

§ 40.411 What is the role of the DOT Inspector General's office?

(a) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

(b) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(c) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

§ 40.413 How are notices sent to service agents?

(a) If you are a service agent, DOT sends notices to you, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph (b) or (c) of this section.

(b) DOT may send a notice to you, your identified counsel, your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by you if sent to any of these persons.

(c) DOT considers notices to be received by you—

(1) When delivered, if DOT mails the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if DOT sends the notice by fax or five days after we send it if the fax is undeliverable; or

(3) When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

APPENDIX A TO PART 40—DOT
STANDARDS FOR URINE COLLECTION KITS

The Collection Kit Contents

1. *Collection Container*

a. Single-use container, made of plastic, large enough to easily catch and hold at least 55 mL of urine voided from the body.

b. Must have graduated volume markings clearly noting levels of 45 mL and above.

c. Must have a temperature strip providing graduated temperature readings 32–38 °C/90–100 °F, that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (*e.g.*, temperature device built into the wall of the

container) are acceptable provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

e. May be made available separately at collection sites to address shy bladder situations when several voids may be required to complete the testing process.

2. *Plastic Specimen Bottles*

a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

b. Must have screw-on or snap-on caps that prevent seepage of the urine from the bottles during shipment.

c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it nor with the chance that the seal overlap would conceal printed information.

e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

f. Plastic material must be leach resistant.

3. *Leak-Resistant Plastic Bag*

a. Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. *Absorbent material*

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. *Shipping Container*

a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (*e.g.*, standard courier box, small cardboard box, plastic container).