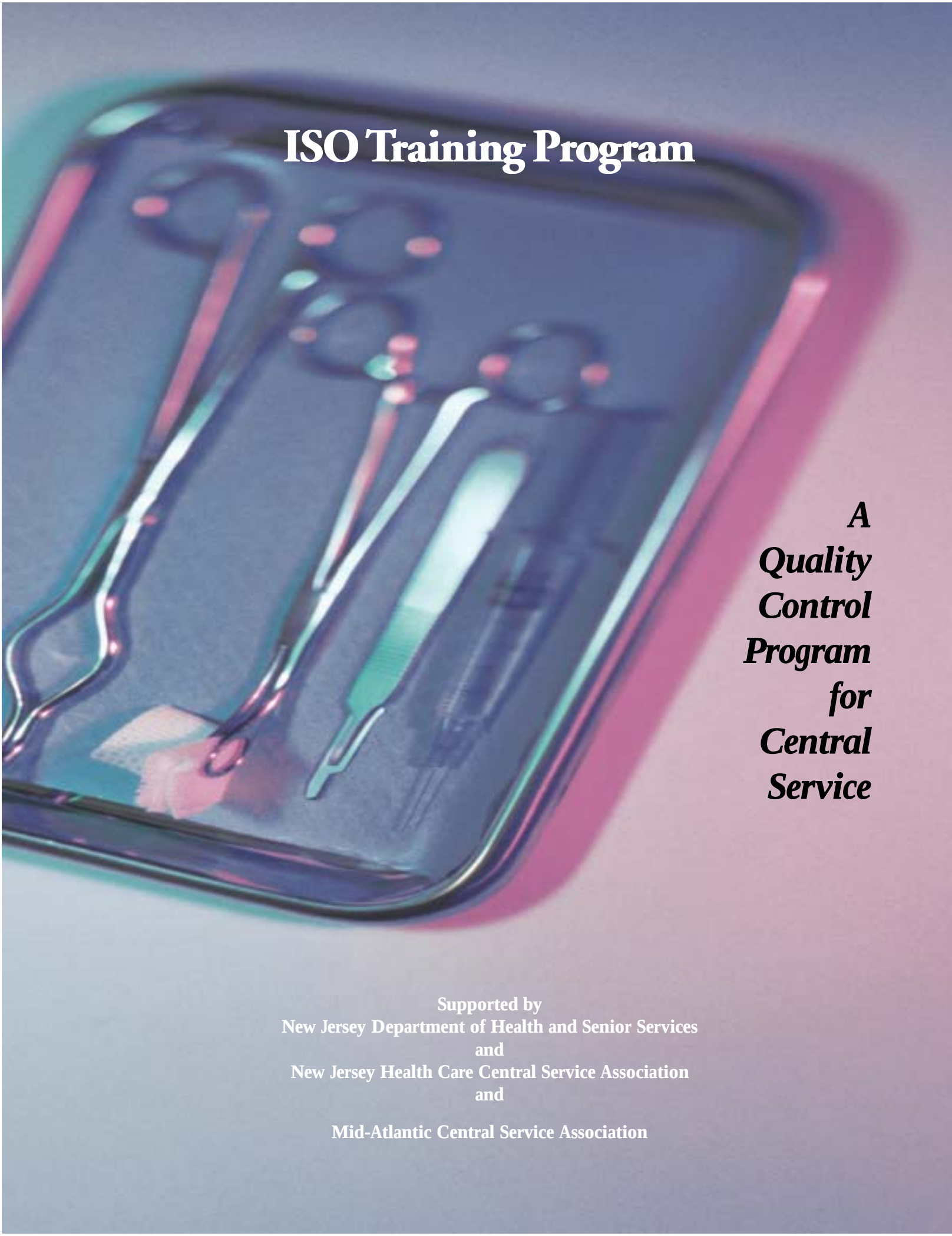

ISO Training Program

A Quality Control Program for Central Service

Supported by
New Jersey Department of Health and Senior Services
and
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and

Mid-Atlantic Central Service Association

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INTRODUCTION

Quality assurance systems have been applied to many services within health care facilities, often leading to great confusion and misunderstanding. The intent of this document is to apply the widely accepted "International Standards Organization" (ISO) quality system model to Central Services. We believe that this system, which was developed in 1987, is applicable to Central Services as manufacturers of sterile reusable instruments and devices. The production of a sterile product encompasses many complex manual and mechanical processes. In today's health care system, the customer base has expanded to include ambulatory care facilities, physicians and even neighboring hospitals. The suppliers of medical devices are manufacturing complex instruments that require specialized cleaning methodologies including specific detergents and equipment. All these factors make the task of documenting a quality system based upon ISO an important mandate.

In order to establish a starting point for Central Service in their quest for a quality system, it was necessary to identify the primary functions within the department. Thirteen functions common to Central Service were identified. With these functions in mind, you are ready to move on to the first step in creating a quality system, which is to document your process. Since each hospital provides different services based upon its customer base and its mechanical and physical layout, it is important to develop policies and procedures that are specific to your process. State Regulations and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) require hospital policies to be reviewed and updated every three years. It is important to follow government regulations as well as national guidelines when developing hospital policy as it provides the means to defend proposed policies and enhances the professionalism and credibility of the manager and department.

Policies are broad based documents that provide direction to personnel in all aspects of Central Service such as, but not limited to: receiving; decontamination; preparation; sterilization; storage and distribution. Government regulations are minimum standards that must be met and may differ from national standards or guidelines. In cases where they differ, the more stringent of the two should be selected. Each chapter of this document references the state and federal regulations as well as the national guidelines that should be utilized when creating or revising hospital policy. In order to develop meaningful policies, it is necessary to obtain the most current versions of these regulations and standards. Once you have the current regulations and standards, you need to compare existing hospital policy to these guidelines to determine discrepancies and correct them. Once policies have been reviewed and/or revised, they must be submitted through your organizational chain of command for final adoption. In most cases, revisions will be submitted to the infection control committee and or safety committees for review and approval.

The next step in establishing a quality system is to develop specific work practices or procedures. Staff involvement is critical to developing procedures for each step of the manufacturing process as you will be asking them to document how they perform their duties on a daily basis. There are many different approaches to accomplish this task. However, the following method may prove to be the easiest.

First, choose a procedure and have your employees develop a handwritten flow chart of each step in the process. It is best to begin with a basic process and avoid unusual, or special situations such as an OR emergency, loaner instrumentation, or portable patient care equipment. These situations require deviation from the normal process and should be avoided until the basic process is developed. Specific flow charts will need to be established for each situation. Once a flow chart has been established for each step of the manufacturing process, employees should provide a written description of exactly what they do at each step of the flow chart. In essence you are looking for: "what to do, when to do it, and who and what are needed to do it?"

Once the current work practices have been developed, and flow charts developed, a review process should be performed by management and staff. The department's work practices should be compared to the ISO outline in this document to ensure that all issues are covered. At the same time, work practices can be compared to hospital policy, state and federal regulations, and national guidelines. By including staff in the process of comparing their work practices to outside sources you are empowering them to identify problems and improve practices.

Management and staff should review existing work practices looking for the following:

1. Poor work practices.
2. Short cuts.
3. Duplication of effort.
4. Staffing shortfalls.
5. Special requirements for specific products.
6. Additional training/in-servicing needs for staff.
7. Compliance with State and Federal regulations as well as national standards.

As part of this process, each should prepare recommendations for change.

Consideration of customer needs is also a major component of the quality system process. The department's ability to satisfy its customers' needs on a consistent basis is the first step towards being considered "reliable" and "professional" by your organization. In each section of this ISO guidance document, key players are identified. Although it is the manager's responsibility to work with the department's customers to identify their needs, at least one staff member should be included in the process. Time should be taken to work with departments to:

1. Review and revise forms.
2. Determine documentation issues.
3. Determine appropriate scheduling.
4. Develop communication systems.

Once management and staff have had an opportunity to review the work practices and prepare their recommendations, it's time to meet and collaborate to improve these practices. You should have before you, the actual practices, changes based on government regulations and/or national guidelines, input from customers, revised documents and forms, and management assessment of work practices. Before the process begins, a recorder should be appointed to keep the minutes and prepare drafts of the final document for review prior to the next meeting. Each step of the process should be reviewed and input solicited from each person present. There should be rules set for the process to assure that everyone is heard in an orderly and fair manner.

It is important that the group set attainable goals for each session and not attempt to do more than is reasonable at one session. Once the work practices have been revised and all parties are in agreement, a draft will be prepared. This draft will be distributed to all members of the group for final review before the next session. At the next meeting the changes should be minimal and, once everyone has had the opportunity to comment, the practice should be unanimously approved. Once done, the practice will be initiated. It is imperative that the practice not be changed or adapted to individual circumstances. Any recommendations for change or improvement must be made to, and approved by, the group. This will assure standardized practice and improve the performance of all employees and on all shifts.

