

Comments on 12/9/99 NPRM 49 CFR 40
(64 FR 69076 - 69136)

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From: A University of California prime contractor to the Department of Energy
and a DOT employer of drivers subject to DOT regulations.

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§40.13 (a). As indicated on page 69077 of the NPRM, in response to a comment received from the Nuclear Regulatory Commission, this proposed section would allow employees who are double-covered by both DOT and NRC regulations to use either agency regulation to administer the same drug and alcohol test under the authority of both federal agencies in lieu of having to conduct nearly duplicate tests in compliance with each federal agency. It is unfair that NRC should be singled out by DOT for special treatment to avoid redundant testing. This should be expanded to include employees who are double-covered by other federally regulated industries in addition to NRC. Suggest either changing the coverage to "DOT and any other federal drug and alcohol testing regulations or changing the coverage to "NRC, DOE, DoD, and NASA drug and alcohol testing regulations."

§40.13 (b). This section instructs employers of double-covered employees collect and maintain testing information in accordance with either DOT or NRC regulations and to make arrangements to make that information available for inspection by either agency (both agencies).

Left unaddressed is the issue of how to count and report these tests to each agency in mandated periodic statistical reports. In order to remain in compliance with both agency regulations, employer credit needs to be allowed within both agency programs. If credit for the tests are not allowed in both of the double-

covered federal programs, this could subject the employer to regulatory noncompliance if the employer fails to meet the annual testing goals of the program which did not take credit for the double-covered tests. Suggest adding the example of an NRC test which was conducted on a DOT-covered employee and recorded to as an NRC test being reported also as a DOT test for DOT MIS statistical reporting purposes.

§40.15 (f). This section appears to prohibit non-DOT federal agencies from using federal CCF forms. This is in conflict with 64 FR 61917, DHHS Notice of Proposed Revision to Federal Drug Testing Custody and Control Form, Discussion, Copy 1, Step 1 in which a block has been proposed to designate the acronym of the Federal Agency under which the specimen was collected and tested (i.e., DOD, DOI etc). Suggest changing the groups prohibited in this section from using the federal CCF form from "non-DOT drug and alcohol testing programs" to "non-federally regulated drug and alcohol testing programs."

§40.31 (d). This section appears to prohibit HHS certified labs from using company employees to perform collections as a subsidiary service to their clients. This is unnecessarily restrictive if the employee has no direct access to lab records or processes. Access to a HHS certified lab's files and operations should be the emphasis of this requirement rather than focusing on the collector's employment category. Suggest redefining this to prohibit those who "work directly for a HHS-certified laboratory and have access to internal laboratory test records and/or the specimen analysis process" from performing collections for the laboratory. This would permit the lab to use either contracted collectors or to use company employees as collectors if both can be shown to have the same restricted access authorizations within the lab.

§40.33 (a) (5). This section requires a collector to be retrained to proficiency who makes a mistake which causes a test to be canceled by the MRO. This new requirement will impose an increased burden on the MRO and will be difficult to enforce. Without a great deal of investigation by the MRO, the blame for errors which result in test cancellations cannot be known with certainty. This is especially true when determining the blame for insufficient volume specimens and leakers. Suggest the regulation better define the type and number of collection errors which must result in mandatory retraining of the collector if the test is canceled. Consideration should be given to requiring retraining if errors resulting in test cancellation exceed one per year per collector.

§40.47. This section answers "No" to the question, "May employers use the CCF for non-DOT collections . .?." Recommend changing the question to "May employers use the CCF for non-federally regulated collections..?" Similar changes should be made within the remainder of this section. See comment above under §40.15 (f).

§40.61 (b). First sentence. This section would require the testing (collection) process to begin without delay as soon as the employee enters the collection site. This is impractical as written in that it does not provide for routine circumstances in which more than one person appears for testing at the same time and not all can be tested without delay. Recommending modifying the requirement to require beginning the testing process "without unnecessary delay."

§40.61 (b). Second sentence. If employees who arrive for testing within the scheduled time and who are not ready to urinate must nevertheless be required to enter the room used for urination to wait until they can urinate this will eliminate the present flexibility collectors have to establish the queuing order for testing when more than one donor is awaiting testing. Present regulations allow the collector to test only one donor at a time. This proposed, inflexible first-in first-out requirement will cause unnecessary lost work time for donors and bottlenecks in the collection process in many situations. This proposed new requirement for first-in first-out testing should be dropped.

