

US EPA ARCHIVE DOCUMENT

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Test Reference: EMD-003& EMD-004

CLBR Training Manual

§1.c. Practicing and performing dosimetry with Pump Spray, Aerosol Spray and Lotion delivery systems

A. Goals of exercise

1. Determine your preferred practices for applying ('self-dosing') spray and lotion repellents to your arms and legs.
2. Assist technicians in measuring the amounts of such repellents that you apply when using your practices

B. General information

1. A technician will measure the surface area of your forearms and lower legs. He or she will introduce you to the repellents and their containers
2. You will work in open air, practicing applying the repellents from each type of container. A technician will help you keep track of your preferred techniques.
3. Using small gauze "bracelets" around your limbs to capture samples of repellent you spray on, you will apply repellents with your preferred practices several times. The bracelets will be quickly removed and weighed. You will thoroughly wash your limbs with a gently skin cleaner between each application of repellent.

C. Materials and equipment needed

1. Test materials
2. Latex or vinyl gloves (various sizes)
3. Bracelet dosimeters with nonabsorbent backing
4. Temperature, humidity and wind speed measuring devices
5. Written copy of the procedures for subjects to read
6. Flexible metric rule

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D. Practicing the methods and performing the measurements

Measuring arms and legs¹:

Limb is use to refer to your forearm and your lower leg. A technician will measure the distance around your limbs at four evenly spaced places on the forearm (elbow to wrist) and lower leg (back of knee to ankle), and also length of those limbs.

Working with the pump spray and aerosol spray, and determining your preferred method of applying the repellents:

Your trainer/technician will help to introduced you to how the spray bottles work and how you will determine your preferred methods of applying them. You will read the written procedures that follow here together.

“Read along on your copy of the procedure as the Researcher reads them to you. Ask questions of the Researcher as they occur to you or at any time thereafter. Be sure to get answers to any questions you feel should be answered before proceeding at any step of this work.

This is a study of your behavior in applying spray insect repellents. You will probably have had experience with applying spray products of some kind to your skin before. If you are uncertain about how to use a spray dispenser be sure to ask the Researcher or one of the technicians. You will each have the opportunity to practice these procedures with the aid of a technician.

Insect repellents function to repel insects from biting the skin. Their effectiveness is influenced by the completeness of their application to the skin surface. Our goal is to determine your preferred method for achieving **full coverage**. At minimum, **full coverage** is defined as a continuous and complete layer of test material. Orienting the arm to light may aid in determining whether full coverage has been achieved. Spray as much as necessary to achieve full coverage.

¹ **Limb dimensions and surface area (technical details):**

The term ‘limb’ refers to the forearm and ¹the lower leg. The surface area of each limb is computed as the average of four evenly spaced circumferences (two peripheral, two central) of the forearm (elbow to wrist) or lower leg (back of knee to ankle) multiplied by the length of treatment area. The locale along the limb at which each circumference is taken will be recorded (for later use to place dosimeters) as the distance in centimeters from the distal margin of the site of the most distal circumference site (i.e., at wrist or ankle).

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In these instructions, the act of spraying a repellent on your arm will be termed 'spraying', 'application', or 'dispensing.'

If you are wearing a long-sleeved shirt roll the sleeves so as to expose the entire lower arm. Wash arms thoroughly with the provided cleanser and dry with a clean towel. Place new latex or vinyl gloves on each hand, choosing the size that fits you most snugly without being uncomfortably restricting or likely to tear when you put them on.

You will work with a technician who will assist you in measuring and recording your use of a repellent product in two delivery systems, a pump spray and an aerosol spray.

Work first with the pump spray, second with the aerosol spray. Because they are similar, the application instructions below describe the procedures for each type of spray together in each paragraph.

Familiarize yourself with the spray mechanism. Any actuation (pushing down on the pump plunger) of the spray must take place out-of-doors. Work at a distance of no less than 6 feet (1.9 meters) from other subjects. Do not dispense the spray at or near your face or anyone else's. Minimize inhalation of airborne spray while working.

Testing will take place out-of-doors during daylight hours at an air temperature (shade) above 14 °C (57 °F) and wind speed below 12 kph (7 mph), with no precipitation. The researcher or a technician will inform you when these conditions are not met and spraying of the repellents will cease until those conditions resume.

