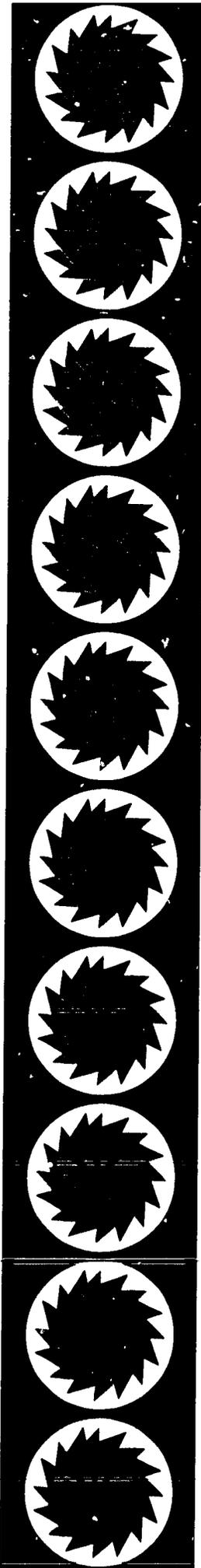


N-ABR- F  
ISA 83437

#3  
Condom  
Series



# Condoms: Quality Assurance Issues

## Project Manager's Information Packet

*other topics in this series:*

- Fixed Interval Condom Tracking System*
- Estimating Condom Needs*

**AIDSTECH**



Family Health International, Durham, North Carolina, USA

**Introduction**

Most condoms are made of latex which breaks down over time and can result in condom failure. Because users rely on condoms to prevent unwanted pregnancies and sexually transmitted diseases (STDs) including HIV/AIDS, the consequences of product failure can be serious. In addition, people may stop using condoms and expose themselves to greater health risks if they feel that the product is not reliable. This packet reviews some condom quality issues and the related techniques used to insure that condoms distributed to users in STD prevention and family planning programs are of high quality.

**Appropriate Environmental Conditions for Condom Storage**

**Provide adequate ventilation.**

Air conditioning is ideal but is also expensive and sometimes not possible. Some alternatives and/or supplements to air conditioning include ceiling fans, forced ventilation, and good insulation. These techniques help to reduce the build-up of heat in the storeroom which causes spoilage/damage. Careful arrangement of stock on pallets (short wooden platforms that keep the cartons off the floor), facilitates proper ventilation.

**Prevent water damage.**

The storage area must be kept in good repair to prevent water from entering, especially through the roof, and damaging the packaging and stock. If flooding is common in the region, the storeroom should be located on high ground in a well-drained area that is less likely to flood. To prevent moisture from contacting the packaging, stack cartons on pallets or shelves.

**Control pests.**

Rodents (i.e., rats, mice, etc.) and some insects (i.e., termites, roaches, etc.) eat through the packaging, including the outer carton, interior boxes, and the condom wrappers. To reduce pest problems, the storage area must be kept clean and free of debris. If a pest problem develops, use cats and pesticides (as directed) to control the pests. *Caution: Do not store pesticides in the same storeroom as the condom stock.*

**Prevent exposure to ultraviolet light, air pollution, and chemical products including petroleum and liquid solvents.**

Sunlight, light from fluorescent lamps, sparks from electrical motors, and lightning from electrical storms can create ozone that can damage condoms. In addition, some chemical products produce vapors that can damage condoms. Contact with petroleum or vegetable oils can break down wrapper seals and destroy latex condoms within minutes.

As much as possible, eliminate exposure to these dangers. Use window shades and store condoms in their shipping cartons as long as possible. Although the storeroom should be well-lit so that it is easy to see package labels, the lights should be turned off when not needed.

When condoms are carelessly exposed to heat, humidity, pests and pollutants, severe deterioration can be observed in less than one year. To prevent damage, it is very important that condoms be protected during both shipment and storage. The likelihood of exposure to damaging elements is the greatest during transport, when conditions are highly variable. The selection of transport method(s) requires a balance between the amount of time the stock is in transit (shorter is better) and the likelihood of exposure to damaging elements (less is better). For example, if shipment by air cargo (generally the fastest) requires that the shipment be exposed to extremely high heat and humidity for several weeks while awaiting transfer flights, then an alternate transport method or combination of methods may be more desirable. When a shipment arrives at the project site it should be placed in the storeroom immediately to reduce the chance of theft and exposure to dangers.

