

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 14, 2025 (Webinar)



Webinar Discussion Topics



- Opening Remarks
- FFD program performance reporting requirements
- FFD electronic reporting forms (NRC Forms 890 and 891)
- Lessons Learned and Best Practices
- Question and Answer Session



Annual FFD Program Performance Reporting Requirements



- FFD program performance data reporting requirements:
 - 26.717 (Operating power reactor; Category I special nuclear material)
 - 26.417(b)(2) (Power reactor under construction) none currently
- Reports due to the NRC before March 1 after calendar year end 26.717(e)
- FFD program performance information reported under 26.717(b) includes:
 - 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)



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:

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



FFD E-forms – Use and Advantages



Advantages:

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



- Performed by NRC FFD staff 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



Forms not Validated & Locked ARF/SPTF Totals Mismatch Multiple SPTFs for the Same Event Reason for Testing – For Cause HHS-Certified Laboratory (Location information) Special Analyses Testing (Dilute specimens, Observed specimens) 24-Hour Event Reports Labor Category – Other All examples based on **Expanded Drug Testing Panel** FFD program performance report reviews and lessons Substituted Test Validity Result learned from those reviews Subversion Reporting (4 Cases) Unique Reference ID Deleting an FFD E-form Submitting E-forms to the NRC (EIE General Form Submissions)

Reporting Error: Unlocked Forms



Validate & Lock

Final Step (Required) – NRC will consider this form (i.e., SPTF, ARF) authentic in accordance with 10 CFR 26.11 only when the "Validate & Lock" button is selected, any errors highlighted in red have been corrected, and the "Locked" button appears on the form.

Locked

Form Locked On: Jan 14, 2025 at 11:13:21 AM

The "Validate & Lock" button will change to "**Locked**" after the data validation process has successfully completed. The form is now ready to submit to the NRC.

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

Reporting Error: ARF/SPTF Totals Mismatch



1. 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 (\underline{21 \text{ results}}) = \underline{\text{Pre-Access (13)}}, Random (6), Followup (2)
SPTF (\underline{20 \text{ results}}) = \underline{\text{Pre-Access (12)}}, Random (6), Followup (2)
```

2. 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 (19 results) = <u>Pre-Access (15)</u>, <u>Random (3)</u>, Followup (1) SPTF (19 results) = <u>Pre-Access (14)</u>, <u>Random (4)</u>, Followup (1)
```

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-2024-01; ABC-2024-02; ABC-2024-03; ABC-2024-05)

Reporting Error





- 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 FFD testing violations, <u>not</u> the number of specimens tested to determine that an individual has violated the FFD 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

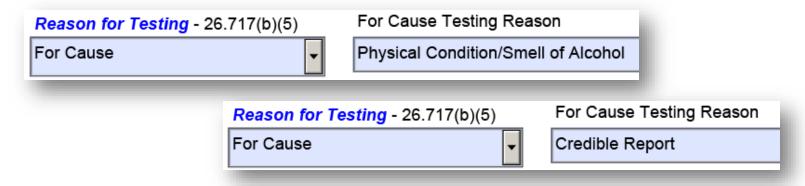
[Over time, this reporting error has declined considerably.]

Reporting Error





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



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

Reporting Errors

HHS-Certified Laboratories (ARF)



- 1) Not including city and state for the laboratory Especially important when a laboratory has multiple locations. For example:
- HHS-Certified Laboratory (Primary)

 HHS-Certified Laboratory (Backup)
- LabCorp (Research Triangle Park, NC; Southaven, MS)
- Alere (Gretna, LA; Richmond, VA)
- 2) Not providing a response for both HHS-certified laboratory fields

HHS-Certified Laboratory (Primary)	_
HHS-Certified Laboratory (Backup)	

- Include City and State for each HHS-certified laboratory
- Include Backup laboratory (performs Bottle B split specimen testing, or retesting of an aliquot of a single specimen)
- If no Backup laboratory maintained under contract, provide that information in the Summary of Management Actions section in the ARF

Reporting Error (SPTF) (2022 Part 26 Final Rule)

Dilute Specimen, Limit of Quantitation (LOQ) Testing



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

Test Validity	Test Validity Was special analyses LOQ testing conducted - 26.163(a)(2)?						
Dilute	Yes			~			
Was this collection ob	served? - 26.717(b)(7) & 26.75	No 🔻		_			
How many substances were confirmed positive for this individual?							
Substance - 26.717(b)(2	2) & (b)(6)	Use NRC Cutoffs?	Initial Cutoff	Confirmatory Cutoff	Limit of Quantitation		
Marijuana		No 🔽	20		3		

