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Annual Fitness-For-Duty (FFD) Program Performance Reporting of Drug and Alcohol Testing Information under 10 CFR Part 26

Lessons Learned, Best Practices, and Use of NRC Forms 890 and 891

January 17, 2023
(Webinar)

Webinar Discussion Topics

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- Opening Remarks
- FFD reporting requirements (10 CFR 26.717 and 26.417)
- FFD electronic reporting forms (NRC Forms 890 and 891)
- Lessons Learned and Best Practices
- Question and Answer Session

Annual FFD Program Performance Reporting Requirements

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- 10 CFR 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 - 26.717(e)
- Information to be reported under 26.717(b) includes items such as:
  - ❑ Random testing rate
  - ❑ Substances tested and testing cutoff levels used
  - ❑ Populations tested (licensee employee, contractor/vendor)
  - ❑ Conditions for testing (pre-access, random, for-cause, etc.)
  - ❑ Substances identified
  - ❑ Subversion attempts (number by type)
  - ❑ Summary of management actions

FFD Electronic Reporting Forms (E-forms)

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

- **NRC Form 890, Annual Reporting Form for Drug and Alcohol Tests (ARF):** One ARF completed per site.

- **NRC Form 891, Single Positive Test Form (SPTF):** One SPTF completed for each D&A testing violation per 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

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All sites using FFD e-forms since 2014, available to use since 2009

Advantages:

- ❑ Adaptive form functions (fields appear/disappear based on entries)
- ❑ Built in validations improve data quality
- ❑ In form guidance (pop-up text boxes appears if hold mouse over fields)
- ❑ Detailed event specific data

Data used to:

- ❑ Evaluate Part 26 effectiveness, trending
- ❑ Inform stakeholders on substance use trends
- ❑ Inform NRC inspection process
- ❑ Estimate burden for 3-year Part 26 information collection extensions (Office of Management and Budget)

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

NRC Receipt Reviews of FFD Program Performance Reports

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- Performed by NRC to ensure information is accurate and complete
- Data quality has significantly improved with FFD e-form use
- Likely reasons for reporting inconsistencies:
  - New staff completing forms
  - New reporting circumstance not previously encountered
  - Disconnects between form completer(s) and submitter(s)

Common Reporting Errors

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- 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

All examples based on FFD program performance report reviews and lessons learned from those reviews

Reporting Error: Unlocked Forms

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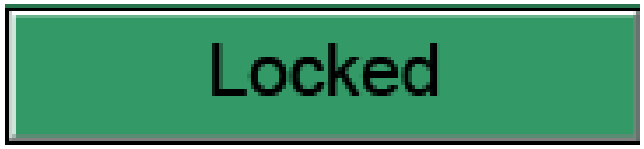
Final Step (Required) -- NRC will consider each SPTF and ARF authentic in accordance with 10 CFR 26.11 only when the "Validate & Lock" button is clicked and all errors (highlighted in red) have been corrected

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



Best practice: Before submitting files to the NRC, open each e-form, scroll to the bottom, and confirm the "Locked" green button is displayed

Reporting Error: ARF/SPTF Totals Mismatch

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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. For example:

- ARF: Pre-Access (13), Random (6), Followup (2) = 21 results
- SPTF: Pre-Access (12), Random (6), Followup (2) = 20 results

Reason for Testing – Must be the same for each D&A test result and refusal to test reported in the ARF and in the SPTFs. For example:

- ARF: Pre-Access (15), Random (3), Followup (1) = 19 results
- SPTF: Pre-Access (14), Random (4), Followup (1) = 19 results

Typical reasons for reporting inconsistencies:

- Same SPTF submitted more than once (uploaded same file twice)
- Same SPTF "Unique Reference ID" but different data (copy/paste issue)
- Inconsistent Reason for Testing selected in SPTF and ARF
- Missing SPTF(s) (if use sequential Unique Reference ID – easy to identify; e.g., ABC-2021-01; ABC-2022-02; ABC-2022-03; ABC-2022-05)

