U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Fitness for Duty Drug Testing Requirements Final Rule

Cumulative Effects of Regulation

Public Meeting
April 13, 2021

ADAMS Accession No. ML21096A010

Announcements

- Information Meeting with a Question and Answer Session
- Teleconference Number (for audio)
  1-800-857-4880 passcode: 9110579
- WebEx (to view presentation only)
  https://usnrc.webex.com/usnrc/onstage/g.php?MTID=e2310294fec870e6d5acad2a21196dca3

Meeting Guidelines

- Identify yourself when speaking
  - Please state your name, organization, and question
  - Feedback during the meeting can only be provided using the bridge line

Agenda

9:00–9:10 AM	Welcome/Introductions/Logistics
9:10–9:30 AM	Substantive Changes to Final Rule
9:30–9:40 AM	Effective Date of Final Rule (Cumulative Effects of Regulation)
9:40–10:00 AM	Public Feedback and Questions, Closing NRC Remarks, and Adjourn

Providing Feedback

- Feedback received today on cumulative effects of regulation (CER) issues will be captured in the meeting transcript
- Feedback on this meeting can submitted in two ways, discussed at the end of the presentation

Meeting Purpose

- Discuss proposed effective date of final rule
- Obtain public feedback on the effective date as it pertains to CER
- Discuss substantive changes to final rule
- NRC will not provide written responses to any comments made at this meeting

Background–Schedule

Sept. 16, 2019	Proposed rule published (84 FR 48750) to align Part 26 with select drug testing provisions in the 2008 HHS Guidelines
Dec. 2, 2019	Public comment period closed (22 public comment submissions)
Sept. 15, 2021	NRC staff submits the final rule package to the Commission to obtain approval to publish the final rule

Cumulative Effects of Regulation

- CER is a term used by the NRC to refer to the challenges that licensees and other entities face while implementing multiple regulatory actions within a limited implementation period and with limited available resources
- This CER public meeting is intended to obtain feedback during the final rule development to inform the implementation schedule

CER Considerations

- Substantive changes to the final rule
- NRC staff's expectations for rule implementation date
- Public feedback

Drug Testing Panel
Proposed Rule Changes

- Lower testing cutoff levels:
  - Amphetamine
  - Methamphetamine
  - Cocaine metabolite
- Add two amphetamine-based drugs:
  - Methylenedioxymethamphetamine (MDMA)
  - Methylenedioxyamphetamine (MDA)
- Revise testing approach for 6-Acetylemorphine (6-AM)

Subversion Attempt Detection
Proposed Rule Changes

Revise special analyses testing provisions in § 26.163(a)(2):

- Require special analyses testing when a specimen with a dilute validity test result has a drug or drug metabolite concentration at least 40 percent of initial test cutoff
- Change confirmatory test cutoff from the Limit of Detection (LOD) to the Limit of Quantitative (LOQ)

Subversion Attempt Detection
Proposed Rule Changes

Add special analyses testing for four direct observation collection conditions:

- Donor provided a urine specimen with a substituted, adulterated, or invalid test result with no adequate medical explanation
- Donor's specimen outside acceptable temperature range (90–100°F)
- Donor's conduct indicates possible subversion attempt
- Specimen unavailable for retesting (Bottle B or single specimen)

Shy-Bladder Process
Proposed Rule Change

- Permit a member of the FFD program personnel to observe a donor during the hydration process. Change would permit the initial collector to perform other activities (e.g., other collections)

Final rule eliminates proposed requirement that hydration monitor be FFD program personnel

Questions in Proposed Rule Substantive Comment Received

- *2017 HHS Guidelines—New Test Analytes*

  Should hydrocodone, hydromorphone, oxycodone, and oxymorphone be added the drug testing panel?

- *Direct Observation of Specimen Collection*

  Any effective alternatives to direct observation that will assist in preventing subversion of the drug testing process?

