

Comment Resolution Matrix
December 16, 2008
NRC Comments on NEI 06-06, Revision 4, October 2008

Comment #	Page	Section	Paragraph/line	NRC Comment	NEI Comment Resolution	NRC Response
NEW	1	1	2/5			"COL" is an abbreviation for "construction permit and operating license." The previous reference to a "Combined License" was correct.
1	2	2	First complete sentence	Change this sentence to reflect the date of issuance of the Regulatory Guide, not 30 days after publication of the final rule.	Accept Comment	This sentence may be removed because once the Regulatory Guide (RG) is published the RG will have its own effective date.
2	2	3	1/1	Revise this sentence, and the subsequent sentences in this section, to indicate that the COL holder/CP holder/LWA holder is responsible to the NRC for ensuring that the FFD program/program elements is/are implemented at the construction site.	Accept Comment The last sentence in the 2 nd paragraph, section 1 has been modified to include COL holder/CP holder/LWA holder as part of the term construction site entity.	The "NRC" abbreviation should be defined the first time "NRC" is used (on page 1, section 1, paragraph 2).
10	4	4	4 th and 6 th lines in definition of "security-related SSCs"	Remove "Part" from "10 CFR Part 26.3(c)" and make this change throughout the document with any reference to a specific section or paragraph. For example, "10 CFR Part 26" is correct; however, "10 CFR Part 26.3" is not and should be revised to "10 CFR 26.3."	Accept Comment Comment 5: 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." (NEI accepted comment)	The Part 26 definition of "security-related SSCs" includes ESP applicants with LWA, but the definition in NEI 06-06 does not. Given NEI's response to comment 5, remove this definition and others that are identical to the Part 26 definitions.

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13	4	5	4 th bullet	Define "facility".	Accept Comment – replaced facility with site. If necessary, we can say owner controlled area or something like that to be clearer.	Given that "construction site" is a defined term in the guidance document, this bullet should be revised to say "...arrival at the construction site...."
NEW	5	5	1 st bullet	This provision does not demonstrate that the procedures will protect the donor's privacy and the integrity of the specimen, etc. per § 26.405(e). Because § 26.401(b) requires applicants to describe the implementation of their FFD program, NEI 06-06 must provide a description of the FFD program implementation to demonstrate <u>how</u> the construction site entity will comply with § 26.405(e).		
20	7-8	5.3		When an entity submits NEI 06-06 as part of its application, it 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.	The entities may not know which specimens will be tested, by which construction entity, and which methods will be used to test them at the time of the application. This detail will be specified in the implementing procedures and may not be determined until after the application is submitted. It is the industry position that the application should specify through NEI 06-06 what standards must be met (e.g. NHTSH, 10 CFR 26.91 (c)) and that the implementing procedures will contain this type of information. The NRC will verify that the requirements are met through their inspections as it is done at the operating plants.	Section 26.405(e) requires that the "specimen collection and drug and alcohol testing procedures of FFD programs under this subpart must ... implement stringent quality controls to ensure that test results are valid" To enable the NRC to determine that the applicant will comply with the requirement that the test results will be valid, the applicant will need to submit a description of the testing methods and by which construction entity. NEI 06-06 should help applicants meet these requirements. Also, to be an acceptable means of satisfying subpart K requirements, NEI 06-06 must include one method to meet the subpart K requirements.

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35	13	6.3	“On-site Testing Facilities”	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.	Each applicant will determine whether to operate a licensee testing facility and whether alternative collection/testing sites will be used. This facility will be specified in the implementing procedures and may not be determined until after the application is approved. It is the industry position that the application should specify through NEI 06-06 what standards must be met (e.g. 49 CFR Part 40) and that the implementing procedures will contain this type of information. The NRC will verify that the requirements are met through their inspections as it is done at the operating plants.	<p>Section 26.405(f) contains requirements, and applicants will need to show how they will satisfy them. For instance, testing of urine specimens for drugs and validity, except certain testing that may be performed by a licensee testing facility, must be performed in an HHS-certified laboratory.</p> <p>Applicants will have to describe in their applications how they will comply with the requirements of § 26.405(f), e.g., will the applicant use an HHS-certified lab or instrumented initial test facility to perform the initial testing of urine specimens for drugs and validity. To be an acceptable method of complying with the requirements, NEI 06-06 must provide a means of allowing licensees to meet the requirements. For example:</p> <p>Initial testing of urine specimens for drugs and validity will be performed by:</p> <ul style="list-style-type: none"> <input type="checkbox"/> An HHS-certified laboratory <input type="checkbox"/> The licensee testing facility <input type="checkbox"/> An HHS-certified instrumented initial test facility
41	9	6.2.1	1/1	Replace “directing or constructing” with “start of the worker’s construction, or direction of the construction”	Accept Comment	The second sentence should be consistent with the first sentence: “This drug/alcohol test must be administered no more than 30 days prior to the start of the worker’s construction, or direction of the construction, of an SSC.”