Reporting Error
Multiple SPTFs for the Same Event

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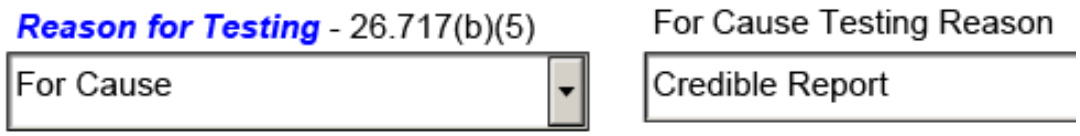
- Instances associated with subversion attempt reporting when more than one specimen was collected from a donor, such as:
  - Specimen 1 = out of acceptable temperature range (negative)
  - Specimen 2 = collected under direct observation (positive)
- We count the number of individuals with testing violations, 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

[Over time, this reporting error has declined considerably]

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."



- Some licensees mistakenly selected "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)

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1) Not including city and state for the laboratory

HHS-Certified Laboratory (Primary)	Quest Diagnostics	HHS-Certified Laboratory (Backup)	Alere

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)

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

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

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 (SPTF)
Dilute Specimen, Limit of Detection (LOD) Testing

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HHS-certified laboratory reports Test Validity as "Dilute" and special analysis LOD testing under 10 CFR 26.163(a)(2) determines the specimen is drug positive

Test Validity	Was LOD testing conducted - 26.163(a)(2)?
Dilute	Yes

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

How many substances were confirmed positive for this individual? 1

Substance - 26.717(b)(2) & (b)(6)	Use NRC Cutoffs?	Initial Cutoff	Confirmatory Cutoff	Limit of Detection
Marijuana	No	25		3

Things to remember:

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

Reporting Error
24-Hour Event Reports (SPTF)

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- Typically receive a few SPTFs each year with inconsistent information from that provided in the 24-hour event report made under 10 CFR 26.719
- Inconsistency is often because the Labor Category chosen is not the "reportable" Labor Category (e.g., Facility Support instead of Supervisor)

Things to remember:
- Always select the Labor Category that required the 24-hour report (i.e., Supervisor, Licensed Operator, FFD program personnel, SSNM Transporter)
- The SPTF auto-populates "Yes" for "Is this a 24-hour reportable event" when a 10 CFR 26.719 reportable labor category is chosen
- If a Licensed Operator is also a Supervisor, report Licensed Operator

Reporting Error
Labor Category - Other (SPTF)

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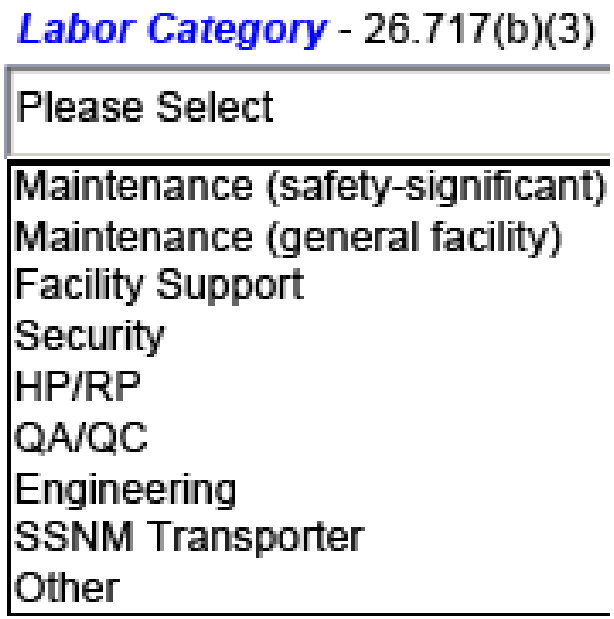
- "Other" labor category primarily selected when "Maintenance (general facility)" or "Facility support" would be appropriate

- Example "Other" labor category descriptions: 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



Are we missing any helpful Labor Categories? Let us know

Next slide provides descriptions for maintenance associated labor categories

Reporting Error
Labor Category (continued)

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Best Practice: Instead of "Other," consider one of these:

- **Maintenance (general facility)** – maintenance activities not performed on safety-or security-related structures, systems, and components (SSCs) (e.g., cleaners, painters, roofers, scaffolders)

- **Facility support** – activities and positions associated with delivery, equipment room attendant, warehousing, stocking, janitorial services, cafeteria, administrative assistants, landscaping, etc.