Dispense the spray on one forearm, using the opposite hand. By successively moving the spray nozzle closer to and farther from the arm, identify a distance between nozzle and skin that seems most appropriate for effective application to the skin. The technician will measure and record that distance to the nearest centimeter on the provided datasheet.

Have the technician wash and dry the treated arm so that none of the repellent you have applied is visible on close inspection.

Now, using the spray nozzle at or near the distance from the skin that you have just chosen to be effective for application, determine the minimum number of actuations (pumps of the pump spray) or longitudinal passes (aerosol) required to give full coverage of all surfaces of the forearm. For the pump spray, depress the plunger fully each time, and count them aloud beginning with "1, 2, 3" etc. If you partially depress the plunger (rather than fully depress it) in order, e.g., to apply to a small skin area not covered by initial application, report that to the technician as a "half pump." Each partial depression should be so reported as it occurs. If on any given actuation material fails to be delivered, do not count that actuation. If a partial amount is delivered, consider it either 'whole', 'half' or 'none' and report it as such. For 'none', simply resume counting at the next actuation that delivers material to the skin.

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Report the count to the technician who will record it on the data sheet. The technician will also assist you in keeping track of whole versus half pumps.

When applying the aerosol, announce each onset of spraying with the word “START” and each cessation with the word “STOP”. This will aid the technician who is counting your application time. Apply the aerosol in a series of full “sweeps” (passes) between the wrist and elbow. There may be more than one start and stop while working to achieve full coverage of the arm. Count each one-way sweep as one sweep, and count passes in a manner analogous to that used for pump spray (above). If you make a partial sweep that you judge to be closer to a “half sweep” than a “full sweep”, call it out to the technician as a “half”. Treat accidental under-applications in the same manner as for the pump spray (described above). Try not to let your awareness of the technician’s timing to influence you dispensing behavior. If the technique of using mainly full sweeps seems awkward or unnatural to you, inform the technician immediately. Your preferred method should be demonstrated for the Researcher, who will determine how it may be quantified.

Repeat the application procedure and collect the same data for the other arm.

Discard your latex gloves, and wash both arms with cleanser and dry them thoroughly with a towel.

Put on new gloves, and repeat the application procedure twice more (both arms) with the pump spray. During these two repetitions the technician will again measure your preferred distance between the nozzle and the skin, and quantify the application as before. However, in these repetitions, if you are confident that you have learned and remembered your preferred distance, you and the technician can measure the distance you used *after* reporting the data on number spray pumps/number and duration of aerosol sweeps. This will avoid interrupting your application with additional arm washing by the technician.

Try to be consistent with your use of the spray apparatus. If you are clear and confident about the distance from the arm that works best, pay enough attention to keep the nozzle in that general range while maintaining a natural delivery as you would use the product under normal personal use. Keep the nozzle aimed at the skin surface, and avoid orienting the containers in any ways that you determine, as you proceed with the trial, to interfere with delivery of the repellent to the skin surface.

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Now move onto the **Spray Sampling** exercise described in the next section for the spray pump. After completing that exercise, you will return to the instructions above that you have just carried out and conduct the procedure for the lower legs, and then conduct Spray Sampling for the legs. Next repeat all of the above with the aerosol.”

Spray Sampling²

Spray Sampling is the procedure by which the spray is “subsamped” with “patch dosimeters”. Dosimeters of known surface area will be placed on subject lower arms. These dosimeters will intercept a portion of the spray applied to the arm. By weighing dosimetry patches before and after treatment, the mass of the intercepted material can be calculated. The spray delivery systems will also be weighed before and after each application.

Spray sampling will be conducted according to the following procedure.

“Please read along with the Study Director as he reads aloud the following description of the procedures you will employ in spray sampling. Please be sure to ask questions at any point.

This procedure is very similar to what you have just performed. The main difference is that for spray sampling, a technician will place four narrow rings of plastic-backed gauze around each of your forearms. The rings are about one-half-inch (1.5 cm) wide. Each of these “gauze bracelets” will be centered on each of the four positions on the arm at which we initially measured the circumference. These positions may be marked on the skin with small but visible dot using a temporary marker.