**Promote safety/security.**

The storeroom should be a secure area that is used exclusively for storage of stock. It should be kept locked to prevent theft of supplies and/or entry by unauthorized personnel. To prevent confusion, only trained personnel should have access to the storeroom. At least one fire extinguisher should be located in an easy-to-reach place. Observe all precautions provided by the product manufacturer and outlined in this packet.

**Keep accurate records.**

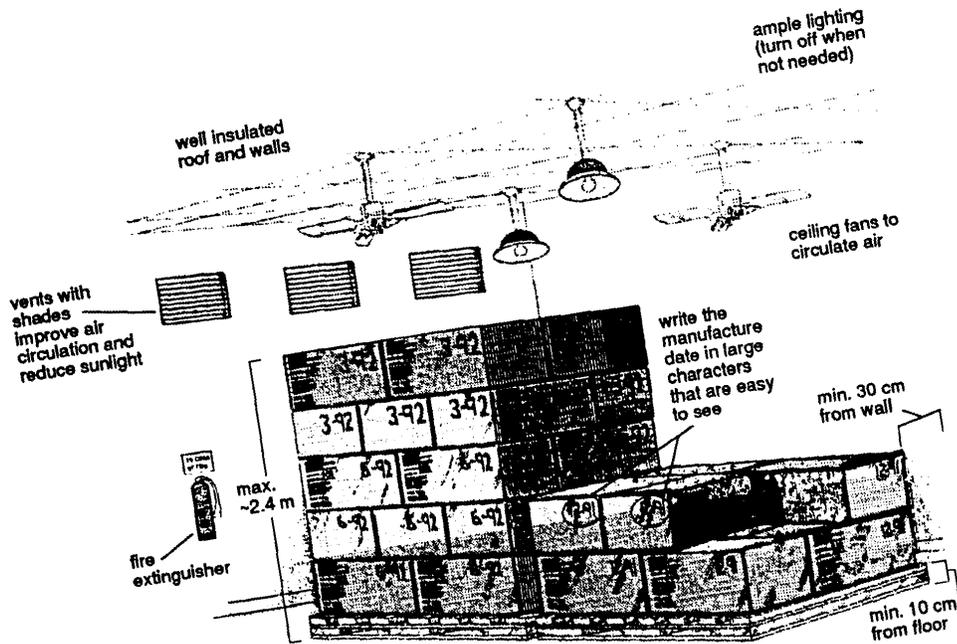
All transactions should be recorded on the appropriate form(s) and reported according to the established procedures, including receipt, distribution, damage, theft, and expiration of unused stock. (*See Fixed Interval Condom Tracking System Information Packet for details.*)

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**Planning  
the Storage  
Space**

In addition to the space required to house the stock, ample space must be provided in the storage area to permit air circulation and facilitate cleaning, unloading of shipments, and orderly distribution of stock. Most storerooms/warehouses use a combination of pallets and shelves to organize stock and reduce exposure to pests and moisture. Pallets are usually best for bulky items and/or cartons which arrive in large quantities and can be easily stacked; shelves work best for smaller items or lesser quantities. Condom shipments are usually stacked on pallets rather than on shelves because the cartons are large and bulky. However, in some projects where smaller amounts of stock are stored, shelves may be more suitable. (*See pages 6-7 of this packet for information regarding shelf arrangements that facilitate orderly distribution.*)

As shown in the illustration on page 3, cartons should be placed on pallets and stacked no more than 2.4 meters (~8 feet) high. The pallets should be positioned at least 30 cm (~1 foot) from the wall and should raise the cartons off of the floor at least 10 cm (~4 inches). The manufacture date or an expiration date should be clearly written in large letters/numbers on each carton (if it is not already). To facilitate orderly distribution, the cartons should be stacked so that the markings are easy to see.



Arrange stock to facilitate distribution of the oldest stock first. Stack cartons with the same lot number and manufacture date together.

## Estimating the Size of Storage Space Needed

To ensure that a storage area will be large enough to meet the needs of the project, complete the simple steps described below using the worksheet on page 9.

