

Christian Araguas

From: Jan Mazza
Sent: Monday, May 12, 2008 10:43 AM
To: Davis, James T.
Cc: Christian Araguas; Howard Benowitz; Stephanie Coffin; Timothy McCune
Subject: Fitness for Duty comments
Attachments: Votgle ESP Rev 4 Comments 5-12-08A.doc

Jim,
Attached are the comments we will be discussing today on Fitness for Duty.

Jan Mazza

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From: Jan Mazza
To: Davis, James T.
Cc: Christian Aragues; Howard Benowitz; Stephanie Coffin; Timothy McClure
Subject: Fitness for Duty comments

Sent: Mon 05/12/2008 10:43 AM

Message [Word Document] Voight ESP Rev 4 Comments 5-12-08A.doc (159 KB)

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Jan Mazza

Fitness for Duty comments Properties

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Comments on Vogtle Rev. 4 FFD Program during LWA Construction (5-12-08)

Page	Section	Paragraph/line	Comment
1	2	1/4	Delete "that are required to be described in the - construction entities site safety analysis report or physical security plans." Definitions of safety-related and security-related SSCs make this language unnecessary. Also, the term, "construction entities," is not defined.
1	2	1/7	Part 52 does not require FFD program descriptions for LWA applications. Part 52 applies to COL applicants. This is an LWA application, which is covered by Part 50.
1	2	2/4	The sentence "LWA construction activities include any fabrication, erection, integration, or testing of safety- or security-related SSCs" is incorrect. The LWA requested by Vogtle would not authorize these activities. The sentence should be changed to the following: "LWA construction activities include the installation of the foundations of safety- or security-related SSCs, including the placement of concrete, which includes the installation of rebar."
1	2	3/1	The sentence limits the individuals who will be subject to a "full" Part 26 program to SNC management and oversight personnel. However, 10 CFR 26.4(e) requires that "any individual" who performs the activities specified in that paragraph must be subject to a "full" program, no matter by whom they are employed.
1	2	3/2	Replace "10 CFR 26" with "10 CFR Part 26, subparts A through H, N, and O."
2	3	1/1	This sentence, and the subsequent sentences in this section, should be revised to indicate that SNC, as the LWA holder, is responsible to the NRC for ensuring that the FFD program/program elements is/are implemented at the construction site.
2	3	1/4	Change "a negative drug and alcohol test" to "negative drug and alcohol test result."
2	3	1/8	Insert "result" after "drug or alcohol test".
2	3	1/7-8	Insert a comma after "LWA construction," delete "and" in line 8, and insert ", and is subject to a behavioral observation program" after "when tested."
2	3	1/10	"Construction facility" is not defined.
2	4	1/1	Add a note that states "NOTE: "As used herein, any term that is not defined in this document but is defined in 10 CFR Part 26 has the meaning given in 10 CFR Part 26."
2	4	Definition of "criminal drug statute"	Replace "controlled substance" with "illegal drug as defined in 10 CFR Part 26 and herein."
3	4	Definition of "management and oversight"	These categories of personnel are defined, but the term is not used throughout the remainder of the document. Because these individuals are already listed in section 2 on page 1 as "SNC management and oversight personnel," the definition can be removed.
3	4	Definition of "Medical Review"	What is a "10 CFR 26 drug testing program?" Is this term intended to include MROs who review drug test

