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Manufacturing—Bulk and Sterile

Statistical data on manufacturing or bulk compounding in hospitals[1] revealed that approximately 41% of 1853 hospital pharmacies operate a manufacturing program. The survey further demonstrated that 78% of the sample group prepared galenical pharmaceuticals; 74%, products not commercially available; 42%, sterile solutions for topical use; 33%, sterile pharmaceuticals such as collyria, ointments etc.; and 30%, small volume injectable solutions.

In addition, the same survey[2] showed that hospital pharmacists were also active in the preparation of sterile products such as surgical irrigating fluids, large volume injectable solutions, and special sterile products for investigational use.

This volume of hospital manufacturing may surprise the neophyte pharmacist particularly when viewed in the light of the magnitude of the American pharmaceutical industry. Obviously, there must be some explanation to this paradox. Those knowledgeable in the ways of the profession have advanced a number of reasons the more important of which are *(a)* that there exists a close relationship between doctors and pharmacists in hospitals, *(b)* that commercially available products are not often suited for the treatment of certain unusual illnesses which the physician with a hospital practice is expected to cope with, and *(c)* that, because of the physician-pharmacist relationship in the hospital, doctors feel at ease in requesting the pharmacist to prepare a special pharmaceutical form either for clinical or experimental use.

Also worthy of consideration here is the fact that hospital pharmacists engaged in this type of practice often encourage and promulgate its expansion and growth because they are of the consensus that such an activity promotes economy within the hospital, complements the operation of the formulary system, increases the prestige of the hospital pharmacist, and provides the research clinician with the opportunity to develop new pharmaceutical formulations.

Those responsible for the education and training of future hospital pharmacists consider a manufacturing or bulk compounding program to be an extremely useful endeavor which draws together the classroom

concepts of courses in product development, physical chemistry, instrumental methods of analysis, and preservation and stabilization of pharmaceutical products.

A manufacturing program within the department of pharmacy is also of interest to trustees and administrators because of its ability to reduce the cost of pharmaceuticals to patients and is, therefore, encouraged by them, whenever the pharmacist shows the desire and the ability to undertake such an endeavor.

For the purposes of this chapter, a manufacturing program for the hospital pharmacy shall be deemed to encompass both bulk compounding of pharmaceuticals and the preparation of sterile products. The same meticulous standards and principles should apply to the preparation of both classes of products.

Control

The word "control" is defined[3] as

"To test or verify (a statement or experiment) by counter or parallel evidence or experiment."
"To exercise directing, guiding or restraining power over."

The ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control makes the following provision:[17]

ASHP TECHNICAL ASSISTANCE BULLETIN ON HOSPITAL DRUG DISTRIBUTION AND CONTROL

In-house Manufacturing, Bulk Compounding, Packaging and Labeling. As with commercially marketed drug products, those produced by the pharmacy must be accurate in identity, strength, purity, and quality. Therefore, there must be adequate process and finished-product controls for all manufacturing/bulk compounding and packaging operations. Written master formulas and batch records (including product test results) must be maintained. All technical personnel must be adequately trained and supervised.

Packaging and labeling operations must have controls sufficient to prevent product/package/label mixups. A lot number to identify each finished product with its production and control history must be assigned to each batch.

The Good Manufacturing Practices of the Food and Drug Administration is a useful model for developing a comprehensive control system.

The pharmacist is encouraged to prepare those drug dosage forms, strengths, and packagings which are needed for optimal drug therapy,

but which are commercially unavailable. Adequate attention must be given to the stability, palatability, packaging, and labeling requirements of these products.

Klemme[4] has suggested that hospital pharmacists should consider control of their manufacturing program from two vantage points—"quality control" to govern the quality, purity and strength of the manufactured product and "budgetary control" to regulate the economic aspects of the program. All too often, the hospital pharmacist devotes a great deal of thought and effort to the quality control aspect of the manufacturing program only to learn that he has a technically and professionally sound program but at the same time one which is in economic distress.

Accordingly, the principles of budgetary and quality control will be discussed under separate sections within this chapter.

BUDGETARY CONTROL

In order to develop adequate budgetary control over the manufacturing program, the hospital pharmacist is required to give lengthy consideration to his *inventory* and *consumption rate* for the *finished product, raw materials requirement, manufacturing capacity, available personnel* and *operating costs.*

Manufacturing Requirements

Probably the most difficult task lies in prognosticating, with reasonable accuracy, the consumption rate for each item to be included in a manufacturing program. This can be done by reviewing the records of the previous year or two and comparing this figure with the staff's present prescribing pattern. Since the figure to be arrived at is, at best, an educated guess, the pharmacist should not become too alarmed if, at the end of the first quarter, he realizes that he has overestimated or underestimated his requirements. Whichever the case may be, corrective measures may be put into effect for the second quarter, namely, increase the rate or volume of production or reduce the batch quantity or frequency of manufacture or eliminate one batch of the product which is considered to be above desirable inventory limits.

Material Requirements

Once the hospital pharmacist has determined what products he intends to manufacture and in what volume and quantity, he must next arrange for the procurement of the necessary supplies. These supplies should include, in addition to raw materials, such items as containers,

labels and ancillary materials such as filter paper, filter pads, boxes, and special labels.

The first step in this direction is to take each formula and determine the quantity of chemical or other material which will be required to produce the annual supply. This is done by taking the quantities of raw materials from the working formula and packaging specifications of each item and multiplying these quantities by the number of times the formula must be produced to satisfy the estimated annual requirement.

The second step is to enter these quantities on a *summary sheet* because the same drug, chemical or container may be required by many different formulas.

By totaling the quantities under each item on the summary sheet, the pharmacist will now have available to him his annual supplies and material needs to undertake the contemplated manufacturing program.

Since the budget period of the hospital is on a yearly basis, the purchasing agent or the purchasing pharmacist will divide the material and supply requirements into four quarters. This will allow the purchasing group ample time to utilize the basic principles of good purchasing technics and at the same time ensure against over inventory and shortage of materials in the pharmacy.

Manufacturing Capacity

Two important considerations in any bulk compounding program are first whether or not the pharmacist has available to him the kind of equipment necessary to produce the formulas selected and secondly, whether or not the machinery is capable of producing the desired quantity.

Because time is the costliest factor in any manufacturing program, it behooves the pharmacist to utilize the maximum capacity of his equipment. In addition, the selection of equipment should be made on the basis of the multiple or variety of uses to which a single piece of equipment can be put. This will prevent costly equipment from accumulating idle time.

Manufacturing Equipment and Its Sources

The kind and size of manufacturing equipment required in the hospital pharmacy will vary from institution to institution. Primary consideration must be given to the scope of the manufacturing program, the quantities to be produced during any production run as well as to the length of time that will be required to consume the product, the availability of personnel and the availability of physical facilities.

Modern technology has developed equipment to meet every production need. The available machinery can handle amounts that are con-

sidered to be of "practical volume or quantity" for a small or medium sized hospital. In addition, the larger hospitals have available to them automatic and semi-automatic heavy duty production equipment which is capable of handling large volume in a minimum of time.

In *Remington's Practice of Pharmacy*,[5] the student will find pictures and a brief description of the various pieces of equipment which may be useful in the formulation of pharmaceutical preparations.

As a means of assisting the pharmacist desirous of mechanizing his bulk compounding department, many producers of pharmaceutical manufacturing and packaging equipment have prepared excellent descriptive brochures and catalogues which are of value in assisting the pharmacist in selecting the most versatile equipment for his particular use and needs.

Manufacturing Staff

Next to equipment, personnel represent the most important consideration in a bulk compounding program. Too many personnel will raise the cost of a manufactured product to the point where it would be more economical to purchase it from a commercial supplier and too little help may mean the inability to maintain an adequate production schedule and potential errors—neither of which may be condoned.

Accordingly, production time must be determined for each formula in order that proper planning and scheduling be effected.

The manufacturing section of the pharmacy must be supervised by a technically competent, legally qualified pharmacist. In addition he must be supported with ancillary personnel who can be trained to carry on such non-technical pursuits as bottling, filtering, labeling, etc. Under no circumstances should a bulk compounding program be undertaken without the services of a pharmacist under the pretense that this is justified by the reduction in labor cost and that reasonably intelligent lay help can be trained to perform specific tasks with accuracy and dependability.

Operating Costs

A review of the literature pertaining to manufacturing programs in hospital pharmacies and central sterile supply rooms leads one to believe that many so-called "profitable ventures" are classified as such mainly because of an understated operating cost. In these instances, the operating cost was shown to consist of the direct costs only—direct labor and cost of materials.

Correctly used, operating costs should include both direct and indirect costs.[6] The terminology "overhead costs" is usually used interchangeably with "indirect costs" and, for the purpose of this section,

is intended to include such items as the cost of supervisory personnel, space rental, insurance, equipment depreciation, maintenance, housekeeping, etc. In some hospitals, those items not directly connected with the pharmacy operation are included in a figure obtainable from the comptroller's office known as the *"overhead per square foot"* figure.

By whatever means obtainable, the indirect costs should be compared with the direct costs for the purpose of calculating a ratio of overhead dollars to direct labor dollars which may later be applied in ascertaining the true dost of the product.

An example of the above principle is best demonstrated as follows:

a. Assume that the ratio of indirect costs to direct costs in hospital X is 100%.

b. Further assume that 5 gallons of product "A" require $4.25 in materials and $5.50 in direct costs. Therefore,

Direct Cost	
Materials	$ 4.25
Labor	5.50
Indirect Cost	9.75
TOTAL COST	$19.50 for 5 gallons

It is of importance to call the student's attention at this point to the fact that if the quantity of product "A" in the above example were doubled, only the cost of materials could double. The direct and indirect costs *do not* increase in direct proportion because it requires little more time to manufacture 10 gallons than it does to manufacture 5 gallons. The packaging segment of the operation is where the direct labor cost will be in direct proportion to the batch size.

Since the increase in batch size will, to a point, reduce the unit cost, the student is cautioned that the cost curve does not decrease geometrically with the increase in batch size. Also, it is unwise to manufacture in a volume which will not be consumed within a reasonable period of time for this will now introduce problems in storage, long term product preservation, and reduced inventory turn-over.

QUALITY CONTROL

The term "quality control" should not be confused with the term "statistical quality control" which involves the application of statistics for the control of sizes, weights and other physical characteristics of articles undergoing mass production. Statistical quality control plays an important role in large scale pharmaceutical production plants but has little value in the control aspect of hospital pharmacy manufacturing programs.

What is more important to hospitals, their staff and patients is a

quality control that will ensure the integrity of the label. This can best be accomplished by developing a series of cross checks and laboratory analyses.

It should be clearly understood that no two hospitals develop control systems which are identical in every respect,[7,8] and therefore no system can here be recommended which will serve every purpose. Accordingly, it becomes the responsibility of the hospital pharmacist to make whatever modifications he deems necessary to ensure a product which will meet high pharmaceutical standards.

The FDA has published good manufacturing practices regulations which went into effect on March 28, 1979. Because one lawyer specializing in pharmacy law has stated[16] the concern that pharmacists may be required to comply with these regulations, they are presented here in order to permit the hospital pharmacist to compare his recent quality control program with the specific considerations which ordinarily form the basis of a quality control program utilized by the pharmaceutical industry.

GOOD MANUFACTURING PRACTICE REGULATIONS

Title 21, Code of Federal Regulations sections 211.1 through 211.208 provides cogent minimum current good manufacturing practice for preparation of drug products for administration to humans or animals.

SUBPART B—ORGANIZATION AND PERSONNEL

§ 211.22 Responsibilities of Quality Control Unit

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

§ 211.25 Personnel Qualifications

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any com-

bination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned fuctions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

§ 211.28 Personnel Responsibilities

(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

(b) Personnel shall practice good sanitation and health habits.

(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

(d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

§ 211.34 Consultants

Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

SUBPART C—BUILDINGS AND FACILITIES

§ 211.42 Design and Construction Features

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product

containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas for the firm's operations to prevent contamination or mixups as follows:

(1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;

(2) Holding rejected components, drug product containers, closures and labeling before disposition;

(3) Storage of released components, drug product containers, closures, and labeling;

(4) Storage of in-process materials;

(5) Manufacturing and processing operations;

(6) Packaging and labeling operations;

(7) Quarantine storage before release of drug products;

(8) Storage of drug products after release;

(9) Control and laboratory operations;

(10) Aseptic processing, which includes as appropriate:

(i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;

(ii) Temperature and humidity controls;

(iii) An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;

(iv) A system for monitoring environmental conditions;

(v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;

(vi) A system for maintaining any equipment used to control the aseptic conditions.

(d) Operations relating to the manufacture, processing, and packing of penicillin shall be performed in the facilities separate from those used for other drug products for human use.

§ 211.44 Lighting

Adequate lighting shall be provided in all areas.

§ 211.46 Ventilation, Air Filtration, Air Heating and Cooling

(a) Adequate ventilation shall be provided.

(b) Equipment for adequate control over air pressure, microorganisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.

(c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants.

(d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.

§ 211.48 Plumbing

(a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Public Health Service Drinking Water Standards set forth in Subpart J of 42 CFR Part 72. Water not meeting such standards shall not be permitted in the potable water system.

(b) Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage.

§ 211.50 Sewage and Refuse

Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner.

§ 211.52 Washing and Toilet Facilities

Adequate washing facilities shall be provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working areas.

§ 211.56 Sanitation

(a) Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner.

(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed.

(c) There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135).

(d) Sanitation procedures shall apply to work performed by contractors or temporary employees as well as work performed by full-time employees during the ordinary course of operations.

§ 211.58 Maintenance

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair.

SUBPART D—EQUIPMENT

§ 211.63 Equipment Design, Size, and Location

Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

§ 211.65 Equipment Construction

(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity or the drug product beyond the official or other established requirements.

§ 211.67 Equipment Cleaning and Maintenance

(a) Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use;

(6) Inspection of equipment for cleanliness immediately before use.

(c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in § § 211.180 and 211.182.

§ 211.68 Automatic, Mechanical, and Electronic Equipment

(a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the

computer or related system of formulas or other records or data shall be checked for accuracy. A backup of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.

§ 211.72 Filters

Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may not be used in the manufacture, processing, or packing of these injectable drug products unless it is not possible to manufacture such drug products without the use of such filters. If use of a fiber-releasing filter is necessary, an additional non-fiber-releasing filter of 0.22 micron maximum mean porosity (0.45 micron if the manufacturing conditions so dictate) shall subseqently be used to reduce the content of particles in the injectable drug product. Use of an asbestos-containing filter, with or without subsequent use of a specific non-fiber-releasing filter, is permissible only upon submission of proof to the appropriate bureau of the Food and Drug Administration that use of a non-fiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the injectable drug product.

SUBPART E—CONTROL OF COMPONENTS AND DRUG PRODUCT CONTAINERS AND CLOSURES

§ 211.80 General Requirements

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed.

(b) Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination.

(c) Bagged or boxed components or drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection.

(d) Each container of grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected).

§ 211.82. Receipt and Storage of Untested Components, Drug Product Containers, and Closures

(a) Upon receipt and before acceptance, each container or grouping of containers of components, drug product containers, and closures shall be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination.

(b) Components, drug product containers, and closures shall be stored under

quarantine until they have been tested or examined, as appropriate, and released. Storage within the area shall conform to the requirements of § 211.80.

§ 211.84 Testing and Approval or Rejection of Components, Drug Product Containers, and Closures

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

(b) Representative samples of each shipment lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by § 211.170.

(c) Samples shall be collected in accordance with the following procedures:

(1) The containers of components selected shall be cleaned where necessary by appropriate means.

(2) The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, the drug product containers, or closures.

(3) Sterile equipment and aseptic sampling techniques shall be used when necessary.

(4) If it is necessary to sample a component from the top, middle, and bottom of its container, such sample subdivisions shall not be composited for testing.

(5) Sample containers shall be identified so that the following informaiton can be determined: name of the material sampled, the lot number, the container from which the sample was taken, the data on which the sample was taken, and the name of the person who collected the sample.

(6) Containers from which samples have been taken shall be marked to show that samples have been removed from them.

(d) Samples shall be examined and tested as follows:

(1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used.

(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on each component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

(3) Containers and closures shall be tested for conformance with all appropirate written procedures. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such container/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through the appropriate validation of the supplier's test results at appropriate intervals.

(4) When appropriate, components shall be microscopically examined.

(5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination.

(6) Each lot of a component, drug product container, or closure that is liable

to microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.

(e) Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity and related tests under paragraph (d) of this section may be approved and released for use. Any lot of such material that does not meet such specifications shall be rejected.

§ 211.86 Use of Approved Components, Drug Product Containers, and Closures

Components, drug product containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

§ 211.87 Retesting of Approved Components, Drug Product Containers, and Closures

Components, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with § 211.84 as necessary, e.g., after storage for long periods or after exposure to air, heat, or other conditions that might adversely affect the component, drug product container, or closure.

§ 211.89 Rejected Components, Drug Product Containers, and Closures

Rejected components, drug product containers, and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

§ 211.94. Drug Product Containers and Closures

(a) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

(c) Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

(d) Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures.

SUBPART F—PRODUCTION AND PROCESS CONTROLS

§ 211.100 Written Procedures; Deviations

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including

any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

§ 211.101 Charge-in of Components

Written production and control procedures shall include the following, which are designed to assure that the drug products produced have the identity, strength, quality, and purity they purport or are represented to possess:

(a) The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient.

(b) Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information:

(1) Component name or item code;

(2) Receiving or control number;

(3) Weight or measure in new container;

(4) Batch for which component was dispensed, including its product name, strength, and lot number.

(c) Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that:

(1) The component was released by the quality control unit;

(2) The weight or measure is correct as stated in the batch production records;

(3) The containers are properly identified.

(d) Each component shall be added to the batch by one person and verified by a second person.

§ 211.103 Calculation of Yield

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall be performed by one person and independently verified by a second person.

§ 211.105 Equipment Identification

(a) All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to include their contents and, when necessary, the phase of processing of the batch.

(b) Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the the equipment may be used in lieu of a distinctive identification number or code.

§ 211.10 Sampling and Testing of In-Process Materials and Drug Products

(a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

(1) Tablet or capsule weight variation;

(2) Disintegration time;

(3) Adequacy of mixing to assure uniformity and homogeneity;

(4) Dissolution time and rate;

(5) Clarity, completeness, or pH of solutions.

(b) Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process averages and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications.

(c) In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

(d) Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

§ 211.111 Time Limitations on Production

When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product. Deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug product. Such deviation shall be justified and documented.

§ 211.113 Control of Microbiological Contamination

(a) Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of any sterilization process.

§ 211.115 Reprocessing

(a) Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics.

(b) Reprocessing shall not be performed without the review and approval of the quality control unit.

SUBPART G—PACKAGING AND LABELING CONTROL

§ 211.122 Materials Examination and Usage Criteria

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled and examined or tested upon receipt and before use in packaging or labeling of a drug product.

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

(c) Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected.

(d) Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel.

(e) Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed.

(f) Gang printing of labeling to be used for different drug products or different strengths of the same drug product (or labeling of the same size and identical or similar format and/or color schemes) shall be minimized. If gang printing is employed, packaging and labeling operations shall provide for special control procedures, taking into consideration sheet layout, stacking, cutting, and handling during and after printing.

(g) Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record.

§ 211.125 Labeling Issuance

(a) Strict control shall be exercised over labeling issued for use in drug product labeling operations.

(b) Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records.

(c) Procedures shall be utilized to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192.

(d) All excess labeling bearing lot or control numbers shall be destroyed.

(e) Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification.

(f) Procedures shall be written describing in sufficient detail the control

procedures employed for the issuance of labeling; such written procedures shall be followed.

§ 211.130 Packaging and Labeling Operations

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features:

(a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products.

(b) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

(c) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record.

(d) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

§ 211.134 Drug Product Inspection

(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label.

(b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling.

(c) Results of these examinations shall be recorded in the batch production of control records.

§ 211.137 Expiration Dating*

(a) To assure that a drug product meets applicable standard of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

(e) Homeopathic drug products shall be exempt from the requirements of this section.

(f) Pending consideration of a proposed exemption, published in the FEDERAL REGISTER of September 29, 1978, the requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage

*EFFECTIVE DATE NOTE: The expiration dating requirements under these amendments that have not been previously in effect shall apply to drug products packaged after September 28, 1979. See 44 FR 11064, Feb. 27, 1979.

limitations and they are stable for at least 3 years as supported by appropriate stability data.

SUBPART H—HOLDING AND DISTRIBUTION

§ 211.142 Warehousing Procedures

Written procedures describing the warehousing of drug products shall be established and followed. They shall include:

(a) Quarantine of drug products before release by the quality control unit.

(b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.

§ 211.150 Distribution Procedures

Written procedures shall be established, and followed, describing the distribution of drug products. They shall include:

(a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

(b) A system by which the distribution of each lot of drug product can be readly determined to facilitate its recall if necessary.

SUBPART I—LABORATORY CONTROLS

§ 211.160 General Requirements

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory mechanisms shall be recorded and justified.

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(1) Determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

(3) Determination of conformance to written descriptions of sampling pro-

cedures and appropriate specifications for drug products. Such samples shall be representative and properly identified.

(4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

§ 211.165 Testing and Release for Distribution

(a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.

(b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms.

(c) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested: such written procedure shall be followed.

(d) Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels.

(e) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

(f) Drug products failing to meet established standards of specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and other relevant criteria.

§ 211.166 Stability Testing

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining approximate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

(b) An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to

support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.

(c) For homeopathic drug products, the requirements of this section are as follows:

(1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use.

(2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.

§ 211.167 Special Testing Requirements

(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed.

(b) For each batch of ophthalmic ointment there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed.

(c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed.

§ 211.170 Reserve Samples

(a) An appropriately identified reserve sample representative of each lot in each shipment of each active ingredient shall be retained for at least 1 year after the expiration date of the last lot of the drug product containing the active ingredient or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last drug product lot containing the active ingredient. It shall consist of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except the quantity requirement shall not apply for sterility and pyrogen samples.

(b) A properly identified reserve sample representative of each lot or batch of drug product shall be stored under conditions consistent with product labeling and shall be retained for at least 1 year after the expiration date of the drug product or in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the lot or batch of drug product. The sample shall be stored in the same immediate container-closure system in which the drug product is marketed or an immediate container-closure system having essentially the same characteristics. The sample shall consist of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Such samples shall be at least visually examined annually for evidence of deterioration unless such examination would affect the integrity of the samples. The results of such examination shall be recorded and maintained with other sta-

bility data on the drug product. Samples of compressed medical gases need not be retained.

§ 211.173 Laboratory Animals

Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use.

§ 211.176 Penicillin Contamination

If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in "Procedures for Detecting and Measuring Penicillin Contamination in Drugs."[a]

SUBPART J—RECORDS AND REPORTS

§ 211.180 General Requirements

(a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of the drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the batch.

(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.

(c) All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph.

(d) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available.

(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of

[a]Copies may be obtained from: Director, NCAA (HFD-430), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204.

each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of every batch, whether approved or rejected, and, where applicable, records associated with the batch.

(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

(f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under § § 221.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration.

§211.182 Equipment Cleaning and Use Log

A written record of major equipment cleaning, maintenance (except routine maintenance, such as lubrication and adjustments), and use shall be included in the individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots of batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

§ 211.184 Component, Drug Container, Closure, and Labeling Records

These records shall include the following:

(a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in § 211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier shall be listed if known.

(b) The results of any test or examination performed (including those performed as required by § 211.82(a), § 211.84(d), or § 211.122(a), and the conclusions derived therefrom.

(c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component, drug product container, and closure.

(d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with § 211.122(c) and § 211.130(c).

(e) The disposition of rejected components, drug product containers, closure, and labeling.

§ 211.186 Master Production and Control Records

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.

(b) Master production and control records shall include:

(1) The name and strength of the product and a description of the dosage form;

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit;

(3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic;

(4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided thay are justified in the master production and control records;

(5) A statement concerning any calculated excess of component;

(6) A statement of theoretical weight or measure at appropriate phases of processing;

(7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to § 211.192 is required;

(8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;

(9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

§ 211.188 Batch Production and Control Records

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

(1) Dates;

(2) Identity of individual major equipment and lines used;

(3) Specific identification of each batch of component or in-process material used;

(4) Weights and measures of components used in the course of processing;

(5) In-process and laboratory control results;

(6) Inspection of the packaging and labeling area before and after use;

(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(8) Complete labeling control records, including specimens or copies of all labeling used;

(9) Description of drug product containers and closures;
(10) Any sampling performed;
(11) Identification of the persons performing and directly supervising or checking each significant step in the operation;
(12) Any investigation made according to § 211.192.
(13) Results of examinations made in accordance with § 211.134.

§ 211.192 Productions Record Review

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

§ 211.194 Laboratory Records

(a) Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows;
(1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.
(2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, Association of Official Analytical Chemists, Book of Methods,[a] or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice.) The suitability of all testing methods used shall be verified under actual conditions of use.
(3) A statement of the weight or measure of sample used for each test, where appropriate.
(4) A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, drug product container, closure, in-process material, or drug product, and lot tested.
(5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors.
(6) A statement of the results of tests and how the results compare with

[a]Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20204.

established standards of identity, strength, quality, and purity for the component, drug product container, or drug product tested.

(7) The initials, or signature of the person who performs each test and the date(s) the tests were performed.

(8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

(a) Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method.

(b) Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions.

(c) Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by § 211.160(b)(4).

(d) Complete records shall be maintained of all stability testing performed in accordance with § 211.166.

§ 211.196 Distribution Records

Distribution records shall contain the name and strength of the product and a description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product.

§ 211.198 Complaint Files

(a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, or any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with § 211.192.

(b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, such written records shall be maintained for 3 years after distribution of the drug product.

(1) The written record shall include the following information, where known: The name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant.

(2) Where an investigation under § 211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with § 211.180(c).

(3) Where an investigation under § 211.192 is not conducted, the written

record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

SUBPART K—RETURNED AND SALVAGED DRUG PRODUCTS

§ 211.204 Returned Drug Products

Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specification, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of § 211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed.

§ 211.208 Drug Product Salvaging

Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is (a) evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and (b) evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products to this section.

WORK SHEET

The master formula card and work sheet must never be removed from the control of the pharmacy office. Therefore, a means must be devised whereby the manufacturing pharmacist will have available all of the necessary data for the production and packaging of the finished product, as well as having a form to record the necessary information obtained from the control laboratories.

This can be easily accomplished by the use of any of the modern day

duplicating devices. A stencil can be cut, showing all the essential data on the master formula and work sheet, and readily duplicated within the hospital. These sheets when completed must be filed since they represent the detailed history of the manufactured product.

A good control system record will provide the hospital pharmacist with the following informaiton on each product manufactured:

1. Name
2. Strength
3. Date of manufacture
4. Formula
5. Ingredients
   a. Manufacturer
   b. Lot number
6. Method of compounding
7. Person who prepared finished product
8. Person who checked the materials and process
9. The hospital lot number assigned to the product
10. Its disposition
11. Its packaging
12. Laboratory control data
13. Percentage yield
14. Time consumed in its preparation
15. Raw material cost
16. Packaging cost

In addition to the above, some authors recommend the use of a receiving number for all raw materials as a means of completely identifying each raw material container. In those hospitals where serially numbered receiving slips ar utilized, the number on the receiving slip constitutes a suitable receiving number. (For information on the use of a receiving memo the reader is referred to Chapter 9 dealing with purchasing and inventory control.)

Also suggested as an additional means of control is a so-called "Identification Number" which is issued to each raw material, whether it be a chemical, bottle, cap, tube or drug.

If all these numbers are used, they should be attached to the raw material container and shown on the pharmacy inventory card. Although some hospital pharmacists write the numbers on the fiber drum containing the chemicals or on the label, if the material is in a glass bottle, the use of an ancillary colored adhesive label is suggested, one color to indicate the receiving number and a second color to identify the raw materials identification number.

Prior to the release of a manufactured product, it should be subjected to chemical or bacteriological analysis. In some hospitals, this control work is performed within the department of pharmacy by a group of pharmacists specifically assigned to the control laboratory. This, of course, is the ideal situation and those institutions with sufficient volume to support such a unit are strongly advised to do so.

On the other hand, small or medium sized hospitals that cannot afford this luxury are nonetheless not excused from the obligation of checking formulas for purity and accuracy produced in the pharmacy or central sterile supply room. This can be done through the close cooperation

of the department of pathology (pyrogen testing), the chemistry laboratory (chemical analyses utilizing the spectrophotometer) and the bacteriology laboratory (for sterility determinations).

After all is said and done, none of the above described procedures will guarantee the purity and integrity of every product every time it is produced, unless the individuals concerned with the manufacturing program can be adequately supervised and trained.