**Step 1:** Determine the size and the number of cartons that need to be stored. The storage area must accommodate at least the number of cartons required to meet your project's maximum stock level (see the *Fixed Interval Condom Tracking System Information Packet* for determining the maximum stock level/number of cartons your project will require). Condoms from donor agencies are usually shipped in quantities of 6,000 (60 boxes of 100 condoms per carton). The cartons measure 47 cm (18.5 inches) tall by 39.4 cm (15.5 inches) wide by 58.4 cm (23 inches) long, cubic cm = 108145 or 0.11 cubic meter (6595.25 cubic inches or 3.82 cubic feet). It is best to check with the supplier regarding the actual size of the shipping cartons you will be receiving.

**Step 2:** Determine the type and amount of storage unit(s) needed. If your project will need to store more than 10 cartons, pallets are a good choice. Closets and shelving may work for smaller amounts provided they meet the conditions for appropriate storage and can be arranged in an orderly manner.

The following is a brief description of how to determine the number of standard-size (1.2 m x 1.2 m) pallets your project will require. As shown in the illustration (using cartons matching the measurements described above), cartons can be stacked 25 per pallet, five cartons high with five cartons on each layer. To determine how many pallets are needed for your project, divide the number of cartons by 25, then round the figure to the next whole number.

**Example 1:**

222,000 condoms maximum stock level  
37 cartons + 25 = 1.48, rounded to 2 pallets

**Example 2:**

120,000 condoms maximum stock level  
20 cartons + 25 = .8, rounded to 1 pallet

Or refer to the chart below:

If the number of cartons is:

10-25	1 pallet is required
26-50	2 pallets are required
51-75	3 pallets are required
76-100	4 pallets are required

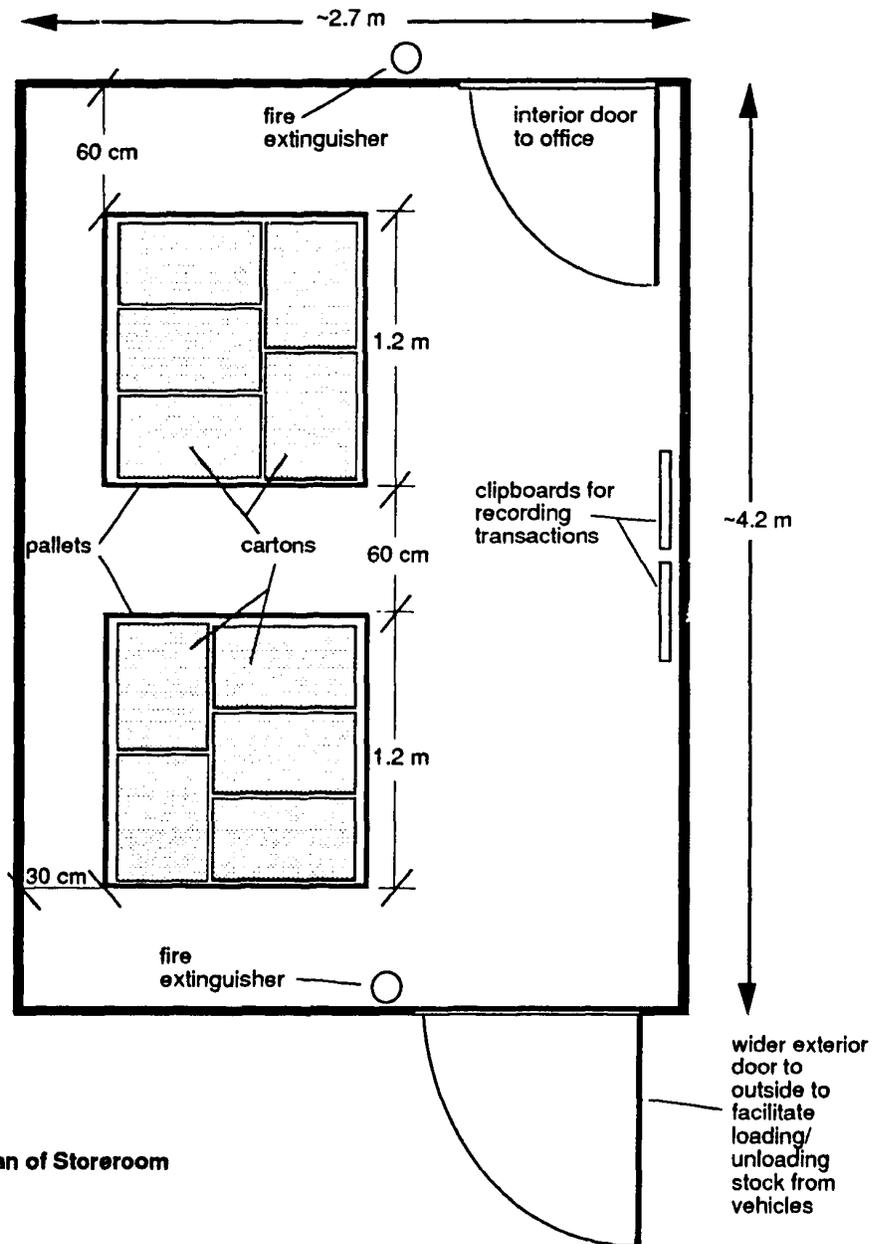
**Step 3:** To determine the amount of space needed in addition to the space occupied by the pallets and/or shelves, it is best to sketch out a floor plan of the storage space. The additional space is needed to permit air circulation, appropriate arrangement of pallets and/or shelves, unloading of new shipments, and distribution of stock. As shown in the sample floor plan, access aisles should be at least 60 cm (2 ft) wide to permit passage; non-passage spaces between the wall and the cartons should be at least 30 cm (1 ft) to permit air circulation; fire extinguishers should be ready in case of a fire; and additional open space should be left in front of the doors to facilitate entering and exiting with large packages. If available, wider doors should be used on the exits where stock is received to make loading and unloading large cartons easier. Also, if space permits, the stack height can be lowered to three or four cartons to make access easier. If possible, the storage room should provide some extra space to permit a moderate amount of program expansion.

