Guide to Random Drug Testing

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GUIDE TO RANDOM DRUG TESTING

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1. THE COLLECTOR

A collector is the person who instructs and assists donors at a collection site and receives the specimen provided by the donor.

The following restrictions apply:

- The immediate supervisor of an employee may not serve as the collector when that employee is tested, unless there is no feasible alternative. A supervisor serving as a collector must be a trained collector.

- The hiring official of an applicant may not serve as the collector when the applicant is tested, unless there is no feasible alternative. A hiring official serving as a collector must be a trained collector.

- A co-worker who is in the same testing pool or who works with an employee on a daily basis must not serve as a collector when that employee is tested.

- An applicant or employee must not serve as the collector by collecting his or her own specimen.

- An individual who has a personal relationship with the employee (e.g., spouse, ex-spouse, relative, close personal friend) must not serve as the collector.

To qualify as a collector an individual must:

- Receive training from a qualified trainer for collectors on the following topics:
  - The steps to correctly perform a collection,
  - Problem collections,
  - Fatal and correctable flaws and how to correct problems in collections,
  - Collector responsibilities to maintain the security and integrity of specimens, to protect the privacy of donors, and to maintain proper conduct

- Complete refresher training at least every 5 years from the date of initial training.

The collector should have identification with his or her name. The collector is required to provide his or her identification if requested by the donor.

To qualify as an observer for a direct observed collection, an individual must:

- Be knowledgeable of the direct observed collection procedure; observer does not have to be the collector

- Receive training on the following subjects:
  - The steps necessary to perform a direct observed collection correctly,
  - Ensuring the integrity and security of the specimen throughout the collection process by maintaining visual contact with the collection container,
Ensuring the privacy of the donor,

Ensuring that the observation is done in a professional manner, to minimize discomfort of the donor,

Avoiding conduct that can be interpreted as offensive or inappropriate,

- Be the same gender as the donor. There are no exceptions to this requirement.

2. COLLECTOR/COLLECTION SITE RECORDS

The collector should maintain his or her original collector training records (i.e., for initial and refresher training). Collection site records must be stored for a minimum of 2 years. Collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained.

3. THE COLLECTION SITE

A collection site is a permanent or temporary facility where donors present themselves for the purpose of providing a specimen for a drug test. When there is an immediate need to collect a specimen (e.g., a post-accident situation), and there is no agency-designated site available, a collection may be conducted in a public restroom. The site must have all necessary personnel, supplies, equipment, facilities, and supervision to provide for specimen collection and security, and for temporary storage until the specimen is transferred to the laboratory.

A facility used as a collection site must have:

1. Provisions for donor privacy while he/she provides the urine specimen. The following facilities provide adequate privacy for urine collections:

   - An enclosed stall in a multi-stall restroom,
   - A single-person restroom,
   - A partitioned area that allows for individual privacy,
   - A mobile restroom (e.g., a vehicle with an enclosed toilet stall).

2. A means for washing hands:

   - If practical, the water source should be external to the restroom where collection occurs. If a water source is in the enclosure where the collection occurs, the collector must secure it prior to the collection or conduct a monitored collection.

   - If a water source is not available, another means (e.g., waterless cleanser, moist towelettes) outside the restroom is an acceptable alternative.

3. A suitable clean surface, inaccessible to the donor, for the collector to use as a work area:

   - If practical, the collector work area should be external to the restroom where collection occurs.

   - The collector work area may be inside the restroom, only if the donor can have privacy while providing the urine specimen.
4. A secure temporary storage area for maintaining specimens until they are transferred to the laboratory. **Note: Specimens should NOT be exposed to high temperatures for an extended time. These conditions may affect the test results of a urine specimen.**

5. Procedures or restrictions to prevent:
   - Unauthorized access to the site during the collection,
   - Unauthorized access to the collection materials/supplies,
   - Unauthorized access to collection site records,
   - Donor access to items that could be used to adulterate, substitute, or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water).

### 4. BLIND SAMPLES

Blind samples (i.e., negative samples, positive samples, adulterated samples, substituted samples are submitted and used to evaluate and assure that the analytical procedures are being met) are submitted quarterly along with the donor specimens for QA/QC at the approximate percentage of each type (i.e., 75% negative, 15% positive for one or more drugs, 10% either adulterated or substituted). The blind samples should be distributed throughout the donor specimens rather than being submitted as one group.