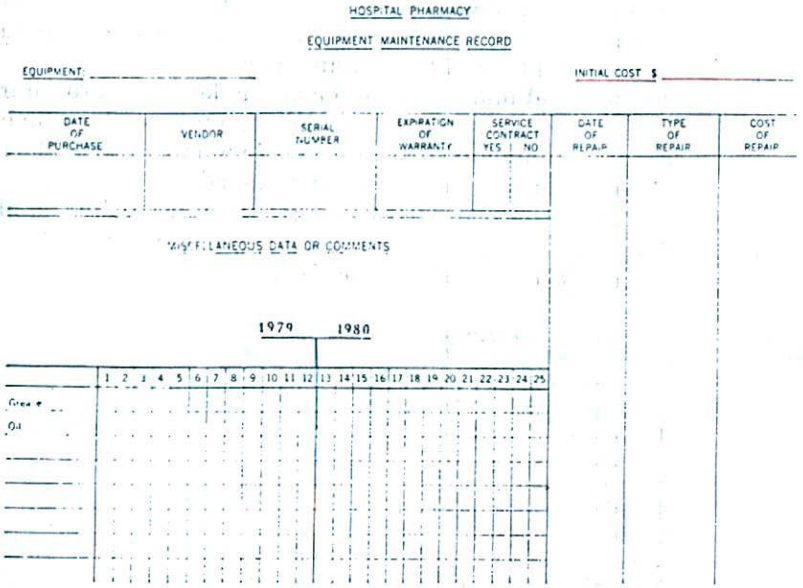
With this in mind, it is of interest to present at this point the philosophy of Sr. Francis[9] on how to avoid troubles in the manufacture of parenteral solutions in the hospital pharmacy.

"1. *Pharmaceutical Supervision:*
   a. of the formulae prepared
   b. of the procedures
   c. of the cleaning process
   d. of controls
2. *Exacting cleanliness:*
   a. of the manufacturing room
   b. of flasks and other glassware
   c. of rubber tubings
   d. of flask closures
   e. of stored chemicals
3. Routine cleaning of water still
4. Careful selection of chemicals
5. Production of a pure, pyrogen-free distillate which is checked electrically before and after each operation of the still, and which is sterilized within 8 hours
6. *Accurate measurements:*
   a. of original chemicals
   b. of the finished solution
7. Controlled sterilization process guided by exhaust line thermometer readings
8. Hermetically sealed flasks
9. Prompt and proper filling
10. Inspection and checking of finished products."

MAINTENANCE OF MANUFACTURING EQUIPMENT

Because of the hospital's high investment in pharmaceutical manufacturing equipment and the expense associated with frequent repairs, it behooves the pharmacist to develop an equipment maintenance program which will ensure maximum performance with the lowest possible repair cost.

This can be accomplished by establishing an Equipment Maintenance Record (Fig. 77) which may be kept by the pharmacist or the plant engineer. In addition to identifying clearly the equipment as to name, vendor, serial number and cost, the Equipment Maintenance Record provides the interested parties with a quick history of the repairs required on the apparatus. Furthermore, the routine or preventive


HOSPITAL PHARMACY

EQUIPMENT MAINTENANCE RECORD

EQUIPMENT: _____ INITIAL COST $ _____

DATE OF PURCHASE	VENDOR	SERIAL NUMBER	EXPIRATION OF WARRANTY	SERVICE CONTRACT YES / NO	DATE OF REPAIR	TYPE OF REPAIR	COST OF REPAIR

MISCELLANEOUS DATA OR COMMENTS

1979 1980

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

Fig. 77

monthly maintenance required by the equipment can be recorded and checked off when performed. Omission of the monthly service can be easily detected by reference to this record and corrected prior to the onset of mechanical difficulties.

Parenteral Hyperalimentation

Parenteral hyperalimentation is the intravenous administration of sufficient nutrients above the usual basal requirements to achieve tissue synthesis, positive nitrogen balance and anabolism.[10]

The preparation of parenteral hyperalimentation solutions must be considered as an integral part of the pharmacy department's manufacturing program irrespective of its size. The procedures employed are not unduly complicated and do not require extensive capital outlay for equipment.

Most hospital pharmacists prepare these solutions by using a technique described as the "wet method" through the extemporaneous compounding techniques of an intravenous admixture program.[10] This consists of mixing the dextrose solution from one flask with the fibrin hydrolysate solution in another flask utilizing a solution transfer set. In the "dry method" the pharmacist adds the appropriate amount of

anhydrous glucose to the fibrin hydrolysate solution. Both methods must be carried out under a laminar flow hood.

Because of the nature of these products, the pharmacy must have available appropriate refrigeration equipment and the pharmacist must become familiar with membrane filtration processes in view of the fact that the heat associated with the normal sterilization process will cause caramelization of the dextrose contained in each formula.

INTRAVENOUS ADDITIVE PROGRAM

One writer has stated that an *intravenous additive program* and an *intravenous additive service* may not be the same.[11] The differentiation cited is that an IV additive program consists of policies and procedures for both the preparation and administration of intravenous fluids to which drugs are to be added under aseptic conditions, on an around-the-clock basis, and controlled as to location and person preparing the product. On the other hand, the IV additive service usually refers only to the preparation of the product by individuals who may not necessarily be the same as those who will administer them and assume the responsibility for the monitoring of its clinical effects. The conclusion

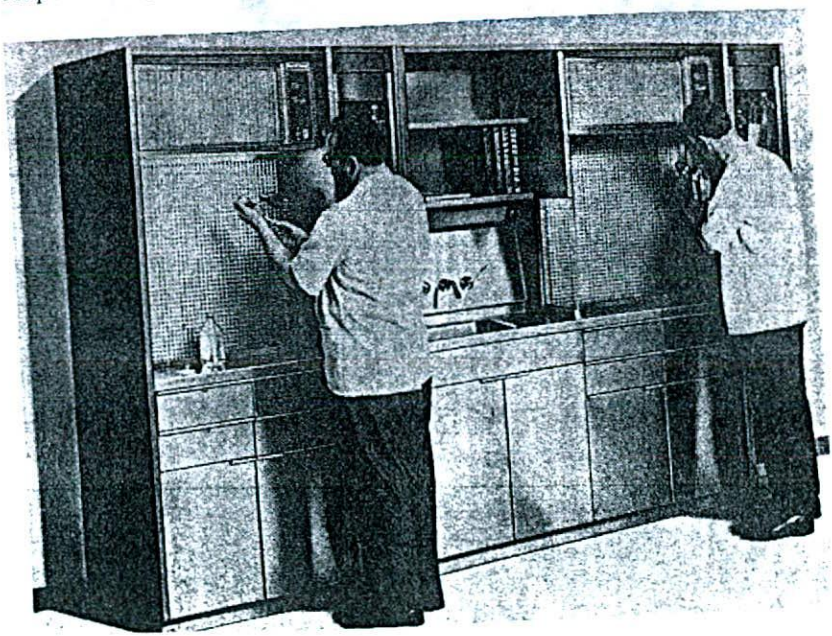


Fig. 78. The Market Forge IV Prep Station. Units such as this offer the pharmacist and the nurse an area for the preparation of intravenous additives in a controlled environment. (Courtesy of Market Forge Co., Everett, Massachusetts.)

arrived at is that an IV additive service is a part of an IV additive program.

Through the implementation of an IV additive service, the hospital pharmacist might be expected to achieve the following objectives:[11] *(a)* that the preparation of the final product be accomplished under aseptic conditons; *(b)* that drug interactions be avoided through the judicious choice of additive and mixing techniques; and *(c)* that the final product is appropriately labeled, dispensed and stored.

In the not too distant past, the preparation of intravenous solutions with their additives was a task performed on the nursing floor by nurses

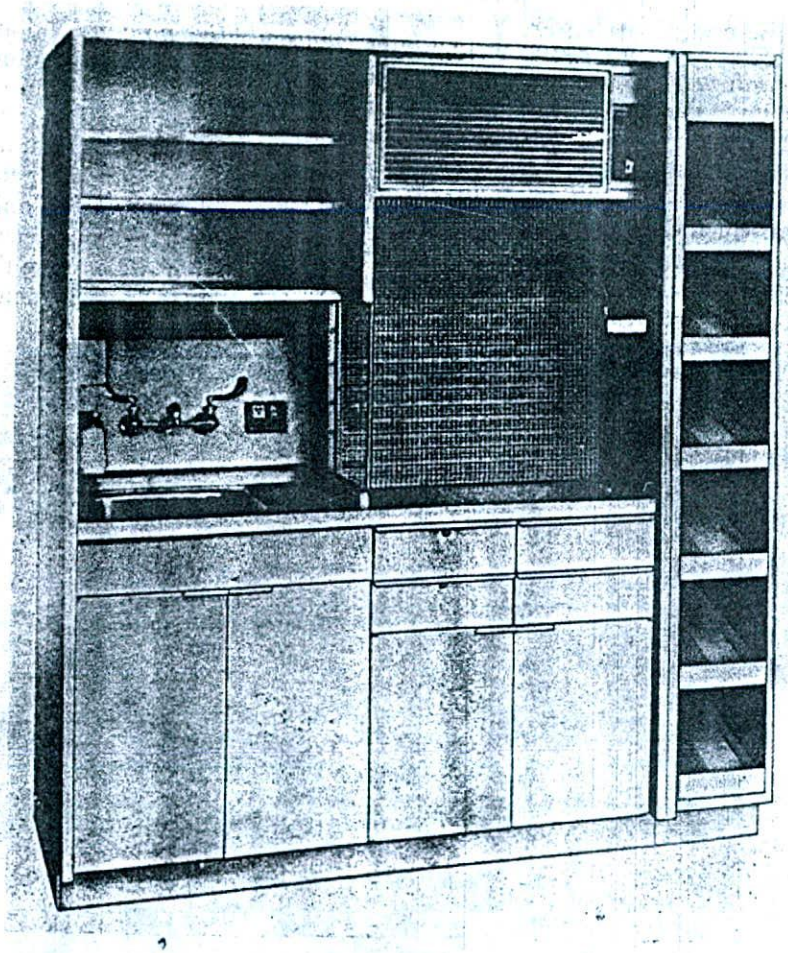


Fig. 79. The Market Forge IV Prep Station. (Courtesy of Market Forge Co., Everett, Massachusetts.)

or interns and residents. The concept that the preparation of these products requires the skills of a pharmacist has raised many other questions not the least of which is availability of the product at odd hours particularly if the site of preparation is moved to the main pharmacy. Thus, has evolved the satellite pharmacy, staffed by a clinical pharmacist and pharmacy technicians. (See Figs. 78, 79, and 80 for medication station for IV preparation.) On final analysis, it is irrelevant where the additives are added so long as definite policies are formulated which spell out responsibilities. In addition, it is imperative that the pharmacist become involved in the preparation of these products in an environment conducive to the efficient and safe preparation of them.[12]

PREPARATION OF IV ADDITIVE SOLUTIONS

In the preparation of these solutions, the pharmacist should work from the physician's original order sheet or from a direct copy. Upon receipt of the order, a pressure-sensitive label must be prepared which provides the following information: *(a)* patient identification; *(b)* patient location; *(c)* physician's name; *(d)* name of drugs with quantities added; *(e)* date of compounding; *(f)* expiration date; and *(g)* identification of the pharmacist preparing the product. If necessary, any ancillary labeling should also be prepared at this time. When applying

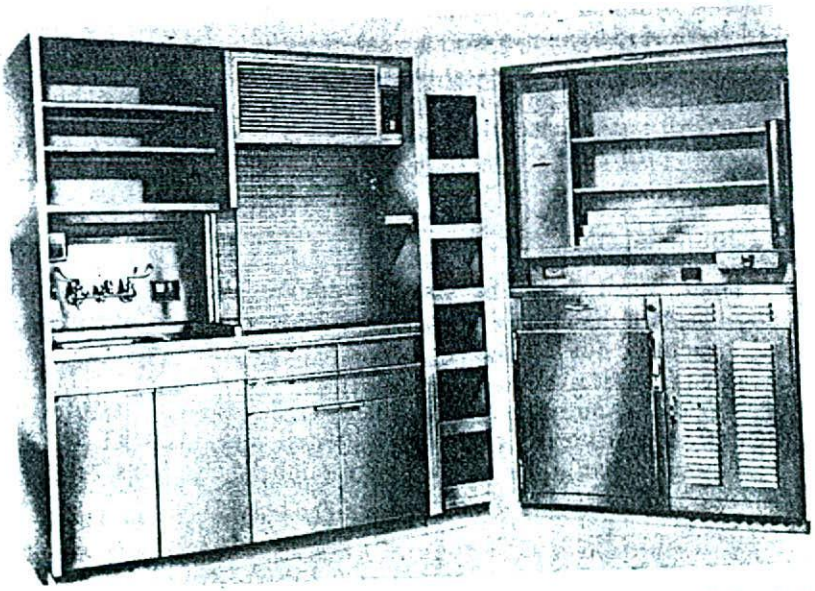


Fig. 80. Combination installation of a Market Forge IV Prep Station and a Medi-Prep Unit. (Courtesy of Market Forge Co., Everett, Massachusetts.)

the label to the container, it must be positioned in an upside down order to facilitate reading when the container is hung from an intravenous solution pole on the patient's bed.

Preparation of the solution should always take place under a laminar flow hood using sterile needles and syringes or double ended transfer needles. In some instances, a Cornwall syringe is useful in reconstitution procedures.

Once the transfer is made, the metal disc must be replaced and a new seal crimped on to the container. As a safety device, a different colored seal should be used in view of the fact that it warns individuals that drugs have been added.[13]

Before permitting the admixture to leave his control, the pharmacist must carry out a final inspection of the product. The inspection should include a review of the label, clarity of the solution, and the mathematics involved in the preparation.[14]

ASHP GUIDELINES FOR PHARMACIST PARTICIPATION IN HOME PARENTERAL NUTRITION PROGRAMS[18]*

Home parenteral nutrition (HPN) programs have been developed to meet the needs of patients who require prolonged or lifelong intravenous feeding. In many hospitals, pharmacists have assisted in solution preparation and supply; in patient training in solution preparation, infusion technique, and catheter care; and in monitoring side effects of HPN. Hospital pharmacists may question under what circumstances they should become involved in the care of patients requiring HPN. Certain institutional, personnel, and patient-resource needs are necessary to provide services to these patients safely. The following guidelines will assist pharmacists in deciding whether they should develop an HPN program.

Institutional Qualifications

The hospital should have an i.v. admixture program. Because HPN is an around-the-clock, long-term form of therapy, the institution must be able to provide for 24-hour service. While a nutrition support service is not a prerequisite for provision of HPN, a team approach is helpful. A formalized nutritional support service is desirable. The institution should be able to respond to HPN-related concerns, such as catheter and pump repair, fluid and electrolyte imbalance, sepsis, and support

*Approved by the ASHP Board of Directors, June 6, 1983. Developed by the ASHP Council on Clinical Affairs.

of the patient's underlying disease. Reimbursement arrangements for supplies and services should be established.

The institution must have criteria by which patients can be selected for HPN. Criteria should embrace a patient's learning ability, physical capability, family support, medical condition, and prognosis. A written protocol for training patients should be prepared.

Personnel Qualifications

The pharmacist should have an understanding of parenteral feeding therapy, including a knowledge of acid-base balance, nitrogen balance, fluid and electrolyte therapy, metabolic and mechanical complications, total parenteral nutrition delivery systems, catheter care and management, and drug-nutrient and drug-laboratory interactions. Good aseptic technique and experience in preparing intravenous admixtures is essential. A sufficient understanding of infectious disease is needed to differentiate HPN-related sepsis from underlying disease or drug reaction. The pharmacist should also be aware of current standards and recommendations on sterile admixtures and quality assurance. Assessment skills sufficient to allow monitoring of a patient's progress on a specific nutritional regimen and to recognize emergent problems, such as fever, emesis, and hematemesis, are important.

The pharmacist should be knowledgeable in the unique aspects of HPN, such as chronic infections, nutrient requirements, and effects of parenteral nutrition. A caring, patient-oriented attitude and good teaching skills are important in teaching HPN techniques to patients.

Other personnel such as physicians, nurses, dieticians, and medical social workers are important in assuring success with a patient on HPN. Working together, these health-care professionals must have interests and abilities to meet the needs of HPN patients in their particular areas of expertise.

Resource Requirements

Substantial personnel and equipment are needed for HPN programs. Though the time will vary, available information indicates that 7–44 hours are required to train a patient. Staff must be available on a 24-hour basis to answer questions for inpatients and outpatients. Teaching procedures may extend from early morning to late evening so as to involve both patients and families. Therefore, involvement of more than one pharmacist may be required. The institution must plan for and support the long-term obligation its staff will have to HPN patients.

The following types of equipment are required as a minimum for HPN programs.

- Infusion devices;
- HPN base solutions;
- Drug additives;
- Needles, syringes, and alcohol wipes;
- Dressing-change kits;
- I.V. sets, cassettes, and filters;
- I.V. pole; and
- Catheter accessories

Knowledge of alternate sources of HPN drugs and supplies is important. Procedures for dealing with emergency shortages must be established.

Most patients can be taught at least some aspects of nutritional self-care. This is worthwhile because it enhances feelings of self-esteem and increases quality of life. Given this philosophy, some special patients will require more than the expected amount of teaching time and personnel resources.

Summary

Pharmacists must make their own decisions as to whether they elect to participate in HPN programs. They need to determine the financial, social, and professional impact of an HPN program upon their institution. They need to consider the availability of these services from other hospitals or through private providers of home-health care. These guidelines are intended to help pharmacists make these decisions.

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SAMPLE HOSPITAL INTRAVENOUS ADMIXTURE PROGRAM

Hospital intravenous admixture programs vary by institution due to the lack of space, personnel or equipment. This suggests a word of caution—an intravenous admixture program must have sufficient controls to assure the safety of the product for patient use.

The following is an intravenous admixture program utilized by one hospital.[15] Note the double component; one section outlines the responsibilities of physicians and nurses whereas the second features the pharmacy duties.

Action	*Responsibility*	*Notes*
1. Intravenous solutions with or without additives are ordered on the Doctor's Order Form.	Physician	A legible and complete copy of the Doctor's Order is sent to the Pharmacy. The rate of administration must be indicated by the physician. When no infusion rate is indicated, the solutions will be administered at the rate of 75 to 100 ml per hour. "Keep Open" I.V. solutions will be administered at the rate of 30 to 50 ml per hour, unless otherwise indicated by the physician. Children under the age of 12 must have the rate of infusion indicated without exception.
2. Forward a carbonless copy of the original Doctor's Order Form to the Pharmacy Department.	Nursing Personnel	Intravenous solution orders not requiring additives will be administered from the patient unit floor stock and charged accordingly. Orders containing intravenous solution admixture requests will be forwarded to the Pharmacy for compounding.
3. Add medications to running I.V. solutions.	Nurse	The system in no way prevents or prohibits a nurse or physician from adding medications to an I.V. bottle which is already hanging (when appropriate), or from adding drugs into the tubing or a running I.V., or from preparing I.V. admixtures when emergency situations arise.
4. Telephone the Pharmacy for I.V. solution admixtures needed "STAT."	Nurse or Physician	When an intravenous admixture is needed immediately, the nurse or physician telephones the Pharmacy and dictates the admixture order to the pharmacist.

Action	*Responsibility*	*Notes*
5. Reduce to writing the nurse's or physician's verbal request for "STAT" I.V. solution admixtures.	Pharmacist	The pharmacist immediately reduces the verbal order to writing, using the I.V. Admixture Worksheet, and proceeds to prepare the admixture. Before dispensing the admixture, the pharmacist must check it against the copy of the physician's original order to verify its accuracy.
6. Reduce to writing on Doctor's Order Form all physician's verbal orders pertaining to I.V. solution therapy.	Nurse	A carbonless copy of the I.V. solution order must be forwarded to the Pharmacy
7. Interpretation of the physician's I.V. admixture order.	Pharmacist	Upon receipt, the pharmacist interprets the order, checks the dosage, and checks for incompatibilities. Problems in incompatibilities or stability arising from an order should be immediately directed to the prescribing physician by the pharmacist.
8. Preparation of I.V. solution label.	Pharmacy Personnel	All intravenous admixtures prepared are labeled according to the I.V. admixture label format. Infusion rate conversion from ml/hr to gtts/min is determined by the use of the conversion table located in the admixture room.

Action	*Responsibility*	*Notes*
9. Assembly and preparation of the I.V. admixture.	Pharmacy Personnel	Routine orders with at least 24-hour stability are filled in two peak work periods during working hours. Orders needed for administration from 12 noon until 12 midnight are filled during mid-morning. Orders needed from 12 midnight until 12 noon the following day are filled during the midafternoon. The Admixture Schedule Worksheet, labels, additives, I.V. solution bottle, needles and syringes are assembled together on a small tray prior to preparation. The assembled tray is placed in the hood and the I.V. admixture is aseptically prepared. Only one admixture should be prepared at any one time. Work flow in the hood is from the right side to the left side. Particular attention is given to the order in which drugs (a) must be protected from light, (b) must be reconstituted with non-preserved water, (c) must be buffered and (d) have limited stabilty.

	Action	*Responsibility*	*Notes*
10.	Delivery of I.V. admixtures to the patient units.	Pharmacy Transport Nursing	Intravenous admixtures prepared by the Pharmacy are usually delivered by Pharmacy personnel. When the I.V. admixtures are brought to the nursing unit, they are placed in the nursing unit refrigerator. The Pharmacy technician places them on the designated shelf in a neat and orderly manner by patient name according to bottle number. He also checks all admixtures on the unit noting all expiration dates on the admixtures. All outdated or discontinued admixtures are removed from the refrigerator and returned to the Pharmacy for credit and/or disposition.
11.	Preparing emergency intravenous solution admixtures on the patient units.	Nursing Personnel	Nursing personnel will retain the responsibility for preparing I.V. solution admixtures in emergency situtations when time is critical.
12.	Preparing intravenous admixtures on the patient units for orders received after the Pharmacy closes for the day.	Nursing Personnel	Indicate on the carbonless copy forwarded to the Pharmacy that the admixture was prepared on the patient unit.
13.	Prepare own I.V. solution admixtures.	Operating Room Recovery Room	
14.	Discontinue administration of any admixture exhibiting a color change, turbidity or precipitate.	Nurse	Return admixture to Pharmacy for replacement.
15.	Check intravenous solution admixtures prepared by the Pharmacy for accuracy against the physician's order.	Nurse	

Action	*Responsibility*	*Notes*
16. Forward to the patient units sufficient I.V. solution admixtures to maintain the patient during those hours that the Pharmacy is closed.	Pharmacy Personnel	All I.V. solution admixture orders received before the Pharmacy closes for the day will be processed, compounded and delivered to the patient unit.

Pharmacy Procedure

Action	*Responsibility*	*Notes*
1. Prepare a separate Admixture Worksheet for each different admixture.	Pharmacy Technician	The Admixture Worksheet and a copy of the original Doctor's Orders are then brought to a pharmacist for checking. The expiration date placed on the label must be 24 hours after actual admixture compounding time unless the solution is stable for less than 24 hours when an appropriate time adjustment must be made. One admixture worksheet may be used for more than one I.V. in a series provided that the solutions are identical.
2. Initial Admixture Worksheet in designated area to indicate technician's accuracy of transcription from the copy of the original Doctor's Order to the Admixture Worksheet.	Pharmacist	The copy of the original Doctor's Order is to be filed once the Admixture Worksheet has been initialed by the pharmacist. The Admixture Worksheet now becomes the reference document.
3. Assemble supplies and medications.	Pharmacy Technician	The special I.V. admixture compounding trays are to be used to hold all supplies, medications, labels and Admixture Worksheets.

Action	*Responsibility*	*Notes*
4. Compound admixture.	Pharmacy Technician	Hands are to be washed with antiseptic detergent. The entire compounding tray is brought into the hood. Attention should be given to the method of assembly so that no additional items are needed once preparation begins. Only one admixture should be compounded at any one time.
5. Perform visual check on completed admixture.	Pharmacy Technician	The admixture should be checked for particulate matter, cores, precipitates, unusual color changes. If any of the above is seen, it should be brought to the attention of a pharmacist. The pharmacist will determine if it is necessary to prepare a replacement.
6. Place label on finished infusion.	Pharmacy Technician	The label is to be stamped with the expiration date before being placed on the admixture bottle.
7. Check the admixture.	Pharmacist	The check list includes: (a) Check the label against the Admixture Worksheet (no strikeovers are permitted on the label). (b) Check expiration date. (c) Check amount of additive used against empty or partially empty vials or ampuls. (d) Check used syringes, noting distance plunger is pulled out. (e) Check basic solution and quantity used. (f) Check for particulates, color change or physical incompatibilities.

Action	*Responsibility*	*Notes*
8. Approve admixture.	Pharmacist	The pharmacist will place his initials opposite the compounding technician's initials signifying the admixture is acceptable and is ready for dispensing or storage in the refrigerator. The pharmacist will reject suspicious admixtures and request the technician to again compound the admixture.
9. Forward to patient units all I.V. admixtures needed during those hours that the Pharmacy is closed.	Pharmacy Technician	All admixture orders received before the Pharmacy closes for the day will be processed and delivered before closing.

Technician Duties

Action	*Responsibility*	*Notes*
1. Transcribe all necessary information, prior to making morning rounds, to the "I.V. Check List" after reviewing each Admixture Worksheet.	Pharmacy Technician	Information to be transcribed includes: (a) Patient's last name and room number. (b) Basic solution. (c) Additives and amounts. (d) Solution volume and infusion rate. (e) I.V. solution series number (if any).
2. Check the patient unit medication refrigerators for unused intravenous solution admixtures.	Pharmacy Technician	Outdated, discontinued, changed, unusable, soiled or contaminated admixtures should be returned to the Pharmacy for disposition.
3. Check patient's room to determine status of admixture therapy.	Pharmacy Technician	Confirm that the information on the bottle or bag corresponds with the information on the I.V. Check List. In addition, the volume remaining and the expiration date of the admixture should be noted.

Action	*Responsibility*	*Notes*
4. Process the I.V. Admixture Worksheet when the admixture has been discontinued or changed.	Pharmacy Technician	A changed order constitutes modification of the: (a) Basic solution (b) Volume (c) Additive (d) Additive volume or strength.
5. Prepare new I.V. Admixture Worksheet to accommodate new or changed orders.	Pharmacy Technician	A registered pharmacist must initial the Admixture Worksheet to verify the accuracy of the technician's transcription.
6. Prepare admixture labels.	Pharmacy Technician	The number of labels prepared will correspond with the number of admixtures to be compounded.
7. Prepare sufficient admixtures to cover the time increment through the next scheduled rounds.	Pharmacy Technician	Usually sufficient for a period of 24 to 26 hours.
8. Deliver completed I.V. admixtures to the patient units.	Pharmacy Technician	Those solutions that are not needed immediately are placed in the patient unit medication refrigerator.
9. Dispose of or salvage returned admixtures.	Pharmacy Technician	Returned preparations must be kept in the Pharmacy refrigerator until utilized or expired. Issue credit to patients whose preparations have been utilized.

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22

The Pharmacy—Central Sterile Supply Room

The Central Supply Department of a hospital has been defined as—

"... a centralized unit ... which provides professional supplies and equipment (sterile and non-sterile), to all specialized departments. ..."

A review of the literature will reveal that this specialized area of hospital operation is also known by other names, such as Central Sterile Supply Room, C.S.R., C.S.S.R., and Sterile Supply Room.

The "special departments" which are served include all nursing pavilions, clinics, certain specialized laboratories, such as the Cardiac Catheterization Laboratory, and the operating rooms.

In the early days of development, the majority of the items dispensed by the central supply room consisted of re-usable material. Today, with the advent of the age of plastics and disposables the reverse is true. Disposable drapes, syringes, tubing, urine collection sets, intravenous administration sets, needles, gloves and blood bags are an example of the inroads made by the plastic industry into the field of supplying hospitals with single use items.

In addition to the dispensing of the above mentioned items, the modern central sterile supply room may be involved in the cleaning, storage and dispensing of specialized equipment such as suction pumps, cardiac catheters, monitoring equipment, surgical dressing carts, resuscitation carts, and a myriad of special kits and trays.[2]

In 1960, the central sterile supply room was a relatively modern innovation in the hospital.[3,4] From its beginning as an equipment washroom with autoclaving facilities, it has adapted itself to modern production line technics with automatic control recording devices to insure sterility, modern washing, drying and powdering equipment for surgical gloves as well as taking an active role in developing the various gas and cold sterilization technics.

As to the management function of the central supply room, there are three schools of thought. One group[5,6] is of the opinion that the procurement, storage and distribution of supplies as well as the preparation

of the various sterile solutions, when necessary, lend themselves to the training of a pharmacist. In fact, the pharmacist is performing these very same functions within the department of pharmacy; therefore, if only from an economic point of view, it is feasible to incorporate into the pharmacist's duties the responsibility for the management of the central sterile supply room.

A second group contends that the majority of the items dispensed are ultimately used by nurses in the care of their patients and therefore since a nurse fully comprehends the intended use of the products, she logically should be responsible for the operation of the central sterile supply room.

The third group accepts the fact that the central sterile supply room has a dual function, namely, the cleaning, packaging and distribution of medical equipment and supplies as well as the manufacture of sterile fluids. Accordingly, it is the consensus that a nurse should be responsible for the former and a pharmacist should be responsible for the latter.

In actual practice, all three of these views are accepted and each can claim a representative number of hospitals which have adopted the respective ideology of each group.

CSSR—PHILOSOPHY AND OBJECTIVES

The Central Sterile Supply Room (Central Processing Department) is a centralized system practicing total decontamination and gives professional support and service for improved patient care by maintaining high processing standards.

The objectives of the department generally encompass the following:

1. Assume total responsibility for direct Operating Room supply.
2. Assume total responsibility for processing hospital items, thereby assuring that all of them receive the same degree of cleaning and sterilization.
3. Strive for uniformity and simplicity in preparation of procedural trays and sets used in the care and treatment of patients.
4. Maintain accurate and current inventory of supplies and equipment in the department.
5. Maintain an accurate record of the effectiveness of the various processes of cleaning, disinfecting and sterilization.
6. Contribute educational programs within the hospital relating to infection control.
7. Develop a cost effective program by cost analysis of personnel, supplies and equipment.

