulation. Additionally, 10 CFR 26.153(c) does not preclude a laboratory from leasing equipment to conduct specimen analysis as long as the instrumentation and analytical processes meet 10 CFR Part 26 requirements and applicable sections of the U.S. Department of Health and Human Services’ Mandatory Guidelines for Federal Workplace Drug Testing (HHS Guidelines).

With regards to reports, 10 CFR 26.169(h)(8) requires that the HHS-certified laboratory include “the number of specimens reported as rejected for testing and the reason for the rejection” in the annual statistical summary provided to the licensee’s or other entity’s official responsible for FFD program coordination. The NRC does not impose a requirement specifying how the reasons for rejection are to be described. Therefore, HHS-certified labs are permitted to use established terminology to report the reasons (such as those described in the HHS Guidelines or 49 CFR Part 40, Appendix B) for which specimens have been rejected, unless the NRC licensee or other affected entity has established a contractual agreement that specifically requires an HHS-certified laboratory to report other reasons for which the specimen was rejected for testing.

Additional information on Fitness for Duty is available through the U.S. Nuclear Regulatory Commission’s (NRC’s) public Web site: <http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty.html>.

The NRC hopes that the information above answers your question. Please feel free to contact the agency should you require any additional information.

Regards,

Melissa Ralph,

Security Specialist, Fitness for Duty Program
Security Programs Support Branch
Division of Security Policy
Office of Nuclear Security and Incident Response
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Melissa.Ralph@nrc.gov
Phone: (301) 415-7609
Fax: (301) 415-5373

Note that the information herein 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 Title 10 of the *Code of Federal Regulations* (10 CFR) 26.7, "Interpretations," on any matter to which the information may relate. The opinions, representations, positions, interpretations, guidance, or recommendations that may be expressed by the NRC technical staff in response to your inquiry are solely those of 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.

From: Barbara Rowland[SMTP:BARBARA.J.ROWLAND@QUESTDIAGNOSTICS.COM]
Sent: Thursday, October 04, 2012 4:30:38 PM
To: FitnessForDuty Resource
Subject: Response from "Contact Us About Fitness-for-Duty"
Auto forwarded by a Rule

Below is the result of your feedback form. It was submitted by

Barbara Rowland (barbara.j.rowland@questdiagnostics.com) on Thursday, October 04, 2012 at 16:30:38

comments: Our laboratory would like to have clarification regarding 10CFR26.153(c) and 10CFR26.169 (h)(8). The laboratory utilizes some temporary employees in the specimen receiving and the testing departments. These employees, like the full time employees, are subject to the same pre-hiring criteria. They must pass a background check and pre-employment drug test prior to a job offer. They complete the same training and development checklists as permanent Quest employees. We would like to clarify that the use of temporary employees would not violate 10CFR26.153(c) as the temporary employees are viewed as Quest Diagnostics temporary employees and not as "contractor" or "subcontractors".

Our second question is concerning statistical summary reports for NRC clients. The current annual statistical summary reports contain all the required information including the number of specimens reported as rejected. The report further describes the reason for rejection as either a fatal flaw or an uncorrected flaw. We would like to clarify whether this statistical summary meets the intent of 10CFR26.169 (h)(8). The current DOT rules listed in 49CFR Part 40 Appendix B states that the statistical summary must include the total number of specimens reported as rejected for testing and the reason, either fatal flaw or uncorrected flaw. The HHS Mandatory Guidelines (fr25no08N) also states the statistical summary must include the number of specimens rejected for fatal flaws and the number of specimens rejected for uncorrected flaws.

Thank you for reviewing our request.

organization: Quest Diagnostics

address1: 10101 Renner Blvd.

address2:

city: Lenexa

state: KS

zip: 66062

country: USA

phone: 913-577-1828