The last step is to determine how you are going to monitor and measure the efficacy of the process. Determine the critical steps in the process and develop a method to continuously monitor and measure the efficiency of the process. Prepare documentation that will allow you to collect the data necessary to monitor the process. Internal audits should be conducted. You may use peer review, management audits or outside audits as a means of detecting problems. It's important to determine how the audit function will be performed, the frequency of the audit process, verification of corrective action, and report on the effectiveness of corrective action. It's important to focus on the process and not the outcome. Important tools to use are the responses from customers such as customer surveys, informal customer comments and complaints. The group must decide how you collect this data and how to analyze the data?

The final issue is process improvement. Think of process improvement as a race without a finish line. At each stage of the system, identify goals or objectives that the staff can use to improve the system. Start small and work off your successes. You may include both corrective action and preventive action as process improvement. In the case of corrective action, you are fixing problems in an effort to make the system meet your known needs. In this instance, the process isn't working as planned or wasn't right from the beginning and is in need of repair. Preventive action, on the other hand, is intended to avoid potential problems.

Regardless of the role that you play, you must follow the documented procedure for corrective action. It's important to have good closure, which means that the problem has been completely analyzed, permanently remedied, recorded, implemented, and reviewed.

Now you may begin your journey down the quality systems path. Please use this guidance document as a guiding light. As time goes on and we receive feedback from those brave souls that embark on this most difficult journey, we will revise and update this document. This is truly an endless journey, which will lead to a more efficient system, safe medical/surgical devices for patients, increased productivity, reduced costs, and employee satisfaction.

This is a guidance document that should be used as a tool in developing a quality control system in Central Services. References will change over time as well as Central Supply issues.

ISO COURSE OUTLINE

I. KEY ISSUES

❖ Manufacturer's Written Recommendations
Prior to purchase of a medical device, the Materiel/Purchasing Management department should confirm that the facility has the capability to follow the manufacturer's recommendations for reprocessing the item. (The responsibilities for purchasing medical devices may vary from institution to institution.) It may also vary by department within any given institution.)

- A representative from CS/SPD shall be a member of any committee involved in product evaluation or purchasing.
- Manufacturers are required to provide validated instructions for reprocessing reusable medical devices.
- Compare the device manufacturer's recommendations to the facility's own processing capabilities. The facility is responsible for insuring that they have the facilities and equipment to execute the instructions.
- The CS/SPD department should have a policy and procedure for reporting to the FDA any manufacturer who does not provide validated instructions for cleaning and sterilization of their device.

1. References:
    a. www.fda.gov/medwatch/report/hcp.htm for "voluntary reporting procedures."

❖ Develop a check sheet to assure that all possible needs are addressed during interaction with manufacturer or review of their literature:

- Method(s) for cleaning;
- Can the item be immersed in solution;
- Chemical restrictions;
- Temperature restrictions;
- Exposure time;
- Drying requirements;
- Aeration requirements if EtO sterilized.
- Packaging requirements.
- If the device has its own sterilization container, consideration must be given to its care and handling as well as testing for process efficacy in your sterilizer.
- How was the product tested? Pre-vacuum? Gravity Displacement? EtO? LTGP?
- What was the load configuration?
- Where was the item placed inside the sterilizer? Middle shelf? Bottom shelf?

❖ Develop procedures for complex devices. Maintain instructions in a file readily accessible to employees performing the tasks as well as end users.

- Develop staff competencies for processing of complex devices.

    1. Key Players:
        a. Department Manager
        b. Employees
        c. Manufacturer
        d. Materiel Management
        e. Risk Management
    2. References:
        a. AAMI Recommended Practices:
            i. TIR12 – "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers"
            ii. ST33 – "Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide and Steam Sterilization in Health Care Facilities."
        b. FDA Guidelines for the Reuse of Single Use Devices.
        c. New Jersey State Regulations:
            i. NJAC 8:43G-8.1(d)
            ii. NJAC 8:43G-8.4(b)
        d. IAHCSMM "Central Service Technical Manual" Chapter 8
        e. ASHCSP "Training Manual for Central Service Technicians"
        f. "Management of Loaner Instrumentation and Implants"; Position Paper #2; ASHCSP & IAHCSMM 10/95

II. DECONTAMINATION

A. PPE / Dress Code

❖ Develop policies and procedures for the uses of personnel protective equipment (PPE) that are clear, concise and include the potential for disciplinary action.
- PPE is dependent upon the task to be performed.

❖ Educate employees with regards to what attire is to be worn during specific activities, how it is to be worn, and why it is worn.
- Impervious gown
- Cuffed gloves
- Face mask
- Face/Eye protection
- Shoe covers
- Head cover

❖ Develop annual competencies for the use of PPE.
- As part of JCAHO survey practices, they may ask to see documentation as to what action is taken if an employee fails to follow procedure.
- OSHA makes mention in the Blood Borne Pathogen Ruling that not only the employer who fails to provide PPE, but the employee who fails to follow procedures for the use of PPE, both face disciplinary action. As a useful tool to meeting these standards, and as a means to stress the importance of PPE, you may want to develop a written agreement between employer and employee. Such an agreement should be reviewed and signed by the employee annually. When developing such a policy, it is imperative that the agreement has the approval of Human Resources and/or Risk Management.
- Employees do not wear protective attire because it is uncomfortable. When employees feel the PPE is uncomfortable, it may help to investigate other materials and products. It is important to involve the staff in the selection process. If an impervious gown or jump suit is being used as part of the protective attire, consider changing to a long-sleeved impervious apron.

❖ The environment may be the cause of the uncomfortable working conditions and may warrant the following action:
- Discuss available environmental controls with engineering to determine what limitations exist, such as the ability to control environmental conditions within decontamination without affecting other areas.
- Request that available systems be checked to verify function.
- Maintain a log of the temperature and humidity in the area to determine actual values and their relationship to staff complaints.
- Have air exchanges and negative pressure verified.
- Investigate possibility of utilizing a free-standing, area-specific, air conditioner, (if warranted).

- In cases where the problem can only be solved with major changes to the department, you will need support from Infection Control, Risk Management, Employee Health and Administration.

    1. Key Players:
        a. Infection Control Committee
        b. Infection Control Professional
        c. CS/SPD Manager/Director
        d. Human Resources
        e. Risk Management
    2. References:
        a. New Jersey State Regulations:
            i. NJAC 8:43G-8.4(a)1
            ii. NJAC 8:43G-14.1(d)2
            iii. NJAC 8:43G-8.6(e)
        b. AAMI Recommended Practices:
            i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings"
            ii. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
        c. 29 CFR 190030 OSHA's Blood Borne Pathogens Regulation
        d. ASHCSP "Training Manual for Central Service Technicians", Chapter 4
        e. IAHCSMM "Central Service Technical Manual", Chapter 4
        f. AORN Standards, Recommended Practices and Guidelines

B. Soiled Transport (confine/contain)

❖ Policies and procedures must be established for containment systems for used instruments. There may be different containment systems based upon the individual needs of the user (i.e., OR, ER, Med-Surg., ICU, Same Day, Off-Site Facility).

❖ Responsibilities for pre-cleaning and soaking should be clearly defined and include:
- Suitable detergent.
- Removal of gross soils at point of use.
- Proper storage location and use of biohazard labels.
- Transport procedures.

❖ Scheduling pick up or delivery of soiled instruments may vary from hospital to hospital based upon the number of shifts that CS/SPD operates. It is important to establish the flow of soiled instruments and equipment from the various users with time frames:
- A flow chart will help to identify sources, volume of goods, and times.
- Identify the unexpected situations that arise such as unscheduled surgeries, emergencies, back-to-back cases, or special requests.

- Communicate with the units to insure impact on labor, product, patient care or quality is not compromised.

    1. Key Players:
        a. Department Managers in various units should help to identify the role of their staff and needs of their units.
        b. CS/SPD employees will help to define current practice
        c. Infection Control for review and comment.
        d. Safety Officer to identify any unsafe practices
    2. References:
        a. AAMI Recommended Practices:
            i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings"
            ii. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
        b. 29 CFR 190030 OSHA's Blood Borne Pathogens Regulation
        c. New Jersey State Regulations:
            i. NJAC 8:43G-8.1(b)
        d. ASHCSP "Training Manual for Central Service Technicians", Chapter 4
        e. IAHCSMM, "Central Service Technical Manual", Chapter 5

C. Selection & Use of Chemicals

❖ The selection of chemicals is based on the following factors:

- Identify types of soils you will be dealing with.
- Identify methods of cleaning available, their mechanics and limitations:
    1. Manual
    2. Mechanical
- Identify items being processed and any special needs such as pre-soaking, manual cleaning, susceptibility to heat and moisture and potential damage from alkaline or acid detergents/chemicals.
- Select cleaning agents (detergents) that are designated for use by the methods you will be using to clean, and the products you will be cleaning.
- Make sure selected detergents are compatible with items (and their components) being cleaned.
- Read and follow manufacturer's instructions on all selected agents (i.e., dilution, water temperature & soak time).
- If working with enzymatic agents designed to work on protein soils, make sure they contain detergents and are not designed as a pre-soak only.
- Know the water chemistry and effect it may have on your detergents:
    1. Coordinate activities with your plant engineer.
    2. Water hardness and pH of your water supply should be provided to the detergent manufacturer.