CSSR IN THE HOSPITAL ORGANIZATION

Unlike the pharmacy which has been accorded full departmental status, the central sterile supply room is, in many hospitals, considered as a sub-department. In these institutions, the department may fall under the aegis of the Operating Room Supervisor or the Nursing Service. Under this type of organization, the director, supervisor or manager of the unit does not report to the administrator or his assistant but to some major department head.

In some hospitals, a division of surgical care is established as a section of the general nursing service. Within this division are the central sterile supply room, operating rooms, recovery rooms and intensive surgical care unit. Here again, the head of the central sterile supply room is operating at a sub-departmental level.

In still other hospitals, the manufacture of sterile injectable or irrigating solutions is separated from the central sterile supply room and this "solution room" is placed within the administrative scope of the pharmacist. Under this arrangement, the pharmacist reports directly to the administrator or to one of his assistants. The same rung in the organizational structure of the hospital is retained if the pharmacy and central sterile supply room are considered as one unit.

It is of interest to note at this point that pharmacy and central sterile supply may have a joint responsibility. The situation is brought about when the pharmacy (1) prepares the solutions in bulk and transports the tanks to the central sterile supply room for bottling and sterilization, (2) prepares and packages the solutions for sterilization by the central sterile supply room, (3) prepares a concentrated solution which is then diluted, packaged and sterilized in the central sterile supply room, or (4) prepares a mixture of the chemicals in the dry state which when dissolved in a specified volume of distilled water results in the desired product which is then packaged and sterilized by the central sterile supply room personnel.

Although it may seem strange to the reader to have the pharmacy prepare and bottle the various solutions and the central sterile supply room assume the responsibility for their sterilization, it is, in effect, a very practical solution to the dilemma of whether or not identical sterilization equipment may be installed in both the pharmacy and the central sterile supply room.

QUALIFICATIONS OF THE HOSPITAL PHARMACIST TO MANAGE THE CSSR

Because the modern pharmacy curriculum provides the student with an exposure to bacteriology, the principles of sterilization, accounting and management, the hospital pharmacist is educationally better qual-

ified to manage the central sterile supply room than is the nurse. Admittedly, the nurse has a better knowledge of the ultimate use of the products dispensed, and, in some instances, the experience required for an efficient operation. This is not a reflection upon the nurse who may be presently in charge of a central sterile supply room nor upon the nursing profession as a whole. It is merely a comparison of two different callings—one is devoted to the direct care of the ill patient and therefore does not require training in the principles of procurement, packaging, storage and dispensing, whereas the other is a profession devoted to providing the various services associated with the needs of doctors, nurses and ill patients and therefore requires a thorough grounding in the above principles in addition to certain areas of scientific knowledge.

The pharmacist, as a part of his daily practice in the operation of the hospital pharmacy, performs many functions which are either identical to or closely resemble those which are performed by his counterpart in the central sterile supply room. These duties consist of:

a. Interviewing sales personnel
b. Purchasing of supplies
c. Meeting with and discussing procedures or specific problems with the medical staff
d. Dispensing of supplies in small lots
e. Distributing of supplies to pavilions
f. Receiving and storing of supplies
g. Charging, inventory and accounting procedures
h. Teaching or lecturing to various groups
i. Practicing the principles of standardization
j. Manufacturing in bulk
k. Manufacturing in small lots, both sterile and non-sterile products.

Clearly then, it would appear that the pharmacist is qualified both by education and experience to supervise the activities of the central sterile supply room. It is also reasonable to state that such a consolidation of responsibility will result in more economical management as well as savings which result from a reduction in certain strata of personnel, fuller utilization of space and equipment and consolidation of inventories.

PERSONNEL

Staffing this department is difficult in view of the fact that most applicants have not had any prior experience and must receive on-the-job training. Individuals must be trained in the principles of sterilization, monitoring autoclaves, operating gas sterilizers and aerators,

identification of surgical instruments, assembly of treatment trays, disassembly, cleaning and assembling equipment, decontamination, basic bacteriology and biological testing. Clearly an on-the-job training program is time consuming, varies from hospital to hospital and is costly to the institution. Therefore, the pharmacist-director of the CSSR should undertake a technician training program in order to develop personnel who are qualified in theory and technology.[8,9]

The materials handling aspect of the CSSR operation should be coordinated with those of the departments of pharmacy, purchasing and distribution. By so doing a duplication of services or function will be eliminated or, at least, minimized.

LOCATION

Ideally, the central sterile supply room should be centrally located in relation to the areas requiring the greatest utilization of its services. Consideration must also be given to the fact that the central sterile supply room must be able to receive large quantities of linen from the laundry, surgical dressings from the storeroom and large shipments of sterile intravenous and irrigating fluids if these are not manufactured by the hospital. If an ideal central location is not readily available, then resort must be made to utilize types of conveyor and pneumatic tube systems.

If the pharmacy and central sterile supply room management are to be combined, then, where possible, the two units should be physically combined or at least adjacent to one another. By so doing, there can be closer supervision of the personnel as well as a consolidation of duties and coverage of both services on a twenty-four-hour basis.

PLANNING THE CSSR

A close look at a modern central sterile room quickly reveals that it consists of a series of special work stations in a "dirty area" which is separated from the "clean area" by autoclaving and sterilizing equipment.

In effect then, we have all contaminated or non-sterile material and supplies entering one end of the room, passing through the various work stations and sterilizers and finally reposing in a sterile storage area ready to be dispensed from the clear side of the room. This concept is best illustrated by Figure 81.

The purpose of such a layout is to minimize the cross-flow of contaminated or non-sterile goods with those that are clean or sterile thereby eliminating the possibility of cross contamination or even the dispensing of a "dirty" kit for a clean one.

The number, type and size of work stations required will, of course,

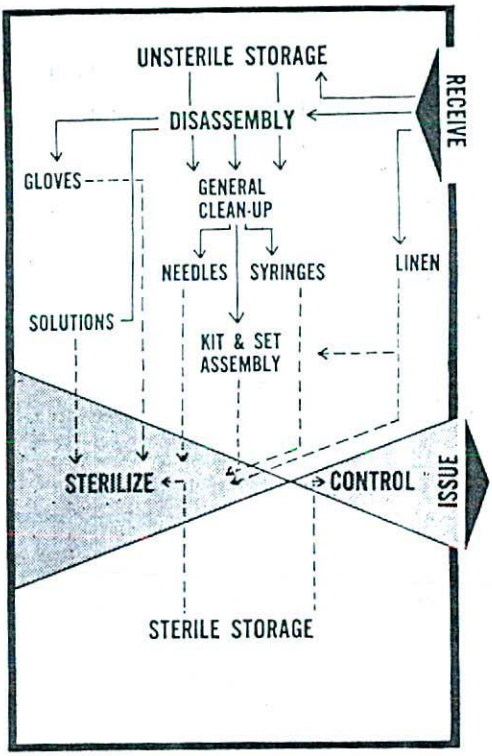


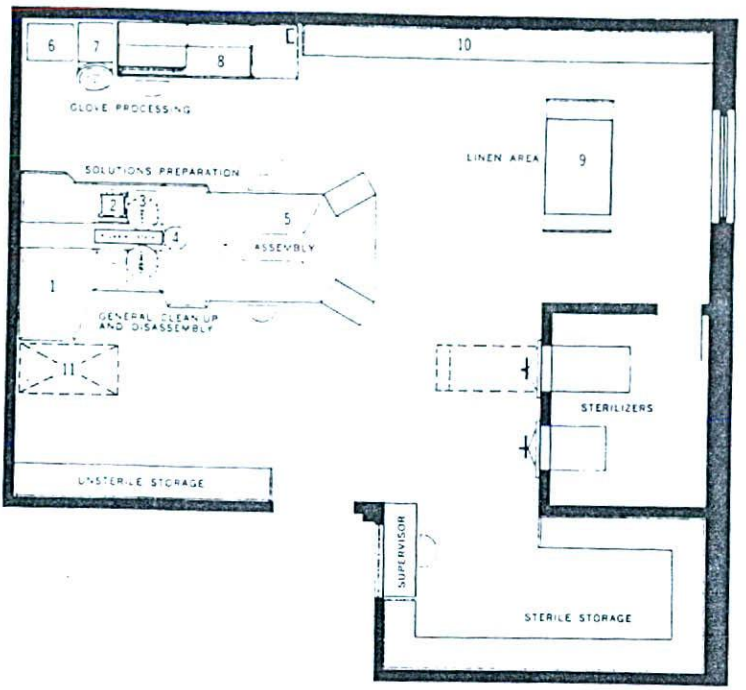
Fig. 81. General concept of material flow in a central sterile supply room. (From *Macbick/CSR Equipment* brochure published by the Macbick Co., Wilmington, Massachusetts.)

depend upon the size and nature of the hospital, the quantity of disposable materials used, the number of work shifts per day, the type of sterilization required, and whether or not the hospital purchases or manufactures sterile intravenous and irrigating fluids.

Because the planning of a central sterile supply room's space requirements cannot be reduced to a square foot per bed formula, any hospital pharmacist who undertakes to assist in the development, planning and construction of a central sterile supply room should avail himself of the technical know-how and experience that can be provided by the design staff of a reputable producer of such equipment.

In order that the student and the pharmacist have an idea as to typical plans for central sterile supply rooms for various size hospitals, Figures 82A, 82B, 83, and 84, are provided.

TYPICAL PLAN –
CENTRAL SUPPLY FOR THE SMALLER HOSPITAL



1. Clean Up and Disassembly Station
2. Flask Washer (set in sink)
3. Flask Rinser (set in sink)
4. Still
5. Kit Assembly Station
6. Glove Washer Drier
7. Glove Powderer
8. Glove Packaging Station
9. Linen Inspection and Folding Station
10. Linen Storage
11. CSR Truck

Fig. 82. *A.* Typical plan of a central sterile supply room for a small hospital. (From *Macbick/ CSR Equipment* brochure published by the Macbick Co., Wilmington, Massachusetts.) *(Figure continues on next page.)*

LAMINAR FLOW HOODS

Although many hospitals have abandoned the preparation of large volume, sterile intravenous fluids, a large number have commenced other programs, such as the intravenous solutions additive procedure, which require sterile technics to be performed in an atmosphere of microfiltered air.

1. Cart washer
2. Double sink
3. Quadruple sink
4. Table
5. Sink
6. Table
7. Washer/steriliser
8. Washer/steriliser
9. Feeding table
10. Washer/steriliser
11. Work table
12. Overhead cabinets
13. Overhead cabinets
14. Overhead cabinets
15. Stainless steel cabinet
16. Table
17. Steam steriliser
18. Steam steriliser
19. Gas steriliser
20. Alcove for steriliser controls
21. Tables
22. Cabinets

Fig. 82 (Continued). *B.* Floor plan of the Central Processing Department at the Brigham and Women's Hospital in Boston, Massachusetts.

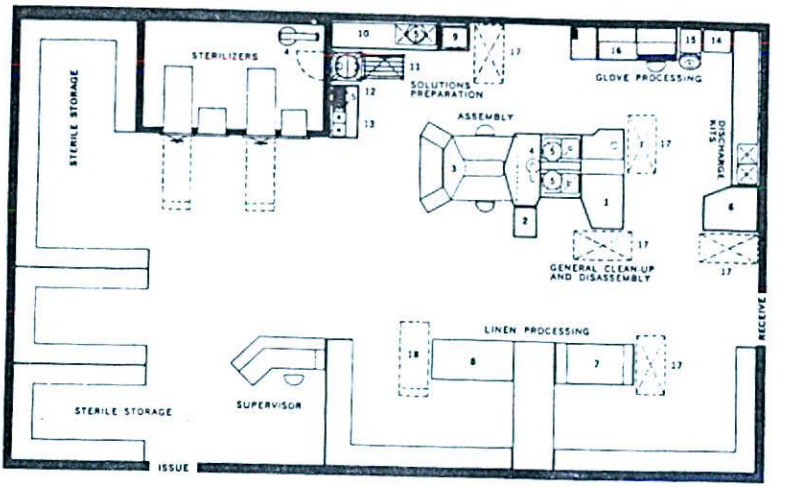
In order to create such an atmosphere, various manufacturers of hoods have incorporated into them the laminar flow principle.

Laminar air flow is defined by Federal Standard 209[7] as:

". . . air flow in which the entire body of air within a confined area moves with uniform velocity along parallel flow lines, with a minimum of eddies."

By providing a constant outward flow of microfiltered air over the entire face of the hood's work area opening, dust particles may be kept from entering the work area from the ambient atmosphere.

Hospital pharmacists who plan to commence intravenous solutions



1. Clean-Up and Disassembly Station
2. Utility Washer
3. Kit Assembly Station
4. Still
5. Storage Tank
6. Clean-Up and Disassembly
7. Linen Inspection and Folding
8. Linen Packaging
9. Flask Washer
10. Solutions Clean-Up
11. Flask Drain Truck
12. Batch Tank
13. Flask Filling and Capping Station
14. Glove Washer-Drier
15. Glove Powderer
16. Glove Packaging Station
17. CSR Truck
18. Autoclave Truck

Fig. 83. Typical plan of a central sterile supply room for a medium size hospital. (From *Macbick/CSR Equipment* brochure published by the Macbick Co., Wilmington, Massachusetts.)

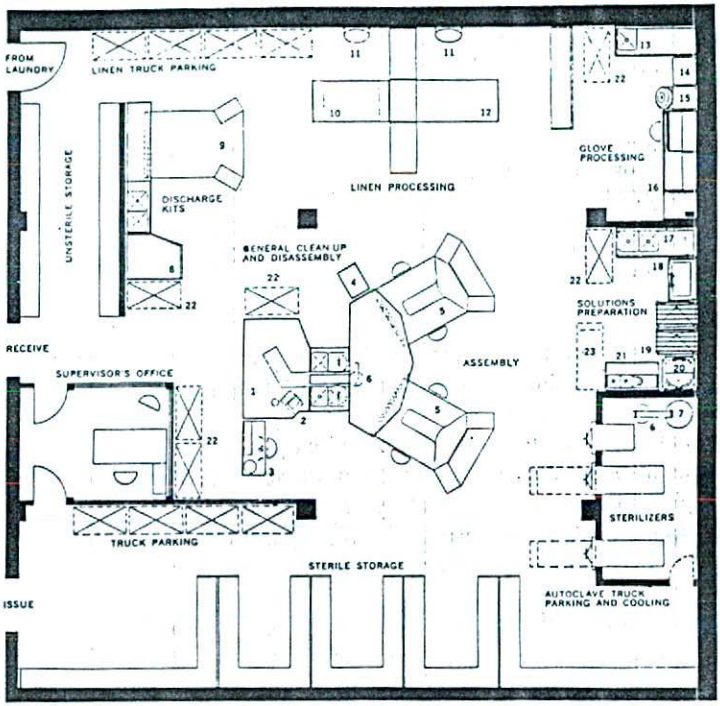
additive programs or those who are called upon to produce special sterile research products should investigate the possibilities which such an installation offers.

Pharmacy-Central Sterile Supply Rooms that still produce parenteral fluids should install laminar flow hoods in order to ensure safe, sterile products.

STANDARDIZATION COMMITTEE

The Standardization Committee may be defined as that group within the hospital which is commissioned with the responsibility to investigate, to develop and to standardize procedures and equipment. In some institutions, this group is also known as the Current Practices Committee.

If such a committee is not in existence, it behooves the Director of Pharmacy and Central Sterile Supply Services to take the initial steps to have such a committee formed. By so doing, he will be assured of



1. Clean-Up and Disassembly Station
2. Needle Washer
3. Needle Packaging Station
4. Utility Washer
5. Kit Assembly
6. Still
7. Storage Tank
8. Clean-Up and Disassembly Station (CD-0)
9. Kit Assembly Station
10. Linen Inspection
11. Linen Hamper
12. Linen Packaging
13. Accumulation Counter
14. Glove Washer-Drier
15. Glove Powderer
16. Glove Packaging Station
17. Solutions Clean-Up
18. Flask Washer-Rinser
19. Flask Drain Truck
20. Batch Tank (50 gal.)
21. Flask Filling and Capping Station
22. CSR Truck
23. Autoclave Truck

Fig. 84. Typical plan of a central sterile supply room for a large hospital. (From *Macbick/CSR Equipment* brochure published by the Macbick Co., Wilmington, Massachusetts.)

the creative thinking of a group of individuals who are intimately associated with the use of the supplies and products to be dispensed from the central sterile supply room. In addition, the Director of Pharmacy and Central Sterile Supply Services can then assure the hospital administration that a concerted effort is being made to reduce duplication of inventory and produce standardization of procedures.

Membership on this committee should be by appointment of inter-

ested staff members, the appointment being made jointly by the chief of staff and the administrator of the hospital. Each major discipline in the hospital should be represented on the committee. Ideally, the following represents a good working group.

Administration (1)
Director of Laboratories
Surgery (2)
Medicine (2)
Radiology (1)
Pathology (1)
Nursing Service (2)
Nursing School (1)
Director of Pharmacy and Central Sterile Supply

Other areas such as Dietary, Engineering and Maintenance should be invited to attend the meetings during which subjects pertaining to their services are discussed.

A chairman and a secretary should be appointed from the committee membership. Meetings should be held according to a set schedule throughout the year. The secretary of the committee should be assigned the responsibility of gathering all samples and prices of material as well as other pertinent data dealing with a particular procedure or type of equipment.

The chairman of the committee may then assign the responsibility for the investigation and development phases of the problem under discussion to a sub-group of the master committee. Once this smaller group has reached a decision as to equipment or developed a new procedure, the secretary should write up the material in accordance with a predetermined format and submit it to the master committee for approval. Once approved, the report should be distributed to the staff and pavilions.

To encourage proper filing of these documents, some hospitals provide each recipient with a binder and appropriate separators to demarcate the various divisions of the hospital—*i.e.*, surgery, medicine, nursing, pharmacy, etc.

An index should be published periodically and distributed to all those on the mailing list. The bound volume of "bulletins" may then be referred to as the Standardization Manual or the Current Practices Manual and should serve as an authoritative procedural manual.

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23

The Nuclear Pharmacy

With the increased use of radioactive isotopes in the hospital, many administrators and isotope users have felt the need to develop a means whereby there is a centralized responsibility for the dissemination of information, purchase, use, storage, disposal and monitoring of these potentially hazardous materials.

Hospital pharmacists have been quick to recognize this situation as one whereby they may fill the void and expand the professional services rendered by the pharmacy department. In addition, the American Society of Hospital Pharmacists in order to guide this movement established a Committee on Isotopes which was staffed by a group of hospital pharmacists who had already gained considerable experience in this new phase of hospital pharmacy.

In 1955 the committee submitted a comprehensive report[1] with a proposed outline for a course in isotope pharmacy. This report was followed by the report of the 1958 committee in which the following objectives were proposed.[2]

1. To develop suggestions for special courses for hospital pharmacists in the handling of isotopes in hospitals.
2. To determine the feasibility of an isotope section operated by the hospital pharmacy.
3. To determine layout and design for a radioactive branch of a pharmacy department.
4. To compile a bibliography on isotopes.

In the meantime, hospital pharmacists were publishing articles dealing with the fundamentals of radioactivity,[3] the various aspects of radiologic health,[4] and descriptions of programs within hospitals having an established radioisotope pharmacy.[5,12]

Simultaneously the hospital literature began to publish articles concerning facilities and equipment for isotope programs[6] and data on the types of facilities required for the use of isotopes in the general hospital.[7]

Simultaneously, the American Hospital Association developed and distributed a *Manual on the Use of Radioisotopes in Hospitals*[8] with the following stated purpose.[9]

"... for use by hospitals when setting up a radioisotopes program or when reviewing their current procedures for handling radioisotopes. It is intended to guide the administrator of the general hospital in the procurement procedures for radioactive materials, in the radiation protection measures necessary for their handling, in the allocation of space and equipment for isotopes laboratories, and in the organization and training of the hospital staff for the utilization of radioactive materials."

Thus, it becomes necessary to expose the student in hospital pharmacy to the licensing requirements of the Atomic Energy Commission, the radioisotope committee and its function and the role which the alert hospital pharmacist can assume in this rapidly developing phase of therapeutics and diagnosis.

Because of the limited scope of this text, and the highly technical nature of the equipment, no data concerning the various types of monitoring, handling or measuring devices in current use will be presented or the physical facilities needed to establish a radioisotope pharmacy.

A large number of hospitals and clinics in the United States are currently using radioisotopes for diagnostic, therapeutic and research purposes. The use of those potentially dangerous materials is subject to the control and supervision of the Atomic Energy Commission, a governmental agency established by the United States Congress under the **Atomic Energy Act of 1954.**

Jurisdiction of the AEC

The Act provides that the Atomic Energy Commission has jurisdiction over all "by-product material" which is further defined by the Act as—

"... any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material."

Perusal of the Federal regulations reveals that jurisdiction of the AEC applies not only to radioisotopes produced in the United States, but also to those imported into this country.

Radioactive isotopes may be used only by duly licensed individuals who have complied with the statutory provisions of the Atomic Energy Act and the latest AEC regulations appearing in the *Federal Register.*

LICENSURE INFORMATION

In order that the hospital pharmacist render a high quality, knowledgeable service with regard to isotope materials, it is necessary for him to have a general understanding of the basic requirements which

must be met, by both individuals and institutions, before they may become licensed for the medical use of radioisotopes.

Accordingly, the following discussion relates to the types of licenses that can be issued, the types of applications which should be submitted to obtain the licenses, and the information which should be included in the application.

Licenses may be issued to institutions or to private practitioners. The type of licenses available and their characteristics are as follows:

Institutional License

This type of license is specific in that it limits the use of the isotopes to those listed on the license. It also restricts the clinical use and the physicians who may use the material to those named on the license document.

In addition, the regulations require that an institutional licensee have a medical isotope committee to evaluate all proposals for research, diagnostic, and therapeutic uses of isotopes within the hospital.

One advantage of such a license is that it provides a means whereby physicians desiring licensure for the use of radioisotopes may obtain basic and clinical isotope training to meet the criteria required to qualify as an individual user.

Broad Medical Licenses Issued to Institutions

This type of license is issued to those institutions that meet the following criteria:

a. previous experience operating under a specific institutional license and,
b. are engaged in medical research, as well as routine diagnosis and therapy.

Although a medical isotope committee is required, no physicians are listed as individual users on the license, nor are the radioisotopes limited to specified users.

This type of license also permits physicians to obtain basic and clinical radioisotope training and experience.

Specific Licenses Issued to Physicians for Their Private Practice

This license is usually issued to the private practitioner of medicine irrespective of whether or not his office is or is not located on the hospital premises. The license usually specifies the isotope and its clinical use. These licenses do not permit or provide for other physicians to obtain basic and clinical radioisotope training and experience. In addition, the licenses are limited to well-established uses of by-

product materials and require that the physician, so licensed, personally conduct the program.

TYPES OF APPLICATION FORMS

Form AEC 313 and Form AEC 313a are two application forms upon which information concerning a proposed medical radioisotope program may be submitted.

Form AEC 313MC may be appropriate for a specific institutional or for a specific private practice license. In addition, this form should be used only by physicians who are qualified to handle one entire category of uses. If the physician does not so qualify, application should be made upon Form AEC 313.

Form AEC 313a must be submitted for each physician who is to be listed on an institutional license or for each physician applying for a private practitioner's license.

RADIOISOTOPE COMMITTEE

The regulations of the Atomic Energy Commission require that a radioisotope committee be established for the supervision and control of the hospital isotope program. The committee should include a radiation physicist, a clinical radiologist, an internist, a hematologist and a surgeon. Other members or specialties to be represented on the committee should be determined by the type and scope of program being undertaken by the hospital.

In addition to the above, it is also suggested that a representative from nursing service, administration and pharmacy be included on the committee roster.

The reasons for the participation of nursing and administrative representatives are that the nurses will become familiar with the type of work carried out on the pavilions, the associated dangers and the means whereby the patient, doctor and nurse may protect themselves. The administrator can contribute to the development of the entire program through his efforts with the board of trustees and the pharmacist may be of assistance in the purchasing, receiving and storage of isotopes until such time as the theory of a centralized isotope pharmacy within the hospital materializes.

Generally the radioisotope committee should have the following responsibilities:[9]

1. Review, grant permission for, or disapprove the use of isotopes within the institution.
2. Prescribe special conditions as may be necessary, such as training of

personnel, designation of limited areas of use, disposal methods and the like.
3. Receive reports from the radiation protection officer and review his records.
4. Recommend remedial action when an individual fails to observe protection recommendations, rules, regulations.
5. Keep a record of actions taken in approving the use of isotopes.

In order to acquaint the hospital pharmacist with the type of instructional and precautionary literature prepared by the committee, the following bulletin entitled *Protective Procedures for Personnel Caring for Patients Receiving Therapeutic Isotopes* is presented,[10]

"Radioactive isotopes are administered to patients for treatment of various conditions, *e.g.*, radioactive iodine for hyperthyroidism, radioactive gold for malignant effusions, radioactive phosphorus for malignant hematological conditions. These emit beta and gamma rays and exposure should be reduced to the minimum by:

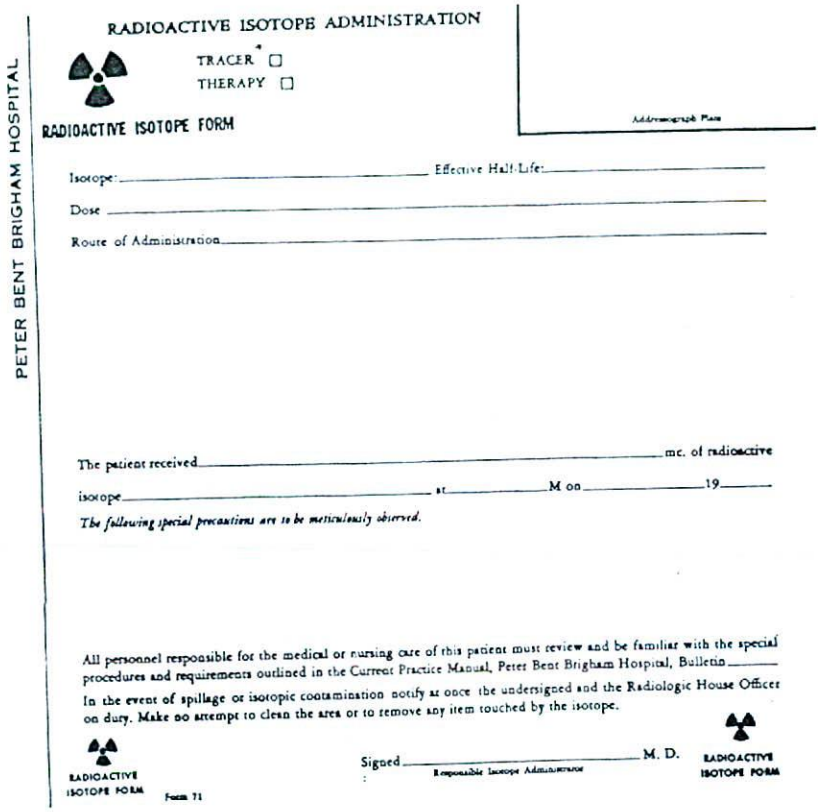
a. avoiding contamination of clothing and skin from body secretions of the patient.
b. keeping the time close to the patient as short as possible.
c. keeping as great a distance from the patient as possible when in the unit.

General Precautions

1. A radioisotope administration sheet (Fig. 85) is placed in the medical record by the isotope administrator at the time of treatment and is to remain there permanently. Particular precautions required by the specific isotope used will be listed on this sheet by the isotope administrator and called to the attention of the medical and nursing staff caring for the patient. These will be written in the Doctor's Order Book by the physician in charge of the patient.
2. An isotope sign is placed at the entrance of the room or unit by the isotope administrator.
3. The isotope administrator will provide the name of a substitute who may be contacted in case the administrator is not readily available.

Care of the Patient: for most patients, these precautions should be taken:

1. No nurse should care for more than one radioactive patient at a time.
2. The patient should be encouraged to do as much as possible for himself so that close bedside nursing can be reduced to the minimum.
3. Gloves are to be worn when the nurse handles the patient's linen, skin or excreta utensils.
4. A plastic apron or sheet of expendable plastic is to be worn for bedside nursing (to protect from spoilage). If an apron is worn, it should be used for one patient only and marked clearly which is the inside of the apron.
5. Excreta utensils should be marked with a "radioactive" sign and reserved for one patient's use. These utensils should be flushed clean with a superfluous amount of water; dilution is the best protection. If the radioactive element is difficult to flush, carrier solution (the ordinary substance such as iodine, not radioactive) will help and can be supplied by the isotope administrator.



PETER BENT BRIGHAM HOSPITAL

RADIOACTIVE ISOTOPE ADMINISTRATION

TRACER ☐
THERAPY ☐

RADIOACTIVE ISOTOPE FORM

Addressograph Plate

Isotope:_____ Effective Half-Life:_____

Dose _____

Route of Administration_____

The patient received_____mc. of radioactive

isotope_____ at_____M on_____19_____

The following special precautions are to be meticulously observed.

All personnel responsible for the medical or nursing care of this patient must review and be familiar with the special procedures and requirements outlined in the Current Practice Manual, Peter Bent Brigham Hospital, Bulletin_____

In the event of spillage or isotopic contamination notify at once the undersigned and the Radiologic House Officer on duty. Make no attempt to clean the area or to remove any item touched by the isotope.