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)

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A positive is reported for an "Other" substance in a 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 AND at the NRC-specified minimum cutoff levels? (Yes / No) **No**

Do you test for additional substances? (Yes / No) **Yes**

How many additional substances do you want to add? (up to 6) **1**

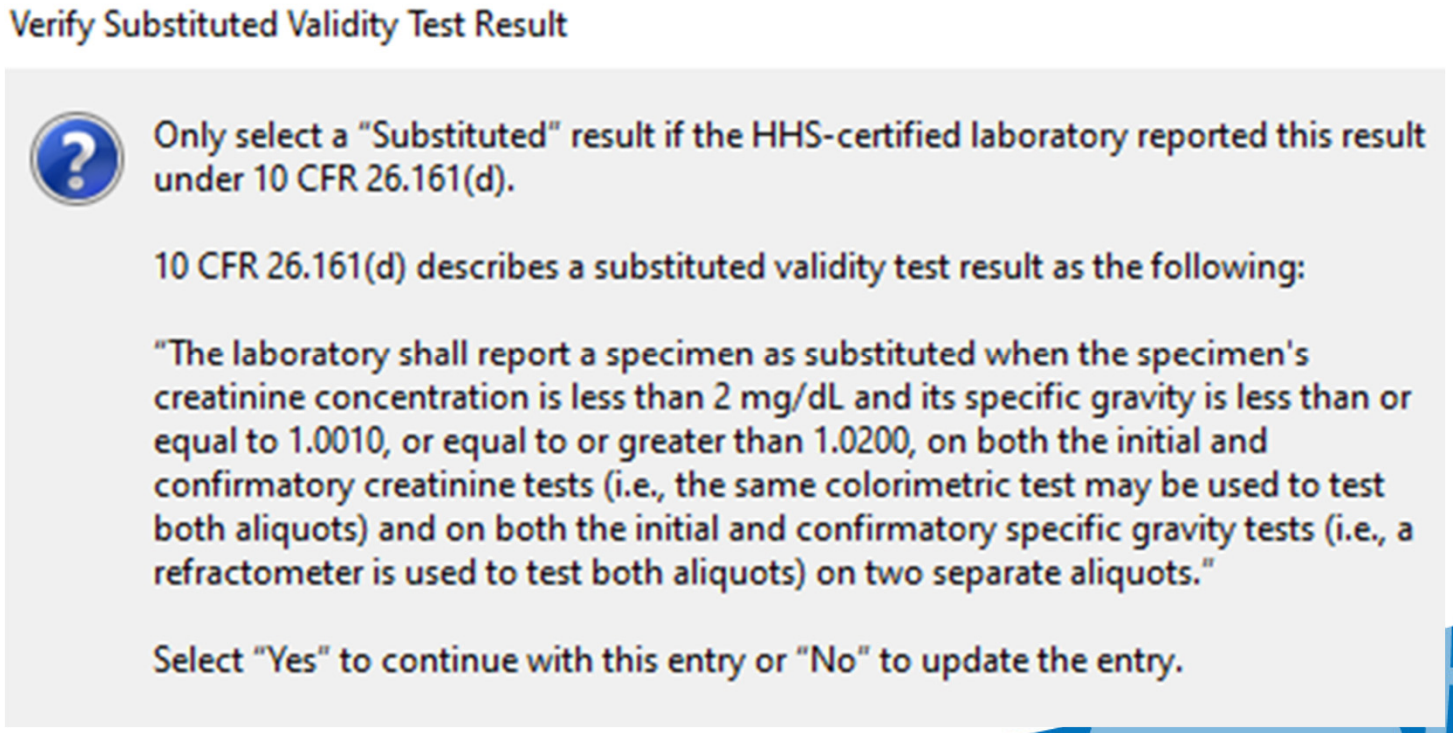
Additional Substance	Initial Cutoff	Confirmatory Cutoff	LOD Testing? (Yes / No)	Comment (Optional)
Tramadol	300	300	No	Limited to for-cause testing of two individuals