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42	11	6.2.3	All	The guidance does not discuss followup testing. However, 10 CFR 26.405(c)(4) requires followup testing as part of the FFD program.	Accept Comment	The sentence is not a complete sentence. Suggest that the guidance be revised as follows: "For individuals covered by a follow-up plan, the construction site entity must conduct follow-up testing to verify their continued abstinence from substance abuse."
44	10	6.2.2	"Occupational Injury and Illness..."	The first sentence is not a complete sentence; it is a definition.	Accept Comment.	Suggest that the guidance be revised as follows: "An OSHA recordable incident is defined as a significant illness or personal injury....standards contained in 29 CFR 1904.7."

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46	11	6.2.4	1/3	<p>1. The approach presented in the guidance should be modified so that random testing rates are lowered only if the overall FFD program (and not just the random testing element) is shown to be highly effective. Effectiveness might be evaluated by (1) using a more comprehensive set of metrics, and (2) showing that the results for the Subpart K program are at least as effective as the corresponding results for the licensee's operating reactors (or, if the licensee does not have operating reactors, then at least as effective as the industry average figures reported on the NRC website in the FFD Information Notices). Absent such modification, the staff believes that the approach in the guidance should only be used to increase random testing rates, and not to reduce them.</p> <p>2. The guidance should be revised to increase the annual random testing rate based on warning signs associated with other FFD program elements (e.g., if the number of positive test results from observed behavior per 100 Subpart K workers exceeds the corresponding number for workers covered by a full program).</p>	<p>The performance-based approach described in this section is based on the FFD program used by the DOT. The DOT has a long-standing, respected FFD program that encompasses a very large population in diverse and safety/security conscious industries such as the FAA. The industry sees no reason to fundamentally deviate from this proven federal government approved approach.</p> <p>Therefore, the industry has not made any changes as a result of this comment.</p>	<p>See the pages accompanying this matrix for the NRC Response for comment #46.</p>

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NEW	12	6.2.4	3/5	<p>Regarding the sentence, “the construction site entity will establish a method, through site procedures, on how to determine the current workforce and the frequency that it is determined...,” the term “workforce” needs to be defined.</p> <p>Also, to comply with Part 26, licensees will not be able to establish through site procedures a method on how to determine: (1) the current workforce and (2) the frequency with which that workforce is determined.</p> <p>Licensees should know which individuals are onsite on any given day and, of those individuals, who is working on the SSCs of interest. That second group is the random testing pool from which the licensee will select individuals for testing. Also, at the time a COL application is submitted, an applicant should know how it will know which individuals are onsite on any given day and, of those individuals, who is working on the SSCs of interest.</p> <p>(continued, next page)</p>		

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				<p>(cont.) Because § 26.401(b) requires applicants to describe the implementation of their FFD program, applications will need to include a description of the method by which the applicant proposes to determine the current workforce and testing pool on a given day.</p> <p>Also, licensees should know the frequency with which that workforce and the testing pool are determined. If the workforce and testing pool are not updated frequently (e.g., daily), the selected individuals may be comprised of short-term workers who are no longer working onsite. Not only would such individuals go untested, they also would prevent the testing of others who are onsite and might have been selected instead. Moreover, if the testing pool is outdated, newer short-term workers could not get selected because they would not be in the testing pool.</p> <p>To be acceptable guidance, NEI 06-06 must include one method, with some details, to meet the requirements.</p>		

