

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

February 13, 2024 (Webinar)

ML24043A177

Webinar Discussion Topics



- 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



- 10 CFR Part 26 reporting requirements:
 - 26.717 (Operating power reactor; Category I special nuclear material)
 - 26.417(b)(2) (Power reactor 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)



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



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

A d	lvantages:
	☐ 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
Dа	ta 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 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



- Unlocked Forms
- ARF/SPTF Totals Mismatch
- Multiple SPTFs for the Same Event
- Reason for Testing For Cause
- HHS-Certified Laboratories
- Special Analyses Testing (Dilute specimens)
- 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



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 selected and all errors (highlighted in red) have been corrected

Validate & Lock

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

Locked

Form Locked On: Feb 13, 2024 at 10:22:01 AM

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



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)
```

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-2023-01; ABC-2023-02; ABC-2023-03; ABC-2023-05)





- 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, <u>not</u> 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)

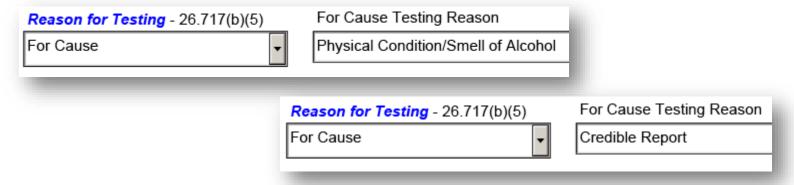
- One individual one SPTF
- One individual one Reason for Testing

[Over time, this reporting error has declined considerably]

Reason for Testing – For Cause



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" information and the Subversion Description detail

HHS-Certified Laboratories (ARF)



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) (pre-2022 Part 26 Final Rule)



Dilute Specimen, Limit of Detection (LOD) Testing

HHS-certified lab 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 - 26.1 Dilute ▼ Yes	63(a)(2)?			
Was this collection observed? - 26.717(b)(7) & 26.75	No 🔻			
How many substances were confirmed positive for this indiv	ridual?	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 (SPTF) (2022 Part 26 Final Rule)

Dilute Specimen, Limit of Quantitation (LOQ) Testing United States Nuclear Regulatory Commission



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

Test Validity	Was special analyses LOQ testing	conducted - 20	6.163(a)(2)	?	
Dilute ▼	Yes			•	
Was this collection ob	served? - 26.717(b)(7) & 26.75	No 🔻			
How many substances w	vere confirmed positive for this indiv	idual?	1	•	
Substance - 26.717(b)(2	2) & (b)(6)	Use NRC Cutoffs?	Initial Cutoff	Confirmatory Cutoff	Limit of Quantitation
Marijuana		No 🔽	20		3

Things to remember:

- Choose "Dilute" for Test Validity
- Ensure initial cutoff is 40% of the standard cutoff level
- Confirmatory cutoff is the LOQ for the testing assay (do not report the actual quantitation of the test)

24-Hour Event Reports (SPTF)





- A few SPTFs each year have inconsistent information from that provided in the 24-hour event report made 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)

Things to remember:

- Always 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 Labor Category that is reportable under 10 CFR 26.719 is chosen
- If a Licensed Operator is also a Supervisor, report Licensed Operator

Labor Category - Other (SPTF)



- "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 "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 (SPTF/ARF)



"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 N	RC-required sub	ostances <u>AND</u> a	t the NRC-specified minimum cutoff levels?
Additional Substances Tested			
Did your program test for any additional substa	ances? Yes	▼ How r	many additional substances do you want to add? (up to 6)
Additional Substance	Initial Cutoff	Confirmatory Cutoff	Comment (Optional)
Methadone	300	300	

Remember this:

- 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 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 🔻	
		Please elaborate on the choi	ce(s) selected:
Subversion Attempt - Did this collection i	nvolve a subversion atte	Subject provided an initial specim	•
☐ Did not appear for testing	☐ Specimen character	The results of this specimen were immediately recollected under dir	