Remember this:

- If an "Other" substance is tested (either reported in a SPTF for a positive OR not), ensure that the substance is reported in the ARF.
- Use the "Comment" 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 occasionally identify the incorrect reporting of "substituted" test results for subversion attempts
- The following pop-up message will appear with additional guidance if a "Substituted" result is selected for Test Validity



Next five slides discuss how to report subversion attempts (4 cases)

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," and 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

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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? - 26.717(b)(7) & 26.75 Yes

Substance - 26.717(b)(2) & (b)(6)	Use NRC Cutoffs?
Marijuana	Yes

Subversion Attempt - Did this collection involve a subversion at

- ☐ Did not appear for testing
- ☐ Shy-bladder (no medical condition)
- ☐ Refused to provide initial specimen
- ☐ Refused to provide second specimen
- ☒ Specimen temperature (out of range)
- ☐ Specimen paraphernalia identified
- ☐ Specimen characte
- ☐ Invalid test result (i
- ☐ Refused to follow c
- ☐ Donor admitted to
- ☐ Other

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 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)

Was this collection refused? - 26.717(b)(7) & 26.75 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 Attempt - Did this collection involve a subversion

- ☐ Did not appear for testing
- ☐ Shy-bladder (no medical condition)
- ☐ 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
- ☒ Donor admitted to subversion attempt
- ☐ 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? - 26.717(b)(7) & 26.75 Yes

Substance - 26.717(b)(2) & (b)(6)	Use NRC Cutoffs?
Marijuana	Yes

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 Attempt - Did this collection involve a subversion attempt? -

- ☐ Did not appear for testing
- ☐ Shy-bladder (no medical condition)
- ☐ 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
- ☐ Donor admitted to subversion attempt
- ☐ Other

Subversion Reporting – Case 4

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

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- 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 privacy enclosure, physical characteristics of initial specimen, donor statements)

Was this collection refused? - 26.717(b)(7) & 26.75 Yes

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:

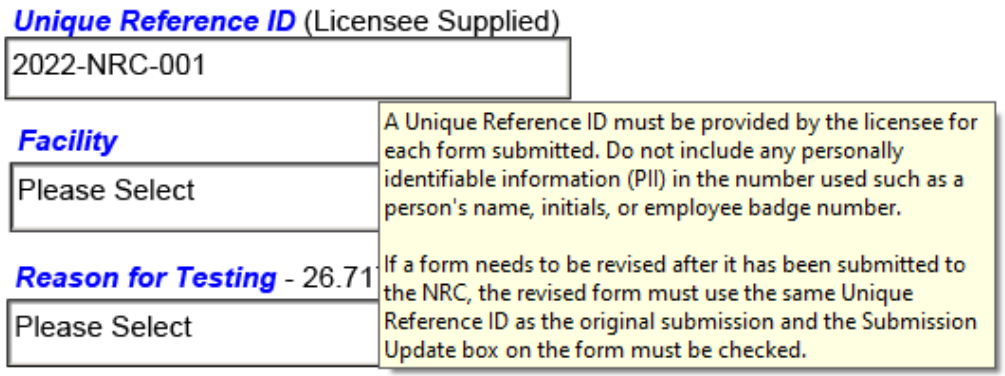
Initial specimen temperature - Temp. 101.8, Cr - 32.7, pH 7.0. Observerd collection - Temp. 97.2, Cr - 192.8, pH 6.2. Per MRO, not possible to have specimen less than 15 mins apart with this huge difference in Cr.