RADIOACTIVE ISOTOPE FORM

Signed_____M. D.
Responsible Isotope Administrator

RADIOACTIVE ISOTOPE FORM

Form 71

Fig. 85. Radioactive Isotope Administration form which is placed in the medical record of each patient receiving radioactive isotopes. The sheet is a canary yellow in color and the Atomic Energy Commission insignia is printed in red ink.

6. The House Officer will notify the isotope administrator of any draining wound.
7. Anything soiled with body discharge is to be retained in a plastic bag until monitored and appropriate disposal directed by the isotope administrator. Linen is to be kept in large plastic bags. Dressings, tissues and small disposable articles in small plastic envelops are to be placed in a yellow dump-lid waste container with radioactive marker provided by the isotope administrator and will be removed by him to the decay area properly labeled.

Visitors

No visitors are permitted for the first two weeks except by special dispensation by the isotope administrator. Children and pregnant women are not permitted at any time.

Therapeutic Procedures

Thoracentesis or paracentesis within fifteen days of isotope administration should be carried out only after specific approval of the isotope administrator and with his explicit direction for disposal of material and utensils.
Urine should be collected or sent to the laboratory only under the specific conditions imposed by the administrator.

Routine Post-Operative Orders

1. Usual diet and medication may be resumed on return to the ward unless otherwise specified.
2. Patients receiving therapeutic isotopes are to be cared for in a specified radiation area and to be confined to this area unless bathroom privileges are definitely assigned by the isotope administrator.
3. Soiled or wet dressings are to be brought to the attention of the House Officer immediately.
4. The Radiation Safety Officer should be contacted if the patient has a long distance to travel on discharge.
5. If any doubt arises about the procedure for these patients, contact the isotope administrator whose name is signed on the yellow Form #71 or his deputy as indicated.

INCREASED DISTANCE AND REDUCTION IN THE TIME OF EXPOSURE ARE ALWAYS THE BEST PROTECTION. THE NEED FOR HANDWASHING CANNOT BE OVER-EMPHASIZED.

RESPONSIBILITY OF PERMIT HOLDERS

Those persons who are granted a permit to use radioisotopes have an obligation and a responsibility for the safe use of radiation sources by individuals under their control. Permit holders are therefore generally responsible for the following:[11]

1. Compliance with all rules and regulations for the safe use and handling of radioactive materials.
2. Insuring that employees under their control are instructed in the use of safety devices and procedures.
3. Adequate planning of an experiment, or procedure, to assure that the necessary safety precautions are taken.
4. Informing the Radiation Safety Officer of the hospital, of the names of all personnel involved in operational procedures, and of changes in such personnel; radioactive materials being used; procedures of handling; changes in the laboratory arrangement which could lead to changes in personnel exposure or contamination levels.
5. Direction of personnel under their control to comply with all recommendations by the Radiation Safety Officer relative to dosimeters, and other recommendations to control or to reduce exposure to radiation hazards.
6. Limitation of use of radioisotopes under their permit to those over whom they have direct supervision.
7. Maintenance of required current records of receipt, use, storage and disposal of radioisotopes.

RESPONSIBILITY OF INDIVIDUAL USERS

From the point of view of salf-preservation and moral obligation for the safety of others, each person who uses sources of ionizing radiation has the following responsibilities:[11]

1. To receive instruction in radiation safety as determined appropriate by the Radiation Safety Officer.
2. To keep his exposure to radiation at the lowest possible level and specifically below the maximum permissible exposure.
3. To wear recommended radiation dosimeters for personnel, such as film badges, pocket ionization chambers, and finger dosimeters.
4. To survey his hands, shoes, body, and clothing for radioactivity and remove all loose contamination before leaving the laboratory when appropriate.
5. To use all appropriate protective measures such as protective clothing, respiratory protection, remote pipetting devices, ventilated and shielded glove box and hoods.
6. To prohibit smoking and eating in radioisotope laboratories.
7. To check working areas daily, or after each radioisotope procedure.
8. To maintain good laboratory practices, such as keeping work areas and equipment clean and orderly.
9. To use proper labels on equipment being used with radioactive materials.
10. To place all active waste in proper containers, equipped with proper labels.
11. To report immediately the details of a "spill" or other accident involving radioactive substances to the Radiation Safety Officer.
12. To conduct decontamination procedures as directed by the Radiation Safety Officer.

The National Association of Boards of Pharmacy (NABP) has issued a set of Model Regulations for Nuclear Pharmacy.© The following material[13] is excerpted from this document which is available from the publications desk of the NABP.

NABP MODEL REGULATIONS FOR NUCLEAR PHARMACY

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services

(a) The application for a permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy and shall be in personal attendance at all times that the pharmacy is open for business. In emergncy situations, in the pharmacist's absence, designated qualified licensed professionals may have access to the licensed area. These individuals may prepare single doses of radiopharmaceuticals for the

immediate emergency and must document such withdrawls in the quality control records.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The nuclear pharmacy area shall be separate from the pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance and office area. A nuclear pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the State Board of Pharmacy. Detailed floor plans shall be submitted to the State Board of Pharmacy and the Radiation Control Agency or NRC before approval of the license.

(c) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance and nuclear pharmacy practice.

(d) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs in accordance with the appropriate pharmacy and radiological control agency or NRC.

(e) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing non-radioactive drugs.

(f) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order, from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

(g) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with the appropriate regulations of the radiological control agency. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners for individual patient use.

(h) In addition to any labeling requirements of the State Board of Pharmacy for non-radioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

(1) The standard radiation symbol;
(2) The words "Caution-Radioactive Material";
(3) The radionuclide;
(4) The chemical forms;
(5) The amount of radioactive material contained, in millicuries or microcuries;
(6) If a liquid, the volume in cubic centimeters;

(7) The requested calibration time for the amount of radioactivity contained.

(i) The immediate container shall be labeled with:

(1) Standard radiation symbol;

(2) The words "Caution-Radioactive Material";

(3) The name, address and telephone number of the nuclear pharmacy;

(4) The prescription number.

(j) The amount of radioactivity shall be determined by radiometric methods for each product immediately prior to dispensing.

(k) Nuclear pharmacies may re-distribute NDA Approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

(l) The permit to operate a nuclear pharmacy is conditioned upon an approved Radiation Central Agency or Nuclear Regulatory Commission license. Copies of RCA or NCR inspection reports shall be made available for Board inspection.

Section 4. General Requirements for Nuclear Pharmacists to Obtain a Nuclear Pharmacy Permit

A qualified nuclear pharmacist shall:

(a) Be a currently licensed pharmacist in the state; and

(b) Be certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(c) Meet the following standards:

(1) Meet minimal standards of training for medical uses of radioactive material (cite radiological control agency or NRC licensure guide);

(2) Have received a minimum of 200 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy;

(3) Attain a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a certified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services in a certified nuclear pharmacy residence program or in a structured nuclear pharmacy training program in an accredited college of pharmacy;

(4) Submit an affidavit of experience and training to the State Board of Pharmacy.

Section 5. Library

Each nuclear pharmacy shall have the following reference books. All books must be current editions or revisions:

(a) United States Pharmacopeia/National Formulary with supplements.

(b) State laws and regulations relating to pharmacy.

(c) State and/or Federal Regulations governing the use of applicable radioactive materials.
(d) United States Public Health Service, Radiological Health Handbook.

Section 6. Minimum Equipment Requirements

(a) Laminar flow hood.
(b) Dose calibrator.
(c) Refrigerator.
(d) Class A prescription balance or balance of greater sensitivity.
(e) Single or multiple channel scintillation counter.
(f) Microscope.
(g) A radiochemical hood and filter system.
(h) Other equipment necessary for radiopharmaceutical services provided as required by the Board of Pharmacy.

ROLE OF THE PHARMACIST IN THE HOSPITAL WITH AN ISOTOPE PHARMACY

In hospitals which have established a radioisotope pharmacy, the pharmacist purchases, stores and dispenses the various isotopes required by the medical staff licensed to use these materials.

In these institutions, the physician, upon deciding to prescribe radioactive material, calls the pharmacist and provides him with all of the necessary information.

The pharmacist then makes the necessary calculations in order to arrive at the required dosage, transfers same from the stock container, using a remote control pipette, places it in a paper cup within a lead container and transports it to the patient for administration.

From this point on, the responsibility for radiation protection, contamination, and disposal of waste products will fall under the aegis of the radiation safety officer.

ROLE OF THE PHARMACIST IN THE HOSPITAL WITHOUT AN ISOTOPE PHARMACY

The mere fact that the majority of the hospitals using radioisotopes have not established, as yet, an isotope pharmacy is no criterion for the hospital pharmacist not to make some contribution toward the administrative aspects of the hospital's isotope program. In this regard, the hospital pharmacist may assume the responsibility for the ordering, receiving and storage of all isotopes in current use throughout the hospital. The purchasing phase of such a program is relatively simple and does not differ from the purchase of other pharmaceutical products. In

fact, a number of the commonly used radioisotopes are usually purchased in pre-determined quantities for automatic shipment on a standing order basis.

The receiving aspect of radioisotopes differs from the receiving phase of purchased pharmaceuticals in that all packages coming to the pharmacy must be stored in a lead vault and a record maintained which indicates the date of receipt, the purchase order number, the ordering physician, the name of the isotope and the quantity of isotope received. Upon receipt, the appropriate physician or technician is notified to remove the material from the pharmacy vault.

The radiation safety officer monitors the pharmacy vault and the surrounding area as part of his safety program; therefore, there is little possibility of harmful radiation within the environs of the pharmacy. All records of isotope materials received are to be maintained in the pharmacy office and are made available to the radiation safety officer and the Atomic Energy Commission inspector when necessary.

TRAINING STUDENTS IN NUCLEAR PHARMACY

Because more pharmacists are exhibiting an interest in this branch of pharmaceutical practice, the ASHP developed an Accreditation Standard for Residency Training in Nuclear Pharmacy (With Guide to Interpretation).[14] This document establishes the following standards:

STANDARD I. QUALIFICATIONS OF THE TRAINING HOSPITAL

A. Nuclear pharmacy residency training programs shall be oriented to institutional practice and shall be based, in large part, in a hospital. The hospital shall be accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association. Further, the hospital shall operate an organized nuclear medicine department and shall be licensed by the Environmental Protection Agency or the Nuclear Regulatory Commission and other appropriate agencies, for all categories of radioactive byproduct materials used in humans.

B. Two or more institutions may join together to provide nuclear pharmacy residency training, provided that each meets the intent of this Standard.

C. Nuclear pharmacy residencies shall be conducted only in those institutions in which the educational benefits to the resident are considered of paramount importance in relation to the service benefits which the institution may obtain from the resident.

D. The institutions must provide a wide range of nuclear medicine studies.

E. The institution shall be staffed with at least one board-certified nuclear medicine physician and one nuclear medicine technologist.

Where two or more institutions are used as training sites, at least half of the participating institutions shall be staffed by at least one board-certified nuclear medicine physician and one board-certified nuclear medicine technologist.

STANDARD II. QUALIFICATIONS OF THE NUCLEAR PHARMACY SERVICE

A. The nuclear pharmacy service shall be organized in accordance with the principles of good management under the immediate supervision of a legally qualified pharmacist. It shall have sufficient staff, both professsional and supportive, to carry out a broad scope of radiopharmaceutical services, and shall comply (where applicable) with all federal, state and local laws, codes, statutes, and regulations.

B. The nuclear pharmacy shall have physical facilities that are adequate to permit activities over a broad range of services including, but not limited to, the following professional and administrative areas:

1. Nuclear pharmacy administration,
2. Radiopharmaceutical distribution and inventory control,
3. Technology and quality control,
4. Radiotracer development and evaluation,
5. Radiopharmaceutical chemistry and tracer methodology,
6. Radiological health activities, and
7. Clinical services.

It is necessary that a regular and continuing experience be provided in these activities, and it is not sufficient to create artificial situations for residents to obtain this experience. If any of the designated activities or divisions of pharmaceutical practice are not available in the parent training site, arrangements shall be made with another nuclear pharmacy unit (or other facility acceptable to the American Society of Hospital Pharmacists) to provide the necessary experience.

C. The director of the nuclear pharmacy unit shall have the responsibility and the authority to carry out a broad scope of radiopharmaceutical services.

STANDARD III. QUALIFICATIONS OF THE RESIDENCY DIRECTOR AND PRECEPTORS

A. The director of the nuclear pharmacy service shall be the overall director of the residency training program and shall be subject to general administrative control and guidance by the director of pharmacy services, college dean, institutional director, or appropriate executive officer.

B. The residency director shall be a pharmacist, shall have com-

pleted a nuclear pharmacy residency accredited by the ASHP, and shall have had two years of administrative and clinical experience; or, if lacking a residency, shall have five years of experience in a nuclear pharmacy, a substantial part of which should have been of an administrative nature.

C. The residency director shall have demonstrated superior capabilities in the operation of a nuclear pharmacy service and shall have made significant contributions to the development or improvement of nuclear pharmacy practice.

D. The residency director shall have considerable latitude in delegating preceptorial responsibilities to the staff. Each individual designated as a preceptor must have demonstrated outstanding strengths in one or more areas of nuclear pharmacy practice. The residency director, however, is ultimately accountable for the overall quality of the residency training program.

E. There shall be at least one preceptor employed for each resident in the program.

F. The residency director shall be an active member of the American Society of Hospital Pharmacists. Other designated preceptors should also be members of the Society.

STANDARD IV. QUALIFICATIONS AND SELECTION OF THE APPLICANT

A. The applicant should be a graduate of a school of pharmacy accredited by the American Council on Pharmaceutical Education.

B. The applicant should have a thorough grounding in patient-oriented (clinical) pharmacy services; further, the applicant should demonstrate some degree of knowledge and skills in nuclear pharmacy practice.

C. The applicant should be recommended by his college faculty, previous employers, or professional colleagues.

D. The applicant should be a member of the American Society of Hospital Pharmacists; or, if not, he should become a member of the Society if accepted as a resident.

E. Final approval of the qualifications of the applicant and his acceptance shall be the responsibility of the nuclear pharmacy service director.

STANDARD V. RESIDENCY TRAINING PROGRAM

A. Objectives for the residency program shall be set out in writing and shall be provided to each resident at the beginning of his program. The objectives shall relate both to the administrative and professional practice skills required in contemporary good nuclear pharmacy prac-

tice and shall describe the terminal competencies to be striven for in the residency program. Objectives for training in each of the following areas shall be included:

1. Nuclear pharmacy administration,
2. Radiopharmaceutical distribution and inventory control,
3. Technology and quality control,
4. Radiotracer development and evaluation,
5. Radiopharmaceutical chemistry and tracer methodology,
6. Radiological health activities,
7. Clinical services,
8. Educational experience and activities, and
9. Research methodology.

B. Each resident's activities shall be scheduled in advance and shall be planned to make possible the attainment of the predetermined objectives. The overall schedule shall consist of a minimum of 2000 hours of training (residency-related) time, extending over a period of no less than 12 months.

C. Each resident shall maintain a record of his training activities which clearly delineates the scope and period of training. The residency director shall keep such records on file for review by the ASHP accreditation survey team.

D. Provision shall be made for formalized and regularly scheduled evaluation of the resident's achievement in terms of the objectives previously established.

STANDARD VI. CERTIFICATION

A. An appropriate certificate indicative of successful completion of the residency shall be awarded to the resident by the training institution on the recommendation of the nuclear pharmacy residency program director.

SOURCES OF INFORMATION

Current copies of Atomic Energy Commission regulations may be obtained from the Division of Licensing and Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

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The Physical Plant and Its Equipment

The Minimum Standard for Pharmacies in Hospitals provides as follows:[1]

"Adequate pharmaceutical and administrative facilities shall be provided for the pharmacy department, including especially: (A) the necessary equipment for the compounding, dispensing and manufacturing of pharmaceuticals and parenteral preparations, (B) bookkeeping supplies and related materials and equipment necessary for the proper administration of the department, (C) an adequate library and filing equipment to make information concerning drugs readily available to both pharmacists and physicians, (D) special locked storage space to meet the legal requirements for storage of narcotics, alcohol and other prescribed drugs, (E) a refrigerator for the storage of thermolabile products, (F) adequate floor space for all pharmacy operations and the storage of pharmaceuticals at a satisfactory location provided with proper lighting and ventilation."

Accordingly, this chapter is presented for consideration of the student as well as those seeking information which may be useful in developing plans either for the renovation of an existing department or the construction of a new facility, data concerning location, floor space, general equipment, refrigeration and storage facilities and general construction information relating to lighting, ventilation, plumbing and surface finishes.

FUNCTIONAL PLANNING

Many competent authorities have stated that before the architect's pencil touches paper, he must become thoroughly familiar with the hospital's objectives, plan of operation and operational policies relating to the area to be designed.

The architect may gather this information by attending various meetings with the hospital administrator, the department head and the Building Committee. During these sessions, many questions will be asked and at their conclusion it is possible that a special study or survey will be conducted to confirm or establish the need.

Because hospital pharmacists new to the field have seldom become involved in this aspect of the hospital planning, they are often frightened and confused at the prospect of having to meet with the architect and the trustees with regard to pharmacy construction or remodeling. This is especially so because they do not know what to expect during such sessions.

Prior to exposure to the architect and trustees, the hospital pharmacist should become acquainted with the overall planning process. Basically, it consists of three parts: (1) a master program, (2) functional programming, and (3) equipment planning and architectural design. The master program sets forth goals and objectives. The functional program specifies the operational demands upon the facilities. The architectural design and equipment programming translates these into physical space, equipment and furnishings.[2]

Steps for developing a functional program and supporting materials for the architect are:[3]

1. Identify hospital purposes and goals.
2. Determine pharmacy objectives and plan of operation.
3. Determine functions to be performed.
4. Determine workflow and procedures.
5. Estimate workload.
6. Determine work areas needed.
7. Determine personnel to be accommodated in each work area.
8. Determine space, shape, furniture, equipment and service needs of each work area.
9. Determine interrelationships between work areas and between the pharmacy and other departments. Consider shared services.
10. Arrange work areas to maximize the performance functions.
11. Design one or more schematic floor plans to meet requirements; then reconcile these with "real life" limitations.
12. Evaluate effectiveness of each design for meeting requirements.
13. Review the above steps until an optimal design emerges.

The three broad general functions have been identified as **utility, amenity** and **expression.** Utility is the service the pharmacy provides to the hospital; amenity is the satisfaction of the personal satisfaction of the pharmacy staff and expression is the symbolized significance of the pharmacy to the hospital and its community.[3]

In order to acquaint these pharmacists with the type of information which they will be asked to present, the following questions, although not exhaustive on the subject, are abstracted from a U.S. Public Health Service publication[5] and are herewith presented.

On the right side of the questionnaire are check lines in columns headed A, B, and C. These are intended to help the functional programming team in evaluating and rating the relative significance of all

questions and subfactors to be considered in accordance with the following:[4]

1. Checkmark in Column "A"—indicates the question deserves essential consideration and/or certain of its subparts call for definitive answers.
2. Checkmark in Column "B"—calls for further study before being included or excluded as a program consideration. Following appropriate review, if the factor is to be included in the program, it would be marked "A." If it is to be excluded, it would become a "C."
3. Checkmark in Column "C"—indicates the question will be excluded as a program consideration because it is either impractical or unnecessary.

WORKLOADS AND WORKFLOWS

	A	B	C
(1) Will the inpatient pharmacy be operative 24-hours a day? If not, what will be its hours of operation? What provisions will be made for issuance of medications when the pharmacy is closed	—	—	—
(2) How will physicians order medications so the pharmacy will receive copies of original orders?			
☐ Use of carbonized paper?	—	—	—
☐ Use of automated devices?	—	—	—
Input/output device?	—	—	—
Photocopier?	—	—	—
Telewriter?	—	—	—
Voice recorder?	—	—	—
Other?	—	—	—
(3) How will patient medication profiles be maintained in the pharmacy and on the nursing unit?			
☐ Duplicate orders stored together in individual patient file?	—	—	—
☐ Transcribed onto cards or suitable form?	—	—	—
☐ Use of automated devices?	—	—	—
(4) Will there be a bulk compounding program?			
☐ Where and how will distilled water be obtained?	—	—	—
☐ What type of sterile area will be required?	—	—	—
☐ What equipment will be needed?	—	—	—
☐ What type of quality control programs will be instituted?	—	—	—
(5) Will there be a packaging program?			
☐ Will an outside contractor be used?	—	—	—
☐ What equipment and supplies will be needed?	—	—	—
☐ What type of quality control program will be instituted?	—	—	—
(6) What types of pharmacy educational programs will be developed?			
☐ In-service?	—	—	—
☐ Nursing education?	—	—	—
☐ Interns?	—	—	—

	A	B	C
☐ Residents?	—	—	—
☐ Students?	—	—	—
☐ Technicians?	—	—	—
☐ Patients and families?	—	—	—
☐ Cooperative clinical pharmacy program with school of pharmacy?	—	—	—
(7) What type of pharmacy research program will be developed?			
☐ Administrative or behavioral?	—	—	—
☐ Bench type?	—	—	—
☐ Clinical?	—	—	—
(8) Will the pharmacy be concerned with radio-pharmaceuticals? If so, where located?			
Pharmacy?	—	—	—
Radiology?	—	—	—
Other/	—	—	—
(9) Will there be a drug information center? If so, what will be its hours of operation? Which of the following functions will it have?			
☐ Drug information?	—	—	—
To Pharmacy and Therapeutics Committee?	—	—	—
Within pharmacy department?	—	—	—
On patient care areas?	—	—	—
Regulate activities of drug company representatives?	—	—	—
Answer specific requests, verbal and written?	—	—	—
Prepare periodical bulletins and newsletters?	—	—	—
☐ Poison control?	—	—	—
Respond to calls?	—	—	—
Coordinate poison control with drug information?	—	—	—
Coordinate communications with medical personnel?	—	—	—
Maintain consultant panel?	—	—	—
Coordinate information with treatment center?	—	—	—
☐ Investigational drugs?	—	—	—
Search literature?	—	—	—
Review protocols?	—	—	—
Establish control measures for the hospital?	—	—	—
☐ Drug surveillance?	—	—	—
Conduct current and retrospective reviews of all drug practices (drug selection and utilization, adverse reactions, drug usage studies)?	—	—	—
☐ Education?	—	—	—
Present lectures, consultations, surveys, reports?	—	—	—
☐ Research?	—	—	—
Where would the drug information center be located?			
☐ Pharmacy?	—	—	—
☐ Medical library?	—	—	—
☐ Other?	—	—	—
What staff would be required?			

	A	B	C
☐ Drug information pharmacists?			
☐ Pharmacy residents, interns, students?			
☐ Technicians?			
☐ Secretarial personnel?			

(10) What type of drug distribution system will be employed?

☐ Individual prescription?			
☐ Individual prescription-floor stock combination?			
☐ Centralized unit-dose?			
☐ Decentralized unit-dose?			
☐ Combination centralized-decentralized unit-dose?			
☐ Automated?			
☐ Other?			

(11) If individual prescription or combination system is employed:

☐ How will orders be transmitted to the pharmacy?			
Pharmacy messenger?			
Other messenger?			
Pneumatic tube or drop chute?			
Automated device?			
Telephone (under what circumstances acceptable)?			
☐ How will drugs be packaged?			
Single unit packages?			
Number of doses per package?			
☐ How will orders be filled?			
Plastic bags or envelopes?			
Individual patient drawer?			
☐ How will orders be delivered to nursing unit?			
Pharmacy messenger?			
Other messenger?			
Pneumatic tube?			
Conveyor or dumbwaiter?			
☐ How will *stat* orders be handled?			
Sent to pharmacy by automatic device?			
Telephone?			
Intercom?			
Picked up by pharmacy messenger?			
Delivered to pharmacy by nursing unit personnel?			
☐ How will individual prescription orders be stored on the nursing unit?			
Cart with individual patient drawers?			
Cabinets with individual patient compartments?			
Pass-through closet with doors or other storage area in patient rooms?			
☐ What will be the administrative procedures on nursing unit for:			
Administering medications?			
Charting?			
Maintaining patient medication profile?			
Recording charges?			
☐ How will *prn* orders be refilled?			

	A	B	C
Regular exchange interval?	—	—	—
Special requisition by nursing unit?	—	—	—
Suspense file in pharmacy?	—	—	—
☐ How will routine orders be refilled?			
Regular exchange interval?	—	—	—
Requisition by nursing unit?	—	—	—
Suspense file in pharmacy?	—	—	—
☐ How will written or recorded orders be changed after conference between pharmacist and physician?			
Change noted on all copies of order form?	—	—	—
Computer correction made by physician or pharmacist?	—	—	—
Change card prepared and signed by parties involved?	—	—	—
☐ How will narcotics and controlled drugs be handled?			
Individual prescription with prescription or portion thereof stored in patient's compartment or drawer?	—	—	—
Regular floor stock?	—	—	—
Other?	—	—	—
☐ How will IV additives be handled?			
Solution with additive prepared in pharmacy?	—	—	—
Additives sent to nursing unit ready to add to solution?	—	—	—
Complete procedure handled on nursing unit?	—	—	—
☐ How will cancelled orders and out-of-date prescriptions be handled?			
Returned to pharmacy when cancellation order is written?	—	—	—
Returned to pharmacy when located on nursing unit?	—	—	—
☐ How will absence of medication in usual storage area be noted?			
Reminder card of location (e.g., refrigerator, floor stock, narcotic cabinet)?	—	—	—
☐ How will limited floor stock be replenished?			
Use of preprinted requisition form by nursing unit?	—	—	—
Routine inventory check by pharmacy?	—	—	—
☐ How will charges be handled?			
At nursing unit (doses administered)?	—	—	—
At pharmacy (doses dispensed)?	—	—	—
(12) If centralized unit-dose system is employed:			
☐ How will orders be transmitted to main pharmacy?			
Pharmacy messenger?	—	—	—
Other messenger?	—	—	—
Pneumatic tube?	—	—	—
Drop chute?	—	—	—
Automated device?	—	—	—
☐ How will patient medication profiles be maintained?			
Visible card file?	—	—	—
Envelope?	—	—	—
Card?	—	—	—
Automated device?	—	—	—

	A	B	C
☐ How many unit-doses are expected to be dispensed per day, assuming that a unit-dose may consist of one or more single unit packages?	—	—	—
☐ How will unit-doses be packaged? (Procurement of all possible commercially packaged items?)			
Large packaging program?	—	—	—
Small packaging program?	—	—	—
Outside contractor?	—	—	—
Extemporaneous packaging, including sterile?	—	—	—
☐ How will unit-doses be dispensed?			
Supervised pickers?	—	—	—
Automated devices?	—	—	—
☐ How will unit-doses be prepared for delivery?			
Individual patient containers (envelopes and bags)?	—	—	—
Individual patient drawers?	—	—	—
☐ After routine dosage times have been established (for example, q.i.d. 9,1,5,9-h.s.—10 p.m.) how many dosage intervals will be covered by each delivery, or how many deliveries per day will be scheduled?			
Morning?	—	—	—
Noon?	—	—	—
Afternoon?	—	—	—
Evening?	—	—	—
☐ What is the expected number of orders to be processed by time of day? (Consider *regularly scheduled meds, prns, IVs, stats,* and *pre-ops* separately.)	—	—	—
☐ What is the expected number of prescriptions or unit-doses to be dispensed by time of day? (Consider required scheduled drugs, IVs, IV additives added later, those requiring reconstitution and those requiring varying amounts of compounding.)	—	—	—
☐ How will unit-doses be delivered?			
Pharmacy messenger?	—	—	—
Other messenger?	—	—	—
Pneumatic tube?	—	—	—
Conveyor, dumbwaiter, other automated devices?	—	—	—
☐ How will unit-doses be stored on the nursing units?			
Patient drawers in carts?	—	—	—
Nurserver or other storage area in patient room?	—	—	—
Patient compartment in cabinet?	—	—	—
Other storage area?	—	—	—
☐ What administrative procedures will be established on nursing units for drug administration?			
Nurse, licensed, practical nurse, pharmacy employee?	—	—	—
Chart with schedule, visible card file?	—	—	—
Patient profile?	—	—	—
☐ How will charges be handled?			
Nursing unit, doses administered?	—	—	—
Pharmacy, doses dispensed?	—	—	—
☐ How will *stat* orders be handled?			

	A	B	C
Sent to pharmacy by automated device (e.g., pneumatic tube, conveyor, computer, electrowriter)?	—	—	—
Telephone?	—	—	—
Intercom?	—	—	—
Picked up by pharmacy messenger?	—	—	—
Sent to pharmacy by nursing unit personnel?	—	—	—
☐ How will nonroutine doses be handled?	—	—	—
☐ How will narcotics be handled?			
Unit-dose?	—	—	—
Floor-stock?	—	—	—
☐ How will IV additives be handled?			
Prepared in advance or on order by pharmacy?	—	—	—
Ready-to-use additives sent to nursing unit by pharmacy?	—	—	—
Prepared on nursing unit?	—	—	—
(13) If decentralized unit-dose system is employed: Because pharmacy substations on nursing units are used in this system, answer all questions for centralized unit-dose system wherever applicable after first answering the following questions.			
☐ Where will the pharmacy substations be installed and how many patients will each cover?	—	—	—
☐ What will be the operating hours of the various substations?	—	—	—
☐ How will the substations be staffed?	—	—	—
☐ What will be the activities of the substation pharmacist?			
Review charts?	—	—	—
Consult with physicians on orders?	—	—	—
Consult with nurses?	—	—	—
Conduct patient interviews?	—	—	—
Make round with physicians?	—	—	—
Maintain and review patients' medication profile?	—	—	—
Supervise dispensing and dose preparation on floor?	—	—	—
(14) Will a centralized-decentralized unit-dose system be employed?	—	—	—

(After first establishing the parameters of the extent of use of both systems, proper answers to the applicable questions for centralized and decentralized unit-dose systems should supply all of the information required for establishment of a centralized-decentralized unit-dose system.)