Each blind sample must meet the following requirements:

- Positive and negative samples must be validated using the appropriate initial and confirmatory drug tests.
- The shelf life of each blind sample must ensure that the sample is submitted for testing prior to its expiration date.
- Positive blind samples should be 1.5 to 2 times the initial drug test cutoff and contain at least one of the required drugs.

### 5. VERIFICATION OF DONOR IDENTITY

The donor must provide appropriate identification to the collector upon arrival at the collection site.

**Acceptable** forms of identification are:

- a photo identification (e.g., driver's license, employee badge issued by the employer, or any other picture identification issued by a Federal, state, or local government agency),
- identification by the supervisor of the donor, or
- other identification allowed under the Russian Federation.

If the identity of the donor cannot be established, the collector stops the collection.

**Unacceptable** forms of identification are:
• identification by a co-worker,
• identification by another donor,
• non-photo identification, or
• a faxed copy or photocopy of an identification document.

6. URINE SPECIMEN COLLECTION

6.1 COLLECTION SITE SECURITY

The collection site must be secure to prevent unauthorized access to specimens, collection supplies, and collection site records. A permanent site that is used solely for specimen collections must be secured at all times. At facilities that are not dedicated specimen collection sites, the area of the site used for specimen collections must be secured during the time a specimen is collected.

A collector must:

• prohibit unauthorized personnel from entering the collection site during the collection,
• perform only one specimen collection at a time,
• restrict access to collection supplies before and during the collection,
• ensure that only the collector and the donor are allowed to handle the unsealed specimen,
• ensure that chain of custody is maintained and documented throughout the collection procedure,
• ensure that Copy 1 of the chain-of-custody form is enclosed with the specimen and sealed for shipment to the laboratory; and
• ensure that specimens are transported to the test facility in a sealed and secure shipping container to eliminate the possibility of damage during shipment and to prevent undetected tampering.

6.2 COLLECTION SUPPLIES

The following items must be available at the collection site to conduct proper urine collections.

1. Single-use plastic collection. Each collection must not substantially affect the specimen collected and must be

• supplied as an individually sealed item using a tamper-evident system (e.g., in a sealed plastic bag, shrink wrapped, with a peelable or sealed lid, or another easily visible tamper-evident system),
• large enough to easily catch and hold at least 55 mL of urine, and
• graduated with volume markings clearly showing the volume (e.g., 45 mL).

2. Single-use plastic specimen bottles. Each specimen bottle with cap must not substantially affect the specimen collected and must be
• supplied as individually sealed bottles with a tamper-evident system (e.g., using plastic bag, shrink wrap, with a peelable or sealed lid, or another easily visible tamper-evident system),

• able to hold at least 35 mL, and

• leak resistant (i.e., have a screw-on or snap-on cap that prevents leakage).

3. **Temperature strips.** The temperature strips must be capable of temperature readings between 32–38°C. The temperature strips must accurately measure the temperature of the specimen and not contaminate the specimen. The strips may be affixed to the collection container as supplied or placed on the collection container after the donor gives the collection container with the specimen to the collector.

4. **Tamper-evident seals.** Tamper-evident labels/seals must be used to seal the specimen bottles.

5. **Leak-resistant plastic bags.** The plastic bags must have sealable compartments or pouches.

6. **Shipping containers.** Boxes or bags used to transport specimens must be securely sealed to prevent the possibility of undetected tampering.

7. **Bluing agent.** Bluing agent is added to the toilet bowl and water tank to prevent undetected specimen dilution by the donor.

8. **Secure temporary location.** It is the collector's responsibility to prevent unauthorized access to the specimen bottles. The bottles must be kept

   • within the collector's line of sight or
   • in a secure temporary location (e.g., locked in a refrigerator or cabinet).

   **Note:** Specimens should NOT be exposed to high temperatures for an extended time. These conditions may affect the test results of a urine specimen.

9. **Disposable gloves.** Collectors use single-use disposable gloves while handling specimens.