Substantive Rule Changes Due to Public Comment

- Expand drug testing panel to include four additional opioids (hydrocodone, hydromorphone, oxycodone, oxymorphone) in the 2017 HHS Guidelines
- Provide option to collect an oral fluid specimen for direct observation conditions

Question in Proposed Rule on Effective Date

- One commenter recommended 120 days (to understand and communicate changes to all departments and sections)
- Another commenter recommended 1 year (to implement the new program utilizing established procedures and will need to evaluate change management plan items to include procedures, union/lab contracts, computer systems, and training)

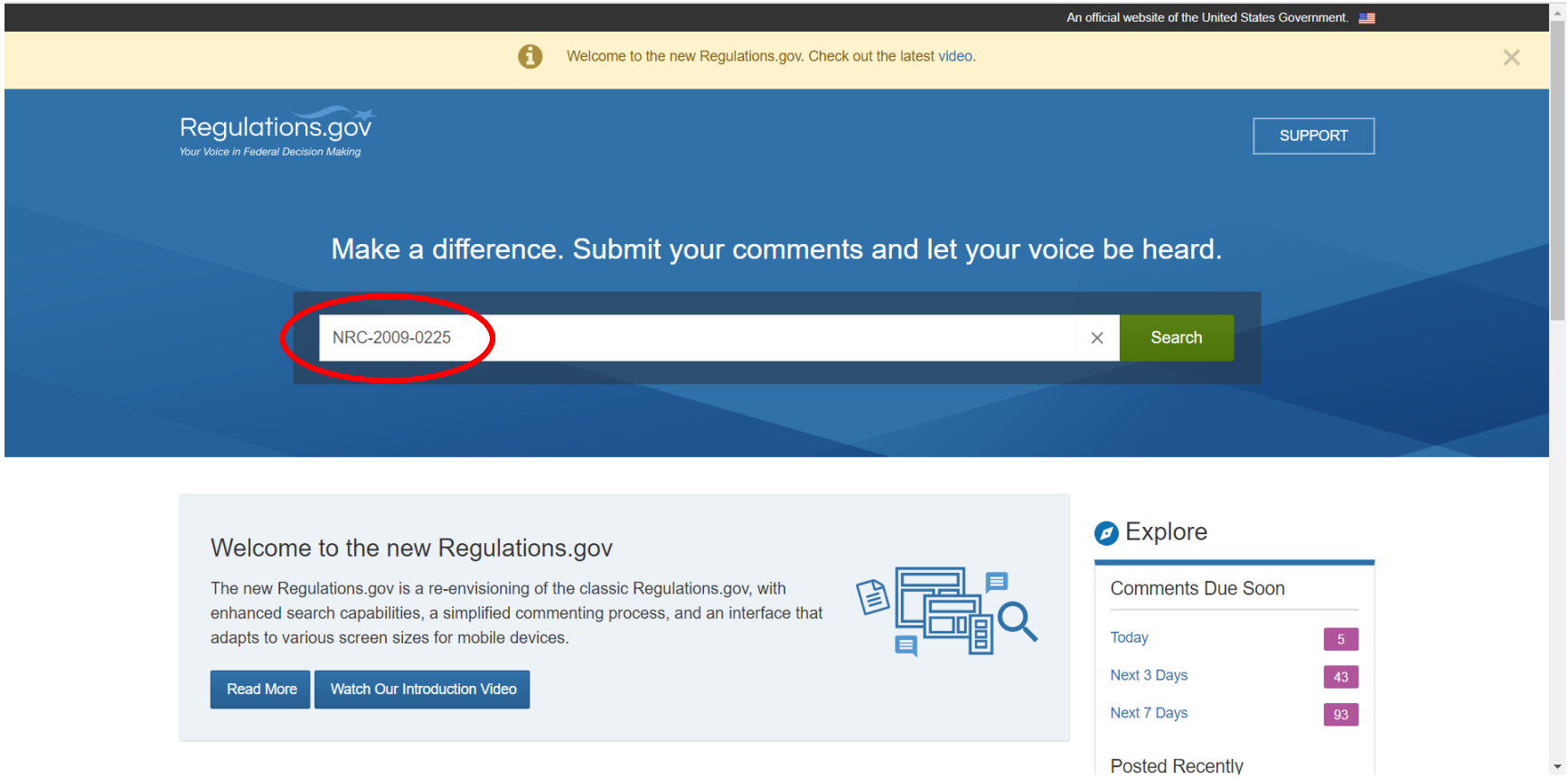
NRC Staff Expectations

Proposed 60-day implementation schedule is not expected to result in a cumulative impact on affected licensees and other entities because:

- No other pending 10 CFR Part 26 regulatory actions exist that would impact the site professionals responsible for implementing the rule requirements
- Changes to FFD policy, procedures, contracts, and training are minimal
- Implementation guidance will be issued with the rule

Open Discussion and Questions

Where to Find Information



Search for docket ID NRC-2009-0225

How did we do?

Use this QR code

OR

Use “Meeting Feedback Form” link available in the NRC meeting notice

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Thank You