What is a Policy Violation?
July 28, 2004

The Draft FFD rule has undergone several changes that have taken the concept of a positive test result as a violation and started using several different terms. In part this was done to address issues of adulterated, diluted and otherwise invalid samples.

However, it does not appear that the application of the concept of a non-negative test result is used consistently throughout the regulation. The concern is that it should be clearly evident when a FFD policy violation has occurred. Adding to this is the addition of the policy requirements the section on "misuse of prescription and over-the-counter drugs"

It is not clear where the problem is, but here is some text extracted from the rule based on the search of the terms "Positive" and "Confirmed" To compound this we have the MRO validating results, whatever that means, and reporting FFD policy violations instead of regulatory violations.

Possible outcomes:

- Negative
- Positive for one of drugs in panel
- Adulterated
- Dilute
- Substituted
- Invalid—requires a retest

There is no definition of a confirmed non-negative test result—which may be a problem. For example it appears that an invalid test can never be "confirmed".

Search on Positive

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 result from an evidential breath testing device without MRO verification of the test result.

Non-negative test result means either a report by the licensee testing facility or the HHS-certified laboratory that a urine specimen appears to be adulterated, substituted, diluted, invalid, or positive for a drug or drug metabolite at a concentration equal to or greater than the designated cutoff

levels, or the results of a test of oral fluids or breath that indicate the presence of alcohol at a concentration equal to or greater than the cutoff levels established by the FFD program or as specified in this part.

§26.103 Determining a confirmed positive test result for alcohol.

A confirmed positive test result for alcohol must be declared under any of the following conditions:

(a) When the result of the confirmatory test for alcohol is 0.04 percent BAC or higher;

(b) When the result of the confirmatory test for alcohol is 0.03 percent BAC or higher and the donor had been in a work status for at least 1 hour at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.); or

(c) When the result of the confirmatory test for alcohol is 0.02 percent BAC or higher

163(b)(1) A specimen that is identified as positive on an initial drug test must be confirmed for the class(es) of drugs for which the specimen initially tested non-negative.

165(a)(4) If initial and confirmatory test results from the specimen in Bottle A are positive for one or more drugs or drug metabolites,

165(b) Donor request to MRO for a retest of a single specimen. For a drug-positive, adulterated, or substituted result reported on a single

185(j)(6) The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 012] as a legitimate medical explanation for a confirmed positive drug test result, even if the drug may be legally prescribed and used under State law.

Conformed non-negative

(h) Sanctions for a confirmed non-negative pre-access test result. If an individual has confirmed non-negative test results from any drug or alcohol tests that may be required in this section, the licensee or other entity shall, at a minimum and as appropriate —

69(b) Authorization after a first confirmed non-negative drug or alcohol test result

69(f) Sanctions for confirmed non-negative test results. If

75(e) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or use of alcohol on site, a confirmed non-negative

test result must be presumed to be an indication of off-site drug or alcohol use in violation of the FFD policy.

(1) The first violation of the FFD policy involving a confirmed non-negative drug or alcohol test result must, at a minimum, result in the immediate unfavorable termination of the individual's authorization for at least 14 days.

(2) A subsequent violation of any licensee's or other entity's FFD policy, including during an assessment or treatment period, must result in denial of authorization for a minimum of 5 years from the date of denial.

(f) Paragraph (e) of this section does not apply to the misuse of prescription and over-the-counter drugs, except if the MRO determines that misuse of the prescription or over-the-counter drug represents substance abuse. Sanctions for misuse of prescription and over-the-counter drugs must be sufficient to deter misuse of those substances.

165(f)(2)...If the original specimen was collected for pre-access, followup, return-to-duty, or for-cause testing, the MRO shall direct the licensee or other entity to collect another specimen for testing as soon as reasonably practical. If test results from the second specimen collected are non-negative and confirmed by the MRO, the licensee or other entity shall impose the appropriate sanctions specified in Subpart D of this part, but may not consider the original confirmed non-negative test result in determining appropriate sanctions

(d) The MRO may verify a non-negative test result, or otherwise make a determination of an FFD policy violation, without having discussed the test result or other occurrence directly with the donor in the following three circumstances:

(1) If the MRO determines that there is no legitimate medical explanation for a non-negative test result for opiates and before the MRO verifies the non-negative test result as a violation of the FFD policy

189(a) A determination of fitness is the process whereby it is determined whether there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties.

Review of 10 CFR Part 26
June, 2004 Draft
July 7, 2004(Rev 3)
ACTION ITEMS

Generic Issues

1. New term "other entities"—need to look for unintended consequences for licensee approved C/V. For example could be read to require EAP by background screeners.
    a. Need to add somewhere (26.3(d)?) in Subpart A that applies to a licensee approved C/V to the extent that the licensee relies on the C/V program.

Industry will submit FFD 28 recommending change to 26.3(d). Some industry members will review for other potential issues.