(15) If automated systems are employed			
☐ What type of system will be used:			
Automated dispensing, pharmacist activated?	—	—	—
Automated dispensing, computer activated?	—	—	—
☐ How will the system be inspected?	—	—	—
☐ Where will automated devices be located?			
Main pharmacy?	—	—	—
Pharmacy substation?	—	—	—
Each nursing unit?	—	—	—
Combination of nursing units?	—	—	—

	A	B	C
☐ How will the pharmacist receive a direct copy of the physician's order?	—	—	—
☐ What type of packages will be used?	—	—	—
☐ How will devices be filled?	—	—	—
☐ How will the automated system be backed up during failures?	—	—	—
(16) Will the pharmacy department include out-patient prescriptions?	—	—	—
(17) Who will be entitled to use outpatient services?			
☐ Hospital outpatients?	—	—	—
☐ Patients treated by physicians whose offices are located in the hospital?	—	—	—
☐ Hospital employees?	—	—	—
(18) Where will the cashier be located?	—	—	—
(19) Will there be a separate outpatient pharmacy?	—	—	—
(20) Will there be partitioned spaces and/or offices for pharmacist interviews with outpatients?	—	—	—
(21) What administrative procedures will be established for:			
☐ Maintenance for outpatient medication profiles?	—	—	—
☐ Prescription files, including records of refills for outpatients?	—	—	—

Work Areas

(1) What are the office space requirements for the following personnel:			
☐ Chief pharmacist?	—	—	—
☐ Assistant chief pharmacist?	—	—	—
☐ Other section chiefs?	—	—	—
☐ Clerical?	—	—	—
☐ Clinical pharmacist (inpatient care areas)?	—	—	—
(2) What are the other work space requirements?			
☐ Extemporaneous compounding?	—	—	—
☐ Inpatient dispensing, centralized?	—	—	—
☐ Bulk compounding?	—	—	—
☐ Packaging?	—	—	—
☐ Drug information center?	—	—	—
☐ Sterile compounding, including IV additive services?	—	—	—
☐ Editing or order review center?	—	—	—
☐ Storage of drugs and supplies (e.g., refrigeration, alcohol and other flammables, narcotics and regular active and inactive)?	—	—	—
☐ Quality control and research?	—	—	—
☐ Educational activities?	—	—	—
☐ Radiopharmacy?	—	—	—
☐ Outpatient dispensing?	—	—	—
☐ Cart storage?	—	—	—

	A	B	C
☐ Staff lockers and lounge area?	—	—	—
☐ Waiting areas (inpatient, outpatient, and offices)?	—	—	—

(3) What are the space requirements for the pharmacy substations in the following areas?

☐ Administration			
Office?	—	—	—
Education?	—	—	—
Drug information?	—	—	—
☐ Dispensing?	—	—	—
☐ Compounding (extemporaneous and sterile)?	—	—	—
☐ Editing or order review?	—	—	—
☐ Storage			
Active?	—	—	—
Bulk?	—	—	—
Refrigeration?	—	—	—
Medication cart?	—	—	—
Narcotics?	—	—	—

Staffing Requirements

Decisions arising from considering questions posed in previous sections will bear importantly on factors presented in this section.

(1) Based on the drug distribution system chosen, to what extent will nonprofessionals be used in the pharmacy for the following activities?

☐ Label typing?	—	—	—
☐ Other clerical duties?	—	—	—
☐ Bulk compounding?	—	—	—
☐ Packaging?	—	—	—
☐ Pickup and delivery?	—	—	—
☐ Inventory control?	—	—	—
☐ Equipment maintenance?	—	—	—
☐ Housekeeping?	—	—	—
☐ Dispensing?	—	—	—
☐ Purchasing?	—	—	—

(2) What supervision will nonprofessionals require? — — —

(3) What will be the education and training requirements for nonprofessionals and how will they be trained?

☐ Inhouse training program?	—	—	—
☐ On-the-job training?	—	—	—
☐ Formal outside training?	—	—	—

(4) How will coverage be provided during meal hours, days off, vacations, and sick leave? — — —

(5) With the increasing use of nonprofessionals, what additional professional duties will be given to pharmacists?

☐ Conduct patient interviews (admission and discharge)?	—	—	—

	A	B	C
☐ Maintain patient medication profiles?	—	—	—
☐ Edit all medication orders?	—	—	—
☐ Discuss drug regimen with physicians?	—	—	—
☐ Provide information to physicians, nurses, and aides?	—	—	—
☐ Supervise preparation of all medication doses?	—	—	—
☐ Supervise medication administration?	—	—	—
☐ Maintain IV additive program?	—	—	—
(6) Will there be a clinical pharmacy training program in conjunction with a school of pharmacy? If so, what will be the student/preceptor ratio?	—	—	—
(7) If 24-hour service is to be given, how will the workload be distributed?	—	—	—
(8) Will volunteers be used? If so, what tasks will they perform? At what hours and on what days?	—	—	—
(9) What are the estimated staffing patterns and hours for:			
☐ Full-time pharmacist?	—	—	—
☐ Part-time pharmacist?	—	—	—
☐ Technician?	—	—	—
☐ Helpers?	—	—	—
☐ Clerical?	—	—	—
☐ Other?	—	—	—
Shifts	—	—	—
8:00 a.m.–4:00 p.m.	—	—	—
4:00 p.m.–12:00 a.m.	—	—	—
12:00 a.m.–8:00 a.m.	—	—	—

Mechanical and Other Requirements for Built-In Equipment

(1) What mechanical systems will be required for carrying supplies and requisitions between the inpatient pharmacy and the following activities:

Activity	*Pneumatic Tube (and size)*	*Vertical Conveyor*	*Horizontal Conveyor*	*Other*
Nursing Unit				
Outpatient Pharmacy				
Central Service				
Operating Room				
Emergency				
General Stores				
Clinical Laboratories				
X-Ray				
Mailroom				
Accounting				
Data Processing				

	A	B	C
(2) If there is to be a separate outpatient pharmacy, what will be its needs in regard to the above activities?	—	—	—
(3) What will be the preferred pharmacy locations for the pneumatic tube and/or conveyor stations?	—	—	—
(4) Will the pharmacy require gas, vacuum, and compressed air; if so, where will the outlets be placed?	—	—	—
(5) Where will 110–120v electrical outlets be placed?	—	—	—
Will there be any special lighting requirements?	—	—	—
Will high voltage voltage lines be required?	—	—	—
(6) Will the pharmacy require its own still?	—	—	—
(7) Will the pharmacy require its own autoclave?	—	—	—
(8) Where will sinks be required and placed? (State type and size.)	—	—	—
(9) Will special flooring be required?	—	—	—
What type?	—	—	—
Where?	—	—	—
(10) What functional elements and service outlets within the pharmacy must be provided with standby power?	—	—	—
(11) What special requirements will be needed in the sterile area?			
A/C vents near laminar flow hoods?	—	—	—
UV light?	—	—	—
Other?	—	—	—
(12) Will any special plumbing fixtures, such as floor drains be required?			
(13) What will be the storage and fixed equipment requirements for each of the following:			
☐ Refrigerated drugs?	—	—	—
☐ Alcohol?	—	—	—
☐ Narcotics and other controlled drugs?	—	—	—
☐ Bulk supplies?	—	—	—
☐ Active supplies?	—	—	—
☐ Documents?	—	—	—
(14) What will be the cabinet, shelving, and work counter requirements for:			
☐ Extemporaneous compounding area?	—	—	—
☐ Inpatient dispensing area?	—	—	—
☐ Sterile production area?	—	—	—
☐ Bulk compounding area, including quality control?	—	—	—
☐ Packaging area?	—	—	—
☐ Administrative areas:			
Office?	—	—	—
Education?	—	—	—
Drug information?	—	—	—
Conference room/library?	—	—	—

	A	B	C
Staff lockers?			
☐ Radiopharmaceutical?	—	—	—
☐ Outpatient dispensing area?	—	—	—
☐ Storerooms?	—	—	—
☐ Pharmacy substations:	—	—	—
Administrative areas?			
Dispensing areas?	—	—	—
Compounding areas?	—	—	—
Editing areas?	—	—	—
Storage areas?	—	—	—
	—	—	—
(15) Will drinking fountains be required?			
Where?	—	—	—
	—	—	—
(16) If bulletin boards are needed, what size and where will they be placed?	—	—	—
(17) Where will central vacuum cleaning outlets be located?	—	—	—
(18) What clocks will be needed?			
Where?	—	—	—
	—	—	—
(19) What signs will be needed?			
Type and size?	—	—	—
Illuminated?	—	—	—
Where located?	—	—	—
	—	—	—
(20) What equipment listed below will be required? (Indicate floor area needed for item and operator and where item will be placed.)			
☐ Duplicating?	—	—	—
☐ Dictating?	—	—	—
☐ Transcribing?	—	—	—
☐ Imprinting?	—	—	—
☐ Computer terminals?	—	—	—
☐ Direct writing intercom?	—	—	—
☐ Teletype?	—	—	—
☐ Calculators?	—	—	—
☐ Closed circuit TV?	—	—	—
☐ Files?	—	—	—
	—	—	—

Interrelationships

What will be the interrelationship between the pharmacy department and the following major departments and/or services relative to the factors listed?

(1) Nursing Units			
☐ Ordering medications (routine prescriptions, refills, *stats, prns,* investigational drugs, back orders, telephone orders, and non-formulary drugs)?	—	—	—
☐ Delivery of written medication orders?	—	—	—
☐ Delivery of medications?	—	—	—
☐ Ordering, delivering, and record keeping of controlled drugs?	—	—	—
☐ Credits for unused medications?	—	—	—
	—	—	—

	A	B	C
☐ Control of medications brought in by patient?	—	—	—
☐ Information on patient census status?	—	—	—
☐ Patient medication charges?	—	—	—
☐ Replacement of emergency drug boxes?	—	—	—
☐ Procedures for discharge medications?	—	—	—
☐ Procedures for obtaining medications when pharmacy is closed?	—	—	—
(2) Administration			
☐ Pharmacy's place in hospital organizational structure?	—	—	—
☐ Authority of chief pharmacist?	—	—	—
☐ Hours of service for pharmacy?	—	—	—
☐ Committees on which chief pharmacist and other pharmacists will serve?	—	—	—
(3) Medical Staff			
☐ Pharmacy and Therapeutics Committee?	—	—	—
☐ Formulary?	—	—	—
☐ Automatic stop orders?	—	—	—
☐ Narcotics control?	—	—	—
☐ Drug informaiton service?	—	—	—
☐ Handling of physician's samples?	—	—	—
(4) Procurement			
☐ Ordering and receiving supplies and equipment for pharmacy?	—	—	—
☐ Setting standards for drugs and supplies?	—	—	—
(5) Central Service			
☐ Common use of delivery equipment and services?	—	—	—
☐ Supply of freshly distilled water?	—	—	—
☐ Common use of sterilizing equipment?	—	—	—
(6) Inpatients			
☐ Medication history?	—	—	—
☐ Patient medication profile?	—	—	—
☐ Discharge interview?	—	—	—
(7) Business Office			
☐ Budget status reports?	—	—	—
☐ Charges to patients?	—	—	—
☐ Credits for unused medications?	—	—	—
☐ Procedure for paying for pharmacy materials?	—	—	—
(8) Personnel Department			
☐ Job descriptions policy?	—	—	—
☐ Awards policy?	—	—	—
☐ Pharmacy staffing patterns?	—	—	—
☐ Staff promotions?	—	—	—
(9) Clinical Support Activities			
☐ How will supplies be requisitioned, issued, delivered, and charged routinely and irregularly to such areas as the laboratory, surgery, and X-ray?	—	—	—

	A	B	C
(10) General Stores			
☐ Requisitioning pharmacy supplies and equipment?	—	—	—
☐ Delivering pharmacy supplies and equipment?	—	—	—
☐ Will a special storage area in general stores be required for pharmacy items?	—	—	—
(11) Data Management			
☐ How will the pharmacy used EDP?			
Patient information for drug distribution system?	—	—	—
Patient medication profiles?	—	—	—
Ward medication schedules?	—	—	—
Patient information for drug utilization reviews?	—	—	—
Patient information for adverse action reporting?	—	—	—
Charges and credits?	—	—	—
Inventory?	—	—	—
Ordering supplies?	—	—	—
Drug formulary?	—	—	—
Drug utilization review?	—	—	—
(12) Housekeeping			
☐ How will cleaning supplies be handled?	—	—	—
☐ How will housekeeping for pharmacy department be handled?	—	—	—
(13) Outpatient Department			
☐ Supervision of outpatient pharmacy?	—	—	—
☐ Required office space for outpatient pharmacy?	—	—	—
☐ Processing of outpatient prescriptions?	—	—	—
☐ Payment method for outpatient prescriptions (Cashier in pharmacy?)	—	—	—
☐ Extent of outpatient department use of different stock (e.g., nonunit dose), thus requiring duplicate inventory contract systems, purchasing, and charging?	—	—	—
☐ Processing of employee prescriptions?	—	—	—
(14) Medical Records Department			
☐ Review of charts for adverse actions and drug utilization review?	—	—	—
☐ Prescriptions filled directly from charts?	—	—	—

Communication and Transport

(1) How many telephones will be required?	—	—	—
What type?	—	—	—
Location?	—	—	—
(2) Will there be direct audio-intercom between pharmacy department and the following:			
☐ Nursing units?	—	—	—
☐ Emergency department?	—	—	—
☐ Central service?	—	—	—
☐ Drug storage area?	—	—	—
☐ Outpatient pharmacy?	—	—	—

	A	B	C
(3) Will the pharmacy be tied into general paging and piped music system?	—	—	—
Location of terminals?	—	—	—
(4) Will pharmacy be tied into emergency alert?			
☐ Cart?	—	—	—
☐ Other equipment?	—	—	—
☐ Signal apparatus?	—	—	—
(5) What are the materials handling needs of the pharmacy?			
Vertical?	—	—	—
Horizontal?	—	—	—
Demand by time of day?	—	—	—
(6) What type of transportation system will be used for drug distribution?			
☐ Large carts?	—	—	—
☐ Individual patient drawer carts?	—	—	—
☐ Automated? *(automated cart conveyor—pneumatic tube—dumb-waiter)*	—	—	—
☐ Other?	—	—	—
(7) Will there be computer input-output devices in the inpatient and/or outpatient pharmacies and, if so, where will they be located?	—	—	—

Location

(1) Where will pharmacy department be located in relation to:			
☐ Main entrance and lobby?	—	—	—
☐ Outpatient area?	—	—	—
☐ Elevators?	—	—	—
☐ Information desk?	—	—	—
☐ General stores?	—	—	—
☐ Central service?	—	—	—
☐ Business office?	—	—	—
☐ Physician's lounge?	—	—	—
☐ Loading dock?	—	—	—
☐ Other?	—	—	—
(2) Will there be more than one inpatient pharmacy substation?			
Locations?	—	—	—
(3) Will there be a separate outpatient pharmacy?	—	—	—
Location?	—	—	—
(4) Will the pharmacy receive supplies directly into its area?			
Loading platform?	—	—	—
Other?	—	—	—

	A	B	C
(5) In the traffic flow, what will be the nature and number of commerce units between the pharmacy department and			
☐ Nursing units?			
☐ Outpatient area?			
☐ General stores?			
☐ Central service?			
☐ Elevators?			
☐ Clinical support services?			
☐ Extended care facility?			
involving people, materials, and information.			

When will peak traffic occur relative to above?

Environmental Requirements

(1) Will carpeting be required in any or all areas?			
(2) Where and to what extent should acoustical treatment be given?			
(3) What type of temperature and humidity controls will be required?			
(4) What is the preferred color scheme by functional areas?			
(5) What door-keying system and controls will be used?			
(6) What will be the air filtration requirements?			

Although the foregoing list provides the hospital pharmacist with a reasonable check on the subjects and areas to be planned for, it is important for the planner to give consideration to the changes that have taken place within the practice of hospital pharmacy since the list was prepared. As a result of the changes made in the health care delivery system during the past 10 years, consideration must now be given to the following subjects and areas in order that the end product be a modern hospital pharmacy.

1. Will the pharmacy have need for a quality control laboratory?
2. Will the hospital pharmacy become involved in the handling and dispensing of radioisotopes?
3. Will the hospital's Allergy Department require the hospital pharmacy to become involved in the preparation of allergenic extracts and subsequent dilutions?
4. Is there a need for a research laboratory?
5. Has consideration been given to providing space for certain specialized functions, *i.e.* unit dose dispensing; I.V. solution additive program; drug information service; patient drug control system (patient profile); unit-dose packaging area and required equipment?

6. Will the pharmacy become involved with educational programs for the benefit of medical, nursing and pharmacy students; interns and residents; graduate physicians, nurses and pharmacists; cooperative clinical pharmacy programs with schools or colleges of pharmacy?
7. Will the pharmacy and its staff be an integral part of the local poison control center? If so, facilities planning should include space for information gathering, storage and a suitable communications system. Consideration must also be given to its location and staffing requirements.
8. With the improvements that have been made in electronic data processing systems, consideration should be given to the use of a computer by the pharmacy. If this is determined to be feasible, planning must include specialists from administration, pharmacy, nursing, medical staff and data processing in order to ascertain the extent of the program required as well as the selection and placement of appropriate equipment. In developing the system, all parties concerned should give consideration to building into it a system of inspections and checks as well as to provide for adequate back-up service in case of mechanical failure.
9. Consideration must be given to the means by which pharmacy supplies and requisitions will be carried between the pharmacy and nursing stations. These mechanical systems may be any one or combination of pneumatic tube, vertical conveyor or horizontal conveyor.
10. Because of the nature of the modern practice of pharmacy, large medical center type operations may require that the planners provide space for direct writing intercoms, teletype, closed circuit television, printing and/or duplicating equipment.

In addition to the above cited questions, the hospital pharmacist should be prepared to furnish answers which pertain to such areas as pre-packaging, methods and statistics involving the volume of dispensing, the number of people who will be in any one sector of the pharmacy at any single time, the peak dispensing hours, the measurements of the various carts or trucks used in the pharmacy, the department's provisions for night emergency service, the number of nursing stations and other departments to be serviced and finally a plan which will allow for a continuation of service to the hospital and yet permit forward progress for the construction crew.

LOCATION

The hospital pharmacy should be located in an area which is convenient for providing service to the many departments and personnel

who make daily use of such service. Therefore, since this is a primary consideration, it is irrelevant where the pharmacy is located in the hospital so long as it meets the test of convenience.

Milne and Taylor[10] in their article dealing with suggested plans for hospital pharmacies have stated:

"In hospitals of less than 200 beds the pharmacy should be located on the first floor, in the center of the activities it is called upon to service frequently, easily accessible to the elevator, and near or adjoining the out-patient department, if such is maintained by the hospital. This will provide the most efficient service and conserve man-hours of work.

Though it is recommended that the pharmacy be all located on one floor, it may be varied in larger hospitals when first floor space is at a premium.

The basement is not desirable for a pharmacy."

Because most hospital pharmacies were designed and constructed during an era before out-patient facilities had developed to their present status, many clinic administrators feel that they are poorly located insofar as the out-patient department is concerned. Since the majority of the hospital pharmacies serving clinic patients combine out-patient and in-patient facilities, the pharmacists concur with the observation made by the clinic administrative personnel.

The *Mirror to Hospital Pharmacy*,[11] in discussing this subject, states:

"If a hospital provides out-patient pharmacy service then, if possible, pharmacy facilities should be located either in or immediately adjacent to the out-patient department. It is not suitable for a cashier, nurse or other hospital personnel to accept the prescription from the patient and send it by pneumatic tube or by other means to the pharmacy located in some other section of the hospital and return the medication to this person for delivery to the patient. Although man-hours may be conserved by combining in-patient dispensing units, this advantage should not take precedence over locating the out-patient pharmacy facility in the immediate area serving out-patients. If a low volume of work does not justify such a location, then it would seem best either to not offer out-patient pharmacy service or to have the patient carry his prescription to the in-patient pharmacy."

In general, the in-patient pharmacy appears to be reasonably well situated to render the services required of it. Where possible, all sections of the in-patient pharmacy—storage, dispensing, manufacturing, parenteral solutions, etc. should be contiguous. When these functions are separated from the main pharmacy, it is recommended that they be in a direct vertical relationship if possible. In addition, this concept of direct vertical relationship should be extended between the pharmacy and the various divisions of the hospital utilizing pharmaceutical services.

With the advent of clinical pharmacy programs, many hospitals have

found it advisable to develop *satellite pharmacies* on the patient pavilions. In effect, these are sub-pharmacies that receive their supplies from the main pharmacy but have the advantage of being able to respond to the clinical needs of the patient on a current basis. In addition, such a system makes available to the patient, physician, and nurse the services of a pharmacist in a clinical capacity rather than as just a dispenser of medications. By being on the nursing floor, the pharmacist is available for the taking of patient drug histories, maintaining patient drug policies, observing the patient for drug reactions and toxicity and dispensing unit-doses and intravenous products with additives.

FLOOR SPACE

Milne, Taylor and their Public Health Service Associates recommend the following floor space and its distribution within the pharmacy area:

AREA DISTRIBUTION FOR GENERAL HOSPITAL PHARMACIES

Areas in Square Feet	50 Bed	100 Bed	200 Bed
Compounding and Dispensing Laboratory	205	320	495
Parenteral Solutions Laboratory		185	200
Active Store Room		125	200
Manufacturing Laboratory			120
Office and Library			105
Circulation			60
TOTAL	205	630	1180

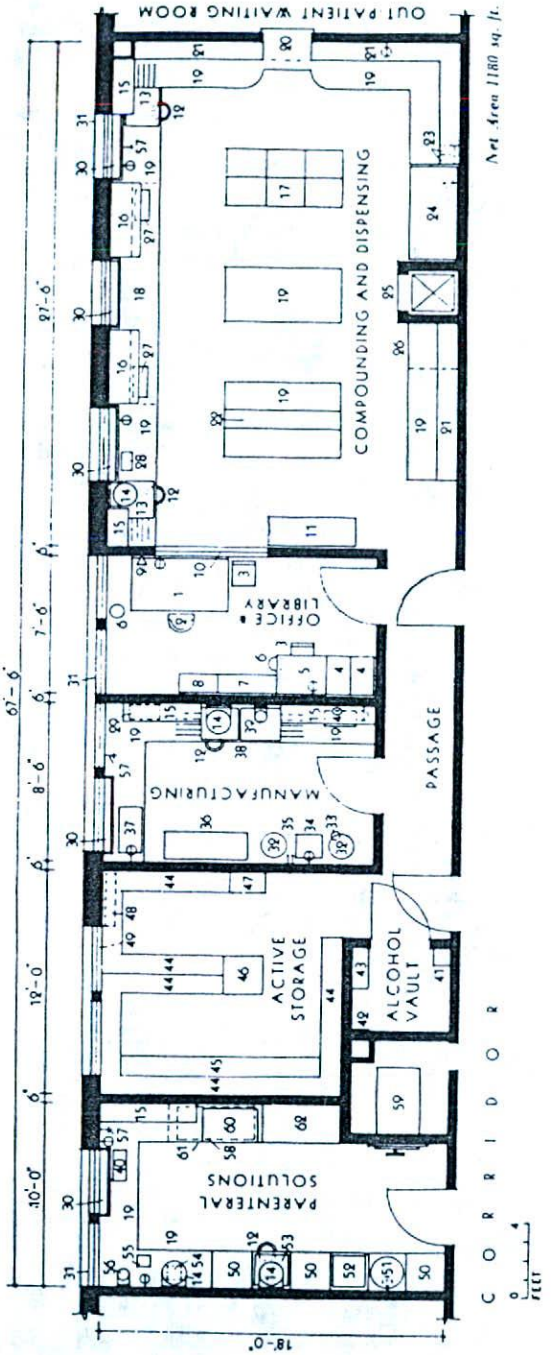
The areas shown in the above chart are net areas and do not include walls and partitions. Additional storage space of approximately 170 square feet per 100 beds is provided for bulk storage in an area directly beneath the pharmacy and separate from the main hospital store room.

Translating the above figures into a square foot per bed ratio, the following is noted:

AREA DISTRIBUTION—SQUARE FEET PER BED

Areas in Square Feet	50 Bed	100 Bed	200 Bed
Compounding and Dispensing Laboratory	4.1	3.20	2.48
Parenteral Solutions Laboratory		1.85	1.00
Active Store Room		1.25	1.00
Manufacturing Laboratory			0.60
Office and Library			0.53
Circulation			0.30
TOTAL	4.1	6.30	5.91

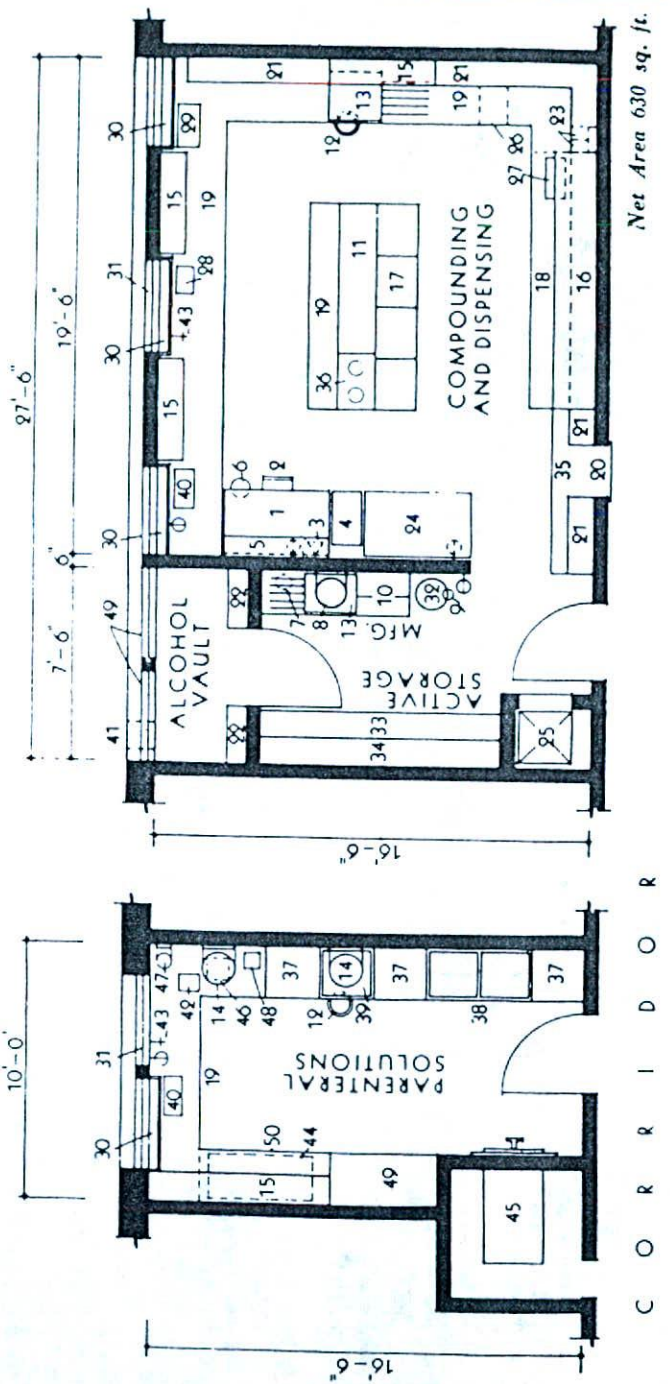
In contrast, Francke *et al.*[12] in their survey requested the survey participants to indicate the number of additional square feet of space


OUT PATIENT WAITING ROOM
Net Area 1180 sq. ft.
COMPOUNDING AND DISPENSING
OFFICE & LIBRARY
PASSAGE
MANUFACTURING
ACTIVE STORAGE
ALCOHOL VAULT
PARENTERAL SOLUTIONS
CORRIDOR
67'-6"
10'-0"
6"
12'-0"
8'-6"
6'
7'-6"
6'
97'-6"
18'-0"
0
FEET

1. Desk, executive
2. Chair, executive
3. Chair, straight
4. File, 4 drawer
5. Table, writing
6. Receptacle, waste paper
7. Case, book
8. Rack, magazine
9. Outlet, telephone
10. Glass panel
11. Rack, carboy
12. Can, sanitary waste
13. Sink, with goose neck spout and drainboard, graduate rack above, cabinets below
14. Tank, glass, distilled water, 12 gallon
15. Cabinets, adjustable shelves
16. Cabinet, drug, sectional type, with shelf above counter
17. Cabinets, drug, sectional type
18. Counter, prescription, cabinets and drawers below
19. Counter, cabinets and drawers below
20. Window, dispensing
21. Shelves, adjustable, open, starting 18 inches above counter
22. Shelf, above counter
23. File, prescription
24. Refrigerator, with biological drawers, 32 cubic feet
25. Dumbwaiter
26. Safe, narcotic, under counter
27. Scale, prescription, class A
28. Scale, prescription, heavy duty
29. Scale, counter
30. Heat outlet grill, inlet grill in base of cabinet
31. Guards, at all windows
32. Tank, mixing or storing, 20 gallons, mounted on stand with casters
33. Mixer, portable, electric
34. Filter press, suction-pressure type, mounted on casters
35. Outlets, hot and cold water
36. Rack, filter
37. Mill, colloidal
38. Sink, two compartment, with drainboard, goose neck spout, cabinets below
39. Still, 2 gallon per hour
40. Hot Plate, double element
41. Vent, outlet, 8 inches above floor to atmosphere
42. Vent, inlet, near floor to atmosphere
43. Shelves, starting 42 inches above floor
44. Shelves, 12 inches wide, adjustable, open
45. Shelves, 24 inches wide, 36 inches high, adjustable
46. Rack, barrel
47. Locker, clothes
48. Radiator, above shelving
49. High windows
50. Rack, bottle
51. Cleaner, bottle, pressure type
52. Sink with goose neck spout
53. Sink, with distilled water rinser, omit hot & cold water supply
54. Drip pan with waste connection in counter top
55. Pump, suction and pressure
56. Still, 10 gallon per hour
57. Outlet, gas
58. Carriage, sterilizer, under counter
59. Sterilizer, 24 x 36 x 48 inches
60. Oven, hot air, 24 x 14 x 14 inches, on counter
61. Counter, open below
62. Cabinet, storage, open adjustable shelves

Pharmacy for a 200 bed general hospital

Fig. 86. The above plan for a pharmacy for a 200-bed general hospital may still be found in a large number of hospitals. With slight modification it is adaptable to modern day dispensing practices. (From Public Health Service Publication No. 891.)


