Questions/Issues for the NRC Workshop March 20-22, 2001

§ 26.2 Scope

§ 26.2(a)(4)—Clarify that these requirements apply only to FFD Program Personnel who meet the criteria defined in (i) through (iv)?

Otherwise, an unintended individual, one who has not been granted unescorted access authorization could be considered for this requirement:

- A corporate person who might make a "management determination of fitness;"
- An off-site medical professional (e.g., emergency room physician) that determines an individual is fit-for-duty or not;
- An off-site supervisor involved in the scheduling of random testing of his/her workers.

§ 26.2(f)—Persons performing activities under this part who are covered by a program regulated by another Federal agency or State need be covered by only those elements of a licensee's FFD program not included in the Federal agency or state program…testing for the drugs specified in the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines…

What is special about the NRC program that makes other Federal Agency programs inadequate requiring a unique validation by licensees? [Most will retain a separate DOT program for FFD because it is too hard to administer a program with exceptions.]

Why does a 2000 ng cut-off level for opiates suffice for DOT but not for NRC? Why are licensees forced to use a different opiate cutoff level than HHS requires the certified labs to test? This makes nuclear licensee programs special and requires higher costs and unnecessary lab audits in addition to those done by HHS.

§ 26.3 Definitions—Please respond to provided questions.

Abuse of legal drugs…

What is the definition of legal action or employment action taken for alcohol or drug use? Does this mean that proven use/abuse of a legal drug (e.g., alcohol, prescription, over-the-counter drugs) in a manner that constitutes a health or safety hazard to the individual or to others, including on-the-job impairment? Is the method of evaluation included in the term "medical determination of fitness?"

Behavior observation…

As before, supervisors will do BO but certainly a peer can also observe and report—is this excluded from the definition?

History of substance abuse…

Does the history of substance abuse include anything beyond the 6 statements included? Isn't the required suitable inquiry sufficient for this? Is a ticket for having an open bottle of an alcoholic beverage in the car included in such a history under the heading of legal action? Please justify?

Medical determination of fitness…

What does "qualifying" mean beyond "related to FFD issues presented by the patient." Wouldn't all licensed physicians be capable of this? Why can't other (non-physician) medical professionals get "qualified?"

What are appropriate, relevant medical records and how would the NRC propose that a licensee obtain such records in view of privacy requirements?

What are the standard clinical procedures referred to in the definition?

Substance abuse…

This definition is tied to the definition of "abuse of legal drugs," which contains the undefined "legal action" term. What is included in the term "other substances?"

Additional questions:

1. How does a licensee determine what is sufficient evidence for "proof of abstinence?"
2. What constitutes a three-year follow up program for transient workers?

   Is the three years consecutive or cumulative?

   Do we credit time spent in other Licensee's programs?

   Actual example: A craft worker was placed on follow-up 10/95 for 3 years. However, due to the nature outage work, giving the worker credit for being subject to random testing at other licensees, the worker only had 17 months credited after 5 years.

§ 26.20(a)—Written Policy and Procedures.

A clear and concise written statement has not been specifically required to be prepared in the past. Does the NRC expect us to do this for all persons that currently hold unescorted access authorization or is this to begin for new people after rule implementation? If employees can't be grandfathered for this, please explain.

Are licensees expected to post the policy in a public place? Provide copies on demand? Is "readily available" sufficient if it meets the licensees normal practices?

Again, those questions that deal with specific statements in the rulemaking that are either unclear or unable to be consistently interpreted are troublesome. The ambiguous/subjective terms that need clarification here are: what is meant by "other factors" and "other means?"

§ 26.20(e)(2)(f)

Requires verification that the individual will continue to be subject to random testing and BO at another licensee's site.

What is the expectation for verification? Is it acceptable to use the industry's Personnel Access Data System (PADS) which already does this for active-at-a-site individuals?

§ 26.22 (c)—Training of supervisors and escorts

"*A written examination on the training material given on a nominal 12-month frequency may be used in lieu of refresher training for escorts and supervisors employed by licensees.*"

"*Refresher training for escorts and supervisors employed by licensees must be completed on a nominal 36 month frequency, even if examinations are used to fulfill the requirement during the interim period.*"

Does "employed by the licensee" limit this section to licensee employees only or does it also include contractors? If not, why not?

Is classroom training every 36 months required or can the refresher training include methods such as Computer Based Training (CBT), specified reading material, etc.? If not, why not?

§ 26.24(a) Chemical and Alcohol Testing.

Explain any difference between pre-access testing and return-to-duty drug and alcohol testing requirements? Please clarify and explain the rationale for setting the parameters spelled out in paragraph 26.24(a)(1).