3. Consideration may be necessary to use softened, filtered, demineralized or even distilled water in at least the final rinse stages.

- The time lapse between use and cleaning process can adversely affect the cleaning process. Foams and gels are recommended for prolonged time lapse.
- Develop the process for use based upon the above-mentioned factors.

1. Key Players:
    a. Manufacturers
    b. CS/SPD Manager/Director
    c. Infection Control Professional
    d. Infection Control Committee
    e. Materiel Management
2. References:
    a. AAMI Recommended Practices:
        i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings"
    b. ASHCSP "Training Manual for Central Service Technicians", Chapter 4
    c. IAHCSMM "Central Service Technical Training Manual," Chapter 5
    d. New Jersey State Regulations:
        i. NJAC 8:43G-8.7(a)
        ii. NJAC 8:43G-8.7(d)
        iii. NJAC 8:43G-8.7(e)
    e. American Journal of Infection Control "APIC Guidelines for Selection & Use of Disinfectants" 1996, 24:313-42

D. Cleaning

❖ Develop policies and procedures that address the information required from the manufacturer before the device(s) can be processed:

- Cleaning agents.
- Cleaning implements.
- Rinse requirements (distilled water, deionized water).
- Disassembly.
- Temperature restrictions.
- Reuse limitations.
- Moisture sensitivity.
- Lubrication via mechanical washers.
- Testing requirements.

❖ The first step is to develop the workflow process starting with inspection of instruments received from patient care areas. Problems should be reported to a point person within Central Service. Safety issues and repetitive problems are issues that need follow up.

- ❖ Follow the manufacturer's instructions for cleaning. Develop procedures which include:
  - Sorting instruments for cleaning & decontamination.
  - Rinse & removal of gross soil.
  - Use of ultrasonic cleaner.
  - Mechanical washer for all hinged and metal instruments.
  - Manual cleaning for items with a lumen, delicate items and/or items that are moisture sensitive (eye instruments).

- ❖ Establish competencies for:
  - Processing equipment.
  - Insuring the temperatures and detergent concentrations are appropriate, monitored, and verified.
  - Each device processed per manufacturers instructions.

- ❖ Preventive maintenance policies for mechanical cleaning equipment should be established regardless of who is to perform the task (manufacturer, vendor, in-house maintenance).
  - Develop maintenance log.

- ❖ Policies and procedures for patient care equipment may differ from medical instruments. A specific workflow will have to be developed to include:
  - Soiled storage on floors, and scheduling and transport must be clearly defined.
  - Cleaning/disinfectant solutions as defined by the manufacturer and approved by the facility's Infection Control Committee.
  - Functional inspection and repairs reported to Bio-Med.
  - Storage

1. Key Players:
   a. Manufacturers
   b. CS/SPD Manager/Director
   c. CS/SPD Technician
   d. Bio-Med Personnel
2. References:
   a. AAMI Recommended Practices:
      i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings"
      ii. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
   b. ASHCSP "Training Manual for Central Service Technicians"
   c. IAHCSMM, "Central Service Technical Manual," Chapter 5
   d. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, CDRH/FDA 8/00

e. New Jersey State Regulations:
    i. NJAC 8:43G-8.1(b), (c)
    ii. NJAC 8:43G-8.7(f)
    iii. NJAC 8:43G-8.4(c)

E. Physical Environment

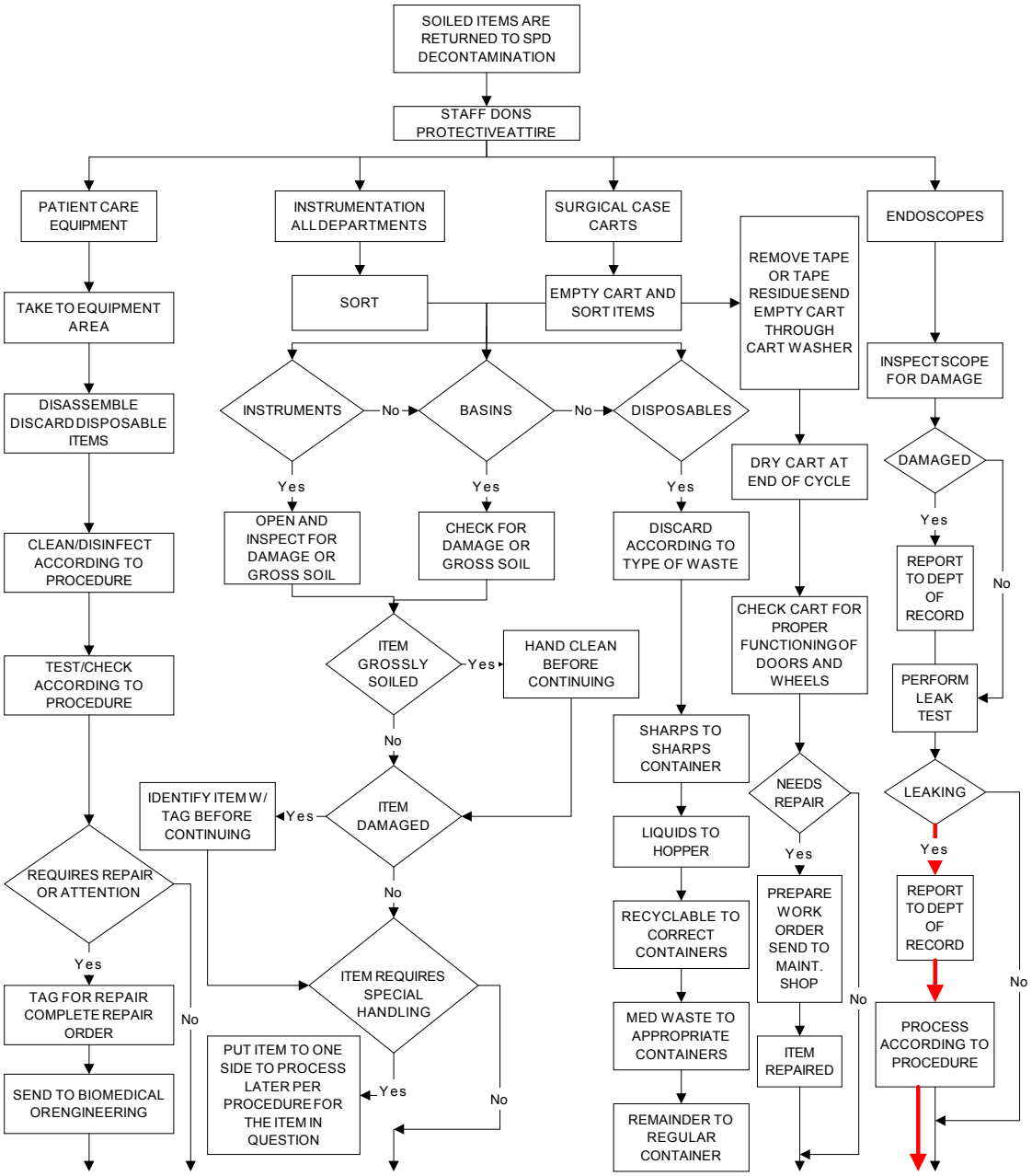
- Specifications for temperature/humidity/air exchanges are clearly defined but monitoring equipment and systems shall be established to insure that environmental conditions are maintained.