### 6.3 COLLECTION PROCEDURE

1. Prepare the collection site to collect urine specimens.

   • Assemble supplies.

   • Ensure that there is bluing agent in the toilet. If no bluing agent is available or if there is an automatic flushing system, turn off the water supply and flush the toilet to remove any water in the toilet, when possible.

   • Turn off the water supply or secure water sources inside the restroom.

     o The collector must provide a means for the donor to wash his or her hands before and after the collection. The collector must secure the water source after the donor washes his or her hands and restore the water supply after the collection, or provide another means (e.g., waterless cleanser, moist towelette).
If a water source inside the restroom cannot be turned off or secured, the collector must perform a monitored collection.

- Remove any soap, cleanser, disinfectant, or other potential adulterants.
- Inspect and/or secure areas or items that could be used to conceal adulterants (e.g., false ceilings, ledges, trash cans, towel dispensers).

2. If a donor does not arrive at the collection site at the assigned time for the drug test, contact the appropriate representative to obtain guidance on the appropriate action to be taken.

3. Begin the collection without delay when the donor arrives at the collection site. **If the donor states that he or she is unable to provide a urine specimen, continue with the collection procedure through Step 11 below.**

4. Verify the donor's identity.

5. Describe the basic collection procedure to the donor.

6. Answer any reasonable and appropriate questions that the donor has about the collection process.

7. Complete the collector's portion of the chain-of-custody form.
   - Ensure that the pre-printed specimen identification number matches the identification number on the specimen bottle labels/seals.
   - If the information is not present, record the information to include:
     - the employer's name, address, telephone and fax numbers, and employer number (if applicable),
     - donor identification (employee number),
     - reason for test (random, for cause, etc.),
     - collection site address, and
     - collector telephone and fax numbers.

8. Ask the donor to do the following:
   - Remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.).
     - The donor must not be asked to remove other articles of clothing (e.g., shirts, pants, dresses, undergarments), or to remove all clothing and wear a hospital or examination gown.
     - It is not necessary for the donor to remove the following items, unless the collector suspects that they are concealing something that may be used to adulterate or substitute a specimen:
       - work boots or
       - a hat or head covering that the donor refuses to remove based on religious practice.
• Leave other personal belongings (e.g., briefcase, purse) with the outer clothing. The donor may retain his or her wallet.

  o To safeguard a donor's belongings, procedures may be established to secure the items during the collection. These may include:
    – an itemized receipt for belongings left with the collector,
    – storage in a lockable cabinet (i.e., with access controlled by the donor), or
    – an envelope, box, or container secured with tamper-evident tape.

• Empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen.

  o If there are no items that can be used to adulterate a specimen, instruct the donor to return the items to the pockets and continue the collection procedure. Go to Step 9.

  o If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, use a direct observed collection procedure.

  o If an item that could be used to adulterate a specimen appears to have been inadvertently brought to the collection site, secure the item and continue with the normal collection procedure. Go to Step 9.

  o If the donor refuses to display the items in his or her pockets, stop the collection. This is considered a refusal to test and note on form.

9. Instruct the donor to wash and dry his or her hands under your observation.

• Liquid soap is preferred over bar soap, because bar soap gives the donor the opportunity to conceal soap shavings under his or her fingernails in an attempt to adulterate the specimen.

• After washing his or her hands, the donor must remain in the collector's presence and not be allowed access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials which could be used to adulterate, substitute, or dilute a specimen.

10. Give the donor or allow the donor to select the specimen collection container (if it is separate from the kit) from the available supply.

11. Unwrap or break the seal of the kit or collection container. You may allow the donor to perform this step.

• Both the collector and the donor must be present.

**Note:** If the donor has stated that he or she is unable to provide a specimen at this point in the collection, request that the donor enter the restroom and attempt to provide a specimen. If the donor comes out of the stall with an empty collection container, he or she has demonstrated the inability to provide a specimen. Follow the Insufficient Specimen procedure in Section 6.6.

12. Direct the donor to

• take the collection specimen container into the restroom/stall to be used for the collection,
• provide a specimen of at least 45 mL,
• not flush the toilet, and
• return with the specimen as soon as he or she has finished completing the void.
  o You may inform the donor that the temperature of the urine specimen must be read within 4 minutes after the void to be valid. Longer wait periods may cause the temperature to be out of range and necessitate an observed collection.
  o A reasonable time limit may be set for completing the void.