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### **When is a condom too old to use?**

When properly transported and stored, condoms can be used up to five years from the date of manufacture. In most cases the date of manufacture is indicated on some or all of the packaging including the carton, interior packing boxes, and the individual condom wrappers. However, as is the case with drug products, some manufacturers indicate an expiration date rather than the manufacture date on their products. When an expiration date is shown it is usually because the condom contains a spermicide that begins to lose its effectiveness after a three to five year period. Regardless of the manufacture/expiration date, the conditions under which condoms are transported and stored will dictate their usability over time.

If condoms which your project receives are identified with an expiration date rather than a manufacture date, make note of this difference and insure that the condoms are distributed well before the expiration date. Remember, if improperly stored, the condoms may be damaged and actually “expire” before the expiration



**Floor Plan of Storeroom**

date. If questions arise (especially regarding condoms that are between three and five years old), a sample from the lot should be tested to determine their suitability for use. (A lot refers to each different production batch at the time of manufacture. Each lot is indicated by a unique lot number. All condoms in a lot have identical chemical formulation and are of the same dimensions, color, shape, and texture.)

Usually, samples of condoms are collected at the central warehouse and shipped to special labs for testing. At the project level little if any testing is possible (except visual inspection). However, if clients report many breakage problems, the project should notify the warehouse that a particular lot appears to be causing problems and needs to be tested. If a question arises regarding a particular lot, the "questionable condoms" should be set aside until testing is complete.

## How to Identify Damaged Condoms

Special laboratory testing by trained technicians helps determine whether the quality of condoms is suitable for use. Laboratory testing can identify condoms that appear fine upon visual inspection but which are slightly damaged or flawed. However, when laboratory testing is not available, it is possible to identify obvious signs of deterioration and/or damage through visual inspection.

Some of the most obvious damage is usually due to improper handling during shipping. Condoms that arrive in cartons which are crushed, punctured, or which have been soaked by water or chemical spills should not be distributed. Rough handling and exposure to excessive moisture tends to break down the seals on the individual condom wrappers. The exposed condoms then degrade rapidly.