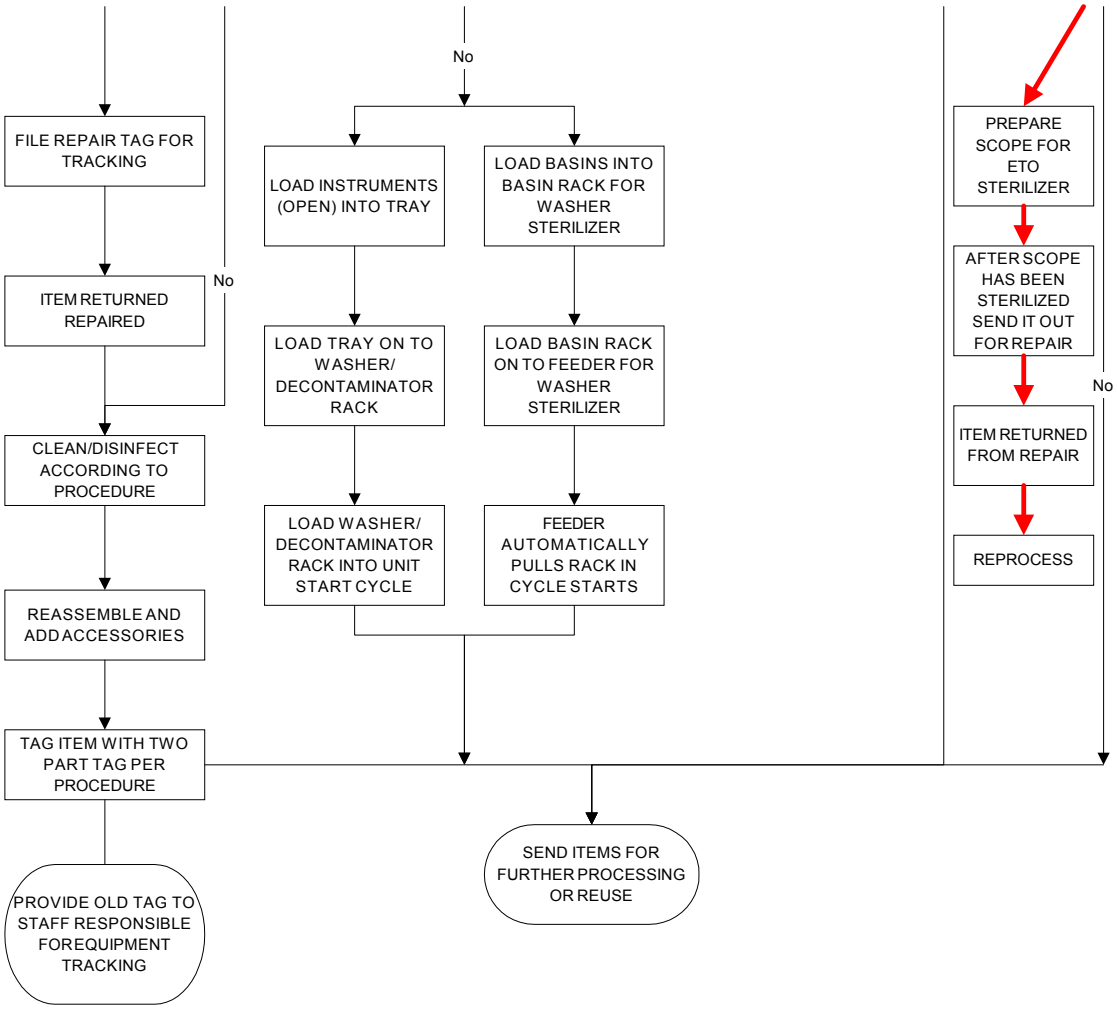
- The space within CS/SPD shall follow the recommended flow of product at each stage of the process.

- Employee policies and procedures must clearly define traffic patterns to prevent cross-contamination and should include hand washing, and appropriate use of PPE.

1. Key Players:
    a. CS/SPD Director
    b. Engineering
    c. Infection Control
2. References:
    a. New Jersey State Regulations:
        i. NJAC 8:43G-8.4(a)
        ii. NJAC 8:43G-8.6(a), (b), (c)
    b. AAMI Recommended Practices:
        i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings"
        ii. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
    c. IAHCSMM, "Central Service Technical Manual" Chapter 5
    d. ASHCSP "Training Manual for Central Service Technicians", Chapter 4
    e. U.S. Veterans Administration, Department of Medicine and Surgery Manual H-08-9 and MP-2, 1983A and 1983B

Decontamination Process Flowchart




FILE REPAIR TAG FOR TRACKING
ITEM RETURNED REPAIRED
No
CLEAN/DISINFECT ACCORDING TO PROCEDURE
REASSEMBLE AND ADD ACCESSORIES
TAG ITEM WITH TWO PART TAG PER PROCEDURE
PROVIDE OLD TAG TO STAFF RESPONSIBLE FOREQUIPMENT TRACKING
No
LOAD INSTRUMENTS (OPEN) INTO TRAY
LOAD BASINS INTO BASIN RACK FOR WASHER STERILIZER
LOAD TRAY ON TO WASHER/ DECONTAMINATOR RACK
LOAD BASIN RACK ON TO FEEDER FOR WASHER STERILIZER
LOAD WASHER/ DECONTAMINATOR RACK INTO UNIT START CYCLE
FEEDER AUTOMATICALLY PULLS RACK IN CYCLE STARTS
SEND ITEMS FOR FURTHER PROCESSING OR REUSE
PREPARE SCOPE FOR ETO STERILIZER
AFTER SCOPE HAS BEEN STERILIZED SEND IT OUT FOR REPAIR
ITEM RETURNED FROM REPAIR
No
REPROCESS

III. PREPARATION/PACKAGING

A. Dress Code

❖ It is important to establish a dress code that is practical and identifies the risks present in the work environment. Non-compliance can be a result of many factors. Policies should address at least the following:

- Clearly define, with signage, restricted areas requiring hospital-laundered attire.
- Determine why people are entering restricted areas and if a process could be changed to make it unnecessary for them to do so.
- Consistently enforce access to restricted areas by properly attired personnel.
- Provide hats, and cover gowns or jumpsuits at entrance(s) to restricted areas.

1. Key Players:
    a. CS/SPD Director/Manager
    b. Infection Control
    c. Staff Development
2. References:
    a. New Jersey State Regulations:
        i. NJAC 8:43G-8.4(a)
    b. AAMI Recommended Practice:
        i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"

B. Assembly

❖ Surgical instruments, supplies, and most other medical devices must be prepared and packaged so that their sterility can be maintained until used. Preparation involves inspecting items for:

- Cleanliness.
- Ensuring that all parts are present and functional.
- Assembling multiple component sets or packs.

❖ Obtain technical data from packaging manufacturer to assure:

- Air removal.
- Permitting the sterilant to contact all surfaces of the device.
- Protecting the device from contamination during storage, handling, and before it is used (shelf life).
- Packaged to allow item to be removed aseptically.

❖ Provide equipment/supplies needed for inspection/testing, functionality, preventive maintenance, (i.e., lighted magnifying lamps, special lubricants, theraband to test sharpness, etc.)

- In-service CS/SPD employees. Determine competencies for each device.

1. Key Players:
    a. CS/SPD Director/Manager
    b. CS/SPD Staff
    c. Device manufacturers
2. References:
    a. AORN Standards, Recommended Practices & Guidelines, "Instruments and Powered Equipment – Care & Cleaning", 2000
    b. New Jersey State Regulations:
        i. NJAC 8:43G-8.1(b),(c),(d)
        ii. NJAC 8:43G-8.4(b)

❖ Policies for assembly of surgical instrument sets should be established:

- Develop accurate count sheets for all trays processed.
- The weight of an instrument set should be based on whether personnel can use proper body mechanics in carrying the set. Also, the design and density of individual instruments and the distribution of mass (the density) in the set will impact the ability to dry the set. The department should work with the end users to control set weight.
- Use copies of catalog diagrams for reference for specialty items.
- Changes to trays shall be authorized by department head/designee. This should be documented on a change form.
- In-service staff and test competencies.
- Precept new employees until competencies are verified for each set.
- Develop and implement a QA tool to track customer satisfaction.
- Ideally, all sets within the hospital should be inventoried. Primary instrument vendors offer this service (usually free) along with computer software (sometimes free depending on yearly instrument expenditure) for instrument count sheets, identification, and cost tracking.
- The process should provide assurance that when changes are made, they occur in all like trays in a timely manner.
- When developing count sheets, use standard descriptions with detail including proper name of instrument, length, curved or straight, as well as the manufacturer and a catalog number (even if the manufacturer is not the same on all trays, the catalog number is a good cross reference), etc.

1. Key Players:
    a. OR Service Leaders
    b. Instrument Manufacturers
    c. CS/SPD Manager/Director
    d. CS/SPD Staff
2. References:
    a. AORN Standards, Recommended Practices & Guidelines, "Instruments and Powered Equipment – Care & Cleaning", 2000

b. New Jersey State Regulations:
    i. NJAC 8:43G-8.3(b), (c)

❖ Missing instruments, broken/damaged instruments can best be addressed by:
- Implement mandatory instrument counts at completion of all surgical procedures
- Implement placement of instruments in respective containers or trays at completion of case.
- In-service all users of surgical instruments in the proper care and handling
- Implement a damaged instrument tagging system to indicate repair needs.
- Document all instances of missing/abused instruments
- Document staff competencies in proper care and handling of surgical instrumentation

1. Key Players:
    a. OR Manager
    b. CS/SPD Manager/Director
    c. OR surgical technicians
    d. OR Nurses
    e. CS/SPD Staff
    f. Surgeons
2. References:
    a. AORN Standards, Recommended Practices & Guidelines, "Instruments and Powered Equipment – Care & Cleaning", 2000

❖ Patient care equipment not set up correctly can be resolved by:
- Obtaining user manuals for all patient care equipment.
- Developing policies and procedures for assembly, testing and cleaning.
- Develop a storage procedure and a means to identify equipment ready for use.
- In-servicing CS/SPD staff.
- Determining staff competencies.
- Assuring supply of needed components readily available.

