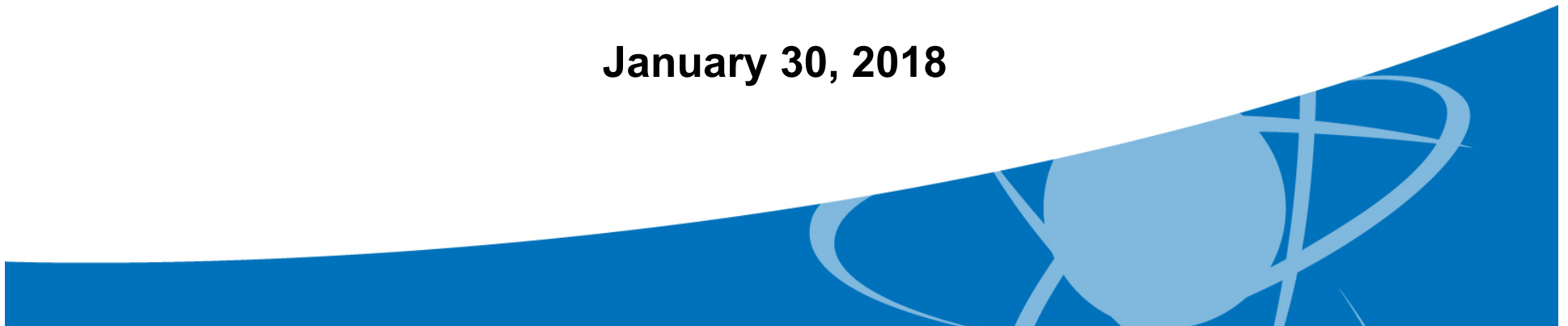


Annual Fitness-For-Duty (FFD) Reporting of Drug and Alcohol Information and Electronic Reporting Submission Forms [Webinar]

10 CFR Part 26

“A Direct Contribution to Safety and Security”

January 30, 2018



Webinar Discussion Topics

- Introduction
- Annual FFD reporting data (10 CFR 26.717 and 26.417)
- FFD electronic reporting forms (drug and alcohol only)
- Common reporting errors and guidance
- Questions



Annual FFD Program Performance Data



- Part 26 reporting requirements:
 - 26.717 (Operating power reactors; Category I fuel cycle facilities)
 - 26.417(b)(2) (Power reactors under construction)
- Due to the NRC before March 1 after calendar year end
- Includes information such as:
 - Random testing rate
 - Substances tested and testing cutoff levels used
 - Populations tested (licensee employees, contractor/vendors)
 - Conditions for testing (pre-access, random, for-cause, etc.)
 - Substances identified
 - Subversion attempts by type
 - Management actions

FFD Electronic Reporting Forms (E-forms)



Each calendar year, a licensee or other entity submits drug and alcohol testing information using two electronic reporting forms (e-forms):

- **Annual Reporting Form for Drug and Alcohol Tests (ARF)** – NRC Form 891 (One ARF is completed for each site)
- **Single Positive Test Form (SPTF)** – NRC Form 890 (One SPTF is completed for each drug and alcohol testing violation at a site)

Latest forms available for download at the NRC website:

<http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html>

FFD E-forms – Use and Advantages



- Voluntary use, first available for calendar year 2009 reporting
- All sites using since 2014
- Advantages:
 - Adaptive form functions (fields appear/disappear based on entries)
 - Built in validations improve data quality
 - In form guidance (pop-up text boxes)
 - Detailed event specific data
- Data used to: evaluate Part 26 effectiveness, inform stakeholders on substance use trends, estimate burden associated with information collections (OMB), and inform the NRC inspection process

FFD e-forms periodically updated (e.g., to improve form completion speed, data uniformity, correct bugs) -- Feedback is *ALWAYS* welcome

FFD E-Form – Expiration Date



- Currently waiting on the Office of Management and Budget (OMB) to approve the information collection request for NRC Forms 890 and 891 (completed every 3 years)

APPROVED BY OMB: CLEARANCE NO. 3150-0146

EXPIRES: 11/30/2017

- Forms currently under review by OMB may display an expiration date that has passed if the OMB does not complete its review prior to the expiration date. In this instance, the expiration date is automatically extended. (<https://www.nrc.gov/reading-rm/doc-collections/forms/>)
- Once OMB approves the information collection, a new expiration date is assigned, and the date will be updated on the SPTF and ARF.

