From: Smith, Will
To: "Nielsen, John A (INPO)"
Subject: INPO Query
Date: Monday, April 29, 2013 3:14:00 PM

Hello John,

First of all, I apologize that I have taken so long to respond to your questions. Regarding your questions, the NRC FFD staff has screened them very closely. Keep in mind that in some cases the staff was not able to give you a direct response to your question. As stated on the phone, the staff responses will be directed at clarifying the rule aspects of your questions. That being said, our responses are as follows:

- Audits – 26.41(e) specifically prohibits knowledgeable INPO staff from "conducting" an audit due to auditor independence, but it is not clear about "participation" on an audit as an Industry Observer or other "dependent" role. Similar to a Knowledgeable & Practiced (K&P) on a UA audit, any participation would be under the direction by & coordinated with the audit team leader (ATL) and/or another qualified independent auditor. (In other words, we could not determine program or element effectiveness, only the ATL.)

Response: The staff feels that the intent of section 26.41(e) is to prevent an auditor from being biased towards the licensee or other entity's FFD program or a contractor that supports the licensee's FFD program. The staff has determine that when a licensee or other entity has contracted an independent auditor to perform an audit on one of their FFD program contractors, that any participation by the licensee or other entity, has the potential to be an influence on their contracted independent auditors. In other words, they are both your contractors, so acting as an observer during the audit allows you the potential to influence the audit team.

- EAP – 26.41(c)(2) discusses audits of FFD program service providers, but exempts the Employee Assistance Program – as noted by 26.4(i)(1). Some discussion about the exemption begins on page 17003 of the Federal Register; the need for EAP confidentiality on FR page 17026; and audit exemption on FR page 17030. (Audits provide details to management and any known or perceived reporting of someone's use of EAP to management represents a "significant barrier to the effectiveness of the EAP." Use of the EAP "must remain confidential" with the exception of harm to self or others.)
    - 26.41(d)(1) discusses audit requirements to be included in contracts with FFD program service providers, but does not carry the EAP exemption forward. (It would be clearer if the phrase "For the services noted in 26.41(c) that are required to be audited," or similar prefaced the remainder of the text.) If the intent is to have provision for EAP audits but not have to conduct them, see next item.
    - 26.41(d)(2) offers ability to reasonably limit audit documents, but is only mentioned for an HHS lab. (This ability to "reasonably limit" is not extended to any other FFD program service provider, yet others often have proprietary, private and sensitive information. Often, there may be an overlap with HIPAA restrictions.)

Response: The NRC's goal for adding § 26.41, as cited in the Part 26 statements of consideration, was to eliminate or modify unnecessary requirements. The final rule does not require licensees and other entities to audit organizations that do not routinely provide FFD services to the licensee or other entity. Therefore, before the licensee or other entity can answer the second part of this question, they must take

a close look at their particular FFD contract service and determine whether they routinely provide FFD services. If they do not routinely provide services, then the licensee or other entity has the option of not including an audit as part of the contract. Conversely, if they do routinely provide FFD services, then an audit would be a necessary part of the contract.

With respect to your concerns regarding propriety, private and sensitive information, audits can be performed to assure compliance to policies and/or procedures, and other aggregate data. For instance, an audit can provide statistical analysis of the FFD program, i.e., type of positives drug tests, number of sanctioned personnel etc., without looking at personal records.

- Reporting of results for "problem" specimens – 26.169(a) specifies reporting test results to the MRO within 5 business days from receipt. For validity tests, 26.161(g) allows discussion with the MRO for consideration of additional testing (not donor retest). Here is the scenario we discussed: Four instances where specimens had interfering substances that prevented validity or confirmation results. Rather than stop at the minimum number of tests and report as "invalid" due to interference, the lab had high confidence that one or more tests would provide true analytical results, and it would best support customer expectations. {26.161(c)& (f) both discuss "any one or more"}
    - All affected specimens were blind specimens. In all instances, the results for the blind specimens were the same as certified by the blind provider.
    - Since the MRO staff tracks reporting of results, the lab was contacted for a status on the specimens.
        - MRO staff knows which specimens are blinds and she made the MRO and INPO aware additional testing was going to delay final test results.
    - The time limit of 5 business days was carried forward from the 1989 Rule. (FR page 17106)
        - Statements of Consideration offer no explanation why the 5-day limit exists or was retained.
        - This time limit is not specified in DOT testing (49 CFR Part 40). DOT requires reporting results the same or next business day the result is known and certified.
    - 26.161(g) specifies that specimens be sent to a second laboratory. This laboratory, because of the special equipment it has purchased, is often the "second laboratory" for other HHS-certified labs because it has a better capability to strip the interfering substances and give an accurate analytical result. It seems more prudent to do additional testing at the same lab with enhanced equipment to get true results than to cause more delays and probably not achieve the same results.
    - For two positive drug blinds, each had a positive initial test but had chromatographic interference when attempting confirmation.
        - The end result due to the additional testing is more timely confirmation of the drugs/metabolites rather than a positive initial and "invalid" confirmation, with more handling delays sending it for additional testing .
        - Had these been actual donors, confirmed positive results with a short delay would be much more desirable than "invalid" by two labs in a longer time span.
    - Since the minimum required tests are conducted within the 5 business day

limit, and delays beyond the 5 days due to additional testing are communicated to & involve the MRO, it is our opinion that providing in-file documentation to explain and justify the actions taken would be in line with the intent of the 2008 rule revision Goals to streamline work, more closely align with HHS regulations, and provide accurate test results in a timely manner. For an actual donor, this would also enable prompt removal from Part 26 duties or other management actions and sanctions could be administered.

Response: § 26.169(a) states in part, "specifies reporting test results to the MRO within 5 business days from receipt." The staff feels that your concern regarding test result that go beyond the five day limit, due to additional testing, and the fact that you may not be able to communicate the final test results to the MRO until after the additional testing has been completed, is an incorrect interpretation of the rule. The rule requires notification to the MRO, of a potential positive test result, within five days. The staff interprets this to mean that the MRO must be notified, within the five day period, of any additional testing that will go beyond the stated reporting requirement. The staff feels that the licensee or other entity has met the intent of the rule as long as the MRO has been a part of the decision process for further testing within the five day period.

Will Smith
Security Specialist
NSIR/DSP/SPSB
will.smith@nrc.gov
W(301) 415-6144
C: (240) 818-7247