Agency Information Collection Ac
CCF Summary of C

Comment Number	Date Received	Organization
1	2/20/2020	(1) Tennessee Valley Authority, (2) First Advantage, (3) Substance Abuse Program Administrators Association
2	2/20/2020	Tennessee Valley Authority Candace Clepper Sr. Program Manager TVA Non-Nuclear Fitness for Duty 400 West Summit Hill Drive Knoxville TN 37902 (423) 751-4502 clclepper@tva.gov
3	2/20/2020	Tennessee Valley Authority Candace Clepper Sr. Program Manager TVA Non-Nuclear Fitness for Duty 400 West Summit Hill Drive Knoxville TN 37902 (423) 751-4502 clclepper@tva.gov
4	4/10/2020	(1) Tennessee Valley Authority, (2) First Advantage, (3) Substance Abuse Program Administrators Association
5	4/10/2020	(1) Substance Abuse Program Administrators Association, (2) First Advantage, (3) FS Solutions
6	4/10/2020	(1) Substance Abuse Program Administrators Association, (2) First Advantage

7	4/10/2020	(1) Substance Abuse Program Administrators Association, (2) First Advantage
8	4/10/2020	(1) Substance Abuse Program Administrators Association, (2) First Advantage
9	4/10/2020	(1) Substance Abuse Program Administrators Association, (2) First Advantage
10	4/13/2020	Carolann Hunt Defense Logistics Agency (DLA) HQ J14 Policy Classification and Drug Testing Programs Carolann.Hunt@dla.mil 717-770-5182 DSN 771
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12	4/13/2020	Dynacare Marilyn Matthews matthewsm@dynacare.ca
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19	4/13/2020	Dynacare Marilyn Matthews matthewsm@dynacare.ca
20	4/13/2020	DriverCheck, Inc. Brandon Kearse Privacy and Compliance Coordinator 1 Manley Street, AYR, ON, N0B 1E0, Canada (800) 463-4310 Ext. 694 DRIVERCHECK@DRIVERCHECK.CA
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:tivities: Proposed Collection; Comments Request 85 Fed. Reg. 7776 (February 11, 2020)
:omments and SAMHSA's Responses as of 5/20/2020

PRA Revised Summary of Comments
The commenter identified an error in the 60-Day FRN published in which a revision was attributed to the incorrect numbered items on the form.
The commenter recommended not removing form completion instructions from back of form copy 5. The recommendation was based on concerns for completion errors or specimen donors challenging being informed of the collection process.
The commenter recommended revision of the specimen collector and donor certification statement to reflect situations when a specimen is not collected.
The commenter recommend not removing the Medical Review Officer (MRO) section from form copies other than the MRO copy.
The commenter requested a revision to add CDL State and No. to the CCF to align it with regulatory changes made by the Federal Motor Carrier Safety Administration (FMCSA).
The commenter requested the addition of a checkbox for situations where oral fluid is being used subsequent to a collection attempt of urine specimen that was insufficient.

The commenter expressed concern that removing analyte names and checkboxes from forms in 5a could lead to confusion due to illegible handwriting and abbreviation use.
The commenter inquired if a plan had been developed to address when specimens are sent to a laboratory not certified to test them. The commenter also inquired whether guidance exists related to the requirement to establish separate account numbers for each specimen type from the same donor.
The commenter recommended the "Observed" box in Step 2 be used only for urine specimen collections.
The commenter expressed concerns over delays related to the use of CCF carbon copies.
The commenter recommeded the addition of a "Shy Bladder" section on the CCF for collector to record attempt information.
The commenter requested a French translation of the new CCF for submissions to a Canadian laboratory.
The commenter recommended OCR revision for the new CCF.
The commenter expressed concerns related to space on the CCF allowing for a Non-DOT version.
The commenter expressed concerns about the ability to access the specimen tube expiration date if seals are applied a certain way.

The commenter inquired about functionality of seals for shorter oral fluid specimen tubes.
The commenter expressed concerns that in Step 5a the space for entering analyte names, results and comments might be an issue for multiple drug positive results.
The commenter inquired whether there is a need for shipping barcodes.
The commenter inquired whether there is sufficient space in Step 5 on form copies 2-5 for email addresses and phone numbers.
The commenter recommended the addition of a section for the inclusion of oral fluid collection device lot number and expiration date on the CCF.
The commenter recommended including word "saliva" in the donor sample certification statement on copy 2 of the CCF.