Net Area 630 sq. ft.
27'-6"
19'-6"
7'-6"
6"
10'-0"
16'-6"
16'-6"
ALCOHOL VAULT
ACTIVE STORAGE
MFG.
COMPOUNDING AND DISPENSING
PARENTERAL SOLUTIONS
CORRIDOR

Pharmacy for a 100 bed general hospital

1. Desk
2. Chair
3. Outlet, telephone
4. File, 4 drawer
5. Shelves, book, over desk
6. Receptacle, waste paper
7. Still, 2 gallon per hour. Required if parenteral solution room is omitted
8. Tank, glass, distilled water, 5 gallon
9. Mixer, portable, electric
10. Counter, cabinets below, shelves above
11. Rack, carboy, above counter
12. Can, sanitary waste
13. Sink, with goose neck spout and drainboard, graduate rack above, cabinets below
14. Tank, glass, distilled water, 12 gallon
15. Cabinet, adjustable shelves
16. Cabinet, drug, sectional type, with shelf above counter
17. Cabinets, drugs, sectional type
18. Counter, prescription, cabinets, sectional type drawers below
19. Counter, cabinets and drawers below
20. Window, dispensing
21. Shelves, adjustable, open, starting 18 inches above counter
22. Shelves, starting 42 inches above floor
23. File, prescription
24. Refrigerator, 16 cubic feet, with biological drawers
25. Dumbwaiter
26. Safe, narcotic, under counter
27. Scale, prescription, class A
28. Scale, prescription, heavy duty
29. Scale, counter
30. Heat outlet grill, inlet grill in base of cabinet
31. Guards, at all windows
32. Tank, mixing, 20 gallons, mounted on stand with casters
33. Shelves, 24 inches wide, 36 inches high, adjustable, open
34. Shelves, 12 inches wide, adjustable, open
35. Counter, 18 inches wide, adjustable shelves below
36. Rack, filter, above counter
37. Rack, bottle
38. Sink, two compartment, goose neck spout, cabinets below
39. Sink, with distilled water rinser, omit hot and cold water supply, cabinets below
40. Hot plate, double element
41. Vent, at ceiling and floor
42. Scale, metric, solution
43. Outlet, gas
44. Carriage, sterilizer, under counter
45. Sterilizer, 24 x 36 x 48 inches
46. Drip pan with waste connection in counter top
47. Still, 5 gallon per hour
48. Pump, suction and pressure
49. Cabinet, storage, open, adjustable shelves
50. Counter, open below

Fig. 87. The above design for a pharmacy for a 100-bed hospital was recommended by the Division of Hospital and Medical Facilities in the early 1950s. (From Public Health Service Publication No. 891.)

they felt would be necessary for them to give the type of service the pharmacy should provide and obtained the following results which are compared with the Public Health Service recommendations for short-term hospitals.

# Beds	Public Health Service Recommendations	Survey Findings
100	6.3 sq. ft./bed	8.12 sq. ft./bed
200	5.9 sq. ft. bed	6.62 sq. ft./bed
300		5.39 sq. ft./bed
400		5.00 sq. ft./bed

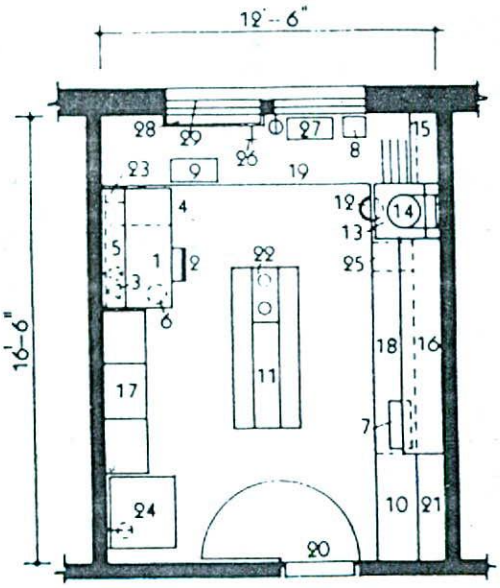
Before utilizing the above figures, it should be remembered that the Public Health Service plans provide an additional 170 square feet per 100 beds for reserve storage of bulk pharmaceuticals outside the pharmacy and that the survey findings make no provisions for this additional storage facility.

Exclusive of the survey conducted by Francke *et al.*, little has been published relative to area distribution for general hospital pharmacies since the work of Milne and Taylor in 1950. Therefore, it is important to recognize the fact that in the intervening years pharmaceutical services in the hospital have expanded considerably thereby suggesting that, until more up-to-date information is developed, the recommendations of the Public Health Service for floor space in hospital pharmacies should be considered minimal for the construction of today's hospital pharmacy.

Furthermore, it is important to note that today's practice of pharmacy provides its practitioners the opportunity to perform variable functions ranging from standard type dispensing methods to unit dose dispensing methodologies. Involvement with intravenous additive programs, drug information centers and clinical pharmacy endeavors simply means that pharmacy floor space requirements must be determined by factors other than bed capacity and ambulatory clinic patient load. Also, no two hospitals should be compared for the purpose of determining the square footage requirements of the other in spite of the fact that both appear to have similar pharmaceutical involvement. It is not the similarity of involvement that determines space requirements but the degree or scope of involvement coupled with the type of equipment used in the programs.

EQUIPMENT PLANNER'S RESPONSIBILITY

The pharmacist, administrator, purchasing agent and architect, as a group, assume the responsibility for the planning and the subsequent purchase of the major equipment items to be located in the pharmacy.



1. Desk
2. Chair
3. Outlet, telephone
4. File, 2 drawer
5. Shelves, book
6. Receptacle, waste paper
7. Scale, prescription, class A
8. Scale, prescription, heavy duty
9. Scale, counter
10. Counter, shelves below, adjustable, open
11. Rack, carboy, above counter
12. Can, sanitary waste
13. Sink, with goose neck spout and drainboard, graduate rack above, cabinets below
14. Tank, glass, distilled water, 5 gallon
15. Cabinet, adjustable shelves
16. Cabinet, drug, sectional type, with shelf above counter
17. Cabinets, drug, sectional type
18. Counter, prescription, cabinets and drawers below
19. Counter, cabinets and drawers below
20. Dutch door
21. Shelves, adjustable, open, starting 18 inches above counter
22. Rack, filter, above counter
23. File, prescription, on desk
24. Refrigerator, 8 cubic feet, with biological drawers
25. Safe, narcotic
26. Outlet, gas
27. Hot plate, double element
28. Heat outlet grill, inlet grill in base of cabinet
29. Guards, at both windows

Net Area 205 sq. ft.

0 4
FEET

Pharmacy for a 50 bed general hospital

Fig. 88. The above design for a pharmacy for a 50-bed hospital was adequate for the type of pharmacy practiced in the period 1950–60. Many hospitals today still have similarly designed units. (From Public Health Service Publication No. 891.)

The less expensive items, commonly used in the daily practice of the profession, are usually purchased by the purchasing agent after he has consulted with the pharmacist.

In selecting the equipment, all parties must exercise extreme care in choosing those items which will provide good service, with minimal maintenance, at a price within the hospital's equipment budget. All too often, many pharmacists succumb to the temptation of equipping a particular section of the pharmacy with elaborate and expensive equipment and then purchase equipment of a lower quality for another division of the pharmacy in order to remain within the budgetary allowance.

The cost of equipment should not be estimated nor should a percentage of the building construction cost be used. Whenever such short cuts are taken, experience has demonstrated that insufficient funds are available for the purchase of the desired equipment. Clearly then, once the equipment list is prepared, it behooves the pharmacist to consult freely with the purchasing agent, manufacturer's representatives and vendors as well as to peruse through the latest editions of the catalogues.

Equipment is segregated into two groups: fixed and movable.

FIXED EQUIPMENT

Fixed equipment is defined as that which requires installation and becomes attached to the building. The single connection of electric power lines into the building's electric system or temporary attachment to a utility system does not qualify the item as fixed equipment. Fixed equipment is usually included in construction contracts and must be purchased and installed in accord with the requirements of the contract. Examples of fixed equipment are cabinets, counters, sinks, dumbwaiters and elevators.[6]

MOVABLE EQUIPMENT

Movable equipment is defined as that equipment which is capable of being moved and is not intended to be permanently affixed to the building. This group includes large items of furniture and equipment having a reasonable fixed position in the building but which can be moved. Examples of movable equipment are carts, desks, balances, mixers etc.[6]

SUGGESTED EQUIPMENT LISTS

Because the scope of service rendered by each hospital pharmacy will vary from one section of the country to the other or, for that matter,

from hospital to hospital, it is an impossible task to attempt to prepare a standard list of equipment which will meet every need.

The Equipment Planning Branch of the United States Public Health Service has prepared a suggested equipment list[13] which may be used as a guide. For the convenience of the student and the hospital pharmacist who may wish to use the said equipment list as a check list for the inventory of basic pharmaceutical equipment within the department, the suggested list is hereinafter published.

The symbols used in these lists have definite meaning as follows.[7]

1. " indicates that the item is required but the quantity is not determined. Quantity is dependent upon correlation of the schematic plans."
2. "— indicates the item is not applicable to the particle size group."
3. "Supplies are not included in the term 'equipment' as they are not participated in for hospital projects constructed under the "Hospital and Medical Facilities (Hill-Burton) Program'."

DRUG DISTRIBUTION

	Suggested Quantity Number of Beds		
	100	300	500
Order Review			
Fixed	—	—	1
Bookshelves, adjustable.	1	1	2
Pneumatic tube station.	2	2	4
Utility pole, phone, electric.			
Movable			
Cabinet, filing	2	2	4
Letter size, 3-drawer	1	1	2
Card size, two-level, revolving.	1	1	2
Visible index type.	—	1	1
Cart, for photocopier, storage shelf.	2	5	10
Chair, swivel, with arms.			
Desk	2	3	6
Office, double pedestal.	—	2	4
Editing, special.	2	2	3
File, swinging panel, strip, insert.	—	1	1
Photocopier, bound volumes, desk type.	2	—	—
Table, writing 2' × 2'	1	1	2
Time/date stamp, electric.	2	3	6
Typewriter, electric, nonmovable carriage.	2	2	4
Waste receptacle.			
Inpatient Dispensing			
Fixed			
Cabinets, wall-mounted.	1	3	6
Counter, prescription, cabinets, bins and drawers below.			

	Suggested Quantity Number of Beds		
	100	300	500
Dumbwaiter.	1	1	1
Pneumatic tube station.	0	1	1
Shelving, adjustable, 12", starting 18" above counter	1	2	3
Ledge, fixed.	0	1	1
Movable			
Cabinet, filing, 5-drawer, letter size.	1	1	0
Cart, delivery, large.	0	1	2
Refrigerator			
Biological type, with freezer.	1	0	0
Pass-through, cafeteria type, for IV solutions.	0	1	1
Open front, refrigerated case type.	0	1	1
Typewriters, electric, nonmovable carriage.	1	2	4
Stool, operator's, adjustable.	1	2	4
Receiving and Storage			
Fixed			
Counter, with adjustable shelving beneath.	1	1	1
Safe.	1	0	0
Shelving, adjustable, wall-mounted, 9"	1	1	1
Rail-mounted			
in narcotic vault. Back 24", sides 12".	—	1	1
in flammables room, 12".	—	1	1
Vent, inlet and outlet, in flammables room.	1	1	1
Movable			
Cradle, drum.	1	1	1
Waste receptacle.	1	1	1
Purchasing and Inventory Control			
Fixed			
Bookshelves, wall-mounted above desk.	1	1	—
Movable			
Cabinet, filing, visible index type			
One section.	1	—	—
Three section.	—	1	—
Letter size, 5-drawer.	1	1	—
Chair, swivel, with arms.	—	1	—
Desk, office, double pedestal.	1	1	—
File, swinging, strip insert.	—	1	—
Waste receptacle.	—	1	—
Extemporaneous Preparations			
Fixed			
Cabinet, wall-mounted.			
Counter with sink, drainboard, adjustable shelves beneath.	2	2	2
Counter, with open adjustable shelving beneath.	1	2	5
Shelving, fixed ledge.	0	1	1

	Suggested Quantity Number of Beds		
	100	300	500
Movable			
Bins, autoclavable.	10	10	20
Cart, flask transport.	1	1	2
Cart, utility, flat top, locking wheels.	2	2	2
Chair, swivel.	1	1	1
Desk, office, single pedestal, file drawer.	1	1	1
Hood, laminar airflow, horizontal or vertical.	1	1	2
Waste receptacle.	2	2	4
Outpatient Dispensing			
Fixed			
Cabinet, wall-mounted.	—	1	—
Counter, with sink, drainboard, file drawer.	—	1	—
Counter, with file drawer, bins, and shelf beneath.	1	1	—
Door, flexible, pulldown type for outpatient dispensing counter window.	1	1	—
Panels, acoustical.	—	1	—
Shelving, adjustable, wall-mounted, 12".	1	—	—
Movable			
Cabinet, filing, rotary, mechanical.	—	1	—
Chairs, guest, for waiting area.	—	4	—
File, swinging panel, strip insert.	1	1	—
Refrigerator, biological, with freezer.	—	1	—
Waste receptacle.	1	—	—
OUTPATIENT PHARMACY (Separate)			
Dispensing			
Fixed			
Counter, with drawers and adjustable shelving beneath.	—	—	—
Counter, with drawer and knee space.	—	—	1
Panel, acoustical.	—	—	6
Pneumatic tube stations.	—	—	1
Shelving, adjustable, wall-mounted, 12".	—	—	—
Movable			
Cabinet, steel, double locks plus alarm buzzer.	—	—	1
Cabinet, filing, letter size, 5-drawer.	—	—	1
Cabinet, filing, rotary, mechanical.	—	—	1
File, swinging panel, strip insert.	—	—	2
Refrigerator, biological, with freezer.	—	—	1
Stool, operator's, adjustable.	—	—	1
Typewriter, electric, nonmovable carriage.	—	—	2
Waste receptacle.	—	—	3
Extemporaneous Preparations (Outpatient)			
Fixed			
Cabinet, wall-mounted.	—	—	4

	Suggested Quantity Number of Beds		
	100	300	500
Counter, with drawers and open adjustable shelving beneath.	—	—	—
Sink unit, with drainboard.	—	—	1
Movable			
Hood, laminar airflow, vertical or horizontal.	—	—	1
Waste receptacle.	—	—	1

PHARMACY SUBSTATION

Order Review

Fixed			
Counter, desk height, with drawers and adjustable shelves beneath.	—	—	1
Shelving, adjustable, wall-mounted, 12".	—	—	—
Movable			
Chair, swivel, with arms.	—	—	1
Waste receptacle.	—	—	1

Distribution

Fixed			
Counter, with open adjustable shelving beneath.	—	—	—
Counter, hinged.	—	—	1
Shelving, adjustable, wall-mounted, 12"	—	—	—
Sink unit, with drainboard.	—	—	1
Movable			
Cart, with cassette storage.	—	—	1
Hood, laminar airflow, vertical or horizontal.	—	—	1
Refrigerator, with freezer, beneath counter.	—	—	1
Waste receptacle.	—	—	1

MANUFACTURING AND PACKAGING

Cleanup Room

Fixed			
Counter, stainless steel, with adjustable shelves and doors beneath, double sink.	—	—	1
Shelving, adjustable, 12".	—	—	—
Wash area, 6" high curb with 1" sill.	—	—	1
Window, pass-through into Injections Filling room.	—	—	1
Movable			
Cart, utility, stainless steel, 23" × 46", with locking wheels, for solution flasks.	—	—	1

	Suggested Quantity Number of Beds		
	100	300	500
Table, utility, stainless steel, 23" × 46", with locking wheels.	—	—	1
Washer, automatic, laboratory type, pass-through on rails into Injections Filling room, to accommodate 25 l flasks per batch, plus two headers for l flasks and one for small glassware, test tubes, and pipettes.	—	—	1
Injections Filling Room and Still Room			
Fixed			
Autoclave, steam, fast exhaust, pass-through into Central Service autoclave area, size suited to solution workload.	—	—	1
Counter, stainless steel, with open adjustable shelving beneath.	—	—	—
Still, capacity 25 gal per hour (mounted in still room).	—	—	2
Storage tank, glass lined or similar, heated, 150-gal capacity, ceiling suspended (mounted in still room).	—	—	1
Movable			
Carriage, autoclave.	—	—	1
Cart, autoclave.	—	—	1
Cart, solution flask drain type.	—	—	2
Conductivity meter, recording.	—	—	2
Filling machine, automatic, dual nozzle type, type, foot operated, for amps and vials.	—	—	1
Hood, laminar airflow, horizontal or vertical.	—	—	1
Stool, operator's, adjustable.	—	—	1
Table, utility, stainless steel, 35" × 70", with locking wheels.	—	—	1
Tank, premix, 50-gal capacity, with pump agitator unit and hand-operated filler mechanism with filter, fitting under table.	—	—	1
Filter, membrane type.	—	—	2
Sterile Preparation			
Fixed			
Counter, with storage cabinets beneath.	—	—	—
Kettle, steam,jacketed, 5-gal capacity.	—	—	1
Shelving, wall-mounted, 12".	—	—	—
Sink unit, laboratory type, corner.	—	—	1
Window, pass-through, to Injections Filling room and Aseptic Filling room.	—	—	2
Movable			
Balance, prescription, type A, with weights.	—	—	1
Balance, single beam, capacity 4.5 kg.	—	—	1
Chair, swivel.	—	—	1

	Suggested Quantity Number of Beds		
	100	300	500
Cabinet, filing, letter size, 5-drawer.	—	—	1
Cart, utility, laboratory type with railed top.	—	—	1
Desk, office, single pedestal.	—	—	1
Filter, membrane type.	—	—	1
Hot plate, electric, double element, heavy duty, variable heat.	—	—	1
Lockers (in air lock).	—	—	3
pH meter.	—	—	1
Pump, suction and pressure, with gauges.	—	—	1
Stirrer, small volume, counter top.	—	—	1
Stool, operator's, adjustable.	—	—	1
Waste receptacle.	—	—	2
Sterile Area Storage			
Fixed			
Counter, 1' × 2', for writing.	—	—	1
Shelving, adjustable, 18", for storage of materials, containers, and supplies.	—	—	—
Movable			
Stool, 2 steps.	—	—	1
Aseptic Filling			
Fixed			
Counter, stainless steel, open beneath.	—	—	3
Shelving, wall-mounted, 12".	—	—	3
Window, pass through to Labeling and Inspection room.	—	—	1
Movable			
Hood, laminar airflow, horizontal or vertical.	—	—	2
Pipetting machine, automatic, foot operated.	—	—	1
Stool, operator's, adjustable.	—	—	2
Syringe, e.g., Cornwall type with Swinney adapter.	—	—	4
Labeling and Inspection			
Fixed			
Cabinet, floor	—	—	1
Counter drawer units.	—	—	3
Counter top units.	—	—	1
Cupboard drawer units	—	—	3
Corner unit.	—	—	1
Desk height.	—	—	1
Small drawer.	—	—	1
Sink unit, corner.	—	—	1
Shelving, wall-mounted, 12".	—	—	—
Movable			
Labeling machine, automatic, with foot operated clutch, plain worktable and offset pad, plus attachments for pressure sensitive labels.	—	—	1

	Suggested Quantity Number of Beds		
	100	300	500
Labeling machine, hand operated.	—	—	1
Light-dark inspection box.	—	—	1
Stool, operator's, adjustable.	—	—	1
Plate imprinting machine, low capacity, for making imprinting plates for use with labeling machines.	—	—	1
Typewriter, manual, ½ line advance, 16 characters per inch.	—	—	1
Waste receptacle.	—	—	1

Quarantine Storage

Fixed			
Shelving, adjustable, 18".	—	—	—

Prepackaging

Fixed			
Cabinet, e.g., Schwartz type.	—	—	3
Counter, wall-mounted, open beneath.	—	—	—
Counter, with drawer and storage cabinet beneath.	—	—	1
Movable			
Filling machine, automatic, dual type, capacity 0.025 to 100 ml, with suck back device, foot operated.	—	—	1
Heat sealer, electric, stick-resistant covered shoe.	—	—	2
Packager, pouch-type, with imprinter and heat sealer.	—	—	1
Stool, operator's, adjustable.	—	—	1
Strip packaging machine, low volume, quick change-over, imprinting.	—	—	1
Table, utility, stainless steel, flat surface 25" × 70", with locking wheels.	—	—	1

Nonsterile Mixing and Filling

Fixed			
Cabinets, e.g., Schwartz type.	—	—	3
Counter, with drawers and storage cabinets beneath.	—	—	—
Kettle, steam-jacketed, capacity 20 gal	—	—	1
Rack, filter.	—	—	2
Range, electric, variable heat, heavy duty, installed flush with counter.	—	—	1
Shelving, adjustable, 18".	—	—	1
Shelving, adjustable, wall-mounted, 12".	—	—	1
Sink unit, laboratory type.	—	—	2
Wash area, 6" curb with 1" sill.	—	—	1
Movable			
Balance, prescription, type A, plus weights.	—	—	1
Balance, single beam, capacity 4.5 kg, weights.	—	—	1
Blender, electric, multispeed.	—	—	1
Chair, swivel, with arms.	—	—	1

	Suggested Quantity Number of Beds		
	100	300	500
Desk, office, single pedestal, with file drawer.	—	—	1
Filter press, suction pressure type, 10 gal per minimum capacity on casters.	—	—	1
Homogenizer.	—	—	1
Mixer, large, tank-mounted.	—	—	2
Mixer-blender, e.g., Hobart type, for semisolids.	—	—	1
Ointment mill, three roller.	—	—	1
Rheostat, variable, for 110-volt line.	—	—	1
Tank, mixing and storage, 50-gal capacity, with spigot, filter attachment, on wheels	—	—	2
Timer, electric	—	—	1
Washer, laboratory type, automatic, for small glassware and control laboratory items, distilled water rinse.	—	—	1
Waste receptacle, large.	—	—	1

ADMINISTRATION

Chief Administrative Officer

	100	300–500
Movable		
Bookcase.	—	1
Chair, guest.	2	3
Chair, swivel, arms.	1	1
Credenza.	—	1
Desk, double pedestal.	1	1
Dictating machine, recorder.	1	1

Secretary/Receptionist

Movable		
Cabinet, filing, 5-drawer.	1	4
Cabinet, storage.	1	1
Chair, guest.	3	3
Chair, swivel, typist's.	1	2
Desk, single pedestal, secretarial.	1	2
Dictating machine, transcriber.	1	1
Table, corner.	1	—
Typerwriter, electric.	1	2
Waste receptacle.	1	2

Conference Room

Fixed		
Blackboard, wall-mounted.	—	1
Movable		
Cabinet, storage.	—	1
Chairs, conference, folding.	—	8

	Suggested Quantity Number of Beds	
	100	300–500
Projection screen.	—	1
Table, conference.	—	2
Table, corner.	—	1
Waste receptacle.	—	1
Assistant for Business Affairs		
Movable		
Adding machine, electric, printing	—	1
Bookcase.	—	1
Chair, guest.	—	1
Chair, swivel, arms.	—	2
Table, desk type.	—	1
Waste receptacle.	—	1

CONTROL

Control Laboratory

	300–500
Fixed	
Counter, with drawers and storage cabinet beneath.	1
Fume hood, with sink, distilled water, and electric gas outlets.	1
Shelving, wall-mounted, 12".	1
Sink unit, corner.	1
Sink unit.	1
Movable.	
Balance, analytical, one-pan, substitution weighing, reading to 0.1 mg.	1
Battery jar, cylindrical, e.g., Pyrex, 16" diameter by 12" high, for use with constant temperature unit.	2
Burets, micro, class A, 3-way stopcock, e.g., Teflon and stopcock plug, 10 ml.	2
Burets, automatic, class A, e.g., Kimax or e.g., Pyrex with stopcock and plug, 10 ml.	5
Burner, e.g., Fisher, high temperature.	2
Burner, e.g., Terrill, natural gas.	1
Cabinet, e.g., Schwartz type.	1
Centrifuge, clinical, 15- and 40-ml tubes.	1
Chromatography apparatus, thin layer type, for 8" × 8" plates	1
Chromatography cabinet, bench type.	1
Constant temperature unit, e.g., Tecam Tempunit.	1
Electrode, silver billet, combination type, for pH meter.	1
Extraction apparatus with, e.g., Friedrichs condenser.	1
Freezer, upright, to include capacity for storing frozen unit-dose injectables.	1
Heating mantle, hemispherical, for 125-ml flask.	1

	Suggested Quantity Number of Beds
	300–500
Hotplate, electric, square, thermostatic.	1
pH meter, line operated, direct reading.	1
Incubator, gravity convection, large size.	1
Melting point apparatus, e.g., Fisher-Johns or equivalent, for determining melting point of paraffix wax.	1
Microscope, polarizing, e.g., Uniton type.	1
Nitrogen distillation apparatus, micro.	1
Oven, gravity convection, 200° range.	1
Power supply for hydrogen lamp.	1
Refrigerator, home type.	1
Shaker, wrist action, e.g., Burrell type.	1
Silica cells for spectrophotometer, set of two.	1
Spectrophotometer, for use in visible and ultraviolet ranges, with deuterium lamp.	1
Stirring apparatus, magnetic, variable speed.	1
Stool, laboratory type, with back.	1
Support stands, various sizes.	1
Table, for balances, adjusting level.	1
Table, utility.	1
Transformer, variable, e.g., Powerstat type.	1
Waste receptacle.	1

Control Office

Movable	
Bookcase.	1
Cabinet, filing, 5-drawer.	4
Chair, guest.	2
Chair, swivel, with arms.	1
Costumer.	1
Dictating machine, transcriber.	1
Table, desk type.	1
Waste receptacle.	2

DRUG INFORMATION

Drug Information/Conference Area

Fixed	100
Bookshelves, wall-mounted, 12".	1
Blackboard, wall-mounted.	1
Movable	
Cabinet, filing, side opening, 5-drawer	4
Calculator, electronic, statistical, printing.	1
Chair, library.	4
Shelving, adjustable, 12".	4
Table, reading/conference.	1
Table, desk type.	1

	Suggested Quantity Number of Beds 300–500
Typewriter, electric, wide carriage, ½ line advance, changeable type.	1
Waste receptacle.	1
Reception	300–500
Movable	
Chair, guest.	2
Chair, swivel.	1
Costumer.	1
Desk, secretarial, single pedestal, typing return.	1
Table, corner.	1
Typewriter, electric, wide carriage, ½ line advance.	1
Waste receptacle.	1
Drug Information Officer	
Fixed	
Blackboard, wall-mounted.	1
Bookshelves, wall-mounted, 12".	2
Counter, desk-height, open beneath.	1
Movable	
Cabinet, filing, under counter, 2-drawer.	1
Calculator, electronic, statistical, printing.	2
Chair, library.	1
Chair, swivel, with arms.	1
Waste receptacle.	1
Library	
Movable	
Cabinet, filing, side opening, 5-drawer.	4
Chairs, library.	3
Microfilm reader.	1
Shelving, adjustable, 12".	1
Table, reading.	1
Processing and Records	
Fixed	
Counter, with storage cabinets beneath.	1
Pneumatic tube station.	1
Movable	
Cabinet, filing, tab card, 8-drawer.	2
Chair, swivel, operator.	1
Collator, punchcard.	1
Keypunch, printing.	1
Photocopier, capable of copying from bound volumes.	1
Photographic equipment, slidemaking.	1

	Suggested Quantity Number of Beds 300–500
Sorter, electronic, punchcards.	1
Waste receptacle.	1

TEACHING

Student Work Area

Fixed	
Desk-height counter, built-in, open beneath, with book shelves above, one desk drawer below.	2
Bulletin board, wall-mounted.	1
Blackboard, wall-mounted.	1
Movable	
Cabinet, filing, 5 drawer.	2
Chair, swivel, with arms.	2
Locker.	2
Lamp, desk type, fluorescent, 2-bulb.	2
Typewriter, electric, wide carriage, ½ line advance.	1
Waste receptacle.	1

Instructor Work Area

Fixed	
Bulletin board, wall-mounted.	1
Blackboard, wall-mounted.	1
Movable	
Cabinet, filing, 5-drawer.	2
Chair, swivel, with arms.	1
Chair, guest.	2
Costumer.	1
Desk, double pedestal, office.	1
Dictating machine, transcriber.	1
Table, desk type.	1
Waste receptacle.	1

EQUIPMENT ELECTRICAL SAFETY

Electrical safety within the hospital has become a topic of major interest amongst physicians, planners, engineers and safety experts. This has arisen because of the inherent danger involved in the use of some of the commonly used equipment in the hospital. At one time or another, articles have been written commenting on electrical hazards in electric beds, monitoring equipment, x-ray machines and cleaning equipment.