**Note:** Neither the collector nor anyone else may go into the restroom with the donor, except in the case of a direct observed collection.

**Note:** Both the collector and the donor must maintain visual contact with the specimen from the time the specimen is transferred to the collector until specimen bottles have been sealed for shipment to the laboratory.

**Note:** After receiving the specimen from the donor, whenever practical, the collector may allow the donor to wash his or her hands and to flush the toilet. (The collector may inspect the toilet for any materials indicative of specimen tampering prior to flushing.)

13. When you receive the specimen from the donor, read the temperature strip affixed to or placed on the outside of the collection container.
   • Do this within 4 minutes after the void.
     o If the temperature is within the acceptable range (32–38°C), mark "Yes" and proceed with the collection procedure.
     o If the temperature is outside the acceptable range, mark "No" and perform a second, directly observed collection.
       – Begin the collection of a second specimen using a direct observed collection procedure and a new collection kit (i.e., a new collection container).

**Note:** If the donor refuses to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test.

14. Inspect the specimen for adulteration or substitution by examining the physical characteristics of the urine.
   • Note any abnormal characteristics such as:
     o unusual color (e.g., specimen is blue),
     o presence of foreign objects or material,
     o unusual odor (e.g., bleach), or
     o signs of adulteration (e.g., excessive foaming when shaken).
   • If you observe any abnormal characteristic(s) that appear to be due to adulteration or substitution by the donor, begin a second specimen collection process using a direct observed collection procedure and a new collection kit (i.e., a new collection container).
o Record an appropriate comment on the chain-of-custody form (i.e., for the first and second specimens), to indicate why two specimens were collected including a cross reference to the associated specimen identification number.

o Complete the first collection by continuing with the procedure.

15. Check the specimen volume to ensure that the specimen contains at least 45 mL of urine.

- If the specimen volume is at least 45 mL, complete the specimen collection procedure and indicate on chain-of-custody form.

- When the specimen volume is less than 45 mL, discard the specimen and immediately begin a second collection using the same procedures and use a new collection container for the second collection.

**Note:** If the donor refuses to attempt to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test.

- When a second specimen must be collected, follow the Insufficient Specimen procedure in Section 6.6.

  o If the donor is unable to provide at least 45 mL for the second specimen after a period of 3 hours, stop the collection procedure and report the failure to provide a sufficient specimen as described in the Insufficient Specimen procedure in Section 6.6

16. Place the appropriate tamper-evident label/seal over the lid/cap of each bottle to ensure that the lid/cap cannot be removed without destroying the label/seal.

- **The donor must observe the sealing of the specimen bottles.**

  - If the tamper-evident label/seal does not adhere properly to the specimen bottle (e.g., due to moisture, temperature, specimen bottle material) or is accidentally broken or damaged during the collection process,

    o apply the unacceptable label/seal to the bottle, and

    o apply a second, separate tamper-evident seal to seal the specimen bottle perpendicular to first seal.

      - Initial and date the second seal,

      - ask the donor to initial the second seal, and

      - provide a comment on the chain-of-custody form explaining why the second seal was used.

17. Write the date on the tamper-evident labels/seals.

18. Ask the donor to initial the label/seal on each bottle, using care to avoid damage.

- If the donor fails or refuses to initial the seals, note this on the chain-of-custody form. This is not considered a refusal to test.
19. Inform the donor that it is not necessary for him or her to continue observing the collection procedure after the bottles have been sealed, and that he/she is allowed to wash his or her hands.

20. Inform the donor that he or she may leave the collection site.

21. Prepare the sealed tamper-resistant plastic bag containing the specimen bottles for transport to the laboratory.
   - Place the sealed specimen bag(s) to be shipped into a shipping container (e.g., box, express carrier mailer). Several specimen bags may be placed into one shipping container.
   - For specimens that will be hand-delivered from the collection site to the laboratory, it is not necessary to use a sealed shipping container. The courier must handle the specimen bags in a manner that protects the specimens from damage.
   - If the tamper-evident label/seal is broken on a specimen bottle after the donor leaves the collection site, the collection must be cancelled.
     - Notify the designated representative that the label/seal was broken on the specimen bottle.