1. Key Players:
    a. CS/SPD Manager/Director
    b. CS/SPD Technician
2. References:
    a. ASHCSP "Recommended Practice for Patient Care Equipment"
    b. IAHCSMM, "Central Service Technical Manual," Chapter 8
    c. New Jersey State Regulations
        i. NJAC 8:43G-8.4(c)

C. Packaging Materials

- To protect wrappers or packaging material from damage and/or tearing, evaluate the following:
  - Evaluate packaging materials used.
  - Evaluate package contents for suitability with packaging materials (i.e., peel pack).
  - Investigate handling of sterile packs post-sterilization.
  - Investigate condition of autoclave and storage racks (wires loose, burrs on edges).
  - Identify storage locations/conditions.
  - In-service CS/SPD and OR personnel on proper handling of sterile packs.
  - Determine staff competencies for handling of sterile packs.
  - Line storage wire shelves with foam, vinyl or plastic in sterile storage.
  - Investigate purchase of additional rigid containers.

D. Rigid & Flash Container Sterilization Systems

- Evaluation - need to evaluate as with any other major change in packaging systems;
  - They are reusable and come in a variety of materials and sizes (various metals, aluminum and polymers).

- Cleaning/Disassembly Recommendations:
  - Reduction of bioburden essential.
  - All non-disposal components must be cleaned after each use, including filters, valves, internal baskets, etc.
  - Reusable identification system (tags) inside and outside of container.
  - Remove all disposable process indicators, locks, filters, etc., prior to cleaning.
  - Dividers/sorting pins may have to be removed if they interfere with proper cleaning.

- Cleaning Agents/Methods:
  - Follow container manufacturer's instructions for detergent selection and usage (manual or mechanical).
  - Configuration of sets inside container can affect drying and sterilization cycles.

- Manufacturer must provide, in writing, their recommended cycles parameters for:
  - Pre-vacuum, gravity displacement, EtO cycles.
  - BI testing performed - cycles and parameters.
  - EtO aeration.
  - Load configurations including location of trays/sets inside sterilizer, maximum number of containers in load, etc.
  - Dry times.
  - Sterility maintenance.

- User Responsibilities:
    - Pre-purchase evaluation BI testing and drying times:
        1. Test representative sterilizer with large load and small load tests. Containers should contain largest # of instruments in sets.
        2. For all other sterilizers only need small load tests (pre-vacuum sterilizers)
    - Maximum load test (pre-vacuum):
        1. Two containers over drain line.
        2. Two containers on each of other shelves.
        3. Chamber fully loaded with other items.
        4. Measures steam penetration in full load/cycle.
        5. Same test for gravity displacement cycles.
    - Small load test:
        1. One container with BIs placed on bottom shelf over the drain in otherwise EMPTY sterilizer.
        2. Measures the effect of small loads where air can get entrapped inside the containers.

- EtO testing – refer to AAMI document for testing of EO cycles

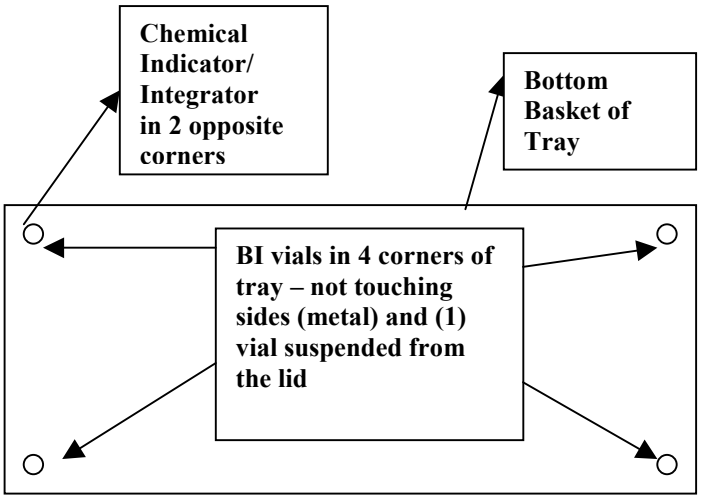
- Drying should be evaluated by controlled random sample in which a set is opened at completion of drying/cooling time and observe for residual condensate. Hospital policy will dictate frequency of sampling. Documentation is maintained within the department.
    - Drying times may have to be extended.
    - Pre-conditioning the load may help.
    - Evaluate weight and density of sets.
    - Evaluate use of absorbent materials inside containers.

- In the best interest of patient care, any set containing moisture or has visible water should be consider contaminated.

- Other QA Issues:
    - SPD shall develop a policy for all end users to report wet packs.
    - Filter material – not interchangeable.
    - Stacking – (inside the sterilizer; steam, ETO, low temperature gas plasma) must follow the container manufacturer's recommendations. Do not stack containers from different manufacturers
    - Develop practice of container inspection before use (i.e., integrity of gaskets)

- Transport of soiled instruments in containers – verify with container manufacturer if container can be used for soiled transport of instruments.
- Need quality repairs - original equipment manufacturer (OEM) preferred
- Check quality of repairs on return
- Get documentation from container manufacturer regarding what items the manufacturer has validated to be processed inside the container (e.g., drills, lumens, etc.).
- Routine BI testing (maximum load type and small load type) should be performed on loads containing mainly containers. Frequency to be determined by the facility but at a minimum annually. Where multiple manufacturer containers are used, BI Testing must be performed for each manufacturers container.

    1. Key Players:
        a. CS/SPD Director/Manager
        b. OR Manager
        c. CS/SPD and OR personnel
    2. References:
        a. AAMI Recommended Practices:
            i. ST46 – "Good Hospital Practice: Steam Sterilization & Sterility Assurance"
            ii. ST33 – "Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide and Steam Sterilization in Health Care Facilities."
            iii. 11607-RCO "Packaging for terminally sterilized medical devices" May 1997
        b. ASHCSP "Training Manual for Central Service Technicians", Chapter 8
        c. IAHCSMM, "Central Service Technical Manual," Chapter 10
        d. New Jersey State Regulations:
            i. NJAC 8:43G-8.1(b)
            ii. NJAC 8:43G-8.3(c)



Rigid Container Test Pack

Should contain instrumentation inside container. Make sure filters in place.

E. Chemical Indicators

❖ To insure that chemical indicators/integrators (CIs) are properly used the following should be performed:

- In-service for CS/SPD or OR personnel in use of CIs.
- In-service CS/SPD personnel in proper location of CI inside packs versus rigid containers.
- Develop a means of reporting sets with missing filters, CI's.
- List CI and filters on count sheets as added reminder to staff.
-

1. Key Players:
    a. CS/SPD Director/Manager
    b. CS/SPD Staff
    c. OR Staff
2. References:
    a. AAMI Recommended Practices:
        i. ST-33 "Guidelines for the Selection and Use of Rigid Container Systems for Steam and Ethylene Oxide Gas in Health Care Facilities"
        ii. ST-46 "Good Hospital Practice: Steam Sterilization & Sterility Assurance"
        iii. ST-60 "Sterilization of Healthcare products-Chemical Indicators"- Part I, 1996
        iv. TIR-25-RCO "Guidance for selection, use and interpretation of results in Health Care Facilities" June 2000
    b. ASHCSP "Central Service Technician Training Manual", Chapter 6
    c. ISHCSMM, "Central Service Technician Manual," Chapter13
    d. New Jersey State Regulations:
        i. NJCA 8: 43G-8.8(c)

F. Product Identification/Labeling

❖ Identification of sets and trays can be enhanced by:

- Marking all flat Mayo trays with permanent, non-toxic marker.
- Utilization of clip-on ID tags for inner baskets
- Assuring that wrapped trays/instruments are identified with contents
- Identifying items that are missing from the set/package
- Verify all tags on baskets; replacing as needed.

1. Key Players:
    a. CS/SPD Director/Manager
    b. CS/SPD Staff

G. Sterility Maintenance (Dust Covering)

❖ Dust covers should meet AAMII recommendations of 2 to 3 mils in thickness.

❖ Dust covers can be correctly applied by:

- In-servicing personnel in selection of correct size for item, correct application and sealing of dust cover.
- Ensure proper labeling of dust cover.
- In-servicing personnel in proper use of heat-seal machine.
- Verification competent return demonstrations.
- Ensuring supply of necessary size dust covers.