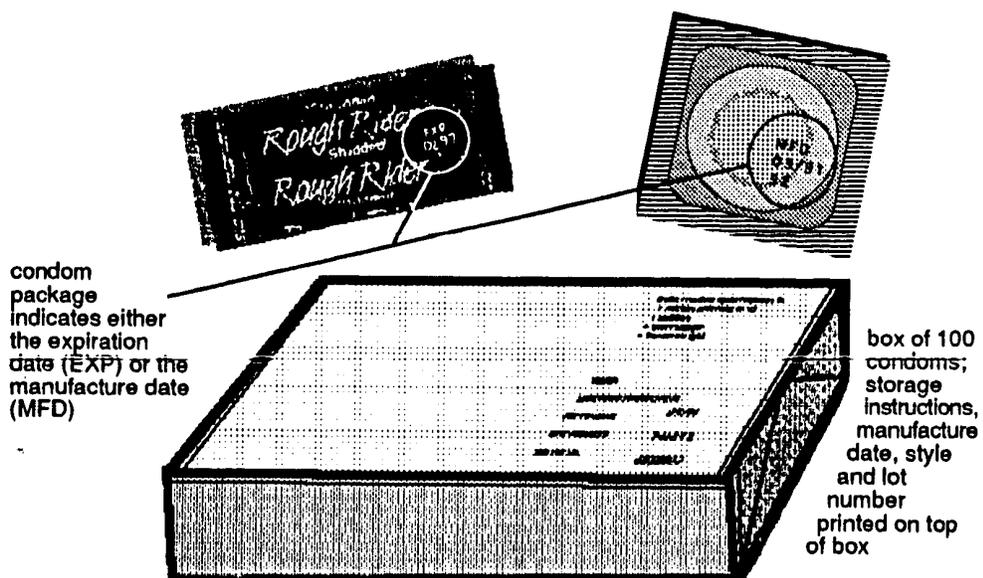
Careful inspection of individual condoms and wrappers can reveal evidence of damage. In addition to condoms with broken wrapper seals, condoms which have discolored (turned yellow or brown), become gummy, or turned brittle, should not be used.

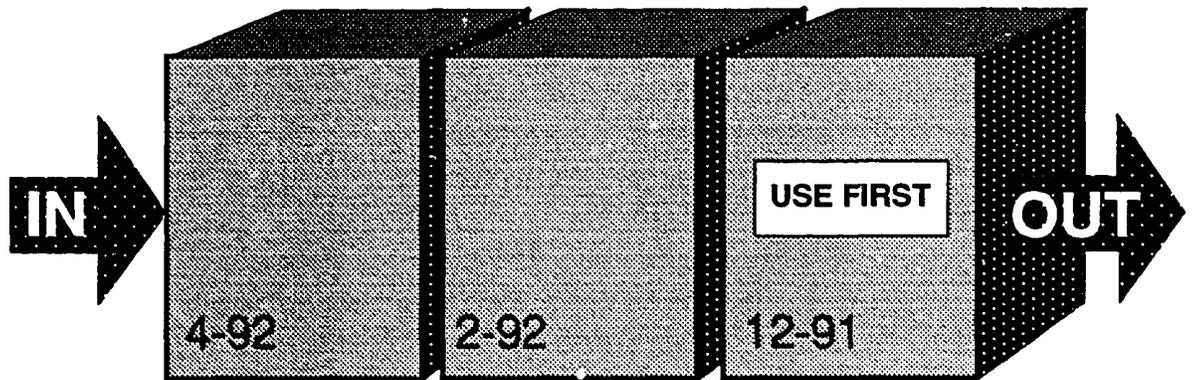
Disposal of condoms should be carried out according to local laws and/or customs for handling solid waste products. In most cases, disposal is by burning or burial. Regardless of the method used, a representative from the project should witness the destruction of the condoms to insure that the condoms cannot be recovered for use or resale.

Because condoms degrade over time, it is important that controls be implemented to reduce waste while providing a high quality product to the user. Waste can be prevented by limiting exposure to the dangers described earlier and by insuring that condoms are distributed for use well before their anticipated expiration date. A well organized storeroom can help insure that no condoms spoil while waiting to be distributed.

As a general rule, new shipments of condoms will be "fresher" than those currently in stock. To keep condoms from spoiling, the older condoms should be distributed first. This practice of First to Expire, First Out (FEFO) is used in virtually all settings where stock is subject to deterioration.