NRC Receipt Reviews of FFD Program Performance Reports



- Performed by NRC FFD team to ensure that information is accurate and complete
- Data quality has been improving as FFD e-form use has increased
- Likely reasons for reporting inconsistencies:
 - New staff completing forms
 - New reporting circumstance not previously encountered
 - Disconnects between form completer(s) and submitter
- All examples in this webinar based on FFD program performance report reviews and lessons learned from those reviews

Common Types of Reporting Errors

- Unlocked Forms
- ARF/SPTF Totals Mismatch
- Multiple SPTFs for the Same Event
- Reason for Testing – For Cause
- HHS-Certified Laboratories
- Dilute Specimen, Limit of Detection Testing
- 24-Hour Event Reports
- Labor Category - Other
- Expanded Panel Testing
- Substituted Test Validity Result
- Subversion Reporting (4 Cases)
- Unique Reference ID
- Deleting an FFD E-form
- EIE General Form Submissions

Reporting Error Unlocked Forms



Final Step (Required) -- NRC will consider each SPTF and ARF authentic in accordance with 10 CFR 26.11 only when the “Validate & Lock” button is clicked and all errors (highlighted in red) have been corrected.

A rectangular button with a red background and a black border. The text "Validate & Lock" is written in black, bold, sans-serif font in the center of the button.

The “Validate & Lock” button will change to “Locked” after the data validation process has been successfully completed, indicating the form is ready for submission.

A rectangular button with a green background and a black border. The text "Locked" is written in black, bold, sans-serif font in the center of the button.

Best practice: Prior to submitting files to the NRC, open each e-form and confirm that the “Locked” button is visible

Reporting Error

ARF/SPTF Totals Mismatch



Total Results -- The “Number of positive, adulterated, substituted, and refusal to test results” reported in the ARF table (Tests Conducted in the Calendar Year) must equal the number of SPTFs submitted. Error example:

- ARF: 2 Pre-Access, 1 Random, 2 For Cause = 5 results
- SPTF: 2 Pre-Access, 1 Random, 0 For Cause = 3 results

Reason for Testing for each positive, adulterated, substituted, and refusal to test result must be the same in the ARF and in the SPTFs. Error example:

- ARF: 3 Pre-Access, 5 Random, 2 Followup = 10 results
- SPTF: 4 Pre-Access, 4 Random, 2 Followup = 10 results

Reasons identified for reporting inconsistencies:

- Same SPTF submitted more than once (duplicate file)
- Some SPTFs not received by the NRC
- Two SPTFs submitted for same event (double reporting)
- Unlocked SPTFs

Reporting Error

Multiple SPTFs for the Same Event



- Instances associated with subversion attempt reporting when more than one specimen was collected from a donor, such as:
 - Specimen 1 = out of acceptable temperature range (negative)
 - Specimen 2 = collected under direct observation (positive)
- We count the number of individuals with testing violations, not the number of specimens tested to make a determination on whether an individual has violated the FFD drug testing policy

Remember this:

Submit only one SPTF per FFD testing violation (not per specimen)

- One individual one SPTF
- One individual one Reason for Testing

Reporting Error

Reason for Testing – For Cause



10 CFR 26.31(c)(2) -- For cause testing is to be conducted
“In response to an individual’s observed behavior or physical condition
indicating possible substance abuse or after receiving credible information
that an individual is engaging in substance abuse, as defined in §26.5.”