Does return-to-duty testing have to be conducted for those individuals who have no history of drug abuse and were under a FFD program for 2 consecutive weeks prior to granting of access or within 6 months?

§ 26.24(a)(1)(i)(B)

What is "no history of substance abuse"—a lack of hits on any of the six item listed under the definition?
[See question concerning the definition above.]

Does behavioral observation coverage for two weeks during a previous six-month period allow for unescorted access without waiting for a negative test result?

§ 26.24(a)(2)

'Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested at the earliest reasonable and practical opportunity and without notification to the individual until immediately prior to his or her reporting for the test."

If the individual returns on a weekend or for the mid-shift when FFD personnel are not scheduled to be available, when does the NRC think it must be done? Is reasonable and practical determined by the licensee?

"Immediately prior to reporting" is not a defined term—is this the minimum time it would take an individual to walk directly to the FFD station? Under what conditions would there be leeway?

§ 26.24(a)(3)(i)(C)

Does "credible information" mean a DUI/DWI charge that is self-reported? Reported by another person but not confirmed? A security guards equivalent of a field sobriety test? Printed in the newspaper? [This term is not clearly defined in this rule.]

[Where is the cost savings and value added of a licensee tracking if a person has been covered by a like program for 30 out of the past 60 days; or no history of substance abuse and a negative test within the past six months or being covered by a program meeting the standards…. for two consecutive weeks during that period.]

26.24(f)

Would the FFD Program Manager qualify as "licensee management"?

Do MROs have to review negative drug screen results?

26.24(h), BAC issues

Clarify when "work status" begins. (Example: Worker's day starts at 0700; worker has doctor's appointment at 0830, reports to work at 1000. If a worker reports to FFD at 1215, blows 0.02%. Does calculation begin at 0700 or at 1000?)

26.24 (2)

Chemical and alcohol testing- Does "off site" only refer to those individuals in a current work status and at a location where testing is not available (attending off site conference, etc..) or does it also include those on annual leave, sick leave, or administrative leave?

What does NRC consider "earliest reasonable and practical opportunity" to test an individual who returns to site and was previously selected for a random test?

Does the NRC expect licensees to conduct for cause drug and alcohol when the arrest occurred (i.e. over the past weekend)?

Why does the NRC want to know about any individual with unescorted access that is arrested for illegal drugs?

What value does notifying the NRC of off-site drug use or possession have? Why notify the NRC within 24 hours.

Is the NRC's expectation that contractors "pre-screen" workers to determine if they have a history of drug abuse prior to requesting unescorted access?

<u>26.27</u> Management actions and sanctions to be imposed

What is the difference between 26.27(A) and 26.27(B)

Please explain the difference between (a)(1)(i)(B) and (C). {Individual written statement}

(4)" …the establishment of an appropriate follow- up testing program, as specified in 26.24(a)(4). Does the MRO or licensed physician have the flexibility not to recommend any form of follow-up testing excluding those individuals with a prior 10 CFR Part 26 violation? (i.e. one DUI in past five years)?

If an individual who tested positive 4 years ago and was terminated, (Therefore, never being subject to follow-up testing.) is hired by a licensee. Is the licensee required to place the individual in a three-year follow-up testing program?

If the above individual is required to be place in follow-up testing, then what is the obligation of the licensee to track the duration of follow-up testing at other licensee's facilities.

Is a management and medical determination of fitness required each time on reinstatements of unescorted access?

(6)(i) Does this include individuals who were suspended for 14 days on their first FFD violation and subsequently returned to work or only those individuals who were removed for a period of three years following their second FFD violation or for 5 years following the use, sell or possession?

(7) Can unescorted access be granted up to 72 hours pending completion of a suitable inquiry on an individual transferring from another licensee?

When unescorted access is granted with a pending suitable inquiry, does the suitable inquiry have to be initiated before access can be granted?

Is the 72 hours to complete the suitable inquiry taken literally? (i.e. Access granted at 1:15 pm must be completed by 1:15 pm 72 hours later?

What is to be gained by initiating SI's for the remaining 4 years? We don't gain any additional information simply by initiating SI's. How do we document these initiations?

What constitutes a best effort for SI's? Who decides when seeking information becomes "too burdensome"?

§ 26.27(a)(2)

The statement made under paragraph must include the individual's declaration as to the specific type, duration and resolution of any such matter.

To what does "type" refer?

Can this be met by means of an applicant's written statement?

26.27(a)(4)

1. Does an applicant for UAA who lists a DUI automatically require a management and medical determination of fitness and/or follow-up testing? Or, must that a DUI "raise a concern about the person's history of alcohol or drug use" for a license to require management/medical determination of fitness and/or follow-up testing?