2. Positive vs confirmed non-negative—looks like a few traps left here.
    a. This area needs discussion. Although there does not appear to be any issue with intent of the rule, it seems that language is slightly different.
    b. May need to add a definition of a confirmed non-negative test result.
    c. Verification of non-negative test results—can we find a better term to say it is bad?
        i. It appears that what we are trying to say is that the MRO reviews and confirms that a FFD violation has occurred. It is not a QA check on the labs process.

Request the NRC review this area and consider: -Adding a definition of confirmed non-negative. -change MRO verification to evaluate or confirm in the definition and where appearing in the rule. -Change confirmed positive results to positive and define in terms of cutoff levels for drugs and alcohol. -review rule to ensure that wherever confirmed non-negative is used it means a violation of the regulation

3. Determination of fitness—The rule has been changed to require the SAE to make a determination in virtually every case where there is FFD PDI. This is too restrictive. The reviewing official should have increased flexibility to decide when this is required and the MRO should be allowed to make the determination as well.
    a. Only place with flexibility is in the case of new PDI for an individual with UA!
    b. Need to discuss what the overall objective should be. Need to get the reviewing official and MRO back into the loop.

Industry will submit FFD 29 recommending changes to provide reviewing official and MRO greater flexibility in this area as was original intent in 2002 discussions.

Subpart A:

1. BAC—"estimates"—this is a regulation—need to fix BAC is... as measured by evidential-grade etc.

Recommend the NRC fix definition by deleting "Breath analysis and saliva analysis provide estimates of BAC" or replacing with ", as measured by an evidential-grade breath alcohol analysis device or an alcohol saliva analysis device."

2. Confirmed positive test results—two issues,
    a. no longer seems to be the term used in the rule "confirmed non-negative.
    b. The MRO does not validate the results by personal observation or etc. as we see in QA programs for validate. It looks like he is the one that confirms that it is a confirmed non-negative.
3. Nominal—need to accept the definition used in the rest of the security and other programs. Has problems as written. Replace (1) and (2) with "The next scheduled date shall be no later than the current scheduled date plus the frequency."

Industry will submit FFD 37 that provides propose definition and wording from recent action from security area.

Subpart B:

1. Developed matrix policies, procedures, and training. Need to discuss what 26.27.(b)(1)(iii) means and relation to (i) and (ii).
2. 26.25.(c)—Still written in a manner that makes it hard to use. Becoming more concerned about ability of small programs to use this rule. Need to allow "turn key, DOT" operation for some covered by this. (not a power reactor licensee issue)

Comment—no action

3. 26.25.(d)—This is still a problem for an applicant—**See this as a major issue and should be deleted.** If you read the policy you will find that an applicant is not subject to any of the provisions until a preaccess test is done or the individual is maintained in a random program. Also training element is missing.
4. 26.27.(b)—applied again—needs to be after at licensee facility. Delete "including individuals who have applied of authorization under this part." It would start on drug testing—when they are subject to this part.

Industry will submit FFD 30 to address the remaining "applicant status issues including 3 and 4 above. The concern is trying to included individuals who have completed some paperwork or processing but are have not reported to the licensees inprocessing center. This will be the second try to address this significant issue.

5. 26.27.(c).(3)(iii)—This is an old issue, but need to make sure this can be applied without telling an individual they can never have a drink—plant manager would respond to any emergency, for example.

Discussed—no changes recommended.

6. 26.31.(b).(1).(i)—What do you do if a direct collection is required? This may be OK as long as the "no coworker issue" does not apply in a direct collection.

NRC will review to make sure there is not an inconsistency between the two sections of the rule.

7. 26.31.(b).(1).(ii)—Requires 5 year update of the psychological—The current rule requires this every 3 years—Need to discuss whether being in the FFD program is now adequate and eliminate this requirement. Would propose placing in a UAA status plus random drug testing IAW applicable regs. and orders would be an acceptable approach.

Industry will submit FFD 31 recommending that periodic psychological not be required for individuals who are maintained under current UAA and random testing requirements. This is a new issue—the rule language has not changed.

8. 26.31.(c).(3).(i)—The industry has been concerned that this will be very difficult to apply and require a lot of extra testing.

Comment only—no action

9. 26.35(c)—For the EAP to report to management there must be a determination that the individual is an immediate hazard to himself or others. This seems to be too high a threshold considering protection of public health and safety and other changes made to access program requirements in the current security environment.

Request the NRC staff review this to establish the correct balance between protection of the public and the individual privacy as well as the effectiveness of the EAP self-referral process

10. 26.37.(b)(2)—Concern that allowing only MRO access is too restrictive.

Request NRC consider changing to "Assigned MROs and MRO staff."

11. 26.39.(c)—is the "by more than one individual" a problem?

Yes--Industry will submit FFD 32 recommending changing back to original language.

12. 26.41.(g)—obtain the same services needs to be deleted. Issue needs to be that the audit covers the services used by the licensee. As written (1) and (2) make no sense—there can be no differences.

Request NRC change to "...subject to this part, for those services that were addressed by the shared audit."