SAMHSA Response
SAMHSA acknowledges the numbering error on 60-Day FRN. The form proof reflects the proposed revision of the correct items.
SAMHSA appreciates the comment but there is insufficient space to provide clear instructions fo each specimen type on the Federal CCF. There are numerous alterantives that collectors/collectio sites can comply with the requirement to allow the donor to read the instructions.
SAMHSA appreciates the comment but will not be making the recommended revision to the statement as the collector must record the reason for not collecting a specimen on the Remarks lir and mark the None Provided box in Step 2. SAMHSA will revise the Urine and Oral Fluid Collection Handbooks to include this instruction.
DOT's Office of Drug and Alcohol Policy and Compliance (ODAPC) requested that HHS keep th MRO reporting sections (Steps 6 and 7) on Copies 3-5, and keep the Public Burden Statement on the back of pages, consistent with the 2017 Federal CCF, to faciliate DOT audits of MRO records HHS has complied with this DOT request.
SAMHSA agreed to the revision to align the CCF with the regulatory changes made by FMCSA.
SAMHSA addresses this topic in UrMG Sections 8.5(f)(3) and 8.7 and OFMG Section 8.6(b)(2). Also guidance will be included in the HHS Specimen Collection Handbooks (i.e., for Urine and f Oral Fluid).

SAMHSA appreciates the comment but disagrees with the recommendation because certifying scientists are currently required to record analyte names/abbreviations, concentrations, and required comments in Step 5a of the CCF.
The National Laboratory Certification Program (NLCP) requires all certified labs to have procedures for misdirected specimens, which would be used if an HHS-certified urine testing laboratory received an OF specimen (or vice versa). The use of account numbers is between the laboratory and its clients, and is outside SAMHSA's purview.
The "Observed" checkbox is intended for urine collections only, and is located on the URINE lin in Step 2. However, SAMHSA made further distinction with the addition of a horizontal line to separate the URINE line from the COLLECTION line above.
SAMHSA currently allows the use of the Federal CCF as a paper, electronic, or combination electronic-paper form.
SAMHSA appreciates the recommendation but there is insufficient space on the CCF for the suggested addition. The HHS Specimen Collection Handbook instructs collectors to record collection events/observations (including the time of the attempt to provide a sufficient volume o specimen) on the Remarks line in Step 2 of the Federal CCF. Required collector training in Secti 4.3 of the Mandatory Guidelines includes a mock collection with an insufficient specimen scenario.
The Canadian laboratory is expected to prepare a draft proof of its proposed French-language Federal CCF for DOT review and approval. DOT will request SAMHSA review. DOT and SAMHSA will determine whether to allow any proposed language or format differences at that time.
SAMHSA has concluded that no change to the proposed Federal CCF is needed. OCR software i readily available, and the NLCP can provide the Federal CCF proof in OCR format to HHS-certified test facilities upon request.
The use of the CCF for non-regulated specimens is not within SAMHSA's scope.
SAMHSA concludes that no change within its scope is necessary. The labels/seals must be designed to facilitate proper application and collectors must be trained to apply labels correctly.

SAMHSA concludes that no change within its scope is necessary. Manufacturers must design labels/seals to facilitate proper application, laboratories and IITFs must verify the products, and collectors must be properly trained.
SAMHSA disagrees as certifying scientists are currently required to record analyte names/abbreviations, concentrations, and required comments in Step 5a.
Federal CCF content must be manually readable. However, certified test facilities may also use barcoded information on the Federal CCF to facilitate processing.
There is sufficient space for email addresseses and phone numbers. However, form suppliers may adjust font size and spacing if this is a concern.
SAMHSA disagrees with this addition as the expiration date is already recorded on the CCF. However, SAMHSA does agree that the devise lot number could be useful to track problems with particular device that fails at the collection site and will include instructions for recording the information in The Oral Fluid Collection Handbook .
SAMHSA diagrees with the recommendation as the specimen type (Urine or Oral Fluid) will be marked in Step 2 by the collector (or, if not marked, by the laboratory accessioner) including the specimen type on all copies of the CCF.