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		Officer	results from specimens collected at a facility that meets the requirements of 49 CFR Part 40 (i.e., a DOT collection site)? Instead of "10 CFR 26 drug testing facility," the definition should refer to the collection and testing facilities SNC proposes to use.
4	4	Definition of "security-related SSCs"	Revise so definition applies to Vogtle's LWA application, not a CP or COL application. See definition of "security-related SSCs" in 10 CFR 26.5.
4	5	1 st bullet	Include a description of the consequences of the use or possession of alcohol while on the construction site.
4	5	4 th bullet	Define "facility."
4	5	8 th bullet	Define "managers and supervisors." Are these first-line supervisors, "management and oversight personnel" or others?
5	5	Last bullet	Replace "10 CFR 26.20(f)" with "10 CFR 26.417(a)".
5	5	After last bullet	State the objective outlined in 10 CFR 26.419 by adding the following statement: "Written procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse."
5	5	Training/6	Insert "fitness for duty," between "individual's" and "trustworthiness".
5	5	Training	Individuals at the LWA construction site who are subject to the FFD requirements of an operating reactor, including managers and supervisors, must pass a comprehensive exam. See 10 CFR 26.29. Define "managers and supervisors."
6	5.1.2	2/4	"and" should be "an".
6	5.1.2	3/6	The reference in "these cases" is unclear. Specify that this refers to individuals who have been called-in and report having consumed alcohol. Define "appropriate management."
6	5.1.3	1/1	Replace "engaged in the performance of construction site entity work at the construction site" with "subject to the provisions of this document".
6	5.2	1	The consent form in Attachment A does not address the individual's understanding of the consequences of violating "this policy." Also, "this" is an LWA application, rather than a "policy."
7	5.3	1/1	Replace "approved by 10 CFR 26" with "as permitted by 10 CFR Part 26".
7	5.3	2/2	Replace the term "construction site entity testing facilities" with "licensee testing facility compliant with 10 CFR Part 26 Subpart F."
7 & 8	5.3		The application should specify exactly which specimens will be tested, by which construction entity, and which methods will be used to test them. This level of specificity is required to clarify how the FFD program will be implemented.
7	5.3	1/3	Insert a new second sentence to reflect 10 CFR 26.405(d): "At a minimum, the construction site entity shall test specimens for marijuana metabolite, cocaine

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			metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol, at the cutoff levels specified herein or comparable cutoff levels if specimens other than urine are collected for drug testing.”
7	5.3	2/5	Remove “subject to this subpart”.
7	5.3	2/8	Insert “in accordance with 10 CFR Part 26.161” after “HHS-certified laboratory”.
7	5.3	3	In the first line, the methods for testing for alcohol are limited to the use of breath measurements, but fifth line indicates that oral fluids could be used for testing for alcohol. If oral fluids are to be used, include them in the first sentence. Otherwise, remove language after “Georgia statutes.”
7	5.3	3	10 CFR 26.91(a) requires that alcohol screening devices (ASDs), including devices that test saliva or breath, must be approved by NHTSA <u>and</u> listed on the most recent version of NHTSA’s CPL for such devices. 10 CFR 26.91(b) specifies the acceptable evidential testing devices that may be used to conduct initial alcohol tests (listed on the NHTSA CPL for evidential breath testing devices). Revise the guidance to comply with 26.91(a) and (b) such that breath measurement devices and ASDs used for initial alcohol testing must be on the NHTSA CPL.
7	5.3	3/4	Remove “to”.
7	5.3	3	Does not specify the requirement in 10 CFR 26.91(b) regarding evidential breath testing devices used to conduct confirmatory alcohol testing. The evidential breath testing device must be on NHTSA’s CPL for evidential devices and listed “without an asterisk (*).” Devices identified with an asterisk do not meet the 10 CFR 26.91(c) requirements.
7	5.3	Table “Initial Test Cutoff Levels (ng/ml)”	Although this table includes “ng/ml” in the title, it contains the cutoff level for alcohol which has a different unit of measurement (i.e., % BAC). Replace “ng/ml” in the table title with “ng/mL unless otherwise noted” or moving “ng/ml” out of the title and into each applicable row.
7	5.3	Table “Initial Test Cutoff Levels (ng/ml)”	Remove the “>” symbol from the cutoff levels listed in the table for marijuana, cocaine, opiate, phencyclidine, and amphetamines. See the cutoff levels specified in 10 CFR 26.133 and 10 CFR 26.163(a) for drugs and drug metabolites.
7	5.3	Table “Initial Test Cutoff Levels (ng/ml)”	The alcohol initial test cutoff of “>0.04% BAC” does not meet the requirements in 10 CFR 26.405(d) and 10 CFR 26.99. The initial alcohol test must be able to detect to a cutoff level of 0.02% BAC.
7	5.3	Note 1 to the	Revise the statement “(1) Applicable only for breath