2. Key Players:
    a. CS/SPD Manager/Director
    b. CS/SPD Staff
3. References:
    a. AAMI Recommended Practice:
        i. ST-46 "Good Hospital Practice: Steam Sterilization & Sterility Assurance
    b. ASHCSP "Central Service Technician Training Manual", Chapter 6.
    c. IAHCSMM, "Central Service Technician Manual," Chapter 12

IV. STERILIZATION

A. Selection of Sterilization Process

❖ CS/SPD managers should in-service surgical staff and user departments regarding the total time required to complete sterilization cycles, including EtO aeration and steaming cool-down time, and communicating with user departments as needed to prioritize their needs. Standardize EtO cycle start times to insure devices are available for first case.

- CS/SPD, Operating Room, and Infection Control should adopt policies and procedures that include, but are not limited to the following:
    - Coming from the OR to CS/SPD to be cleaned and sterilized (e.g., "Stat" stickers, flagging, phone communication, etc.)
    - In CS/SPD, and must be sent to the OR to be flash sterilized for immediate use (e.g., complete cleaning, inventory, etc.)
    - In OR, and will be cleaned and sterilized for immediate use.
- Certain principles should apply:
    - The item should be cleaned in CS/SPD if the OR cannot meet the same standards for proper cleaning (e.g., suitable work area and equipment, proper attire, etc.)

- The OR should maintain a file of manufacturers' instructions for flash sterilizing their devices. Many manufacturers of complex instrumentation do not recommend flash sterilization for their device. While there are specific cycles for porous and non-porous items, complex instrumentation may require special exposure times.
- It is the responsibility of the OR to maintain documentation of items being flashed. This record should be audited on a regular basis and used for budget preparation to increase inventory of those items being frequently flash sterilized.
- The CS/SPD Director is ultimately responsible for all sterilization within the facility and must audit the flash sterilization log as well as the sterilizer monitoring records on a regular basis.

1. Key Players:
    a. OR Director/ Instrument Technician
    b. Infection Control Professional
    c. Instrument Manufacturer
    d. CS/SPD Manager/Director
    e. CS/SPD Technician
2. References:
    a. "Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities", FDA Document - www.fda.gov/cdrh/ode/198.pdf
    b. New Jersey State Regulations
        i. NJAC 8:43G-8.1 (d)
    c. "Selecting a Sterilization Process" by Natalie Lind, Infection Control & Sterilization Technology, December, 1996

B. Documentation

❖ For each sterilization cycle, load contents and lot control information are recorded on a sterilization log, which includes:

- The contents must be specific and identify each item in the load.
- The Sterilizer used.
- Operator.
- Presence of an implant if applicable.
- Presence of a biological if applicable.

❖ A policy should be established to affix lot control label information immediately before the sterilization process.

- An exception shall be made for low temperature gas plasma.

- ❖ The sterilizer-recording chart or print out tape should be dated and maintained with the load information. Each cycle printout should be reviewed and signed by the operator. Bowie-Dick / Dynamic Air Removal tests should be run daily on all pre-vacuum sterilizers and be part of this record. The process should include an audit of these records on a regular basis to insure their completeness and accuracy.
    - Sterilizer test results are monitored and documented before sterilizer is put to use.
    - Sterilization records shall be monitored on a daily basis.
    - Sterilization records should be retained according to legal or risk management policies.
    -

        1. Key Players:
            a. CS/SPD Manager/Director
            b. CS/SPD Technician
        2. References:
            a. AAMI Recommended Practice:
                i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
            b. New Jersey State Regulations:
                i. NJAC 8:43G-8.8(c)
                ii. NJAC 8:43G-8.11(f)

C. Loading Sterilizer

- ❖ Similar items requiring the same cycle parameters should be grouped together.

- ❖ Procedures describing load contents and placement configurations should be developed.

- ❖ Procedures for configuring mixed or heterogeneous loads should be developed.

- ❖ Process audits should be performed and documented to ensure compliance.

- ❖ Staff competencies for proper package placement and sterilizer rack loading need to be documented.

1. Key Players:
    a. CS/SPD Manager/Director
    b. CS/SPD Technician
2. References:
    a. AAMI Recommended Practice:
        i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
    b. Sterilizer manufacturer's user manual

D. Steam Sterilization Processes

- ❖ Physical settings:

- The sterilizer manufacturer's recommendation for cycles should be followed at all times. If a device manufacturer recommends a different cycle for a particular device, the sterilizer manufacturer should be consulted and the issue resolved by verification of results.
- A rigid sterilization container system frequently requires changes in the normal cycle, and it is important to verify that the cycle selected accomplishes sterilization.
- All rigid container systems must be verified in the facility's sterilizer upon purchase or if significant changes in the process occur. Documentation should be maintained on file.

❖ Chemical Indicator/Integrator/Biological Testing:

- The selection of biological and chemical monitors is based upon the intended use of the monitor. The manager should obtain data from the manufacturer on the reliability, sterility assurance level, safety, performance characteristics, storage requirements and shelf life. This data will support the manager in developing specific polices for use, placement, and storage.
- The Bowie-Dick / Dynamic Air Removal test is used to evaluate the effectiveness of air removal during the pre-vacuum phase of a pre-vacuum sterilizer cycle and to detect air leakage into the sterilizer during the vacuum phase. This test is not a routine sterilization cycle indicator and the manufacturer's instructions for use must be followed when establishing a monitoring program for this test.
- An auditing system should be established to insure system compliance with chemical monitor procedures. This system may consist of a reporting system from the end user, or breaking down completed packs or customer complaints.
- The selection of biological indicators varies based upon response characteristics desired for the type of steam system employed. The manufacturer of the biological indicator (BI) should provide the user written instructions on storage, handling, use, sterility assurance level (SAL) and microbiological testing of their products. This data will support the manager in developing specific policies for use, placement, handling, incubation, reading results, record keeping, storage and disposal of processed and unprocessed indicators.
- Policies for use of biological monitors should address frequency of use, installation of new equipment, relocation of equipment, repairs of sterilizers, implantable devices, verification of rigid containers, test packages, and positive test results.
- Written documentation or a decision tree should be established as to the actions taken in response to a positive biological monitor.

1. Key Players:
    a. CS/SPD Manager/Director
    b. Manufacturer
    c. CS/SPD Technician
2. References:
    a. New Jersey State Regulations:
        i. NJAC 8:43G-8.8(c)1, 5
        ii. NJAC 8:43G-8.8 (a)4
    b. AAMI Recommended Practices:
        i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
        ii. TIR-25 – "Chemical Indicators-Guidance for the Selection, Use and Interpretation of Results in Health Care Facilities" June 2000.
        iii. ST 60 – "Sterilization of Health Care Products-Chemical Indicators-Part I" 1996
        iv. ST 59 – "Sterilization of Health Care Products-Biological Indicators" Part I, 1999.
        v. ST19 – "Sterilization of Health Care Products-Biological Indicators, Biological Indicators for Moist Heat Sterilization" Part III, 1999
        vi. Sterilization Part 3, Industrial Process Control (2003 edition)

E. Unloading Sterilizer

❖ A system shall be established and maintained for release of product after sterilization. Each release decision shall be documented, including identification of the person making the decision. Release documentation shall:

- Specify the load or include a reference to the specification for the load.
- Include records from routine testing.
- Include records from the sterilization cycle.

❖ Documentation shall be maintained whenever a breach of hospital policy or procedures occurs (i.e., cleaning, release of items, etc.)

1. Key Players:
    a. CS/SPD Manager/Director
    b. CS/SPD Technician
2. References:
    a. ISO 13683 "Sterilization of health care products- Requirements for validation and routine control of moist heat sterilization in health care facilities" January 1996
    b. ASHCSP "Central Service Technician Training Manual", Chapter 5
    c. New Jersey State Regulations:
        i. 8:43G-8.1(e)6

F. Quality Assurance

❖ Quality Control:

- A system shall be established and maintained for release of product after sterilization. For each load the release documentation shall:
  - Specify the load or include a reference to the specification for the load.
  - Include records from routine testing.
  - Include records from the sterilization cycle.
- The quality of steam is an important aspect of successful steam sterilization. CS/SPD Directors should work closely with their Plant Engineering Directors to ensure that the recommended steam quality and purity are consistently maintained.
- Wet packs most frequently occur in the steam sterilization process and policies should be established to respond to this issue.

1. Key Players:
   a. CS/SPD Manager/Director
   b. Plant Engineer
   c. CS/SPD Technician
2. References:
   a. Technique Manual, "Wet Pack Problem Solving Guide." Steris Corporation, 2003
   b. AAMI Recommended Practice:
      i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
   c. New Jersey State Regulations:
      i. NJAC 8: 43G-8.10

❖ Results

- The quality of the entire sterilization process depends on the accuracy and reliability of cycle parameters. This data is necessary to determine if a product can be released. The records should be retained so that it is possible to demonstrate retrospectively that the load had been properly sterilized. Identification of the operator should be unique and restricted to the individual for traceability.
  - Cycle failure must be reported to a designated person and documentation of actions taken in response to the failure should be maintained on file.