☐ Shy-bladder (no medical condition)	☐ Invalid test result (in	results from the observed collecti	on were confirmed positive
☐ Refused to provide initial specimen	☐ Refused to follow di	for marijuana by the MRO. Subvithe MRO based on drug test resu	ersion was determined by
☐ Refused to provide second specimen	☐ Donor admitted to s	upversion attempt	into:
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) se	elected:
Subversion Attempt - Did this collect		Individual provided specimen that was clember with no temp. While re-hydrating, individual technician that he brought in his wife's urpant leg and showed the technician that sock.	vidual admitted to ine. He lifted up his
☐ Did not appear for testing	☐ Unusual sound(s)/ab	sence of sound during unobserved collection	
☐ Shy-bladder (no medical condition)	⊠ Specimen characteri	stics (e.g., color, odor, precipitant)	
☐ Refused to provide initial specimen	■ Invalid test result (initial)	tial specimen collected) - 26.185(f)	
☐ Refused to provide second specimer	n ☐ Refused to follow dire	ections	
⊠ Specimen temperature (out of range) ⊠ Donor admitted to su	bversion 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	v
		Please elaborate on the choice(s) selected:
Substance - 26.717(b)(2) & (b)(6) Marijuana	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 (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	sound during unobserved collection
Shy-bladder (no medical condition)	Specimen characteristics (e.g.	, color, odor, precipitant)
	☑ Invalid test result (initial specing)	nen collected) - 26.185(f)
Refused to provide second specimen	n Refused to follow directions	
☐ Specimen temperature (out of range	e) Donor admitted to subversion	attempt
☐ 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)
 - 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



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.



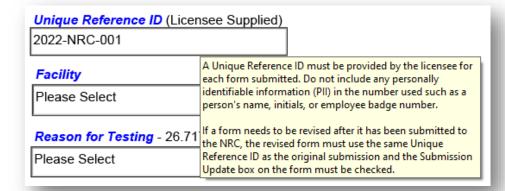
Unique Reference ID (SPTF)



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:

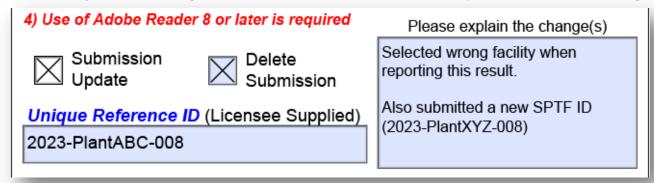
- (1) Delete the original SPTF submitted that used that ID (see next slide)
- (2) Submit a new SPTF with the new Unique Reference ID (this is a new submission, do not select Submission Update box)

Deleting an FFD E-Form

U.S.NRC 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

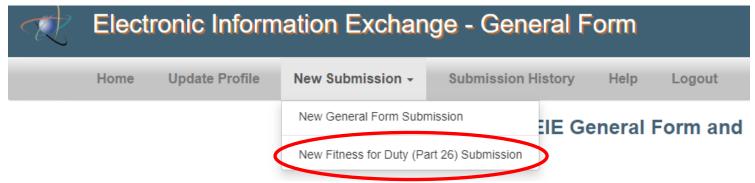


"Validate & Lock" form and submit to the NRC using the EIE General Form

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

Reporting Error: 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 No PII In "File Name" or "Document Title"





Electronic Information Exchange - General Form

Do not provide any information in t			ty (Part 26) Subr	NRC FFD Form to an individual. For e	example, the file r
contents within the NRC Form mus					
* Required field					
Submitter's Information					
Submitter Name	Brian Zaleski		Email Address	Brian.Zaleski@nrc.gov	
Certificate Expiration Date	01/09/2026				
Submission Information					
Submission Title *					
Submission Comment					
Availability	Publicly Available	Submission Date	02/13/2024		
Attachment File(s)					
Each submission must have at leas	t one file attached. You ma	ay attach multiple files to	a single submission so lon	g as no single attachment exceeds 1	GB and the aggre

EIE General Form – Submission Confirmation U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

General Form Submission (39956) Received → Forward ← Reply ≪ Reply All mshd.resource@nrc.gov 1. Email receipt To Brian Zaleski Mon 1/9/2023 10:52 AM Retention Policy 7 Year Deletion Policy (7 years) The NRC received your General Form submission on: 01/09/2023 at 10.51 AM. It is being tracked as submission D# 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)

updated 26.717 annual performance 2023-01-09

10:50:05

Part 26

reports for 2021

Electronic Information Exchange - General Form 2. Check Submission History in EIE Home **Update Profile** New Submission -Submission History Help Logout **Update Profile** New Submission -Submission History Home Help General Form / Fitness For Duty Submission Received My Submission History 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 Start Date: End Date: 01/02/2023 01/09/2023 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/. Submission Title Docket(s)

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