Subpart C:

1. This section has been reorganized, with many of the comments of FFD paper 14 included—In general the flow of this section is good.
2. 26.55.(a)—need to look at terminated favorably closely. Change to "...whose authorization has been interrupted for a period of 3 years or more or whose last period of authorization was terminated unfavorably."

Industry will submit FFD 33 to address changes that require an initial under 26.55 for anyone terminated unfavorably and links 26.69 back to the inidial part of the investigation.

3. 26.61.(a).(2)—Why 29 days instead of 30?—Leave at 30. Every new number generates more flaps. It is clear from other sections that must bel completed before the start of the 31st day.

Request NRC change to 30 days to be consistent with rest of rule.

4. 26.61.(b).(3)(iii)—may need to change this to terminated favorably.—Yes put favorable back in. Will need the extra data for 26.69 if terminated unfavorably.

Part of FFD 33

5. 26.69—Flow map of this section made. Can simplify (b) and (d), leave (c) alone since a 5 year denial requires more information than in the initial, and make (d)(2) a new section since maintaining and granting do not cross well.

Part of FFD 33

6. 26.69.(d).(1).(iii) allow the reviewing official to decide if a determination of fitness is needed as in (2)(ii) below it.

Part of FFD 29

7. 26.69(d)(2) needs to be a separate section under 26.69

Part of FFD 33

8. 26.69.(b).(7)—No one likes this change. Would prefer to stay with the 1 per months for 4 months and quarterly for 2 yr 8 months. Lots of work here—2% rate is a new concept, number of tests per month better—what if do not have 15 in 3 years because of periods in which did not have access—How do transient workers ever get out of the program? Also need to discuss the transient worker situation.

Industry will submit FFD 34 to address this. In general would like to keep the current monthly then quarterly scheme which works for long term employees. Need to develop words to allow ultimate closure for those with breaks in access, while still requiring a series of tests over a rational period of time.

Subpart D:

1. 26.75.(h)—Not sure what this section is trying to say with all the new words—It does not have clarity at this point. Part of the generic discussion at the front of this paper.

Part of Generic issue 2.

2. 26.77.(c)—New—looks like a problem. Need more data on accuracy of devices at 0.00 level. Is there any MRO that would ever remove an individual from duty for a 0.01. Is there data to prove that there are observable symptoms?

Industry will submit FFD 35 to address significant concerns with this late addition and the added burden. It is believed that this was added to address a relatively minor FAQ issue that does not need to be solved in the rule at this late date. Placement and impact is not commensurate with the gain. If required should be added as part of 26.103

Subpart E:

1. 26.87.(b)—does this solve the privacy issue for alcohol testing?

yes—no further action

2. 26.91.(a)—what do we mean by "only if there are instructions for its use in this part" –I don't see any device specific instructions. I thank we are trying to say that the device must be useable without rewriting any of the steps—for example a display of the unique number at the right time in the test.

Request NRC staff develop a fix.

3. 26.109.(a).(3) seems to duplicate the words in (1) above.
4. 26.109.(b).(2) seem to be in conflict with (c) below—can do one or the other but not both.

Request NRC staff develop fix to remove duplication and provide one clear path for items 3 and 4

Subpart F

1. No comments.

Subpart G

1. No comments.

Subpart H

2. 26.183.(a) Note that the MRO and later the SAE have 2 not 3 years to meet requirements—is this a problem?

Comment—No action

3. 26.183(b)(5)—Concern that this section puts burden, inappropriately on the MRO, not the licensee to meet the requirements of regulations.

Industry will submit FFD 38 to propose slight rewording of this section.

4. 26.183.(c).(4) and (5) and .(d)—This is written as if the MRO and his staff are subcontracted. What will happen when they are licensee employees? The concept can be better captured if the focus is on independence and not on who works for.

Industry will submit FFD 36 to address the independence of the MRO staff without reference to whether licensee employees or under contract.

5. 26.185 I am still having problems with the verification issue and what is, or is not an FFD violation. The language drifts a little for A to C to D to H.

Part of Generic issue 2

6. 26.185.(j).(3)—what is a violation—can be read two ways.

Part of Generic issue 2

7. 26.187.(g)—Even more restrictions added to the SAE—what problems will this generate?

No additional comments

8. 26.189.(a).(1)—may changed to shall—means that the SAE is only on who can do fitness evaluation—need to change back to may.

Part of FFD 29

9. 26.189.(b).(4)—Dec 2002 language carried forward required a determination of fitness any time there is FFD PDI—It seems that the reviewing official can disposition some of these historical issues. Need to review this issue

Part of FFD 29

Subpart I

1. Comments will be developed Tuesday July 6.

Subpart J

1. 26.213(a)—need to get the added term "following termination" out or we will be keeping records forever. This was a major step forward in 2002, which has slipped backwards.

This has been a major paperwork burden with the current rule. It is very difficult to determine when an individual, who moves around the industry, is terminated from the industry. The result has been keeping everything forever. Request the NRC staff change to read "...for at least 5 years following termination or denial of authorization from the authorizing licensees or other entities program for each individual or..." This is consistent with the requirements in NEI 03-01 Section 14.

Subpart K

1. No comments.