Reason for Testing - 26.717(b)(5)

For Cause

For Cause Testing Reason

Physical Condition/Smell of Alcohol

- Some licensees mistakenly used “For Cause” for subversion attempt reporting when two specimens were collected
- The NRC typically discovers reporting inconsistencies when reviewing the “Reason for Testing” information and the Subversion Description detail

Reporting Errors

HHS-Certified Laboratories (ARF)



1) Not including city and state for the laboratory

HHS-Certified Laboratory (Primary)	Quest Diagnostics	HHS-Certified Laboratory (Backup)	Alere
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Needed because some labs have multiple locations, for example:

- Alere (Gretna, LA; Richmond, VA)
- LabCorp (Houston, TX; Research Triangle Park, NC; Southhaven, MS)
- Quest Diagnostics (Lenexa, KS; Norristown, PA; Tucker, GA)

2) Not providing a response for both HHS-certified laboratory fields

HHS-Certified Laboratory (Primary)	Medtox Laboratories	HHS-Certified Laboratory (Backup)	N/A
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Remember this:

- Include City and State for each HHS-certified laboratory
- Include backup laboratory (performs Bottle B split specimen testing, or retesting of an aliquot of the Bottle A specimen)

Reporting Error

Dilute Specimen, Limit of Detection Testing



HHS-certified laboratory reports Test Validity as dilute and special analysis (Limit of Detection) testing under 10 CFR 26.163(a)(2) determines the specimen is drug positive

Test Validity	Was LOD testing conducted (Yes / No) - 26.163(a)(2)?
<input type="text" value="Dilute"/>	<input type="text" value="Yes"/>

Substance - 26.717(b)(2) & (b)(6)

Use NRC Cutoff (Yes / No)?	<input type="text" value="No"/>
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Initial Cutoff

LOD (Limit of Detection)

SPTF reporting, things to remember:

- Choose "Dilute" for Test Validity
- Ensure initial cutoff is 50% of the standard cutoff level
- Confirmatory cutoff is the Limit of Detection (LOD) for the testing assay (do not report the actual quantitation of the test)

Reporting Error

24-Hour Event Reports (SPTF)



Is this a 24-Hour Reporting Event (Yes/No)? - 26.719(b)

Please elaborate on the 24-hour reporting event

- Each year we receive several SPTFs with inconsistent information, when compared to the 24-hour reportable event under 10 CFR 26.719
- Selecting any Labor Category that requires a 10 CFR 26.719 report will auto-populate “Yes” for “Is this a 24-Hour Reporting Event?”
 - Supervisor
 - Licensed Operator
 - FFD Program Personnel
 - SSNM Transporter
- Often times, “Is this a 24-Hour Reporting Event?” is “No” because the Labor Category chosen is not a “reportable” Labor Category (e.g., Facility Support instead of Supervisor).

Reporting Error

Labor Category - Other (SPTF)



- Use of the “Other” labor category primarily reflected maintenance activities that could have been characterized under “Maintenance (general facility)” or “Facility support.”
- Examples of “Other” labor category descriptions reported: accounting clerk, administrative assistant, cafeteria worker, carpenter, custodian, electrician, equipment operator, fire watch, general laborer, general mechanic, inspector, janitorial, laborer, painter pipefitter, scaffold builder, student intern, IT support, training proctor, welder

Labor Category - 26.717(b)(3)

Please Select

Maintenance (safety-significant)
Maintenance (general facility)
Facility Support
Security
HP/RP
QA/QC
Engineering
SSNM Transporter
Other

[See next slide for descriptions of maintenance associated labor categories]

Reporting Error

Labor Category (continued)



Best Practice: Instead of “Other,” consider one of these:

- **Maintenance (safety-significant)** – maintenance or surveillance on safety- or security-related structures, systems, and components (SSCs) such as crane, gantry, and lift operators.
- **Maintenance (general facility)** – maintenance activities not performed on SSCs such as cleaners, painters, roofers, and scaffolders.
- **Facility support** – activities and positions associated with delivery, equipment room attendant, warehousing, stocking, janitorial services, cafeteria, administrative assistances, and landscaping.