6.4 DIRECT OBSERVED COLLECTION

A direct observed collection procedure may only be used when:

1. a donor's previous drug test result was reported as drug positive, adulterated, substituted, invalid without a legitimate medical reason, or could not be tested, or

2. at the collection site, an immediate collection of a second urine specimen is required in one of the following situations.
   - The temperature of the specimen collected during a routine collection is outside the acceptable temperature range.
   - There is an indication that the donor has tampered with the specimen (e.g., abnormal physical characteristic such as unusual color, excessive foaming when shaken, or unusual odor).
   - The conduct of the donor clearly indicates an attempt to adulterate or substitute the specimen.
   - The donor has brought an item to the collection site for the purpose of
     - adulteration (e.g., a small vial containing a suspicious liquid),
     - substitution (e.g., a small vial containing water or other liquid), or
     - dilution of a urine specimen.

Before conducting a direct observed collection, the collector must contact a collection site supervisor for concurrence with the collector's decision for a direct observed collection. The collector must make the representative aware that a situation exists warranting a direct observed collection and explain to the donor why a direct observed collection is being conducted. If the donor declines to allow a direct observed collection when one of the above circumstances has occurred, it is considered a refusal to test.
The procedure for a direct observed collection is the same as that for a routine collection except an observer (i.e., of the same gender as the donor), watches the donor urinate into the collection container. At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps.

1. The individual serving as the observer enters the restroom with the donor.
   - The observer must be the same gender as the donor. **There are no exceptions to this requirement. The observer does not have to be the collector.**

2. The observer must directly watch the urine go from the donor's body into the collection container. The use of mirrors or video cameras is not permitted. If the donor fails to follow the observer's instructions related to the direct observed collection, this is considered a refusal to test.

3. With regard to chain of custody, the observer must never touch or handle the collection container unless the observer is also serving as the collector.

4. After the donor has completed urinating into the collection container,
   - the donor and observer leave the restroom and the donor hands the collection container directly to the collector,
   - the observer must maintain visual contact with the collection container until the donor hands the container to the collector, and
   - if the same individual serves as both observer and collector, he or she may receive the collection container from the donor while they are both in the restroom.

### 6.5 MONITORED COLLECTION

A monitored collection procedure must be used when:

1. the collection is being conducted in a public restroom (e.g., when the designated collection site is not available, and there is an immediate need for a collection), or

2. the restroom used for the collection has a water source that cannot be disabled or secured.

If the donor declines to allow a monitored collection when one of the above circumstances has occurred, it is considered a refusal to test.

The procedure for a monitored collection is the same as that for a routine collection except an individual monitors the collection by checking for signs that the donor may be tampering with the specimen. At the point in a routine collection where the donor enters the restroom with the collection container, a monitored collection includes the following additional steps.

1. The monitor accompanies the donor into the restroom and secures the restroom to ensure that no one else can enter during the collection process.
   - The monitor must be the same gender as the donor, unless the monitor is a trained medical professional (e.g., nurse, doctor, physician's assistant, technologist or technician), who is licensed or certified to practice where the collection occurs.
• The monitor is not required to be a trained collector.

2. The monitor listens for signs of tampering with the specimen.

• The monitor must remain in the restroom, but outside the stall while the donor is providing the specimen.

• The monitor must not watch the donor urinate into the specimen container.

3. If there is evidence of specimen tampering, the monitor notifies the collector to immediately begin to collect a second specimen using a direct observed collection procedure.

4. With regard to chain of custody, the monitor must never touch or handle the collection container, unless the monitor is also serving as the collector.

5. After the donor has completed urinating into the collection container,

• the donor and monitor leave the restroom, and the donor hands the collection container directly to the collector,

• the monitor must maintain visual contact with the collection container until the donor hands the container to the collector, and

• if the same individual serves as both monitor and collector, he or she may receive the collection container from the donor while they are both in the restroom.