Reporting Error
Unique Reference ID (SPTF)

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

The NRC's data processing system:

- Uses the "Unique Reference ID" to identify 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 will contact the individual that submitted the form.

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

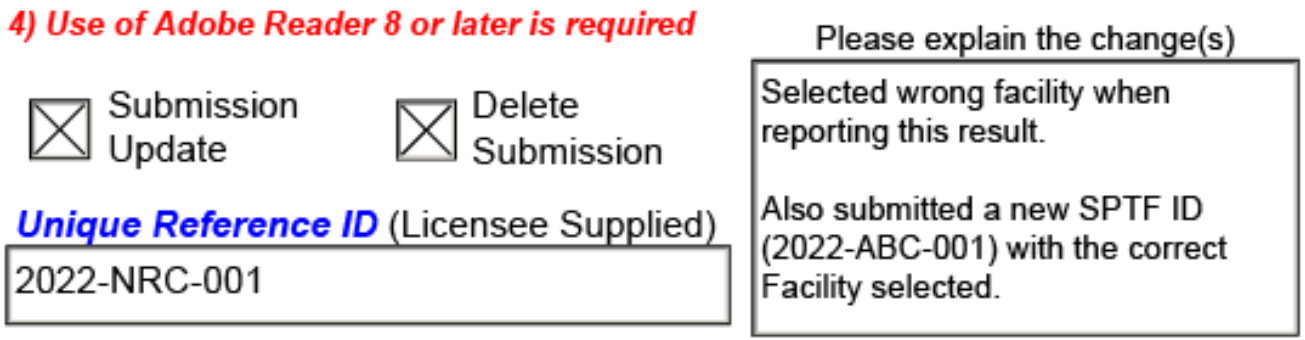
(1) Delete the original SPTF submitted that used that ID (see next slide)

(2) Submit a new SPTF with the new Unique Reference ID (this is a new submission, do not select Submission Update box)

Deleting an FFD E-Form

SPTF:

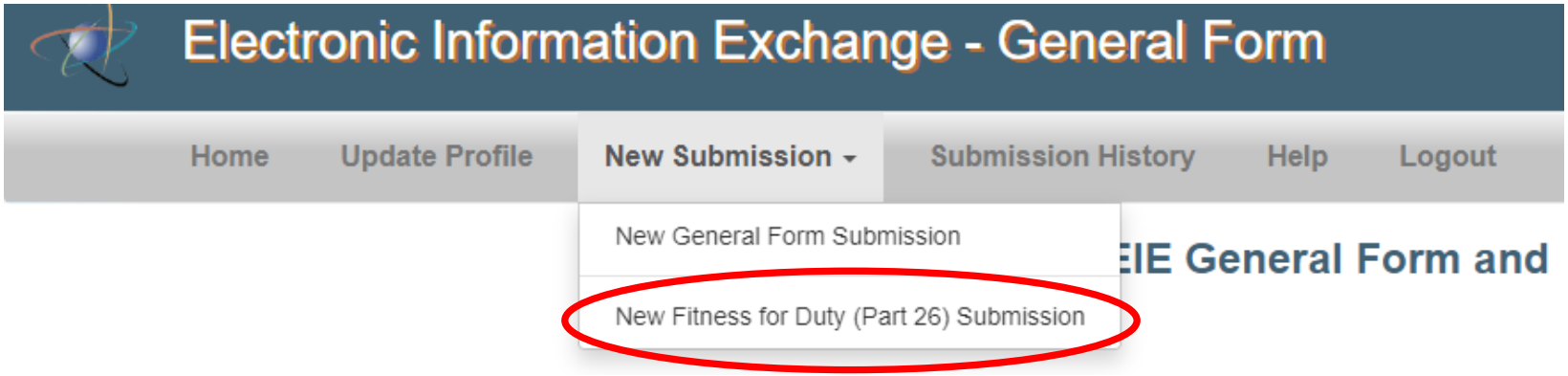
- "Unlock" the original form submitted to the NRC
  [to delete a form the same *Unique Reference ID* must be used]
- Select "Submission Update" and "Delete Submission" check boxes
- Describe why deleting the SPTF in "Please explain the change(s)" text box