Remember this:

SPTF field “Labor Category” pop-up text box guidance contains descriptions of maintenance associated labor categories (hold your mouse over the form field for the information to display)

Reporting Error

Expanded Panel Testing (SPTF/ARF)



A positive is reported for an “other” substance (SPTF), but the substance is not listed in the Substances Tested section of the ARF.

Substance - 26.717(b)(2) & (b)(6) Other: Tramadol		Substances Tested Did your program only test for NRC-required substances <u>AND</u> at the NRC-specified minimum cutoff levels? (Yes / No) <input type="button" value="No"/>		
Do you test for additional substances? (Yes / No) <input type="button" value="Yes"/>		How many additional substances do you want to add? (up to 6) <input type="button" value="1"/>		
Additional Substance	Initial Cutoff	Confirmatory Cutoff	LOD Testing? (Yes / No)	Comment (Optional)
Tramadol	300	300	<input type="button" value="No"/>	Limited to for-cause testing of two individuals

Remember this:

- If an “other” substance is reported in a SPTF, ensure that the substance is also reported in the ARF.
- Use the “Comments” box in the ARF “Additional Substance” table to describe if testing limited to person, a particular reason for testing, etc.

Reporting Error

Test Validity – Substituted Result



- NRC receipt reviews identified incorrect reporting of “substituted” test results for subversion attempts
- A “substituted” validity result is an HHS-certified laboratory result reported under 10 CFR 26.161(d):

“The laboratory shall report a specimen as substituted when the specimen's creatinine concentration is less than 2 mg/dL and...specific gravity is less than or equal to 1.0010, or equal to or greater than 1.0200, on both...initial and confirmatory creatinine...and specific gravity tests”

- SPTF version 1.7.0 (released in December 2016) includes a pop-up message that appears with additional guidance if a “Substituted” validity test result is selected [received fewer reporting errors in 2017]

- Next five slides discuss how to report subversion attempts (4 cases)
- Checklist available for the reporting of some subversion attempts
<http://pbadupws.nrc.gov/docs/ML1234/ML12346A186.pdf>

Reporting Errors

Subversion Reporting – 4 Cases



- **Case 1:** 1st specimen out of temperature range (negative results) and 2nd specimen collected under direct observation is drug positive
- **Case 2:** Testing refusals
(e.g., donor fails to appear for testing; collection process stopped; 1st specimen out of temperature range and donor refuses directly observed 2nd specimen)
- **Case 3:** 1st specimen is reported by the HHS-certified laboratory as “invalid”, after the MRO interview with the donor a 2nd specimen is collected under direct observation and is drug positive
- **Case 4:** 1st specimen out of temperature range (negative results), 2nd specimen collected under direct observation (negative results), subversion determination based on other information

Subversion Reporting – Case 1

1st specimen temp issue, 2nd specimen positive



Initial specimen is out of temperature range (negative results), and directly observed 2nd specimen is drug positive

- Select “Yes” to “Was this collection observed?”
- Report the Substance(s) identified in the directly observed 2nd specimen
- Complete Subversion Attempt information (check boxes and text description)

Was this collection observed (Yes / No)? - 26.717(b)(7) & 26.75

Substance - 26.717(b)(2) & (b)(6)

Marijuana

Please elaborate on the choice(s) selected:

Subject provided an initial specimen with a low temperature. The results of this specimen were negative. The subject was immediately recollected under direct observation. The results from the observed collection were confirmed positive for marijuana by the MRO. Subversion was determined by the MRO based on drug test results.

Subversion Attempts - 26.717(b)(7) and 26.75(b)

Did this collection involve a subversion attempt (Yes/No)?