² Equipment Used to Assess the Dosimetry Variable (technical detail):

Passive dosimeters are 1.5 cm wide strips of 3M Brand Nexcare™ Holdfast™ self-adhesive roll gauze attached to the adhesive side of 1.5 cm wide strips of 3M Brand clear packaging tape. The tape will retard test materials from passing from the dosimeter to the subjects’ skin. The tape strip length will match the circumference of a given region of a subject’s arm. The gauze strip will be 1.5 cm longer than the tape, in order to permit a 1.5 cm overlap onto the self-adhesive gauze bracelet, thus securing the dosimeter in place.

On the non-adhesive side tape strip (the inner surface of the dosimetry bracelet) the following notations will be made before they are used.

- a) Subject number
- b) L (for left placement) or R (for right arm placement)
- c) Position letter: a (wrist), b (next proximal), c (next proximal), d (elbow)
- c) T (for treatment) or C (for control)
- d) Replicate number (1, 2 or 3)

There will be eight bracelets per replicate. Each arm and leg will be treated three times. Each subject will therefore have a total of forty-eight custom bracelets made and labeled in advance.

Bracelets will be weighed before and after treatment on a traceably calibrated Sartorius H51 balance (measurement increment 0.0001 g, 30 g capacity). Test material containers will be weighed before and after dispensing on a traceably calibrated Sartorius GC 2502 (measurement increment 0.001 g, 500 g capacity).

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The function of the “gauze bracelets” is to capture some of the spray that would otherwise reach your arm as you apply the test products. It is important that you do not alter the way in which you apply the materials in any intentional or substantial way from what you have already determined is your best procedure. The technician will review your results from your previous applications with you to assist you in repeating your general procedure (distance of nozzle to skin, number of spray pumps or aerosol sweeps) as you apply the materials to one of your arms with the bracelets in place.

The gauze bracelets are narrow in order to minimize the extent to which your sensation of receiving the spray on the arm is changed. Do your best to proceed as if the sensation is not changed. In other words, attempt to avoid spraying additional material onto areas under the bracelets where the sensation of test material on the skin will be different or absent. Do not attempt to spray additional material directly onto a bracelet unless it is within an area that needs additional treatment. Again, attempt to repeat the procedure that you have already developed, and apply the materials “as if the bracelets were not there.”

Put a new latex glove on each hand. Spray material onto one arm only. The technician will tell you to which arm to apply spray. You and the technician will collect the same data as previously.

After you have completed spraying, keep both arms from making contact with any surface. All bracelets will be removed by a technician and taken for weighing.

Discard your gloves, and wash both arms with cleanser and dry them thoroughly with a towel.

Repeat these procedures until you have made a total of three spray samples for the first arm, and three more for the second arm. Be sure to discard your gloves, and wash both arms with cleanser and dry them thoroughly with a towel, including after the last application.”

Lotion sampling

The amount of lotion applied to limbs will be quantified in a series of three applications analogous to the Spray Sampling above. However, dosimeters are not required, nor are the extensive practice sessions. The amount applied is the weight difference in the dispensing tube before and after application.

The instructions are as follows:

“Put a new latex glove on each hand. You will apply lotion to one arm only. The technician will tell you to which arm to apply. You will begin with an amount that you suppose is about one half of what you will need to achieve thorough and uniform coverage. After spreading

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that around the lower part of your arm, you will apply more as needed to the area closer to your elbow. Begin by gently squeezing lotion from a tube with the cap open directly onto the horizontally-held surface of the opposite arm. Hand the tube to the technician. Using the tips of the index and middle fingers, spread the lotion as evenly as possible on all surfaces of the lower arm. Do not spread it onto the hand or beyond the marking on your wrist. If you have sufficient lotion left to spread it evenly and thoroughly toward the elbow, continue in the direction. Do not spread it beyond the elbow or past beyond the marking near the elbow. If you need more lotion to achieve thorough and even coverage, make sure you have wiped all repellent from your fingertips onto the skin and ask the technician to hand you the tube. Apply as much additional as you think you need, as before, but to complete the coverage. If you decide that you have applied more repellent than you would normally use to achieve thorough and even coverage, immediately have the technician wash and dry the treated arm so that none of the repellent you have applied is visible on close inspection, and begin again. Likewise, be careful to avoid dropping any lotion off of the arm, and if this happens, begin again as you would if you applied too much.

After you have completed an application successfully, the technician wash and dry the treated arm so that none of the repellent you have applied is visible on close inspection, and reweigh the tube. You will continue until you have completed three successful applications. Then you will repeat the entire procedure above, but with the lower leg.”