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

ARF: E-mail/call the NRC FFD team for assistance

Reporting Error: EIE General Form, "New Submission" selection



Only Choose >>> **New Fitness for Duty (Part 26) Submission**

This selection ensures that the e-form(s) are automatically processed [computer code uses information in 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 "New General Form Submission." This choice directs the forms to be docketed by a human being who manually enters information on each form to docket the file in ADAMS (process takes much longer (days) and can result in document profile inconsistencies)

Reporting Error: EIE General Form, PII In "File Name" or "Document Title"

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New Fitness for Duty (Part 26) Submission

Do not provide any information in this Fitness for Duty (Part 26) submission that can connect the contents of the NRC FFD Form to an individual. For example, the file name and contents within the NRC Form must not contain the name of the individual subject to the report.

* Required field

Submitter's Information

Submitter Name Brian Zaleski **Email Address** Brian.Zaleski@nrc.gov

Certificate Expiration Date 07/05/2024

Submission Information

Submission Title *

Submission Comment

Availability Publicly Available **Submission Date** 01/09/2023

Attachment File(s)

Each submission must have at least one file attached. You may attach multiple files to a single submission so long as no single attachment exceeds 500 MB and the aggregate size of the attachments does not exceed 500 MB and the Document Title field may not contain the following characters: & " / \ < > : | ? *. Each file name should not exceed 85 characters. The attachment file type must be either PDF, XLSX, or XLS file type.

File Name *	Document Title *	Action
Choose File 2022-NRC-001.pdf	Do Not Include any PII in this Title	Remove

EIE General Form – Submission Confirmation

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General Form Submission (39956) Received

MR mshd.resource@nrc.gov
To Brian Zaleski

1. Email receipt

Reply | Reply All | Forward

Mon 1/9/2023 10:52 AM

Retention Policy 7 Year Deletion Policy (7 years) Expires 1/7/2030

The NRC received your General Form submission on: 01/09/2023 at 10.51 AM. It is being tracked as submission ID# 39956.

If it is a 'Publicly Available' submission after 6 work days from today the submission's attached document(s) will be available for viewing and download from the Agency's Public Web Based ADAMS website (https://adams.nrc.gov/wba) by searching for the following document accession number(s): [ML12345A001, ML12345A002, ML23009A663]. If this is a 'Non-Public Available' submission the submission's attachment(s) will be retained in NRC's document management system (ADAMS) and will not be published to the public website.

Should you have questions about this submission please contact our Help Desk by phone at 866-672-7640 or by e-mail at Meta_System_Help_Desk.Resource@nrc.gov. When doing so, please refer to the Submission ID# shown above.

Note: The Help Desk is staffed daily from 9:00AM to 6:00PM Eastern Time Monday through Friday (except for Federal holidays)

2. Check Submission History in EIE

Electronic Information Exchange - General Form

Home | Update Profile | New Submission | Submission History | Help | Logout

Home | Update Profile | New Submission | Submission History | Help

My Submission History

Start Date: 01/02/2023 End Date: 01/09/2023

Show 10 entries

ID	Type	# Attach	Submission Title	Date	Docket(s)
39956	Part 26	3	updated 26.717 annual performance reports for 2021	2023-01-09 10:50:05	

General Form / Fitness For Duty Submission Received

Thank you! The NRC has received your General Form submission.

Should you have questions about your submission, please refer to submission ID [39956] when calling our Help Desk at (866)672-7640.

We will notify you by e-mail when your document(s) have been assigned NRC accession number(s). If your submission is designated as 'publicly available', you may, after 6 business days, use that number to search for your document(s) in the NRC's public library at https://adams.nrc.gov/wba/.

Where Can I Get Help on FFD reporting?

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- **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 (digital certificate is locally based on one computer)
  - 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)
  - FAQ email: fitnessforduty.resource@nrc.gov

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Questions