2. If management/medical determination of fitness is required, must it only be done for new applicants (e.g., "…the new assignment of activities within the scope of this part or unescorted access must be based…") or the first time a worker applies for UAA (after a violation)?

3. If an individual has a history of drug abuse, must they have a medical determination of fitness and be put in a follow-up program.?

26.27(a)(7)

Numerous mentions (here and elsewhere) of restoring unescorted access after an absence of more than 60 days from the possibility of being tested, but where does it say you must suspend the unescorted access? (It must be suspended or removed in order to restore it.)

26.27(b)(3)

Clarify expectations for individuals put on suspension (i.e., suspended without pay for 30 days, referred to EAP for treatment.) Explanation in FR notice (Section A, p.65, item 11) indicates "people suspended must still be covered by behavioral observation, chemical testing, and sanctions for violations."

26.80 (a) Audits

If the licensee pays for split specimens to be analyzed at a particular HHS certified laboratory and utilizes that laboratory only for split specimen re-analysis, does this obligate the licensee to perform an annual audit of that HHS certified laboratory?

What does "FFD Services" include with respect to auditing requirements?

App. A, 2.3(b)

If a licensee uses medical department personnel (station nurse) who is independent of administration of the FFD Program, are they subject to the same background checks and psychological evaluations found in 2.3(c).

App. A, 2.4(g)(11)

Must we continue collecting specimens until the participant provides a TOTAL amount greater than that required, or must we wait until we receive a SINGLE specimen that meets or exceeds the volume requirements?

App. A, 2.4(g)(15)(i)

Guidance on acceptable results for oral temperature of participant?

App. A, 2.4(g)(21)

Explain how the individual can be present as required by paragraph (i) when on-site screening is performed, (i.e., specimen collected, COC transferred to collection site person, specimen taken to testing facility by collection site person, test is presumptive positive and must be sent to HHS-lab, but (g)(21) requires that the individual be present when preparing specimen for shipment to HHS lab.)

Appendix A 2.7 (h)(2)

MRO Qualifications - In the Statement of Considerations the NRC states that the MRO or technically qualified staff under the direction of the MRO must review negative results and that negative results may be signed or rubber stamped by the MRO or a technically qualified person. What is the definition of a technically qualified staff person?

Appendix A 2.7(k)

Split Specimens states in part, “The chain-of-custody and testing procedures to which the split specimen is subject must be the same as those used to test the primary specimen…” However; HHS guidelines for re-testing of split specimens prohibit re-screening by immunoassay except for dilution information. Therefore, is it acceptable for split specimens to be tested by GC/MS only for purposes of substantiating the original result?

Appendix A 2.7(h)(5) states,

“The laboratory shall retain the original custody-and-control form and must send only to the MRO certified true copies of the original custody-and-control form and the test report.” Does this mean that HHS laboratories must send the certified true copies of the custody-and-control form to the licensee on negative drug tests?

HHS laboratories utilize two type of negative screening control specimens, a drug free control and a -25% of the cutoff negative control. Appendix A 2.7 (e)(4) states, in part, “The responses of questionable donor specimens must be compared to the acceptable range of negative screening control responses. Those specimens that have responses greater that are greater than the negative control responses must be subject to GC/MS at the limit of detection (LOD).”
Which negative screening control is expected to be utilized in this case? (Note: Our HHS states that use of the drug free control would cause many specimens to be subject to GC/MS unnecessarily.)

Appendix A 2.7(g)(2) states

“That confirmatory test for Amphetamines should be reported as Amphetamine and Methamphetamine.” However, Appendix A 2.7(g) (5) states, “Specimens that have a positive GC/MS result for Amphetamines must be tested for *d* and *l* isomers.” Would it not be more appropriate to state that specimens that have a positive test for Methamphetamine must be tested for *d* and *l* isomers?

Appendix A 2.7(h)(1)

Requires the HHS-certified laboratory to report results within 5 working days and allows 6 working days for suspected amphetamines. Assuming the extra day for suspected amphetamines is for the processing of the *d* and *l* isomer testing, why is an extra day not allowed for 6-AM testing, which requires an extra processing step by the laboratory?

Appendix A 2.8(f)(2)

Investigation of Errors and Other Matters states "Should a false positive error occur on a blind performance test specimen or on a regular specimen, the licensee shall promptly notify the NRC." What is the definition of "*promptly*" in this case?

1. Who were the majority of commenters who were concerned about changing the opiate cut-off level?

§ 26.20 requires policy and procedure changes to implement the revision. A four-unit licensee reported that the one time cost for these revisions would be on the order of $70K. This includes costs associated with revisions of procedures, policies, and training programs, communication of revised policies and procedures to affected personnel, training of personnel on new requirements, revision of agreements with contractors and vendors, and revisions of contractor/vendor access authorization requirements.