6. The collector provides the name of the monitor (if applicable) on the chain-of-custody form.

6.6 INSUFFICIENT SPECIMEN

If a donor tells the collector that he or she cannot provide a specimen, the collector must begin the collection procedure regardless of the reason given. The donor demonstrates his or her inability to provide a valid specimen when he or she comes out of the restroom with an empty collection container. Immediately begin a second collection using the same procedures, and the same collection container.

1. If the donor indicates that he or she may be able to provide a specimen if given more time, do the following.

• Offer the donor a reasonable amount of fluid to drink distributed reasonably through a period of up to 3 hours (e.g., an 8 ounce glass of water every 30 minutes, not to exceed 40 ounces over a period of 3 hours) or until the donor has provided a sufficient amount of urine, whichever occurs first. The donor is not required to drink fluids during the waiting period.

• Instruct the donor to let you know when he or she is able to provide a sufficient quantity of specimen. It is recommended that you allow sufficient time to have only one additional attempt rather than having to document several unsuccessful attempts. Be sensitive to how frequently you ask a donor to attempt to provide a specimen.

• Record the time of the attempt to provide a sufficient volume of specimen.
• The donor must remain under the direct observation of the collector to prevent the donor from possibly compromising the collection process.

Note: The collector must NOT under any circumstances combine urine collected from separate voids to create one specimen of sufficient volume.

2. If the donor states that he or she is unable to provide a specimen, or if the donor has not provided sufficient volume of specimen in 3 hours from the time of the donor's first attempt, discontinue the collection and

• record the reason for not collecting the specimen on the chain-of-custody form,
• notify the agency's designated representative of the situation, and
• discard the urine collected (if any),

3. If the donor refuses to attempt to provide a specimen or leaves the collection site before the collection process is completed, this is a refusal to test.

7. MISCELLANEOUS COLLECTION ISSUES

7.1 DONOR CONDUCT

The collector should pay close attention to the donor's conduct during the entire collection process and take the following actions, as necessary.

1. If the donor's actions or items on his or her person clearly indicate an attempt to tamper with (i.e., substitute, adulterate, or dilute) a specimen, conduct a direct observed collection and document the reason on the chain-of-custody form.

2. If the donor's actions clearly indicate an attempt to substitute or adulterate a specimen and the donor has already provided a specimen, do the following:

• Complete the collection procedure for that specimen and immediately begin a new collection using a direct observed collection procedure, and a new collection kit.

• Provide appropriate comments in the chain-of-custody form (i.e., for the first and second specimens).
  
  o Note whether the specimen is the first or the second of the two collections for the donor.
  
  o Note the reason for the second collection (i.e., the observed conduct or found items indicative of attempted substitution or adulteration).

  o Document that the second collection was under direct observation and write the observer’s name in the chain of custody (if the collector was not the observer).

• Inform the appropriate designated representative that a collection took place under direct observation and the reason for having done so.

• If the donor fails to arrive at the assigned time, contact the appropriate designated representative to obtain guidance on the action to be taken. This is not considered a refusal to test.
7.2 REFUSAL TO TEST

The organization may take adverse action against an employee whose drug test specimen is reported as a refusal to test. The collector reports a refusal to test when the following occurs.

1. The donor fails to cooperate with any part of the testing process (e.g., refuses to provide a specimen, refuses to display the items in his or her pockets at the beginning of the collection, or refuses to wash his or her hands at the beginning of the collection).

2. The donor declines to allow a direct observed collection when required, or fails to follow the observer's instructions related to the direct observed collection.

3. The donor declines to allow a monitored collection when required.

4. The donor declines to continue the collection process when his or her first specimen has insufficient volume.

5. The donor leaves the collection site before completion of the collection (except for leaving before the collection has begun for a pre-employment test).

When reporting a refusal to test, the collector must:

1. notify the appropriate designated representative by any means (e.g., telephone, secure fax machine, e-mail), that ensures immediate receipt of the refusal notification and

2. document the refusal to test.

8. COLLECTOR ERRORS

The collector should never use correction fluid and should never overwrite or scribble out information recorded or printed on the form.

If the collector makes an error, he or she should:

1. make a line through the erroneous information, leaving the original information legible,

2. write the correct information near (e.g., beside) the original annotation, and

3. initial and date the change.