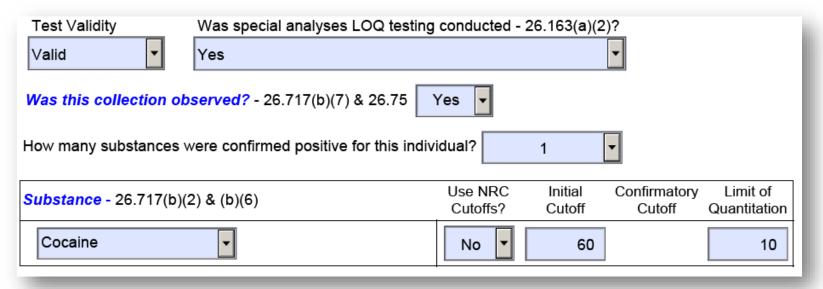
- Choose "Dilute" for Test Validity
- Initial Cutoff value is 40% of the standard cutoff level
- Confirmatory Cutoff value is the LOQ for the testing assay
 (the LOQ is laboratory specific; do not report the actual quantitative test result)

Reporting Error (SPTF) (2022 Part 26 Final Rule)

Observed Specimen LOQ Testing



Donor specimen is collected under direct observation, special analyses LOQ testing is performed under 10 CFR 26.163(a)(2), and the specimen is drug positive.



- Initial Cutoff value is 40% of the standard cutoff level
- Confirmatory Cutoff value is the LOQ for the testing assay
 (the LOQ is laboratory specific; do not report the actual quantitative test result)





Is this a 24-hour reportable event under 2	6.719(b)? Yes ▼	Please elaborate on the 24-hour rep Event 12345 (09/17/2024)	ortable event
Labor Category - 26.717(b)(3) Licensed Operator ▼	Labor Category - 26.717(b)(3) Supervisor	Labor Category - 26.717(b)(3 FFD Program Personnel)

- Each year the NRC identifies a few SPTFs that have inconsistent information from that provided in the 24-hour event report made to the NRC headquarters operations center under 10 CFR 26.719(b)(3)
- The inconsistency is often that the Labor Category chosen is not "reportable" (e.g., "Facility Support" instead of "Supervisor")

- Select the "Labor Category" that required the 24-hour report to the NRC (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 an individual is a Licensed Operator and a Supervisor, choose Licensed Operator for the Labor Category and include additional information in the "Please elaborate on the 24-hour reportable event"

Labor Category - Other



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

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

Next slide provides descriptions for maintenance associated labor categories

Labor Category (continued)



Best Practice: Instead of using **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)

Expanded Panel Testing



"Other" substance positive reported in a SPTF

Sı	ubstance - 26.717(b)(2) &	(b)(6)
	Other: Methadone	-

"Other" substance not reported in the ARF (Additional Substances Tested)

Substances Tested Did your program only test for NRC-required substances AND at the NRC-specified minimum cutoff levels?						
Additional Substances Tested						
Did your program test for any additional substances? Yes How many additional substances do you want to add? (up to 6)						
Additional Substance	Initial Confirmatory Cutoff Cutoff		Comment (Optional)			
Methadone	300	300				

- If an "Other" substance is tested (either reported in a SPTF for a positive <u>OR</u> not), ensure that the substance is reported in the ARF
- Use the "Comment" box in the ARF "Additional Substances Tested" table
 (e.g., to describe if testing limited to a person, a particular reason for testing)

Test Validity – Substituted Result



- NRC receipt reviews <u>occasionally</u> 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"

Verify Substituted Validity Test Result

Only select a "Substituted" result if the HHS-certified laboratory reported this result under 10 CFR 26.161(d).

Test Validity

10 CFR 26.161(d) describes a substituted validity test result as the following:

"The laboratory shall report a specimen as substituted when the specimen's creatinine concentration is less than 2 mg/dL and its specific gravity is less than or

"The laboratory shall report a specimen as substituted when the specimen's creatinine concentration is less than 2 mg/dL and its specific gravity is less than or equal to 1.0010, or equal to or greater than 1.0200, on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots."

Select "Yes" to continue with this entry or "No" to update the entry.