❖ Recalls

- Most positive BIs are the result of operator error. Therefore, it is important to immediately speak with the technician who performed the task, and ask exactly how each step of the process was performed. There are multiple reasons for a positive BI to occur which include:
  - Overloading the sterilizer
  - Selecting incorrect cycle
  - Wrong packaging materials

- Improper handling of BI
- Incubator malfunction

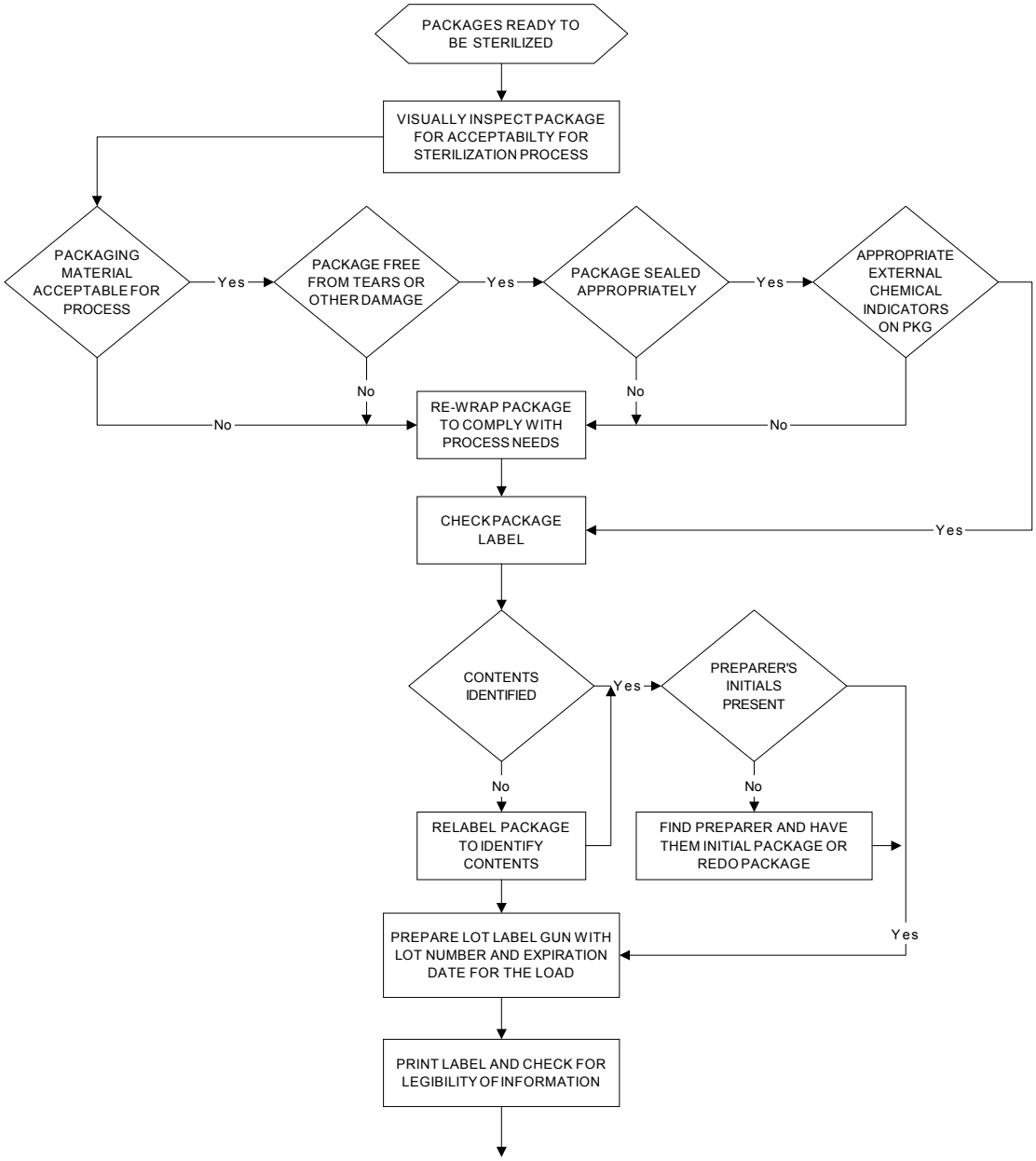
- If the initial BI is positive, use of the sterilizer should be discontinued
- Repeat the BI in a challenge test pack.
- Refer to your decision tree.
- Documentation of all actions taken in response to this event shall be recorded and maintained.

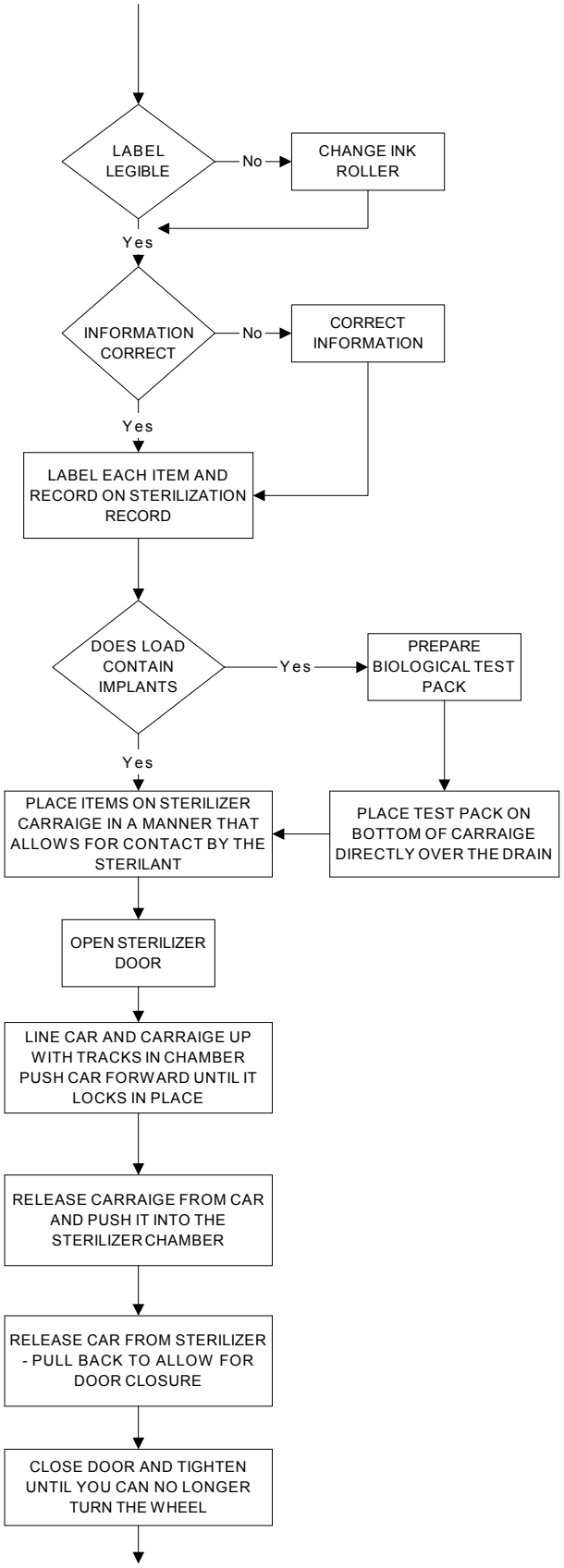
1. Key Players:
    a. CS/SPD Manager/Director
    b. Service Provider
    c. CS/SPD Technician
2. References:
    a. "Here's what to do when a load goes bad" by Karen Sandrick, Materiels Management, September 1998.
    b. New Jersey State Regulations:
        i. 8:43G-8.8(d)1, 2