§40.61 (f). Experience has shown that this long-standing requirement to request the donor to remove personal belongings prior to entering the collection area is ambiguous as presently worded and, thus, lacks uniformity in its implementation by collectors. Clarification is required. For example, do "personal belongings" which have to be removed include utility belts with pockets, pistols and holsters sometimes carried by guards and law enforcement personnel, and items in carrying cases such as CD players, radios, and cell phones? Alternatively, can a search of such utility belt pockets, holsters, and carrying cases be performed in lieu of removing them, similar to the new boot search procedure? In the case of firearms, custody of these items presents legal and procedural problems for an on-duty donor.

§40.61 (e)(4) and (5). These two sections impose a new requirement for the collector to search every donor for items which could be used to adulterate a specimen. This search must be done without the collector needing to have probable cause that the donor may attempt to adulterate the specimen. This proposed new requirement raises two questions. First, is this search, without probable cause, legal? Second, if legal, why were other obvious contraband items not included in this pocket and boot search, such as items which could be used to alter a specimen's temperature or to substitute a specimen?

§40.61 (i) and (ii). These two sections require the collector to make a judgement regarding the donor's intent when suspicious items are found during the DOT proposed new search procedure. Although intent would probably be clear in most cases, other cases would be extremely difficult and would put the collector in the position of being later regarded as being under or over zealous in enforcement of this requirement. Because the consequence of the collector

assuming the donor intended to alter a specimen is serious (i.e. requiring a direct observation collection) such a requirement should be modified to make determining the intent clearer. The procedure should be revised to provide the donor, prior to the search, an opportunity to reveal the possession of specific types of items which may not be taken into the collection area. A list of these prohibited types of items should be part of this regulation. Failure of the donor to reveal such items prior to the search could help establish intent if undeclared items were discovered by the search to be in the donor's possession. This would be especially helpful to collectors in situations where donors possess commonly carried items such as hand warmers, cigarette lighters and matches.

§40.61 (g). This section prohibits requesting a donor to sign any kind of consent form as part of a specimen collection. This should be modified to exempt double-covered employees by stating, "unless consent forms are required by non-DOT federal regulations when an employee is required to be tested under both DOT and non-DOT federal regulations."

§40.63 (d). This section requires the collector to direct the donor not to flush the toilet until the specimen has been delivered to the collector, except in direct observation situations. This requirement should be changed to allow flushing the toilet after use when the toilet and/or plumbing has been designed to eliminate any access to unblued water. Recommend adding, "unless there is no donor access to unblued water during the flush, such as with the use of attachments which continuously blue the intake water to the toilet or use toilets with secured lids over tanks which have multiple flush bluing capability."

§40.65 (a)(5). This section drops the requirement to offer the donor an opportunity to have his/her body temperature taken which was previously used to counter the belief that the donor had falsified a specimen by submitting one which was out of the required temperature range. The new requirement would mandate an immediate observed collection if the specimen temperature were out of the permitted range. Has a study been made of the number of situations in which the donor's body temperature was similar to the out-of-tolerance specimen temperature and, thus, under the proposed rule, would have been unjustly required donors to undergo an observed collection? Recommend retaining the present safeguard which allows the donor's temperature to be taken. Retaining the current practice will continue to protect the privacy of innocent donors and will avoid increasing the cost of collections which would result from increasing the number of required observed collections.

A sentence should be added to this collection of a second specimen similar to §40.65 (a)(2) which instructs the collector not to discard the first, out-of-temperature specimen but to submit it for lab analysis.

§40.65 (c)(3). This section instructs the collector to discard the prior specimen if

a donor refuses to provide a second specimen under direct observation. This appears to be in direct conflict with §40.65 (a)(2) which instructs the collector not to discard the first specimen prior to a direct observation collection but to submit it for lab analysis if the first specimen was out of temperature range or otherwise appears to be adulterated. Recommend changing this section to be consistent with §40.65 (a)(2).

§40.67 (e). This section instructs the collector of observed specimens to make the annotation "collection 1 of 2" in the "Remarks" section of the first CCF and "collection 2 of 2" on the second CCF if the second specimen was collected because of suspected adulteration or substitution. This appears to conflict with §40.65 (b) which requires a second specimen when the first specimen is out of the required temperature range. Recommend modifying this section to include out-of-temperature range situations among those requiring this entry in the "Remarks" column of both CCFs.

§40.69 (d)(1). This requirement to make sure no one but the donor and monitor can enter the collection site during a monitored collection is worded differently from a similar requirement in §40.43 (c)(1) which requires only that the collector "restrict" others from entering a collection area normally used for other purposes. Is "making sure" and "restricting" meant to be the same thing? Restricting implies that a posting is sufficient. Making sure implies that additional means should be used, if necessary, to ensure unauthorized personnel do not enter during this time. If they are intended to mean the same, they should be worded the same.