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

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

1st specimen temp issue, 2nd specimen positive



Initial specimen is out of temperature range (negative results), and the 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? - 26.71	17(b)(7) & 26.75 Ye	Yes 🔻
Substance - 26.717(b)(2) & (b)(6)		Use NRC Cutoffs?
Marijuana		No 🔻
		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
☐ Did not appear for testing		tractility from the observed collection were confirmed notifive
☐ Shy-bladder (no medical condition)	☐ Invalid test result (i	for marijuana by the MRO. Subversion was determined by
☐ Refused to provide initial specimen	☐ Refused to follow of	dthe MRO based on drug test results.
☐ Refused to provide second specimen	☐ Donor admitted to	subversion attempt
Specimen temperature (out of range)	☐ Other	
☐ Specimen paraphernalia identified		

Testing Refusals



- Donor failed to appear for a test
- 1st specimen out of temperature range, donor refused directly observed 2nd specimen
- Collector discovered subversion paraphernalia and collection process stopped
- Inability to provide a specimen (shy-bladder with no 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:
Subversion Attempt - Did this collection		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.
☐ Did not appear for testing	Unusual sound(s)/abs	ence of sound during unobserved collection
Shy-bladder (no medical condition)	Specimen characterist	ics (e.g., color, odor, precipitant)
Refused to provide initial specimen	■ Invalid test result (initial	al specimen collected) - 26.185(f)
Refused to provide second specimer	Refused to follow direct	ctions
Specimen temperature (out of range)) ⊠ Donor admitted to sub	version attempt
Specimen paraphernalia identified	Other	

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	
		Please elaborate on the choice(s) selected:
Substance - 26.717(b)(2) & (b)(6)	Use NRC Cutoffs?	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
Marijuana •	No 🔻	(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
Subversion Attempt - Did this collect	ction involve a subversion attempt? -	confirmed positive test result for marijuana on the 2nd specimen collected under direct observation .
☐ Did not appear for testing	Unusual sound(s)/absence of so	ound during unobserved collection
☐ Shy-bladder (no medical condition)	Specimen characteristics (e.g., or specimen characteristics) ∴ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓	color, odor, precipitant)
	☑ Invalid test result (initial specime)	en collected) - 26.185(f)
$\hfill\square$ Refused to provide second specimen	Refused to follow directions	
☐ Specimen temperature (out of range) $lacksquare$ Donor admitted to subversion at	tempt
☐ Specimen paraphernalia identified	Other	
	_	

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



- Report "Yes" to "Was this collection refused?"
- MRO subversion determination based on one or more of the following:
 - ☐ Significant differences in specimen temperature between two specimens collected
 - ☐ Differences in physiological properties of the specimens (creatinine levels, specific gravity, pH)
 - ☐ Specimen collector observations (e.g., unusual noises in privacy enclosure, physical characteristics of initial specimen, donor statements)

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



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

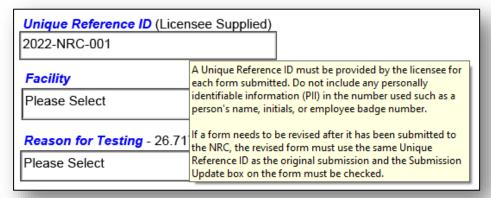
Unique Reference ID (SPTF)



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:

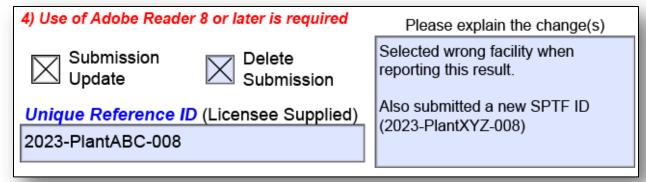
- (1) Delete the original SPTF submitted that used that ID (see next slide)
- (2) Submit a new SPTF with the new Unique Reference ID (this is a new submission, do not select Submission Update box)

Deleting an FFD E-Form

United States Nuclear Regulatory Commission Protecting People and the Environment

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

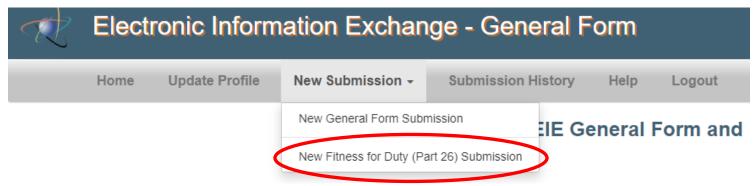


"Validate & Lock" form and submit to the NRC using the EIE General Form

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

Reporting Error: Submitting Forms to the NRC 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 into ADAMS (this process takes much longer (days) and can result in document profile inconsistencies)