Thus it behooves the hospital pharmacist to select all equipment used in the pharmacy with care. In general compliance with the N.F.P.A.

standards (National Fire Protective Association) is a start in the right direction.

Electrical safety in the hospital pharmacy could be improved if consideration is given to the following guiding principles:[15]

1. Keep electrical power cords as short as possible in order to eliminate electrical leakage.
2. Use equipment with proper ground lines. (Three-prong plugs)
3. Purchase equipment with power on-off switches which have clearly visible indication of power status (on or off).
4. Eliminate slow blow fusing whenever possible since this type of fusing increases the exposure time of the operator to the electrical hazards.
5. Before permitting personnel to operate new equipment, be sure that they are properly trained in its use. In addition, it is important that they read the instructional manual—particularly the section dealing with safe use and possible hazards.
6. Train operators to disconnect the power receptacle from the power source by pulling on the connector, not on the cable.
7. Avoid the use of extension cords.
8. Do not attempt to make repairs to the equipment.
9. Cooperate with in-house maintenance programs.

CLEANUP AREA

A pharmacy that is involved in a reasonable volume of extemporaneous compounding or manufacturing should have a cleanup room. A cleanup room designed for joint use by CSSR and pharmacy is the most efficient and economical. Appropriately located pass-through windows and a curbed floor area with floor drain are desirable features.

NONSTERILE MIXING AND FILLING ROOM

The area for mixing and filling ointments should be separate from that for liquids, although both may be in the same room. Provision shold be made for weighing and measuring, mixing and stirring (sometimes over heat), blending, homogenization, filtration and filling. Adequate storage space must be provided.[8]

PREPACKAGING AREA

The prepackaging room is for the packaging of oral solid dosage forms into containers. In hospitals of 300 beds or less without a manufacturing program and without unit dose dispensing it may be possible to prepackage oral solids in the extemporaneous preparations area.[9]

INJECTION RECONSTITUTION AREA

The area for the reconstitution of injections should be equipped with two or more Class 100 laminar airflow hoods. Such units are available with horizontal, vertical, converging 90-degree and converging 180-degree flow patterns.[9]

LABELING AND INSPECTION ROOM

The labeling and inspection room should be adjacent to the filling areas so that the unlabeled drug products can be transferred directly through a pass-through window to eliminate the chance of their being used prematurely. Adequate storage space for labels, printing machine accessories, forms etc., must be provided.[9]

QUARANTINE STORAGE

Products manufactured and filled in the pharmacy are subject to quarantine until appropriate chemical and bacterial testing is complete. Finished products should be transferred directly to the quarantine storage area.[9]

REFRIGERATION FACILITIES

Most hospital pharmacists and architects when developing plans for a new pharmacy are quite cognizant of the desirability and the need for air conditioning and large biological refrigerators in the hospital pharmacy. More often than not, little thought is given to the need of a freezer and a cold room.

A review of the storage requirements for drugs in the National Formulary XIII shows that the thermal storage requirements vary from "cold place" to "store in refrigerator" or "avoid excessive heat or excessive temperature."

The complete list of storage temperature terms and the definitions are as follows:

Cold Place—A cold place is one having a temperature not exceeding 8° (46° F).

Refrigerator—A refrigerator is a cold place in which the temperature is held between 2° and 8° (36° and 46° F).

Cool Place—A cool place is one having a temperature between 8° and 15° (46° and 59° F).

Room Temperature—Room temperature is between 15° and 30° (59° and 86° F).

Excessive Heat—The expression "excessive heat" designates temperatures above 40° (104° F).

Since many of the drugs, so described, are in common use in the hospital, the pharmacist should make every effort to see that proper storage facilities are made available. This is easily done in most hospitals by the purchase of a large biological refrigerator and a freezer. In the small hospital, these two units or, as is usually the case, the refrigerator with a built-in freezer compartment, provide adequate facilities. The problem which usually arises in the larger hospital is that the refrigerator is too small to accommodate the inventory requiring refrigeration. Some pharmacists have tried to solve this problem by purchasing additional refrigerators or by borrowing space in the large dietary walk-in "iceboxes."

Although both of these arrangements are workable, it would seem that a less expensive and a less inconvenient method of cold storage within the pharmacy could be had by the construction of a cold room.

For the purpose of this section, a cold room is defined as an artificially cooled room with a regulated temperature range of 12° to 15° C (53.6° to 59° F).

CONSTRUCTING A COLD ROOM[a]

In existing facilities, a cold room may be inexpensively constructed if the parties involved will use a little imagination. A little-used corner of the basement storage area should be selected and the necessary area marked off. If windows are present, they should be bricked-up or at least double-paned and sealed against the outside atmosphere with caulking compound.

An electric light fixture and the required number of electrical outlets should be installed with the switch controlling the light fixture being on the outside wall nearest the entrance to the room.

The necessary additional walls of the room may be constructed of concrete, cinder block, concrete blocks, or brick. Where the use of the above building materials is not feasible, a similar result may be had by the use of wood studs with aluminum foil insulation. The inner side of this type of wall should be cement plastered and the outer side "finished-off" by covering with masonite or other inexpensive material. The door should fit tightly, be no larger than necessary, and be provided with a good automatic door closer.

An electric motor-driven air cooled Freon compressor unit with a remote blower-type cooling coil will provide the necessary refrigeration. This unit should be installed with the necessary thermostat and expansion valve required to maintain the desired temperature range.

The blower is mounted in the cold room. To it, a small waste line is installed to drain away the condensate which collects on the refrigerator coil. The compressor may be installed outside of the cold room in order to conserve space within.

[a]Adapted from an article entitled "A Cold Room for the Hospital Pharmacy" by William E. Hassan, Jr., and George Stilgoe. Am. J. Hosp. Pharm., *16*:3:120, 1959.

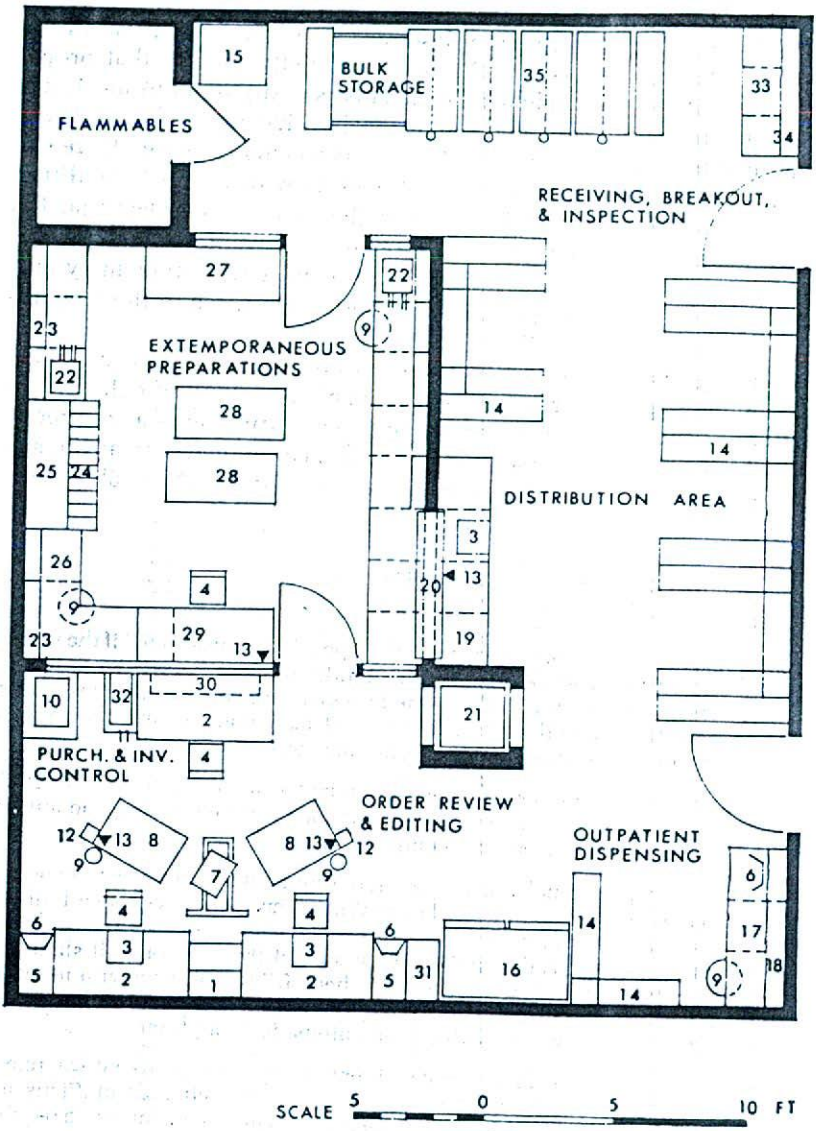


Fig. 89. Pharmacy Department in a 100-Bed Hospital. This plan is to be considered as one example of a modern pharmacy design. (From Planning for Hospital Pharmacies, U.S. Dept. HEW, Health Services & Mental Health Administration, Health Care Facilities Services, Washington, D.C.) (*Legend continues on following page.*)

Legend for Figure 89 (Continued)

1. Pneumatic tube station
2. Desk
3. Typewriter, electric, nonmovable carriage
4. Chair
5. Files, intermediate height
6. Files, swinging panel, strip insert type
7. File, revolving on two levels
8. Table, movable, 2 feet by 3 feet
9. Waste receptacle
10. Photocopier
11. File, 2-drawer
12. Utility pole
13. Telephones
14. Shelving, adjustable, 12 inches
15. Safe
16. Refrigerator, with freezer
17. Counter, with file drawer, bins
18. Shelving, adjustable, 7 inches
19. Counter, dispensing
20. Two-shelf unit above counter
21. Dumbwaiter, open both sides
22. Cabinet, with sink, drain board
23. Cabinet, wall-mounted
24. Bins
25. Hood, laminar airflow, vertical or horizontal
26. Counter, with open adjustable shelving beneath
27. Cart, storage
28. Carts, utility
29. Desks, small
30. Bookcase, wall-mounted
31. File cabinet, 5-drawer
32. File, visible index type
33. Counter, with adjustable shelves beneath
34. Shelving, wall-mounted, 9 inches
35. Shelving, adjustable, rail-mounted

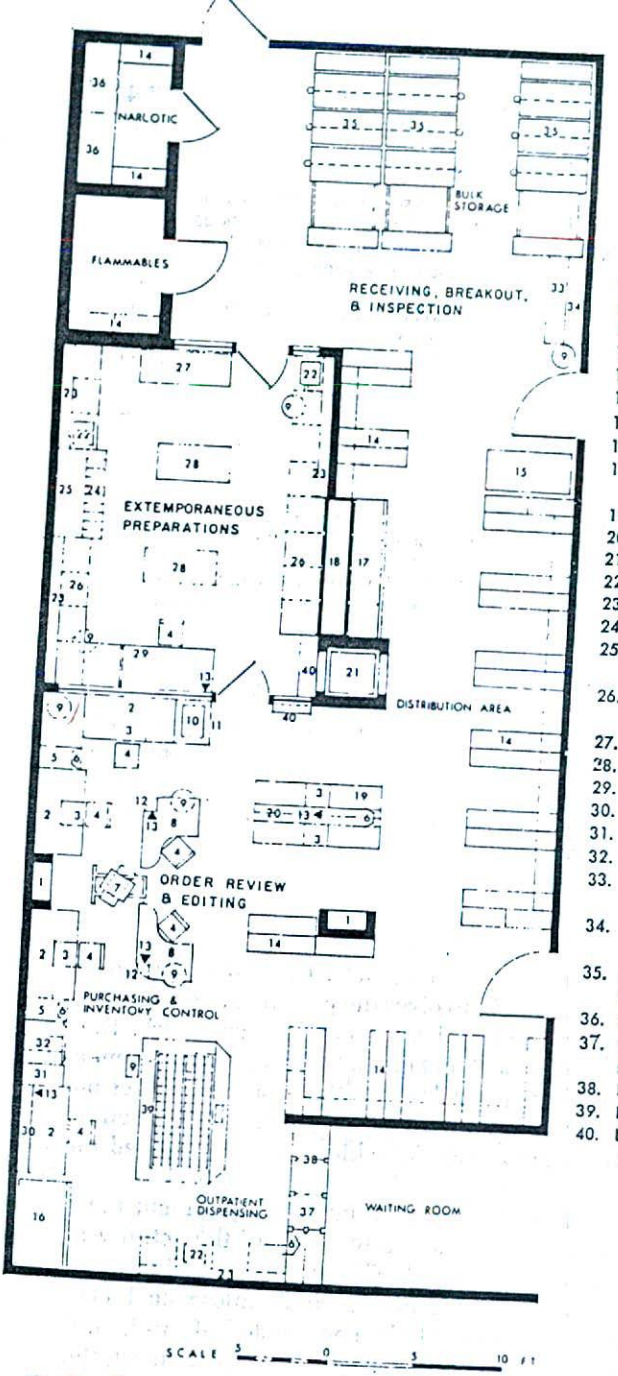
Obviously the size of the cold room to be constructed will determine the capacity of the refrigeration unit to be installed. In general, a room approximately $10' \times 10' \times 10'$ would require one ton of refrigeration to maintain a temperature range of 50° to 60° F.

Once constructed, the room may be equipped with the necessary shelving, storage binds, cabinets, and work bench.

BUILT-IN EQUIPMENT

One of the most important aspects of a pharmacy modernization or construction program is that which involves the planning and selection of the built-in cabinets, counters and other types of casework. Due consideration must be given to such details as the height of the bench or cabinet, the size of the shelving or drawers, the types of handles on drawer and cabinet doors, whether or not the shelving is to be fixed or adjustable as well as the type of material which will be installed on the counter top.

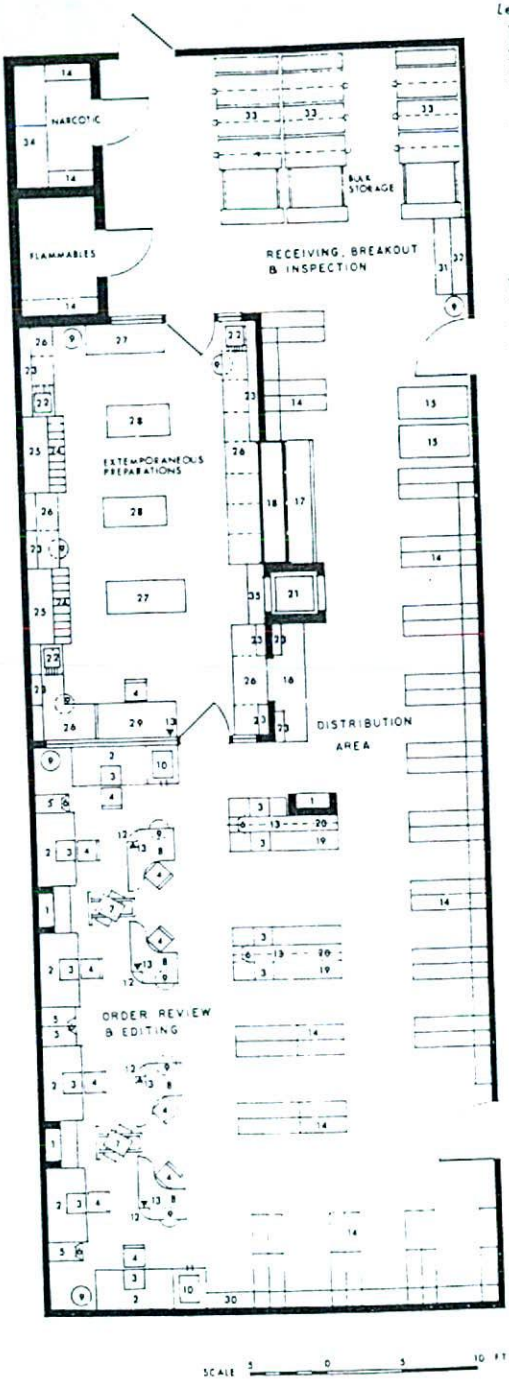
The materials used in the construction of built-in equipment must be reviewed by the hospital pharmacist in the light of the activity to which the equipment will be subjected. Thus it is not sufficient to specify that the equipment will be constructed of stainless steel. One should specify whether it is expected to be constructed of mild, cold rolled, annealed furniture steel; the gauges of the metal to be used; the gauge of the metal to be used in the shelving and whether or not the face of the shelf should be turned back up under the shelf and brought into contact with it in order to provide additional support; and details relative to the doors, adjustability of the shelving, etc. Much of this



Legend

1. Pneumatic tube station
2. Desk
3. Typewriter, electric, non-movable carriage
4. Chair
5. Files, intermediate height
6. Files, swinging panel, strip insert type
7. File, revolving on two levels
8. Desk, special design
9. Waste receptacle
10. Photocopier
11. Photocopier, cabinet
12. Utility pole
13. Telephone
14. Shelving, adjustable, 12 inches
15. Delivery truck
16. Refrigerator, with freezer
17. Refrigerator, open front type
18. Refrigerator, pass-through, counter height
19. Counter, dispensing
20. Two-shelf unit above counter
21. Dumbwaiter, open both sides
22. Cabinet, with sink, drainboard
23. Cabinet, wall-mounted
24. Bins, on top of hood
25. Hood, laminar airflow, vertical or horizontal
26. Counter, with open adjustable shelving beneath
27. Cart storage
28. Carts, utility
29. Desk, small
30. Bookcase, wall-mounted
31. File cabinet, 5-drawer
32. File, visible index type
33. Counter, with adjustable shelves beneath
34. Shelving, wall mounted, 9 inches
35. Shelving, adjustable, rail-mounted
36. Shelving, adjustable, 24 inches
37. Counter, with adjustable shelves beneath
38. Panels, acoustical
39. File, rotary mechanical
40. Ledge

Fig. 90. Pharmacy Department in a 300-Bed Hospital. This plan is to be considered as one example of a modern pharmacy design. (From Planning for Hospital Pharmacies, U.S. Dept. HEW, Health Services & Mental Health Administration, Health Care Facilities Services, Washington, D.C.)



Legend

1. Pneumatic tube station
2. Desk
3. Typewriter, electric, non-movable carriage
4. Chair
5. Files, intermediate height
6. Files, swinging panel, strip insert type
7. File, revolving on two levels
8. Desk, special design
9. Waste receptacle
10. Photocopier
11. Photocopier cabinet
12. Utility pole
13. Telephone
14. Shelving, adjustable, 12 inches
15. Delivery truck
16. Dispatch counter
17. Refrigerator, open front type
18. Refrigerator, pass-through, counter height
19. Counter, dispensing
20. Two-shelf unit above counter
21. Dumbwaiter, open both sides
22. Cabinet, with sink, drainboard
23. Cabinet, wall-mounted
24. Bins, on top of hood
25. Hood, laminar airflow, vertical or horizontal
26. Counter, with open adjustable shelving beneath
27. Cart, storage
28. Carts, utility
29. Desk, small
30. Bookcase
31. Counter, with adjustable shelves beneath
32. Shelving, wall-mounted, 9 inches
33. Shelving, adjustable, rail-mounted
34. Shelving, adjustable, 24 inches
35. Ledge

Fig. 91. Pharmacy Department in a 500-Bed Hospital. This plan is to be considered as one example of a modern pharmacy design. (From Planning for Hospital Pharmacies, U.S. Dept. HEW, Health Services & Mental Health Administration, Health Care Facilities Services, Washington, D.C.)

type of detail is available from the manufacturer's catalogue and specification sheets.

Special attention should be given to the counter tops. All too often, excellent base cabinets are provided but the counter tops do not offer resistance to corrosion and abrasion. Accordingly, it is of importance for the pharmacist to inquire about the physical properties of the counter finishes. Some guidelines are the following:

1. To what degree can it be bent without cracking or breaking down?
2. How much of an impact will it withstand without flaking or peeling?
3. What effect will a high relative humidity have upon it?
4. Is it sufficiently hard to resist erosion?
5. If the material is colored, is the color retention quality sufficient to resist appreciable discoloration?
6. Is the finish coat abrasion resistant to the degree that prevents premature wearing through?
7. Is the finish coat reagent resistant? Bear in mind that it must resist acids, alkalies, oils and solvents.

Many of these units are available from the several manufacturers who specialize in the development and construction of such components.

ELECTRIC LIGHTING AND SERVICE

The availability of good electrical lighting and a sufficient number of grounded electrical outlets is mandatory for a smoothly functioning pharmacy.

Accordingly, sufficient lighting must be provided for the various work areas as well as the library and the offices. Although the present literature indicates that 30 foot candles are adequate for general illumination, and 50 foot candles for special areas, such as the prescription dispensing area, it is recommended that in any new construction the services of a lighting engineer be utilized. This is important because each hospital, or unit within the hospital, has particular needs based upon many factors some of which are characteristic of the operation, whereas others may be due to location and environment.

In selecting the type of lighting and light fixture, care should be given to the selection of a unit which will not become a housekeeping problem. That is to say that, when possible, a fixture which can be mounted in the ceiling is highly desirable since it will not gather dust and dirt. Fluorescent light is recommended; however, recent studies by the various manufacturers of lighting equipment seem to indicate that a combination of fluorescent tube and standard bulb in the same fixture provides a better light.

Grounded electrical outlets should be provided in all areas in which the use of electrical equipment may be indicated. In addition, thought

must be given to the requirements of voltage in the range of 220 volts for some of the ovens or mixers in the manufacturing area.

If volatile solvents are used in the manufacturing areas or are stored in the pharmacy, consideration must be given to the installation of explosion proof fixtures and outlets.

VENTILATION

Air conditioning of the pharmacy is desirable for a number of reasons. First, it obviates the need for the opening of windows and doors through which dirt, dust and other environmental contaminants may enter the pharmacy. Second, the use of the various autoclaves, ovens and steam jacketed kettles may render the working environment too hot. Third, air conditioning permits the maintenance of a temperature which is compatible with the official storage requirements for drugs on a year round basis irrespective of the climatic conditions. Fourth, adequate ventilation is essential for the removal of the strong odors which are characteristic of the chemicals used in the manufacture of the various galenicals, preservative fluids and reagents. Fifth, because doors and windows can be kept closed, there can be effected a saving in the cost of housekeeping service in the pharmacy.

CONVEYOR AND PNEUMATIC TUBE SYSTEMS

Modern engineering technology has made available a means of transporting nearly every item from the pharmacy to its hospital destination. Accordingly, in order to conserve pharmaceutical manpower, thought should be given to the installation of dumbwaiters, pneumatic tube systems and other like devices for the movement of supplies from the pharmacy to their desired hospital destination. The type of combination of equipment necessary will vary with each hospital; therefore, it is recommended that the advice be sought from the hospital's architect and/or the various manufacturers and distributors of such devices.

PLUMBING

It is not expected that the pharmacist should be knowledgeable in the technicalities of the plumbing installation; however, he should be in a position to advise the architect and his plumbing consultant of the particular details and requirements of the pharmacy and the nature of the materials which will be disposed of through the various waste lines.

By so doing, the plans will properly specify acid resistant piping, adequate hot and cold water mixing valves, stainless steel or soapstone sinks, distilled water lines and faucets which will allow gallon jugs or carboys to be filled without the use of a connecting hose.

Type	*Ease of Maintenance*	*Resistance*			*Advantages*	*Disadvantages*
		To Moisture	*To Alkali*	*To Oil & Solvents*		
Asphalt	Fair*	Excellent	Excellent	Poor*	Lowest cost resilient tile Most resistant to cigarette burns Excellent choice for basement floors May be applied and used immediately	Least resilient and least comfortable tile Does not take as high polish as others Very poor indentation resistance Limited color range (dark)
Linoleum	Very Good	Poor	Fair to Poor	Excellent	More comfortable than asphalt Good warmth Low noise level	Can be used only as above-grade floors
Vinyl-Asbestos	Good	Excellent	Excellent	Good	Good wearing qualities at reasonable cost Inexpensive to maintain May be applied above, on or below grade Wider range of colors than asphalt	Only fair resilience and comfort
Cork	Fair	Fair	Fair	Fair	Excellent comfort, warmth, quietness	Can be used only on above-grade floors Soft, easily marred High cost
Rubber	Good	Good	Good	Poor	Almost as comfortable as cork Lustrous sheen Excellent indentation resistance Wide range of colors	High cost Usually unsuitable for below-grade locations Must be polished frequently to maintain high gloss
Vinyl	Very Good	Good	Excellent	Excellent	May be applied above, on or below grade Smooth and polished-looking Widest range of colors and styles	Most expensive of tiles

*New, grease-resistant variety shows good ease of maintenance and excellent solvent resistance.

FINISHES

a. Work Counters

Although many of the work counters will be constructed of stainless steel, others will not require such construction. For those units, Formica or a similar material is suggested as an efficient and durable surface.

b. Floors

The floors of the pharmacy proper should be resilient, smooth but not slippery, stain resistant and yet complimentary to the existing or proposed decor of the department. Many flooring materials are currently available which are highly satisfactory and economical. Some of the floor coverings currently in use are asphalt tile, vinyl tile, rubber tile and heavy duty linoleum. The Hospital Bureau, Inc.[14] has made available information on page 546.

In recent years, many architects and designers have introduced carpeting into the hospital pharmacy with aesthetic results. On the other hand, some of the installations have not been complementary to the operation of a hospital pharmacy. Carpeting has proven to be acceptable in the office, library, waiting room areas but has not been acceptable in the various work areas. Much of the complaint centers around the excessive generation of static electricity and the flammability of the carpet material.

Low relative humidity has always been the major problem in controlling static generation in carpets. The lower the relative humidity, the greater the problem. Thus, it is important to ascertain the kilovolts of static electricity that a carpet will generate at the normal building temperature and with a relative humidity of 10 to 20%. Clearly, the lower the kilovolts generated, the more acceptable the carpet will be for pharmacy installation. The student is cautioned to the fact that a high humidity will also produce low kilovolt readings of static electricity. Obviously, a high humidity does not lend itself to the pharmacy area for a number of reasons associated with drug storage and personal comfort. Also, carpets that are advertised as being "static free" or "static proof" must be viewed with a jaundiced eye in view of the fact that such material does not exist. Static electricity is present, to some degree, in all materials.

With respect to flammability, the United States Public Health Service has promulgated carpet standards for hospitals and nursing homes using Hill-Burton funds. Carpets in these facilities must have a rating of not less than 75 using the Tunnel Test (ASTM Standard #E-84-61).

The floors of the manufacturing and parenteral solutions room should be supplied with a floor drain covered with a durable paint or enamel. Recent literature describes the application of a vinyl epoxy latex coating to concrete floors which permits the routine use of soap and water for

cleaning and yet does not crack and lift as do ordinary paints and enamels.

c. Walls

The walls of the pharmacy should be painted with a material which permits periodic washing without the danger of losing its original color. The selection of the appropriate color scheme is here left to the taste and discretion of the parties involved.

In the manufacturing and parenteral products rooms, painted wall surfaces do not usually withstand the constant washing necessary for the maintenance of the desired degree of asepsis. Accordingly, it is suggested that a ceramic tile, or other comparable material, be utilized in these areas.

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25

The Pharmacy Library—Drug Information Center

In planning the hospital pharmacy of tomorrow, some thought should be given to the library. Too often, this segment is totally neglected and winds up as a file cabinet and a shelf of 6 to 12 books either in the pharmacy office or in some out of the way corner of the department.

Some hospital administrators refuse to allow the pharmacist a budget for the pharmaceutical library, arguing that the hospital already maintains a central professional library or that the hospital is associated with a university and therefore facilities of the university are readily available. To a certain extent this is a valid argument until examined in the light of modern thinking.

Many prominent medical librarians are of the opinion that hospital libraries possess a great potential for continuing medical education. If this is true for the hospital library *per se*, then it should also be true for the pharmaceutical library.

In a study commonly referred to as the Dryer report[1] there are two major observations:

1. Continuing education of physicians is a major problem which confronts medical education.
2. The results of basic research are not brought to bear clinically quite as fast as they should because of the problem of disseminating research results to the person who is to apply them.

The American Hospital Association has conducted surveys amongst member hospitals in an attempt to learn more about their libraries and has devoted a special section on health communications in the June 16, 1964 issues of *Hospitals*, the Journal of the American Hospital Association.

Therefore, it would seem that a well-planned pharmaceutical library can play a major role in the continuation of medical education, the rapid dissemination of basic pharmacologic research and as a source of research reference material.