- | | |
|---|---|
| <input type="checkbox"/> Did not appear for testing | <input type="checkbox"/> Specimen paraphernalia identified |
| <input type="checkbox"/> Refused to provide initial specimen | <input type="checkbox"/> Specimen characteristics (e.g., color, odor, precipitant) |
| <input type="checkbox"/> Refused to provide second specimen | <input type="checkbox"/> Invalid test result (initial specimen collected) - 26.185(f) |
| <input checked="" type="checkbox"/> Specimen temperature (out of range) | <input type="checkbox"/> Refused to follow directions |
| | <input type="checkbox"/> Other |

Subversion Reporting – Case 2

Testing Refusals



- Donor failed to appear for a test
- 1st specimen out of temperature range, donor refused directly observed 2nd specimen
- Collector discovered paraphernalia and collection process stopped
- Shy-bladder with no legitimate medical condition

For these events:

- Select “Yes” to “Was this collection refused?”
- Complete Subversion Attempt information (check boxes and text description)

Refusal - 26.717(b)(7) & 26.75

Was this collection refused (Yes / No)?

Yes

Please elaborate on the choice(s) selected:

Individual provided specimen that was cloudy and exactly 30 ml with no temp. While re-hydrating, individual admitted to technician that he brought in his wife's urine. He lifted up his pant leg and showed the technician that he had a vial in his sock.

Subversion Attempts - 26.717(b)(7) and 26.75(b)

Did this collection involve a subversion attempt (Yes/No)?

Yes

☐ Did not appear for testing

☐ Refused to provide initial specimen

☐ Refused to provide second specimen

☒ Specimen temperature (out of range)

☒ Specimen paraphernalia identified

☒ Specimen characteristics (e.g., color, odor, precipitant)

☐ Invalid test result (initial specimen collected) - 26.185(f)

☐ Refused to follow directions

☒ Other

Subversion Reporting – Case 3

1st specimen invalid; 2nd specimen positive

Initial specimen is reported by the HHS-certified laboratory as “invalid” and the second specimen collected under direct observation is drug positive

- Select “Yes” to “Was this collection observed?”
- Report the Substance(s) identified in the directly observed 2nd specimen
- Complete Subversion Attempt information (check boxes and text description)

Was this collection observed (Yes / No)? - 26.717(b)(7) & 26.75

Substance - 26.717(b)(2) & (b)(6)

Please elaborate on the choice(s) selected:

The donor's 1st specimen had an unusual color and appearance so a 2nd specimen was collected under direct observation. The HHS laboratory test results: invalid result (1st specimen), positive for marijuana (2nd specimen). The MRO determined that the donor attempted to subvert the testing process based on the unusual characteristics of the 1st specimen, including the invalid test result and the confirmed positive test result for marijuana on the 2nd specimen collected under direct observation .

Subversion Attempts - 26.717(b)(7) and 26.75(b)

Did this collection involve a subversion attempt (Yes/No)?

- | | |
|--|--|
| <input type="checkbox"/> Did not appear for testing | <input type="checkbox"/> Specimen paraphernalia |
| <input type="checkbox"/> Refused to provide initial specimen | <input checked="" type="checkbox"/> Specimen characteristics (e.g., color, odor, precipitant) |
| <input type="checkbox"/> Refused to provide second specimen | <input checked="" type="checkbox"/> Invalid test result (initial specimen collected) - 26.185(f) |
| <input type="checkbox"/> Specimen temperature (out of range) | <input type="checkbox"/> Refused to follow directions |
| | <input type="checkbox"/> Other |

Subversion Reporting – Case 4

**1st specimen temp issue, 2nd specimen observed
(both negative results)**



- Report “Yes” to “Was this collection refused?”
- MRO subversion determination based on a combination of the following:
 - Significant differences in specimen temperature between two specimens collected
 - Differences in physiological properties of the specimens (creatinine levels, specific gravity, pH)
 - Information from the collector (e.g., unusual noises in private enclosure, physical characteristics of initial specimen, donor statements)

Please elaborate on the choice(s) selected:

The individual submitted the first specimen temp. out of range (high - 106.8). The individual volunteered an observed collection. The Certified Lab confirmed both specimens negative. The MRO reviewed and obtained detailed information from the Certified Lab and based on the differences of both samples, determined they did not come from the same body at the same time. The MRO declared the collection a subversion attempt.