## First Expiry, First Out (FEFO)





**First to Expire - First Out (FEFO)**

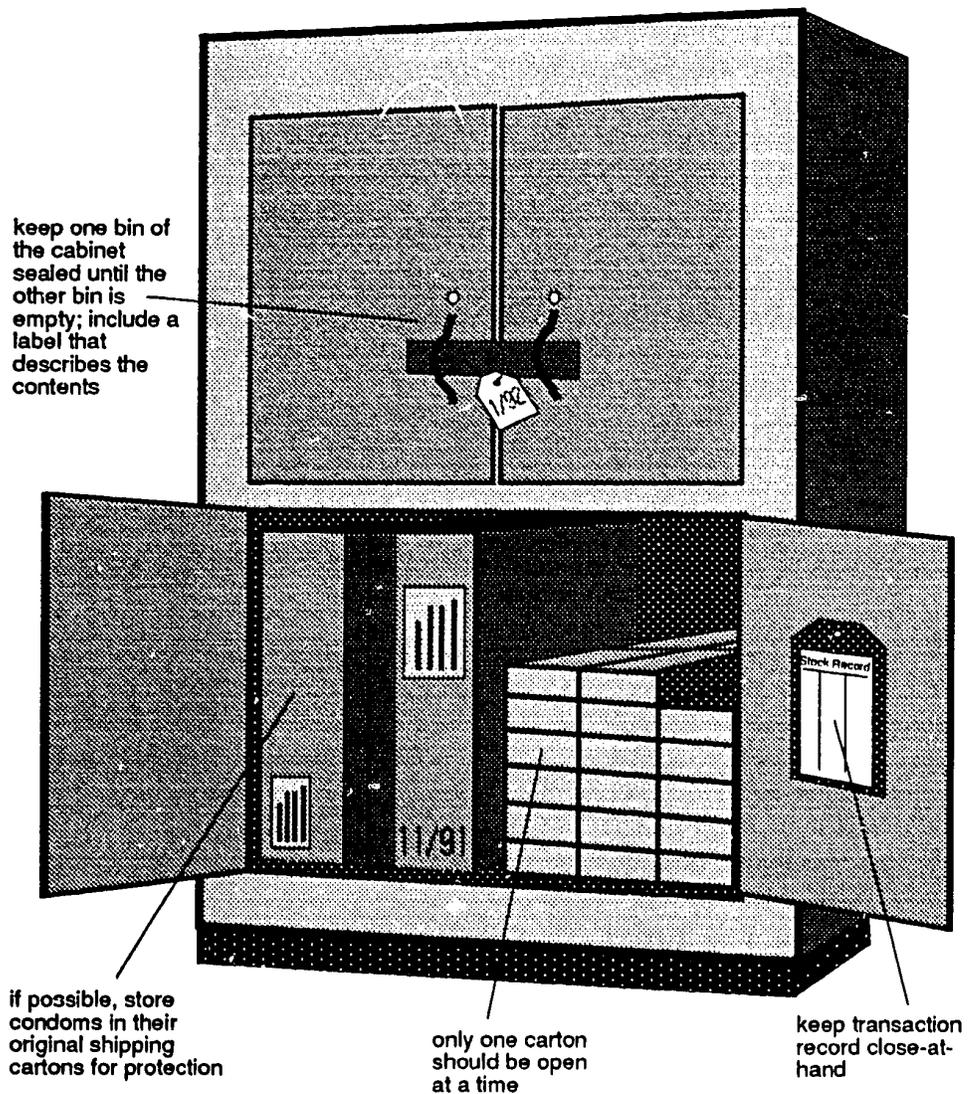
The development of sound FEFO (stock rotation) practices requires attention to the physical arrangement of the storage space and stock. As described earlier, the storeroom should be large enough to house the stock and provide ample access aisles. It is also very important that the stock be arranged on pallets or shelves with the manufacturing date and lot number in clear view.

Staff who are authorized to distribute stock should be trained to use the stock rotation procedures developed by the storeroom manager. All authorized staff should be aware of which stock to distribute first, which carton may already be open, where to place new stock as it arrives, how to record all transactions, how to limit exposure to dangers, and why it is important to follow all of the procedures carefully.

The procedures developed will depend on the size of the storeroom and the amount of stock distributed by the program. Simple reminders such as a note attached to the carton which says "use first" or "take condoms from this carton/shelf" can help to insure that the oldest condoms are distributed first. In the event that a new shipment contains condoms which are older than those in stock, the new shipment should be "rotated" into the distribution arrangement in the order of oldest first.

The illustration on page 8 depicts a method for storing a small amount of stock while insuring that it is dispensed in order. In this example one set of shelves is sealed closed until the older stock is distributed. When the older stock is gone the sealed shelves are opened. When a new shipment arrives, the empty shelves are filled and sealed until needed.