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48	12	6.2.4	7/3	<p>The guidance document includes a provision that "...all individuals in the population subject to testing have an equal probability of being selected and tested."</p> <p>No information is provided to specify how this provision will be met at a construction site. NRC provided an example portal based selection approach at the last public meeting held on November 6, 2007 and NEI indicated during the meeting that an approach would be included in 06-06 revision 2.</p>	<p>The industry agrees with the staff that a portal based selection approach could be used to meet this requirement. However, there are other equally acceptable methods of meeting this requirement. Therefore, the industry does not want to specify only one method. The entity will determine the best method for their site.</p> <p>The industry has revised this section to include the portal based approach as a potential method for meeting this requirement. In addition, the industry has more clearly specified what criteria the selected method needs to meet. The industry expects the selected method to be described in their implementing procedures which will be subject to NRC inspection.</p>	<p>Regarding the following sentence: "The construction site entity will develop procedures to describe the method that will be used," a licensee would not be in compliance with Part 26 by establishing through site procedures a method to ensure that individuals in the testing pool are selected randomly to be tested. Because § 26.401(b) requires applicants to describe the implementation of their FFD program, applications will need to include a description of the method by which the applicant proposes to randomly select the individuals to be tested. To be acceptable guidance, NEI 06-06 must include details, not just one-line sentences, to describe the random selection methods listed in Rev. 4. NEI 06-06 also should include instructions for applicants to provide their particular method in their applications.</p>

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NEW	12	6.2.4	Notification Procedures, 2 nd bullet	<p>Section 26.405(b)(2) requires that “individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program policy.” The NEI 06-06 provision reads that the subject individuals will be “requested” to report to the collection site by a specific time. This provision should be revised for the following reasons:</p> <ol style="list-style-type: none"> 1. A “request” is not a requirement. 2. The rule text requires the person to report “within the time period specified in the FFD program policy.” NEI 06-06’s language of “a specific time” could be very different, and have different impact, than the “time period” in the rule text. 3. What happens if the individual fails to report within the time period? 		

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60	15	6.4	1/1	<p>The guidance document states: "Construction site entity shall arrange for all testing to be performed either on the construction site or at a nearby qualified facility."</p> <p>1. Replace "all testing" with "urine specimen collections and initial alcohol tests".</p> <p>2. Include in the statement the specific term for the location where specimen testing is conducted (i.e., licensee testing facility or HHS-certified laboratory). Also, see comment on page 8, section 5.3.</p>	<p>Accept Comment #1</p> <p>Each applicant will determine whether to operate a licensee testing facility and whether an alternative collection/testing site will be used. This facility will be specified in the implementing procedures and may not be determined until after the application is approved. It is the industry position that the application should specify through NEI 06-06 what standards must be met (e.g. 49 CFR Part 40) and that the implementing procedures will contain this type of information. The NRC will verify that the requirements are met through their inspections as it is done at the operating plants.</p>	<p>Applicants will have to demonstrate in their applications that they will comply with the requirements of § 26.405(f). To be an acceptable method of complying with the requirements, NEI 06-06 must provide a means of allowing licensees to meet the requirements.</p>
61	15	6.5	All	<p>Section 26.405(g) states that an MRO must review invalid drug test results to determine whether the donor has violated the FFD policy. Section 6.5 of NEI 06-06 does not mention invalid specimens.</p>	<p>Accept Comment</p>	<p>Section 26.405(g) requires licensees to provide for MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results. NEI 06-06 refers to samples, not test results, and does not provide for MRO review of "positive, adulterated, substituted, and invalid confirmatory drug and validity" test results. NEI 06-06 needs to conform to § 26.405(g).</p>

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71	17	6.8	Bulleted list	The guidance document lists persons to whom the construction site entity may disclose personal information without consent from an individual. However, the guidance document does not include all of the authorized persons listed in 10 CFR 26.37(b)(1) through (b)(6). Specifically, the guidance document excludes MROs and MRO staff (per 10 CFR 26.37(b)(2)) and the presiding officer in a judicial or administrative proceeding (per 10 CFR 26.37(b)(6)).	As clarification, the document indicates that the construction site entity must obtain a written consent prior to releasing the information, including those in the list. Accept Comment	NEI 06-06 requires a written consent to disclose personal information, even to entities to which the rule permits disclosure without a written consent, e.g. the NRC. Section 26.37(b), which is repeated in section 6.8 of NEI 06-06, permits licensees to disclose personal information to the individuals listed in § 26.37(b) without consent. Why does NEI 06-06 require the written consent to disclose personal information to the individuals listed in § 26.37(b)?