§40.69 (d)(2). Regarding the proposed no-flush policy, for reasons given in comments to §40.63 (d), recommend adding the words, "unless there is no donor access to unblued water during the flush, such as with the use of attachments which continuously blue the intake water to the toilet or use toilets with secured lids over tanks which have multiple flush bluing capability."

§40.93 (c)(1). Typographical error. 1.020 should be 1.020.

§40.93 (d)(1). Typographical error. 11 should be 11.

§40.103 (a). This change would eliminate the blind performance specimen submittal requirement for most in-house administered programs and small employers who are not in a consortium unless they elect to exceed these minimum DOT requirements. Recommend changing the words, "you are not required to provide blind specimens" to "you are not required to provide blind specimens but are authorized by DOT to do so if validation an HHS-certified lab's performance is desired by the employer or service agent."

For those employers who have 2000 or more DOT-covered employees, this

section should address whether blind specimens submitted under another federal agency's authority (e.g. NRC, DOE) can be used to satisfy this DOT blind specimen requirement.

§40.103 (c). This section states that blind specimens must be positive for one or more of the drugs involved in DOT tests. It is unclear why HHS laboratory certification and blind specimen submittal program is intended to assess a lab's ability to test for the required drugs yet no attempt is made to determine if a lab has the ability to test for other substances which this regulation requires them to be able to detect. In addition to the drugs, this section should require blinds to be submitted for the validity testing required in section 40.91 (viz. creatinine, pH, nitrite, pyridine, gluteraldehyde, bleach, soap).

The NPRM solicits comments on this matter. We have included adulteration and substitution blinds in our program for many years and have found some HHS labs have poor procedures for detecting and/or confirming some common substances such as soap. This analysis procedure shortcoming would not have been discovered except through the inclusion of adulteration blind specimens in our blind specimen program. In addition and perhaps more importantly, certification of labs by HHS should include verifying the ability of these labs to detect and report all of the same adulteration substances required to be detected and reported to the MRO in DOT regulations and DHHS Program Documents. These currently are creatinine, pH, nitrite, pyridine, gluteraldehyde, bleach, and soap.

§40.107. This section permits only ODAPC and a DOT agency to inspect a HHS-certified lab. Does this imply that employers and service agents are not permitted to inspect these labs if they are lab clients? If that is not intended, this should be clarified.

§40.131 (c)(2)(ii). This section which prohibits the MRO from revealing the existence of a confirmed but as yet unverified positive to the employer when attempting to contact the donor, conflicts with §40.129 (d)(2) Alternative 2. This sentence should be expanded by adding, "unless the employer has a DOT-compliant stand-down policy as reflected in §40.129 (d)(2)."

§40.307 (b). Please clarify this section. It appears to require a plan for follow-up testing to be created by the SAP even in those cases in which the employee (e.g. a driver) is determined not to need assistance. We support this and believe this is a good policy but it conflicts with 49 CFR 382.311 (a) which authorizes follow-up testing only following a determination by the SAP that a driver is in need of assistance in resolving problems associated with alcohol misuse and/or use of controlled substances.

§40.321 (b). This section says that "blanket releases" of either a category of

information or to a category of parties is not permitted under this part. The use of blanket releases are explicitly required by some other federal agencies. and would pose a compliance problem for dual-covered employees for which a single test will administered. Recommend one of two changes: 1. Add, "unless required by other federal agencies for a test also required by that agency and for which a single test will administered." or 2. Change the word "permitted" to "required" to state that "blanket releases" are not required by this part.

§40.327 (a)(3). This section and section §40.333 should be expanded to apply to dual-covered employees. Specifically, these two sections should allow information generated in connection with the DOT test, including but not limited to the test result, to be provided by the MRO to other federal agencies if, at the time of the test, the donor was given notice regarding which other federal agencies have also required or authorized the test.

§40.330. Add a section which asks and answers an additional question, "May an MRO provide information about a positive drug test directly to an SAP upon specific written request by either the employee or the employer?"

§40.349 (h). As with comments on §40.321, the prohibition of use of "blanket releases" by service agents to authorize the release of employee testing information should be modified to allow this for dual-covered employees in which the other federal agency explicitly requires such blanket release in cases where, at the time of the test, the donor was given notice regarding which federal agencies have required or authorized the test.

Appendix C, Section IV. This section is entitled, "Employee Refusals to Test at the Collection Site." The example cited is an employee who leaves the collection site prior to providing a specimen. Both the title and the example are unnecessarily confusing. As required elsewhere in the proposed rule (ref. §40.61 [a], §40.191 [d], §40.193 [d], and §40.193 [e]) the employer is required to be informed in these situations, not by the MRO as indicated here, but by the collector who notifies the DER. Recommend deleting this section as being unnecessary and confusing. Other appropriate situations requiring MRO reporting to the employer are adequately covered elsewhere in Appendix C.