26.24(a)(5) would require a new category of testing (return to duty), which would require a major rewrite of software used to implement the program. The estimated cost of this revision is $20,000.

26.27(a)(4) would require a medical determination of fitness be performed on all individuals with a history of substance abuse. When the cost of the Medical Review Officer, the cost of the worker's time, and the projected number of medical determinations of fitness are factored in, we estimate an additional cost of $100,100 per year.

26.27(a)(6) and (7) require changes in the process for granting temporary unescorted access authorization and performing suitable inquiries. When cost of performing suitable inquiries for periods of employment of less than thirty days, the delays incurred in allowing the worker to begin work, and the increased cost of performing background investigations, the projected annual increase in cost for this change is $80,566.

2.4(g)(9) requires a change in processing of specimens that do not meet the minimum volume requirements currently found in 10 CFR 26. This change will require that 10% of all specimens collected be sent directly to the HHS-certified lab for analysis rather than subjecting these specimens to on-site screening. Additionally, if these specimens are for pre-access testing, it will result in a delay of granting access. The additional cost associated with this change is $50,390.

There are other issues/perspectives associated with risks that are not easily quantified. Specifically, we need to discuss the potential risks and negative

implications associated with the provisions of Section 26.27(a) regarding the performance of Suitable Inquiries.

As noted in SECY-00-0159, Attachment F, "Analysis of the Application of the Backfit Rule to the Revisions of the Fitness-For-Duty Rule", the NRC plans to require licensees to perform Suitable Inquiry checks for any period of 30 days or less where an applicant for unescorted access was not covered by a FFD program. The NRC staff concluded the following:

> "After the proposed rule was published, the staff was informed that derogatory information is frequently obtained through checks of employment of less than 30 days; in these cases the individual was terminated for cause, frequently for substance abuse. Since it appears that the proposed revision would increase the risk to public health and safety, this proposed revision to section 26.27(a)(4) has been withdrawn.
>
> Licensee Cost Reduction/Increase: None"

FFD Managers feel that the NRC is wrong in its assumption that derogatory information is frequently obtained through checks of employment of less than 30 days resulting in for-cause terminations for substance abuse. It is very rare, if at all, that this type of incident occurs. FFD Managers also feel that the appearance to the NRC of a risk to public health and safety is based solely upon isolated incidents that rarely, if ever, occur.

The NRC has also stated that there is no cost reduction or increase associated with this change to current process. The concern of most licensees is that implementation of this current process change could result in the potential for the completion of outages to be extended as the result of individuals being delayed unescorted access to the licensee facilities because of the additional Suitable Inquiry checks. Licensees have determined, as the result of historical data, that 1) additional Suitable Inquiry checks will serve no benefit, 2) current Suitable Inquiry processes do not pose a risk to public health and safety, and 3) changing the current Suitable Inquiry process may result in unplanned outage delays. Statistical data shows that a one-day delay in the completion of the outage will result in cost increases to the company as follows:

Calendar Year 2001 - $750,000 to $1,000,000 per day
Calendar Year 2002 - $500,000 to $1,000,000 per day

Although the expectations of licensee management is that no outage delays will occur, FFD and UAA Managers can not predict or guarantee that delays will be avoided if the additional Suitable Inquiry requirements are mandated.

Many licensees rely upon contracted background investigation companies and self-screening contractor/vendor companies to perform Suitable Inquiries. As indicated on the industry spreadsheet, licensees have factored additional costs for the completion of these requirements that were not identified by the NRC in their analysis.

Because the amount of approved contracted background investigation companies and self-screening contractor/vendor companies is limited, the additional work load will place a burden on these firms to perform substantially increased Suitable Inquiry activities in a short period of time. This will result in these firms being required to increase staff to meet licensee expectations and regulatory requirements.

A concern in the industry is that adding workers to meet the demand imposed on licensees to complete Suitable Inquiry requirements will result in less competent and qualified workers investigating and verifying information for contracted background investigation companies and self-screening contractor/vendor companies. The current job market indicates that competent and qualified workers may not be readily available to assist these support companies in meeting regulatory requirements and industry expectations.

The risk to licensees is that as these support companies attempt to meet licensee expectations, the frequency of noncompliance Notices of Violation will increase. As we have seen from previous Notices of Violation, licensees are held accountable for the actions of support companies, as well as, proprietary workers who perform activities that result in determinations of unescorted access.

It is requested that the NRC give consideration to these concerns as they relate to the implementation of changes to the FFD Rule and current practices. It is also requested that the NRC provide applicable data to validate the assumption the maintaining Suitable Inquiry activities at the current level would increase the risk to public health and safety.