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		Table	measurement devices.” The cutoff level for initial alcohol testing is 0.02% BAC and this applies to both ASDs and breath measurement devices (see 10 CFR 26.99). An acceptable statement would be “(1) Applicable for breath measurement devices and ASDs.” If SNC proposes to use only breath measurement devices for initial alcohol testing, ignore this comment.
7	5.3	Sentence with asterisk below the table	Insert the word “as” after the word “well.”
7	5.3	Last line	Change the term “Confirmation testing” for alcohol to “Confirmatory testing” for alcohol to be consistent with other uses of the term in the document and Part 26.
8	5.3	First line	Change the term “Confirmation testing” for drugs to “Confirmatory testing” for drugs to be consistent with other uses of the term in the document and Part 26.
8	5.3	Table “Confirmatory Test Cutoff Levels (ng/ml)”	Remove the “>” symbol from the cutoff level listed in the table for each drug or metabolite. See the confirmatory test cutoff levels for drugs and drug metabolites in 10 CFR 26.163(b).
8	5.3	Table “Confirmatory Test Cutoff Levels (ng/ml)”	The confirmatory test cutoff for alcohol of “>0.04% BAC” does not meet the requirements in 10 CFR 26.405(d) and 10 CFR 26.103. The confirmatory test cutoff for alcohol test must be able to detect to a cutoff level of 0.01% BAC (see 10 CFR 26.103(b)).
8	5.3	Middle paragraph beginning with “Testing for additional”	After the first sentence, insert a new sentence specifying that all testing will be conducted in compliance with 26.405(f).
8	5.3	Middle paragraph beginning with “Testing for additional”	If the MRO determines that testing should be conducted for additional substances under for-cause and follow-up testing situations, it is unclear how compliance with 10 CFR 26.405(f) would be achieved unless the licensee had already determined, in advance of any such testing event, all possible additional substances that an individual could be tested for so that the appropriate FDA approved immunoassay(s) were available for use at the time of the testing. Therefore, insert a list of all possible substances that an employee may be subject to testing for under for-cause and follow-up testing situations to be compliant with 10 CFR 26.403.
8 & 9	5.3	“On-site Testing Facilities” & “Alternative Collection and Testing”	Specify whether any construction site entities will operate a testing facility and whether alternative collection sites will be used. This level of specificity is required to clarify how the FFD program will be implemented.
8	5.3	“On-site Testing Facilities”	The title reads “On-site Testing Facilities,” but the document also references a “construction site entity testing facility,” “SNC testing facility,” and “licensee testing facility.” Use one term globally, such as “SNC testing facility compliant with 10 CFR Part 26 Subpart F.”

Page	Section	Paragraph/line	Comment
8	5.3	"On-site Testing Facilities"	It is unclear to whom the third and fourth sentences apply: the individual responsible for day-to-day operations and supervising the testing technicians, the testing technicians, or all of the above?
9	5.3	Second bullet	In i., replace "this part" with "10 CFR Part 26."
9	5.3	Last line	Replace "to collect and test specimens" with "to collect specimens and conduct alcohol tests".
10	6.2.1	1/1	10 CFR 26.405(c)(1) requires drug and alcohol testing "before assignment to construct safety- or security-related SSCs." "Within 30 days of gaining access" could be read to mean 30 days <u>after</u> gaining access, which could be 30 days after assignment to construct safety- or security-related SSCs. Replace paragraph with "Each worker who will construct or direct the construction of safety- or security-related SSCs shall have negative drug and alcohol test results prior to constructing or directing the construction of any safety- or security-related SSCs. These drug and alcohol tests must be administered no more than 30 days prior to the start of the worker's construction, or direction of the construction, of a safety- or security-related SSC."
10	6.2		Follow-up testing is not discussed. 10 CFR 26.405(c)(4) requires follow-up testing as part of the FFD program.
11	6.2.2	Occupational Injury	The first sentence is not a complete sentence; it is a definition.
12	6.2.2	Observed Behavior	In the "Occupational Injury" and "Significant Property Damage" sections, there is a similar third bullet requiring the submission of test results to management. To maintain consistency, recommend adding a similar statement to "Observed Behavior" after first and second bullets.
12	6.2.2	6 th bullet	What does "questionable conditions" mean? What are "questionable conditions"?
12	6.2.2	Custodial Arrest, 1 st bullet	When and to whom will an individual be sent for a fitness-for-duty evaluation?
12	6.2.3	1/4	Under 10 CFR 26.405(b)(3), random testing must "[e]nsure that all individuals in the population that is subject to random testing on a given day have an equal probability of being selected and tested." If an individual is selected, is not at work, and does not have to report for testing that day, then that individual actually has no chance of being selected and tested. Thus, not everyone has an equal probability of being selected and tested. To be consistent with 10 CFR 26.405(b)(3), either another selection must be made to replace the person who was selected but is not at work that day, or the group of individuals eligible for testing must include only individuals at work on the day of selection and testing.
12 and 13	6.2.3		The application should specify the time period within which individuals must report for testing after notification. This level of specificity is required to clarify

