I. Advantages of a centralized IV admixture service

A. More economical
B. Reduce personnel time
C. Safety with standardization of solutions.

II. Equipment and Facilities

A. Environment
   Class 10,000 clean room: Not to exceed 10,000 particles per cubic ft of air.
B. Room design
   Workroom, anteroom, cleanroom
C. Laminar flow hoods

III. IV Admixtures

A. Large Volume Parenterals
   Usually 500-1000ml containers used for hydration or continuous infusion of medications.

B. Small Volume Parenterals

   Mini-bags containing diluent

      Advantages:
      1. Wide availability of products
      2. Simple preparation
      3. Low cost
      4. Ability to individualize doses

      Limitations:
      1. Contamination risks
      2. Preparation time

   Ready to Mix Systems

      Advantages:
      1. Decreased risk of microbial contamination
      2. Decreased preparation time
      3. Reduced wastage

      Limitations:
      1. Expense
      2. Fixed drug and diluent quantity
3. Limited products available
4. Potential for missing dose

Premixed frozen products
Advantages:
1. Manufacturer guarantees stability, sterility, drug dose and identity
2. Decreased preparation time
3. Reduced wastage

Limitations
1. Expense
2. Fixed drug and diluent quantity
3. Limited availability of products

Syringe Systems
Advantages:
1. Less expensive than minibags
2. Decreased preparation time
3. Better for fluid restricted and pediatric patients

Limitations
1. May have capital expense for pumps
2. Limited availability for prefilled syringes
3. Lack of stability data
4. Contamination risk

IV. Quality Assurance

System that identifies problems that can be resolved via education or administrative action that ensures the final products or outcomes meet standards.


1. Risk level 1
   - Sterile products for individual patients
   - Room temperature <28 hours
   - Class 100 environment in separate area.
   - Visual inspection of all finished products.
   - Training and competency evaluation of employees
   - Certification of laminar flow hoods
   - Refrigerator and freezer temperature controls.

2. Risk level 2
   - Room temperature >28 hours
   - Batch prepared and intended for use by more than one patient
- Compounded by complex numerous manipulations of sterile ingredients
- Class 100 environment in class 10,000 clean-room.
- Quantitative end-product testing for complex products.

3. Risk level 3

- Compounded from nonsterile ingredients requiring terminal sterilization.
- Combining multiple ingredients by using an open-system transfer before terminal sterilization.
- Class 100 environment in Class 10,000 clean room. Class 100,000 anteroom.
- Sterilization records of final products.
- Quarantine records.

B. Examples of Quality Assurance Programs

1. Environmental testing
   - Blood Agar Settling plates
   - Rodac plates
   - Agar strips
   - Particle counts

2. Process Validation
   - Aseptic technique
   - Process simulation
   - Cytotoxic drugs
   - End product testing

3. Training and Education
   - Return demonstration documented.
   - Calculations testing
   - Competency testing
   - Aseptic technique evaluation via direct observation