A similar cabinet system may work in a setting where many staff members need to distribute condoms to clients, peer educators, etc., but allowing staff unlimited access to the entire storeroom would create too much confusion. In this case one or two staff would be responsible for stocking shelves at the front of the storeroom with the oldest stock from the storeroom floor. Staff would only distribute stock from the shelves and would be trained to record their transactions.



## Summary

As emphasized throughout this information packet, it is critical that storeroom managers make certain that condoms distributed by the project are of high quality. The procedures and techniques used to insure quality should fit the project's unique situation. In brief, the basic rules to follow are:

- Develop and follow FEFO plan so that older condoms are distributed first.
- Make sure storeroom is large enough for stock and provides access space.
- Arrange cartons with manufacture date and lot number in clear view.
- Prevent exposure of condoms to harmful elements.
- Train staff to keep accurate records of all transactions.
- Keep storeroom clean and secure.

For more information or if you have any questions regarding condom quality assurance issues, contact the Materials Technology Division at Family Health International, P.O. Box 13950, Research Triangle Park, NC, 27709 USA.

# Worksheet for Determining Size and Layout of Condom Storeroom\*

**Follow these simple steps:**

Using the steps described in the *Fixed Interval Condom Tracking System Information Packet*, determine the maximum stock level for your project.

maximum stock level = \_\_\_\_\_ condoms

Determine the number of cartons in the maximum stock level. Divide the number of condoms by 6,000 or use the table provided in the *Fixed Interval Condom Tracking System Information Packet*.

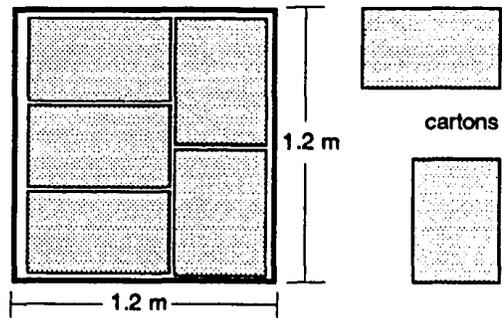
= \_\_\_\_\_ cartons

If the number of cartons is less than 10, you may want to consider a shelf system to store condoms. If the number of cartons is:

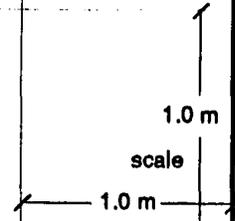
= \_\_\_\_\_ pallets

- 10-25 1 pallet is required
- 26-50 2 pallets are required
- 51-75 3 pallets are required
- 76-100 4 pallets are required

scale drawing of pallet



Use the space below to sketch a floor plan of the storeroom for your project. If you plan to use an existing space for your storeroom, begin by carefully measuring the dimensions of the room and creating a sketch that shows the location of the walls and doors. Pallets are ~1.2 m x 1.2 m. Remember to leave 30 cm between the wall and the cartons and at least 60 cm for passage (wider is better).

\* Assumes condoms are in cartons that meet the specifications described on page 3.

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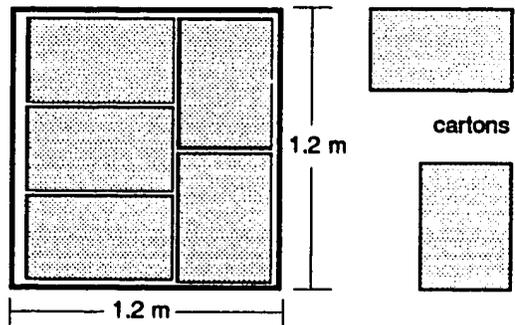
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scale drawing of pallet




1.0 m  
scale  
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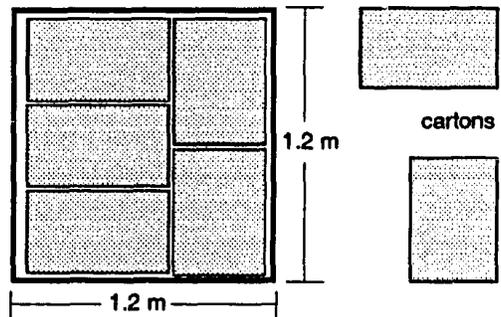
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scale drawing of pallet




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12