Page	Section	Paragraph/line	Comment
			how the FFD program will be implemented.
12	6.2.3	3	What is the "FFD testing pool" and "random pool"? Perhaps revise to "all individuals described in Section 2.0 herein" or "individuals eligible for testing".
13	6.2.3	Second bullet	The document uses the term "designated collection facility" here but also uses "collection site" and "construction site entity collection facility" to describe the same location. Use one term globally for the location that is used for specimen collections.
13	6.3	1	Much of this paragraph repeats section 5.3 on page 7. Why have both? Also, this paragraph is inconsistent with 5.3 because 6.3 provides for the use of oral fluids for alcohol testing and 5.3 does not. Also, as in 5.3, the paragraph is not consistent with 10 CFR 26.91(a) and (b).
13	6.3	2	Part 26 does not permit urinalysis as an alcohol testing method.
13	6.3	4/3	Include specimens suspected of being substituted or invalid. Need to be consistent with Section 5.3, paragraph 2 on page 7.
14	6.3	1	Remove "presumptive" and insert "initial drug" between "positive" and "test." "Presumptive" was in former Part 26 but is not in new Part 26.
14	6.3	1/5	Insert "confirmatory" between "the" and "test".
14	6.3	3/4	What is "a specified periodicity"? Change this language to specify the periodicity.
14	6.3	1/5	Include specimens suspected of being substituted or invalid.
14	6.4	1/1	Include in the statement the specific term for the location where specimen testing is conducted (i.e., licensee testing facility or HHS-certified laboratory)
14	6.4	1/1	Replace "all testing" with "urine specimen collections and initial alcohol tests."
14	6.4	2/1	What are the conditions under which a collection site entity would ship specimens to the SNC testing facility?
14	6.5		10 CFR 26.405(g) states that an MRO must review invalid drug test results to determine whether the donor has violated the FFD policy. Because Section 6.5 does not mention invalid specimens, revise accordingly.
14	6.5	2/1-2	Remove "presumptive" and insert "initial" between "positive" and "drug."
14	6.5	2/6	Replace "presumptive positive result" with "positive initial drug test result".
15	6.6	1/1	Replace "independent" with "objective". See 26.413.
15	6.7	1/1	Replace "supervision" with "supervisors"
15	6.7	1/7	Replace "personnel designation" with "personnel designated."
16	6.7	1 /1	Replace "supervision" with "supervisors"
16	6.7	1/5	Replace "safety" with "safely."
16	6.8	Bulleted list	The list does not include all of the authorized persons listed in 10 CFR 26.37(b)(1) through (b)(6). Specifically, the list excludes MROs and MRO staff (per 10 CFR 26.37(b)(2)) and the presiding officer in a judicial or

Page	Section	Paragraph/line	Comment
			administrative proceeding (per 10 CFR 26.37(b)(6)).
17	6.8	1 st and 2 nd bullets	Insert "construction site" before "entity" in the first line.
17	6.8	1 st bullet	Under 5.1.1, possessing illegal drugs by any individual while on the construction site is "strictly prohibited." In 6.8, possession that results in confirmed positive tests is reportable. If possession is prohibited, why would reporting be required only if possession resulted in a confirmed positive test? Also, what is a "controlled substance" (see previous comment re: definition of "criminal drug statute")? Further, it is unclear whether the confirmed positive test result applies to supervisory personnel and controlled substances, or anyone with illegal drugs within the construction area. Define "supervisory personnel."
17	6.8	2nd bullet	Replace "10 CFR 26.73" with "10 CFR 26.417".
17	6.9	5	Replace "26.70" with "26.417".
18	Consent	1/2	Change "it" to "its".
18	Consent	2/2	Change "it" to "its".
18	Consent	2 nd bullet	Change "performing" to "perform".
19	Consent Form	4/2	The group of people to whom information can be released should be the same group of people listed in 6.8.