Please elaborate on the choice(s) selected:

Initial specimen temperature - Temp. 101.8, Cr - 32.7, pH 7.0. Observerd collection - Temp. 97.2, Cr - 192.8, pH 6.2. Per MRO, not possible to have specimen less than 15 mins apart with this huge difference in Cr.

Reporting Error

Unique Reference ID (SPTF)



Supplied by the licensee or other entity when completing each SPTF.

Unique Reference ID (License Supplied)

2017-NRC-001

The NRC's data processing system:

- Utilizes the “Unique Reference ID” to evaluate if an existing SPTF is being updated or deleted (ensures database integrity)
- Will reject a file if the “Submission Update” check box is selected, but no original SPTF was received by the NRC. In this case, the NRC FFD team would contact the individual that submitted the form.

If a Unique Reference ID needs to be changed you must:

- (1) Delete the original SPTF submitted which used that ID (see next slide)
- (2) Submit a new SPTF with the new Unique Reference ID (do not select the Submission Update box for this file, this is a new submission)

Deleting an FFD E-Form

ARF: E-mail NRC FFD team for assistance fitnessforduty.resource@nrc.gov

SPTF:

- “Unlock” the original form that was submitted
[to delete a form the same *Unique Reference ID* must be used]
- Select “Submission Update” and “Delete Submission” check boxes
- Describe the change in “Please explain the change(s)” text box

4) Use of Adobe Reader 8 or later is required

☒ Submission
Update

☒ Delete
Submission

Unique Reference ID (Licensee Supplied)

ABC-2016-009

Please explain the change(s)

Selected wrong facility when
reporting this result.

Also submitted a new SPTF with
the correct Facility selected.

- “Validate & Lock” form and submit to the NRC using
the EIE General Form

Reporting Error

EIE General Form – Submission Reason



Submission Reason *

10 CFR Part 26 (Fitness for Duty and Annual Fatigue Reporting)

Only Choose:

10 CFR Part 26 (Fitness for Duty and Annual Fatigue Reporting)

- To ensure that each e-form is automatically processed [computer code uses information from each form to create a uniform document profile in the NRC's Agency Documents Access and Management System (ADAMS)] (forms docketed in minutes)
- We have had some issues locating e-forms in previous years when the user selected the Submission Reason "Other (Document Control Desk)". This selection results in a human being manually keying in information on each form (process takes much longer (days), can result in document profile inconsistencies)

Reporting Error

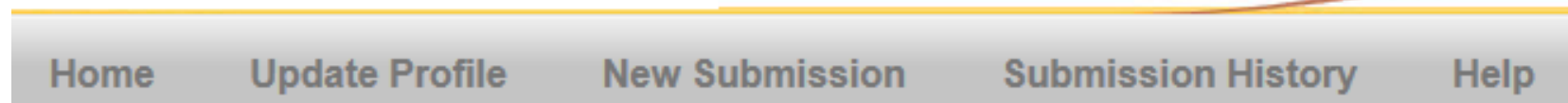
EIE General Form – Missing Submissions



Some sites sporadically have had e-form delivery issues (submitted files using EIE General Form, but files didn't docket in ADAMS)

- The BEST way to ensure that e-forms have been received is with the Email Acknowledgement receipt (includes Submission ID# and ADAMS accession numbers -- ML#'s)
- Can also review "Submission History" tab in the EIE General Form

EIE General Form



- Select "Help" in the EIE General Form window to display a document with additional information on Submission History (pages 17-18)

Where Can I Get Help on FFD reporting?



- **Problems “Delivering the Mail” – EIE General Submission Portal**
Contact EIE help desk at 866-672-7640 (mshd.resource@nrc.gov)
 - Obtain a digital certificate to enable e-reporting
 - Troubleshoot access to the EIE General Submission website
- **Questions on Completing E-forms, Suggestions for E-Form Improvements – Contact FFD program staff**
 - Brian Zaleski (FFD reporting lead)
301-287-0638 (Brian.Zaleski@NRC.gov)
 - Paul Harris (301-287-9294; Paul.Harris@NRC.gov)
 - FAQ email: fitnessforduty.resource@nrc.gov

Questions