Reporting Error: EIE General Form Entries No PII In "File Name" or "Document Title"



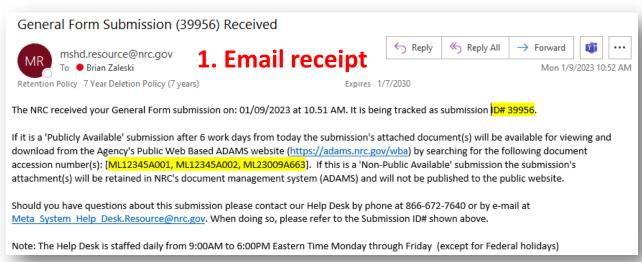


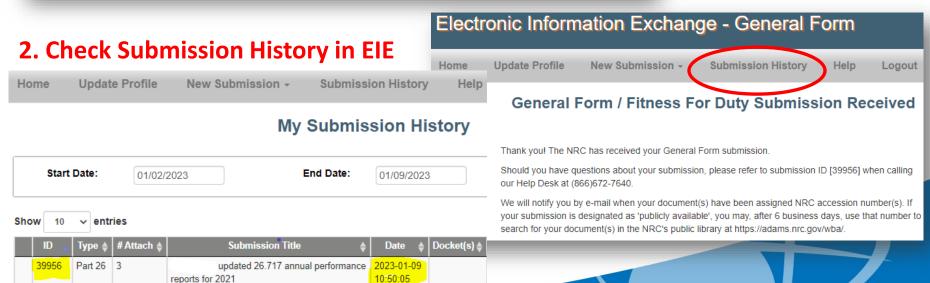
Electronic Information Exchange - General Form

Home l	Jpdate Profile	New Submission →	Submission History	Help	Logout		
		New	Fitness for Duty	(Part 2	26) Subr	nission	
		this Fitness for Duty (Part 2 st not contain the name of t			ntents of the	NRC FFD Form to an individual. For exam	ple, the file name and
* Required field							
Submitter'	s Information						
Submitt	ter Name	Brian Zaleski		Email	Address	Brian.Zaleski@nrc.gov	
Certific	ate Expiration Date	01/09/2026					
Submissio	n Information						
Submis	sion Title *						
Submis	sion Comment						
Availab	ility	Publicly Available	Submission Date	02/13/2024			
Attachmer	nt File(s)						
of the attachm	ents does not excee		itle field may not contain th	_		g as no single attachment exceeds 1 GB & " / \ < > : ? *. Each file name should not	
		File Name *			Docu	ıment Title *	Action
Cho	ose File PlantABC	S-SPTF-2023-01.pdf	Do NOT in	nclude ANY	PII in this TI	TLE or the FILE NAME	Remove

EIE General Form – Submission Confirmation







Checklist Prior to Submitting - Recap



☐ ARF/SPTF: ensure all forms are Validated & Locked to verify complete and accurate (green "Locked" button appears at bottom of form) ☐ ARF/SPTFs: verify Reason for Testing totals are same (no mismatches) ☐ SPTF: subversion attempt information ✓ Verify relevant subversion checkboxes selected to capture text description ☐ SPTF: special analyses testing (verify correct cutoff levels reported) ✓ Use NRC Cutoffs? = select "No" ✓ Initial Cutoff = 40% of standard NRC cutoff listed in 10 CFR 26.163 ✓ Limit of Quantitation = specific to each HHS laboratory □ SPTF: verify 24-hour report information (26.719) is included, if applicable ✓ Labor category requiring 26.719 report is selected (e.g., Supervisor, Licensed Operator) ☐ Delivering the mail – NRC EIE General Form Submission ✓ Select "New Fitness for Duty (Part 26) Submission" to correctly route, automatically docket, and to receive confirmation email of submission

Where Can I Get Help on FFD reporting?



- Problems "Delivering the Mail" EIE General Submission Portal Contact EIE help desk at 866-672-7640 (<u>mshd.resource@nrc.gov</u>)
 - 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 (<u>Brian.Zaleski@nrc.gov</u>)
 - FAQ email: <u>fitnessforduty.resource@nrc.gov</u>



Questions