This chapter will be concerned with the location, organization and contents of a pharmaceutical library.

LOCATION

Ideally, the pharmaceutical library should be located within and as an integral division of the department of pharmacy. Although, if it becomes necessary for one reason or another to consolidate it with the regular hospital library then, rather than risk the chance of having no worthwhile facility, this alternative should be accepted.

The reasons for placing the pharmaceutical library in the pharmacy are many, but probably the most worthy is that an individual using the facility would have available to him on-the-spot consultation with individuals whose forte is information concerning drugs. Also, whenever a clinician's work requires data concerning drugs or drug therapy, he is, more likely than not, inclined to go to the pharmacy for the desired information. Clearly then, it is advantageous to both doctor and pharmacist to have the reference material at hand rather than consume more valuable time in going to the hospital library.

In addition, the pharmacy is the logical repose of all worthwhile drug related literature: the various journals, product reference and price catalogues, and special releases concerning withdrawal, toxicity or contraindications to the use of existing products.

PHYSICAL FACILITIES

Because the pharmaceutical library is usually restricted to the medical and nursing staffs, its dimension will be determined by the size of the utilizing staff, the type of hospital, the number of textbooks, monographs and journals subscribed to as well as accessibility to the hospital library (if any) or to other medical libraries in the area.

Garland[2] quoting the *Handbook of Medical Library Practice*[3] provides the following measurements as being useful in determining space requirements.

1. The reading area should allow 25 to 30 square feet per reader.
2. If rectangular tables are selected, they should measure 36 × 60 feet. These would then require 100 square feet of floor space for each. (Accommodates 4 readers.)
3. Circular tables measuring 48 inches in diameter and accommodating 4 readers also require 100 square feet of floor space.
4. Aisles:
   a. between tables—not less than 5 feet.
   b. between tables and walls—3 to 4 feet.
5. Shelf space:
   a. bound volumes—4 to 5 volumes per foot of shelf.
   b. reference tools—3 to 4 volumes per foot of shelf. An allowance of 7 inches per 3 foot shelf should be made for additions.

SELECTION OF CONTENTS

The pharmaceutical library should contain in it those volumes, monographs and journals dealing with pharmacy and its allied sciences. Volumes and other published materials dealing with the various clinical and pre-clinical subject areas should be reserved for the hospital medical library.

As a nucleus around which to add volumes, the library should contain the *United States Pharmacopeia* and the *National Formulary* and their supplements.

Pharmaceutical subjects which should be represented in the library include pharmacology, toxicology, pharmaceutical organic chemistry, pharmacognosy, physiology, anatomy and bacteriology. In addition, there should be included a dictionary, medical dictionary, abstract journals, and selected journals dealing with the above subjects. The various types of drug reference books should not be overlooked.

Most drug manufacturers provide in addition to their catalogues comprehensive literature concerning each of their products. It is strongly recommended that these be filled for ready reference. Those hospitals using the *American Hospital Formulary System* often file this type of literature according to the system of classification of drugs employed in the *Formulary*.

In January 1964, the American Society of Hospital Pharmacists commenced a new abstract publication entitled *International Pharmaceutical Abstracts*. In keeping with the recommendations of the Commission on Pharmaceutical Abstracts of the International Pharmaceutical Federation, the Society publishes the journal in English, issues it 24 times per year and provides a cumulative index twice annually.

International Pharmaceutical Abstracts includes abstracts of articles on product formulation and formulas; drug stability and storage; drug synthesis; pharmaceutical technology; pharmacognosy; pharmacology; biopharmaceutics; physical pharmacy; investigational drugs; drug evaluations; and history, ethics and sociology.

Some drug companies also produce films and projection slides covering a number of points of clinical interest. Certainly, a listing of these should be available in the pharmacy library and the pharmacist should be acquainted with the procedure for obtaining them for various clinical and nursing groups.

Of late, producers of pharmaceuticals have made available excellent plastic reproductions of various body organs which possess excellent teaching qualities. A collection of these should certainly be available from the pharmacy library to the school of nursing.

Federal publications, particularly those of the U.S. Department of Health and Human Services (HHS), should always be obtained. One of the most recent issues for which every hospital pharmacist should have

his hospital's name placed on the mailing list is *Investigational Drug Circular* issued by the Bureau of Medicine, Food and Drug Administration.

The Federal Food and Drug Administration publishes a journal containing its decisions and views. The name of the journal is *FDA Papers* and is available on a subscription basis from the Government Printing Office in Washington, D.C.

Many house organs contain excellent review articles of clinical interest to both nurse and physician. Accordingly, these should also be part of the pharmacy library.

The American Society of Hospital Pharmacists' *Drug Products Information File* (DPIF) is also a valuable addition to the library. The DPIF is a data bank composed of terms and code numbers for commercially available drug products. The drug data bank is organized to facilitate automatic processing of drug data. This multi-functional drug coding system is based on a 5-digit generic drug product number that identifies the generic product, a 6-digit brand drug product number which identifies a specific manufacturer's brand of drug, and a 5-digit brand drug product package number which extends the information to a specific package of a manufacturer's brand of drug product. In addition, each aspect of a drug product description such as route of administration, dosage form, strength, etc. is systematically coded.

Because of the versatility of the data bank, DPIF has been incorporated into applications such as inventory control; purchasing of drugs; formulary preparation; patient billing; drug therapy auditing; experimental drug information program; adverse drug reaction programs; patient medication records, orders, summaries, charges and labeling.

With the trend towards the utilization of audio-cassettes for continuing education, the American Society of Hospital Pharmacists introduced VOICES 12/60. This is a monthly cassette tape communications program designed specifically for pharmacists, with particular emphasis on clinical and institutional pharmacy practice. Since this is a monthly continuing service, it constitutes the basis for an audio reference library.

The hospital pharmacist desirous of a single source to serve as a check list of possible publications is referred to the *Basic List of Books and Journals for Veterans Administration Medical Libraries,*[4] *The Guide To Information Sources for the Hospital Pharmacist*[5] and to the *World List of Pharmacy Periodicals.*[6]

The decision as to which textbook or journal is necessary for rendering good drug information service is a difficult one to make. Each hospital offering such a service may well have a different source library. The following is a listing used by one hospital and is offered as a guide to the practitioner seeking to create a drug information library. (Use latest available editions.)

American Drug Index
(Billups, N.F.) (J.B. Lippincott Co., Philadelphia)
An alphabetical listing of drugs with cross-indexing by generic, brand and chemical names. Also included are the product composition, dosage forms and use.

American Hospital Formulary Service
(American Society of Hospital Pharmacists, Washington)
Comprehensive presentation of drug monographs on selected commercially available drugs.

Dangerous Properties of Industrial Materials
(Reinhold Publishing Co., New York)
The synonyms, descriptions, physical characteristics, hazards and countermeasures for approximately 12,000 common industrial and laboratory materials are listed.

deHaen Drugs In Use
(Paul deHaen, New York)
Abstracts of clinical studies providing basic clinical data along with product information which is added by the abstract service.

The United States Dispensatory
(Osol, A., Pratt, R. and Gennaro, A.R.) (J.B. Lippincott Co., Philadelpha)
A collection of alphabetically arranged presentations on drugs and classes of drugs. Included in the descriptive matter is data on pharmacology, uses, contraindications, adverse effects and dosage.

Documenta Geigy Scientific Tables
(Konrad Diem, Editor)
(Geigy Pharmaceuticals, Ardsley, New York)
Contains tables of mathematical, physical and chemical data.

Extra Pharmacopoeia—Martindale Edition
(The Pharmaceutical Press, 17 Bloomsbury Sq., London, W.C. 1)
Drug monographs containing the usual information pertaining to physical and chemical properties, pharmacological activity and posology. A source of information for British and foreign drugs.

Facts and Comparisons
(P.O. Box 8, Baden Station, St. Louis)
Comparative listing of drugs to show composition, dosage forms and relative cost. Products are listed by therapeutic use.

FDA Clinical Experience Abstracts
(Dept. HHS, Food and Drug Administration, Washington)
Abstracts of clinical studies on drugs, devices, cosmetics, food additives, pesticides and nutrients with emphasis on adverse effects, hazards and efficacy.

FDA Suspected Adverse Reactions
(Dept. HHS, Food and Drug Administration, Washington)
Abstracts of unusual adverse reactions in single patients.

Handbook of Non-Prescription Drugs
(American Pharmaceutical Association, Washington)
Compilation in tabular form of composition of over-the-counter products with accompanying descriptive monograph on each group of drugs.

Merck Index
(Merck & Co., Rahway, New Jersey
Monographs of physical and chemical data about chemicals and drugs.

Organisch-Chemische Arzneimittel und ihre Synonyma
(Negwe, M., Editor)
(Akademia-Verlag, Berlin, Germany)
Tables of chemical structures, names and synonyms, and uses of organic chemicals. The book provides for a source of information on German drug products.

The Pharmacological Basis of Therapeutics
(Goodman, L.S. and Gilman, A.)
(The Macmillan Co., New York)
Provides information relative to the activity, use and doses of drugs with particular emphasis upon the relationship of pharmacology to clinical practice.

PharmIndex
(Skyline Publishers, P.O. Box 1029, Portland, Oregon)
A compilation of product information including composition, dosage forms, use and cost. Also included are review articles and investigational drug information.

Symptomatology and Therapy of Toxicological Emergencies
(Academic Press Inc., New York)
Provides an alphabetical listing of toxic substances giving expected reactions and suggested treatment.

Unlisted Drugs
(Unlisted Drugs, Box 401, Chatham, New Jersey)
Contains a numeric and/or alphabetical listing of old and new drug items and for each is presented data pertaining to composition, action, dosage, manufacturer and pertinent reference source.

Drug Interactions
(Hansten, Philip D.)
(Lea & Febiger, Philadelphia)
A clinically useful guide to drug-drug interactions and the effects of drugs on clinical laboratory results.

Clinical Toxicology
(Thienes, C.H. and Haley, T.J.)
(Lea & Febiger, Philadelphia)
A grouping of poisons according to their major toxic actions with accompanying method of treatment.

Hazards of Medication
(Martin, E.W., Editor)
(J.B. Lippincott Co., Philadelphia)
A manual on drug interactions, incompatibilities, contraindications and adverse effects of drugs and drug products.

Drug Interactions—
(American Society of Hospital Pharmacists, Washington)
A compilation of abstracts pertaining to drug interactions.

Handbook of Drug Interactions
(Hartshorn, E.A.)
(Hamilton Press Inc., Hamilton, Illinois)
A compilation of articles on drug interactions which have been published in Drug Intelligence.

USP, NF and USP-DI (Latest editions)
(USPC Inc., P.O. Box 2248
Rockville, MD, 20852)

Drug Intelligence & Clinical Pharmacy
(Drug Intelligence & Clinical Pharmacy
P.O. Box 42435, Cincinnati, Ohio 45242)
A journal on drug therapy.

Clinical Pharmacy
(American Society of Hospital Pharmacists
4630 Montgomery Avenue, Bethesda, MD 20814)
A journal containing review articles on drug therapy and experiences.

DRUG INFORMATION CENTER

Of late, editors,[7] physicians,[8] pharmacists,[9-11] and administrators[12] have published much data concerning the use and need for adequate drug information in the treatment and care of patients. Many elaborate systems have been developed and put into use by pharmacists in the large teaching centers. In the small community hospital, it is not possible to install or staff such a drug information center. However, it is not impossible to provide the clinical staff with much vital information concerning the use and abuse of drugs, as well as information concerning the drug's chemical nature, mode of action, side effects, dosage forms, cost, and literature pertinent to its clinical use.

In addition, the hospital pharmacist is in a position to alert the physician of any untoward reactions encountered within the hospital from the use of the particular drug. All of this information can be provided the physician by the hospital pharmacist through the pharmacy library. This is possible because, in addition to the latest texts and journals, the hospital pharmacist is in daily touch with the medical service representatives of the major drug producers. Much vital literature and information can be gathered from this source if the hospital pharmacist will only avail himself of it. Once gathered, it should be properly catalogued and filed in such a manner as to make it readily available to all those desirous of making use of it.

Large university affiliated hospitals have developed and staffed a new division of the department of pharmacy which is commonly referred to as the **Drug Information Center.** This new concept in hospital pharmacy operations is usually located in a separate section of the pharmacy, contains a large number of reference texts, journals, reprints

and brochures, may be equipped with electronic data processing equipment, and has a full-time director and adequate secretarial assistance.

In order to file the vast number of sources of information that are received by the unit, many hospital pharmacists have adopted the classification of drugs employed in the *American Hospital Formulary Service* and thus have a cross-reference between the files and the *Formulary*.

The Drug Information Center may also assume the responsibility of gathering information on all investigation use drugs in current use in the hospital; record all data on drug reactions in the institution; and may participate in the program of the local Poison Information Center. In some hospitals, the Drug Information Center publishes an Investigational Drug Bulletin and an Adverse Drug Reaction Report for the clinical staff.

The need for a reliable local source of drug information within a medical community is of inestimable importance in rendering effective clinical care to the patient. Thus, it behooves every hospital pharmacist to develop a local source of drug information irrespective of whether it be a modest pharmaceutical library or a comprehensive Drug Information Center. The main theme of either type unit should be—providing drug information when it is needed.

Recognizing the need for this type of service to be rendered by the hospital pharmacist, the American Society of Hospital Pharmacists, in 1968, issued a statement entitled *The Hospital Pharmacist and Drug Information Services*. In justification of the involvement of the hospital pharmacists in this endeavor, the statement cites the following:[13]

"1. Traditionally the service orientation of the pharmacist has been related to drugs—their efficacy, safety and control. Therefore, pharmacy encumbers by reason of tradition a special obligation to accept these challenges.
2. Pharmacy is unique among the health professions in that it possesses an established, but unchallenged, capability to adapt its services for specific contributions to drug therapy. Full utilization of the hospital pharmacist's professional potential represents a more efficient and economical application of health manpower resources.
3. There exists today a nucleus of hospital pharmacy practitioners who are engaged in the functional establishment of a service foundation for drug information activities and responsibilities. Increasing clinical involvement of the heretofore cloistered hospital pharmacist has precipitated a growing demand for this drug information support to those in immediate contact with drug care needs of the patient.
4. Increasingly sophisticated concepts of pharmacodynamic and biochemical complexities of drug actions, a burgeoning drug literature, and the scientific and medicolegal difficulties attending clinical surveillance of drug experiences constitute adequate grounds for advocacy of interprofessional teamwork in the clinical use of drugs. Pharmacy's acceptance of its share of responsibility will lessen the formidable burden placed on other components of the health care community."

Clearly, if the profession of pharmacy is to accept the challenge and accompanying responsibility, its practitioners must be capable of performing in their new role. Within the ASHP's statement, the following performance guidelines are presented:[13]

"1. He demonstrates professional and technical competence in the evaluation, critical selection, and utilization of the drug literature. He presents to those whom he serves the maximum relevant information with a minimum volume of pertinent supporting documentation so as to permit independent, informed conclusions and decisions.
2. His knowledge of institutional and extramural library facilities, literature utilization, and librarian services will permit his taking full advantage of all such resourses available to him.
3. He possesses written and verbal communication skills which enable him to contribute effectively to intra- and inter-institutional dialogue relative to pharmacotherapeutic information.
4. He has the capacity for substantial contributions to the continuing education of all health professions.
5. He is involved directly and indirectly in patient care with drugs as a contributor to its continuing quality and as a monitor of its characteristics.
6. He is familiar with electronic data processing methodology to the extent necessary for him to utilize its services for information storage, processing and retrieval.
7. He is qualified to provide professional services in support of the pharmacy and therapeutics committee.
8. He supports, complements and supplements the efforts of colleagues in pharmacy who are now attempting to marshal the knowledge, skills, scientific acumen and professional judgment necessary to bring appropriately effective pharmaceutical services of all types into the mainstream of patient care with drugs. Thus he contributes to and is an integral part of clinical pharmacy practice and the education of clinical pharmacy practitioners.
9. He contributes to the drug literature through appropriate participation in research activities which include, but are not restricted to, (a) clinical and pre-clinical drug studies, (b) surveillance of clinical drug experiences in his institution, and (c) experimentation in professional services."

A review of the literature reveals that drug information services within a hospital are beginning to be created on a more widespread basis. Some of these units are not as well developed as others, however they represent a trend. A good model of a comprehensive in-hospital drug information service is the unit operated within the University of Alabama Hospitals and Clinics.[14]

Regional drug information service or networks are, as yet, not very common. One that is in operation is the Michigan Regional Drug Information Network.[14] Some of the goals of the regional network include the development of a reproducible, standardized reporting system for auditing drug therapy, supplying of information to all hospitals, institutions and health professionals in the region and serving as a prototype

for other medical centers and community hospitals wishing to develop similar services.

Specific objectives related to the latter goals were designed to provide:[14]

(1) An analysis of drug information and drug therapy relating to heart disease, cancer, stroke and related diseases and provision of this information to the physician;
(2) A drug information abstract service to physicians in the region regarding new developments in drug therapy and heart disease, cancer, stroke and related diseases;
(3) An analysis and evaluation of the regional utilization of drugs in the institutions served by the network and dissemination of this information to the respective medical staffs for audit; and
(4) A reduction in the lag time existing between the development of new information and the practical application of this information to patient care—.

Of interest to the student are the criteria set forth for participation by other units in the progam.[14] They are as follows:

(1) That the director of the pharmacy department be interested in establishing a drug information center, be interested in the possibilities of affiliation with a larger center and be willing to continue the drug information center after the period of grant funding.
(2) That the hospital, in particular the pharmacy department, be willing to accept calls from physicians in the surrounding community and other health professionals and to answer these questions to the best of their ability.
(3) That the affiliated drug information center service an area of sizeable population and not impinge on other affilitate's area of coverage. It was also important that the surrounding community physicians related to this particular hospital for the health care of the community.
(4) That the administrative head of the hospital support a drug information center affiliated with the main center and be willing to continue support to the drug information center at the conclusion of the grant.
(5) That the members of the medical staff, preferably those affiliated with the Pharmacy and Therapeutics Committee, show an interest in support of the network.
(6) That the affiliate be willing to provide twenty-four hours a day, seven days a week coverage.

In summary, the drug information function is primarily concerned with pharmaceutical advice and consultation regarding drug therapy, and is involved in the following activities:[15]

1. Establishing and maintaining:
   a. A system for retrieving information from drug literature.
   b. A system for surveillance of the use of drugs in the hospital, including patient drug histories and profiles and reporting adverse drug reactions.
   c. A panel of drug consultants.

2. Answering requests for specific items of drug information for the drug therapy of individual patients.
3. Offering unsolicited drug information for the drug therapy of individual patients.
4. Answering requests for comprehensive drug information complications or bibliographies for:
   a. In-service education programs.
   b. Poison control information centers.
   c. Pharmacy research projects.
   d. Pharmacy and therapeutics committee deliberations—literature searches and background papers on drugs and drug problems.
   e. Pharmacy research projects.
   f. Other pharmacy functions such as manufacturing, control, research and clinical pharmacy.
5. Producing and distributing periodic compilations of drug information directed toward special audiences such as drug information bulletins for physicians, nurses and pharmacists.
6. Maintaining the formulary and/or drug list.
7. Evaluating the detailing activities by drug vendors including promotional exhibits in the hospital.

ASHP SUPPLEMENTAL STANDARD AND LEARNING OBJECTIVES FOR RESIDENCY TRAINING IN DRUG INFORMATION PRACTICE[16]*

Preamble

Definition. A specialized residency in drug information practice is defined as a postgraduate program of organized education and training that meets the requirements set forth and approved by the American Society of Hospital Pharmacists. The ASHP Accreditation Standard for Specialized Residency Training,[1] together with this supplement, are the basic criteria used to evaluate drug information residency training programs in institutions applying for accreditation by the American Society of Hospital Pharmacists.

A specialized residency in drug information practice must be organized and conducted to develop a mastery of knowledge and an expert level of competency in this area of pharmacy, differentiated in scope, depth, and proficiency from the drug information activities of institutional pharmacy residents. Objectives of such training shall include extensive experiences in providing comprehensive drug information services in an institution or with several institutions, integrated with the institution's clinical pharmacy services, drug-distribution systems, and the appropriate committees dealing with drug use.

Qualifications of the Training Site. The parent facility for an ac-

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credited residency in drug information pharmacy practice shall be a general hospital or a health science center that is formally affiliated with one or more general hospitals.

Two or more hospitals may collaborate in conducting a drug information residency program, provided that one hospital is identified as the primary site and one individual is designated as the residency program director.

Qualifications of the Pharmacy Service. The pharmacy department in which an accredited drug information practice residency is based must meet the requirements set forth in Standard II of the ASHP Accreditation Standard for Specialized Pharmacy Residency Training.[1] In addition, the pharmacy department must provide a comprehensive program of drug information services far beyond that required in the ASHP Minimum Standard for Pharmacies in Institutions.[2] The following specific requirements are established for the drug information service program.

Physical Facilities. There shall be a defined area for the drug information center. Space shall be adequate to house the furniture, equipment, literature resources, and personnel of the drug information center.

Resources. There shall be a comprehensive drug information library with appropriate holdings of primary, secondary, and tertiary literature. Scientific and professional practice journals in pharmacy and medicine shall be available in the drug information center or quickly accessible in another location. At least two secondary information services (indexing or abstracting services) shall be available in the drug information center. Reference texts shall be current and provide detailed information in at least the following areas of drug information: administration, adverse effects, availability, bioavailability, chemistry, cost, dose, drugs of choice, efficacy, excretion, formulations, incompatibilities, identifications (foreign and American), indications, interactions, laws, mechanisms of action, nonprescription drugs, pathophysiology, pharmacokinetics, statistics, teratogenicity, tissue distribution, and toxicology.

The drug information center should be located near a medical library that, in turn, has access to a regional medical library.

Computer-search capabilities shall be available in the drug information center or through the medical library.

Staffing. At least one full-time drug information specialist shall be employed in the drug information center. Secretarial and clerical support shall be readily available to the drug information center staff, including typing of communications, filing, and related duties.

Availability of Service. The drug information center shall be open for service at least eight hours per day, Monday through Friday, with off-hours service capability through a paging system, answering service, or other mechanism.

Scope of Service. The drug information service program shall be

oriented toward patient-specific requests, and it shall respond to at least five (minimum average) such requests per day. Documentation of all responses shall be maintained. The drug information center shall also provide the following services on a regular basis: development of drug monographs for use by the pharmacy and therapeutics committee, participation in ongoing drug-use review and medical audits, publication of therapeutics newsletters, and formal instruction of students or residents. The following additional services should be provided where feasible: investigational drug information clearinghouse, adverse drug reaction reporting, drug information support service to other institutions, and formulary revision.

Location. Drug information centers located outside the pharmacy department (e.g., a medical library or college of pharmacy) may be used as training sites, provided that they meet the requirements set forth in this section (Qualifications of the Pharmacy Service) and are routinely used in the hospital pharmacy's drug information service program.

Qualifications of the Preceptor. The area of specialization of the preceptor shall be drug information pharmacy practice. He shall have had a minimum of three years of experience operating a drug information center. In addition, he shall maintain an active patient-care involvement, either through clinical consultations and other patient-oriented services provided through the drug information center or through other routinely provided clinical pharmacy services.

Qualifications of the Applicant. In addition to meeting the requirements set forth in Standard IV, the applicant should have completed formal academic instruction in the following subject areas or their equivalents: drug-literature evaluation, pathophysiology, statistics, and toxicology.

The following learning objectives shall be approved by the Commission on Credentialing following review annually by a committee appointed from the Special Interest Group on Drug and Poison Information Practice of the American Society of Hospital Pharmacists.

Learning Objectives and Areas of Emphasis

I. **Learning Objectives.** A resident who completes an accredited program in drug information practice shall be able to:

A. Develop a plan for the organization and operation of a drug information service, including physical accommodations, reference sources, professional and supportive personnel, budgeting, relationships with other health-care departments, work flow, assumed or designated responsibilities, and documentation of services.

B. Make effective use of institutional and extramural library facilities and librarian services.

C. Select the most appropriate drug information literature sources for any given question.
D. Use the primary literature, including the pharmacy practice literature, in providing drug information services.
E. Demonstrate a mastery of drug information filing systems.
F. Evaluate written and verbal promotional material about drugs provided by pharmaceutical representatives.
G. Apply a knowledge of biopharmaceutics in selecting drug products and in solving patient-specific drug-therapy problems.
H. Evaluate the study design of research articles in the drug literature, and state an opinion on the validity of the published results.
I. Communicate effectively, in person and by telephone, with pharmacists, nurses, physicians, patients, and pharmaceutical representatives in solving drug information problems.
J. Obtain appropriate patient, drug, and disease information from an inquirer initiating a patient-oriented drug information request.
K. Write concise, authoritative, grammatically correct, and clinically applicable consultations, drug monographs, and other drug-related manuscripts.
L. Respond to patient-specific inquiries in time for maximum clinical usefulness.
M. Provide rapid and accurate information relating to poison treatment.
N. Respond with authority to questions relating to drug induced disorders.
O. Provide a pharmacy and therapeutics committee with drug information support, including comparative drug-monograph reviews.
P. Take charge of the organization, preparation, and dissemination of an in-house periodic bulletin or newsletter (e.g., drug information bulletin/newsletter, or P&T committee newsletter).
Q. Contribute to the practice of pharmacy-based drug information services through publication of a therapeutic review, drug monograph, case report, or the results of original research.
R. Make a clear statement about the organization and role of a hospital's institutional review board, the relationship of the pharmacist to its activities, and the role of the pharmacist in distribution and control of investigational drugs.
S. Initiate a drug-use review or medical audit.
T. Participate in the formal inservice training or continuing education of physicians, pharmacists, nurses, or other health-care professionals in therapeutic areas, and conduct classes and training sessions dealing with drug information skills and knowledge for appropriate groups of learners.
U. Develop and defend a proposal for implementing a research project or a new drug information service or other clinical service.
V. Participate in research activities that include, but are not restricted to, clinical and preclinical drug studies, surveillance of clinical drug experiences in the institution, evaluation of new and innovative services, and drug-use review.

II. *Areas of Emphasis.* The resident's training program shall be structured around practical applications of drug-literature retrieval and analysis in solving clinical problems, and associated communications skills. It must be organized in a way that makes possible

the attainment of the learning objectives. Experiences must be provided in each of the following areas:

A. *Use of drug information literature.*
   1. Primary literature (journals). The resident must receive extensive experience in the use of journals in pharmacy, medicine, and the pharmaceutical and biomedical sciences.
   2. Secondary sources. The resident must have an expert knowledge in the use of at least two of the following sources and be capable of using the others when necessary: *Current Contents, de Haen Drugs in Research, de Haen Drugs in Use, Index Medicus, Inpharma, Iowa Drug Information Service, International Pharmaceutical Abstracts, Reactions,* and *Service Citation Index.* Skill in using the following special information systems is also expected: *Drugdex, Poisindex,* and *Unlisted Drugs.*
   3. Tertiary literature (reference books). The resident must have experience in using current, standard textbooks or reference volumes in solving drug information problems. The resident's experience should include use of books in each of the following subject areas: adverse effects, administration, availability, bioavailability, chemistry, drug cost, dose, drugs of choice, efficacy, excretion, formulations, incompatibilities, identifications (foreign and American), indications, interactions, laws, mechanism of action, nonprescription drugs, pathophysiology, pharmacokinetics, statistics, teratogenicity, tissue distribution, and toxicology.

B. *Drug-induced (iatrogenic) disease.* The resident shall receive instruction and training in evaluating the pathophysiology, mechanism of action, and treatment of drug-induced disorders.

C. *Toxic drug ingestion.* The resident shall receive instruction and training in evaluating potentially toxic drug ingestions and providing information to patients and to other health professionals concerning signs and symptoms, general supportive care, and specific treatment.

D. *Information storage.* The resident shall receive training in proper storage (filing) of special drug information, such as formulation contents of pharmaceuticals and drug distribution to specialized body compartments.

E. *Communications skills.* The resident shall have numerous assignments throughout the year aimed at developing written and verbal communications skills. The residency preceptor shall be specifically responsible for setting goals for the resident's growth and development in these areas, monitoring the resident's progress, and counseling the resident on a regular basis concerning communication abilities.

F. *Clinical practice skills.* The resident shall have adequate experiences throughout the year to maintain a good level of expertise in clinical practice.

Extramural Experiences

When appropriate, rotations or visitations to other institutions should be scheduled to augment the resident's training (e.g., a poison control

center, a pharmacokinetics consultation service, a federal drug information agency, a pharmaceutical company information center, and a medical library or pharmacy school information center). If the drug information service does not answer poison information inquiries, a rotation in a poison control center shall be required. Special rotations may also be arranged to strengthen the resident's clinical, communications, and research skills.

Extramural rotations may be conducted either as full-time training activities (e.g., a one-month block), or on a regularly scheduled part-time basis. If extramural rotations are scheduled for the purpose of pursuing one or more of the fundamental learning objectives, there must be a pharmacist preceptor who has defined responsibilities for monitoring the progress and evaluating the accomplishments of the resident. A detailed set of of objectives for extramural rotations must be prepared in advance. The qualifications of the extramural training site are subject to review and approval by the American Society of Hospital Pharmacists.

Research Projects

The residency training schedule shall make provision for the resident's participation in a self-directed or collaborative research project. The final report of the project should be of such quality to merit presentation at a national professional meeting or publication in an appropriate journal.

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