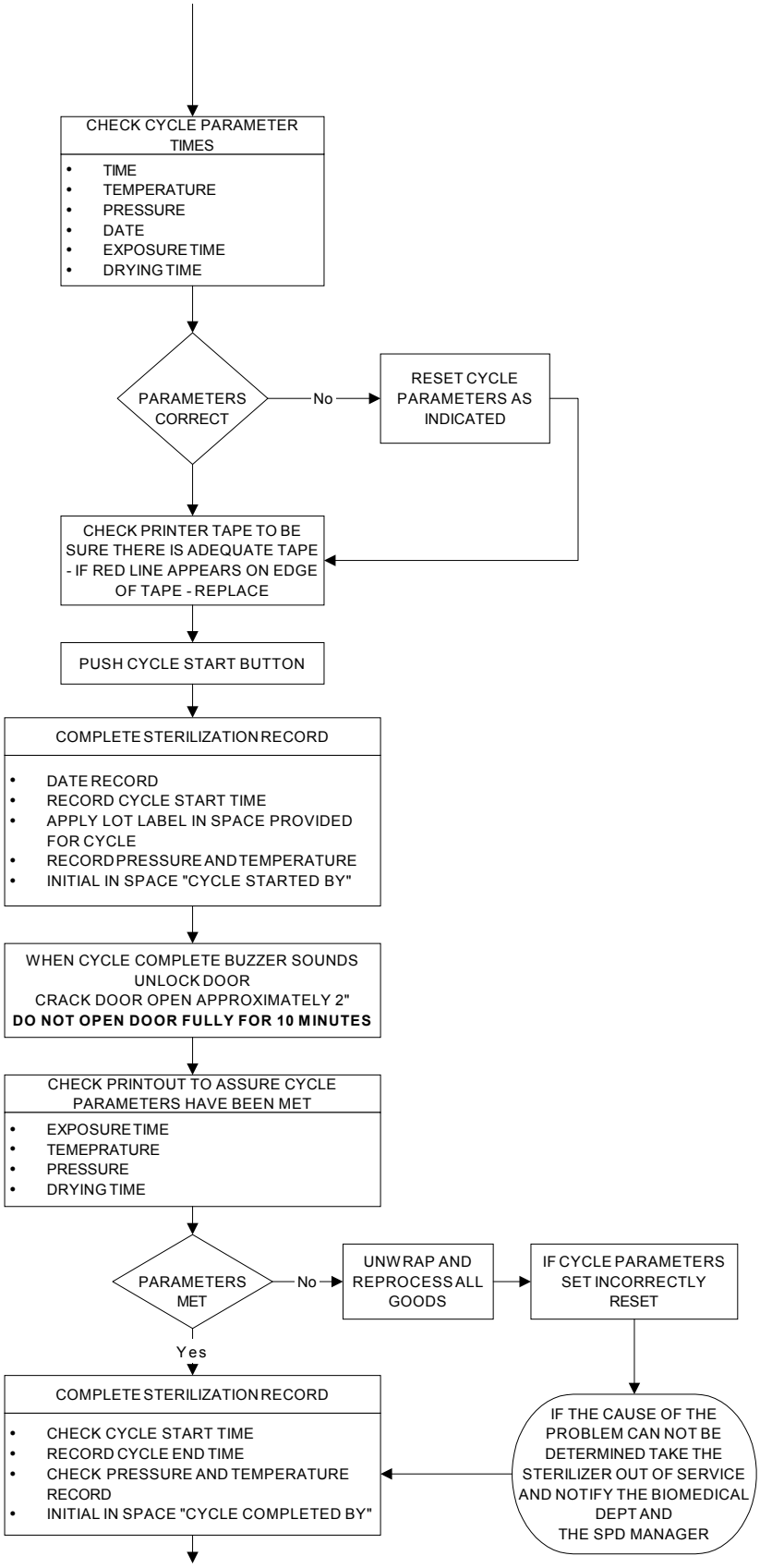
❖ Administrative Concerns

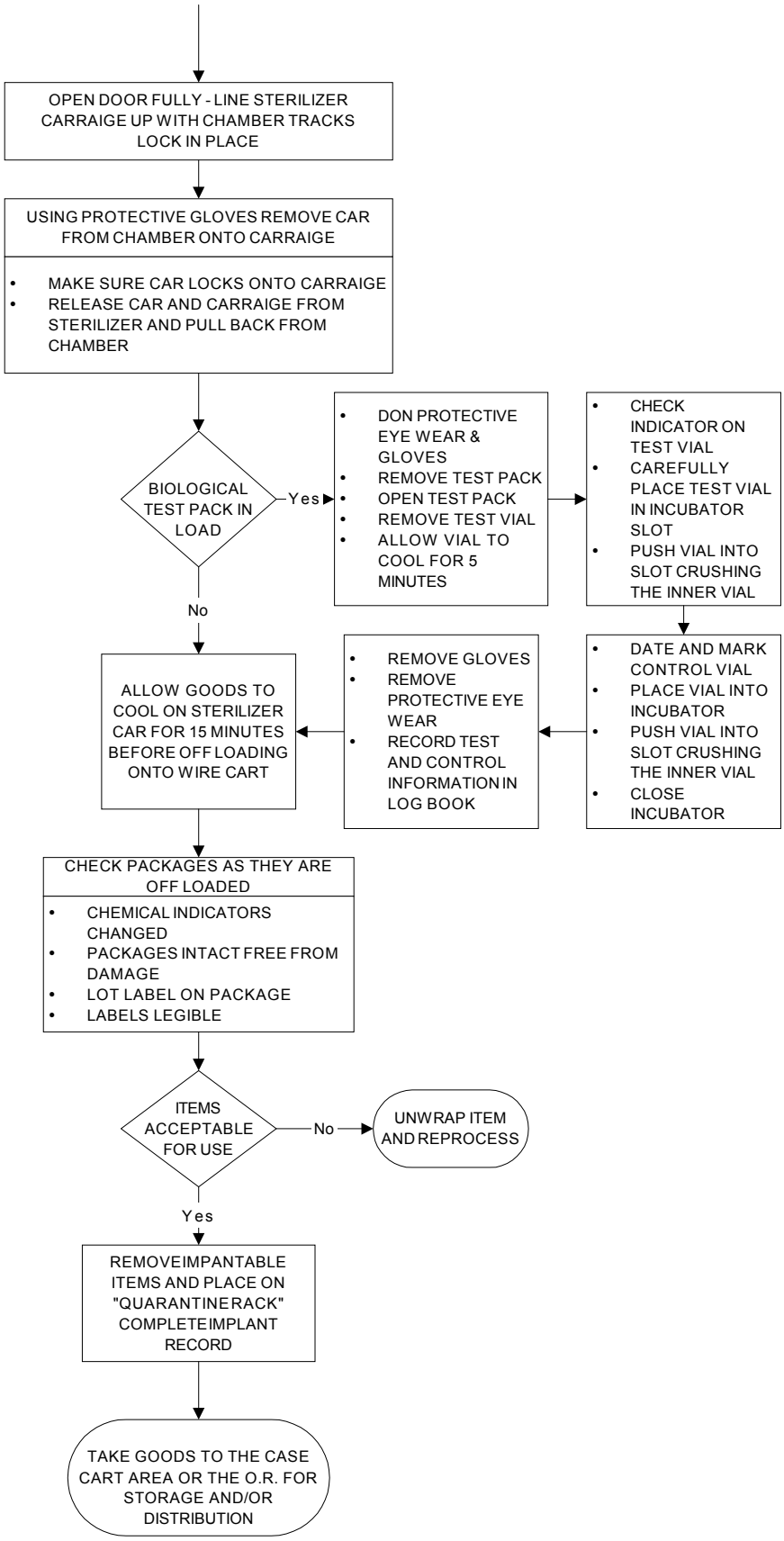
- The CS/SPD Manager/Director is responsible for the safety and effectiveness of the sterilizers, wherever they are located. Regular cleaning and routine maintenance/repair that is documented and kept on file in the CS/SPD department should maintain the sterilizers. The manufacturer's service representative or specifically trained personnel should perform maintenance. A complete service manual and instructions for safe and effective operation of the sterilizer should be available where the sterilizer is located. Sterilizer maintenance records should be retained according to hospital policy.

Steam Sterilization Process




LABEL LEGIBLE
No
CHANGE INK ROLLER
Yes
INFORMATION CORRECT
No
CORRECT INFORMATION
Yes
LABEL EACH ITEM AND RECORD ON STERILIZATION RECORD
DOES LOAD CONTAIN IMPLANTS
Yes
PREPARE BIOLOGICAL TEST PACK
Yes
PLACE ITEMS ON STERILIZER CARRAIGE IN A MANNER THAT ALLOWS FOR CONTACT BY THE STERILANT
PLACE TEST PACK ON BOTTOM OF CARRAIGE DIRECTLY OVER THE DRAIN
OPEN STERILIZER DOOR
LINE CAR AND CARRAIGE UP WITH TRACKS IN CHAMBER PUSH CAR FORWARD UNTIL IT LOCKS IN PLACE
RELEASE CARRAIGE FROM CAR AND PUSH IT INTO THE STERILIZER CHAMBER
RELEASE CAR FROM STERILIZER - PULL BACK TO ALLOW FOR DOOR CLOSURE
CLOSE DOOR AND TIGHTEN UNTIL YOU CAN NO LONGER TURN THE WHEEL


CHECK CYCLE PARAMETER TIMES
• TIME
• TEMPERATURE
• PRESSURE
• DATE
• EXPOSURE TIME
• DRYING TIME
PARAMETERS CORRECT
No
RESET CYCLE PARAMETERS AS INDICATED
CHECK PRINTER TAPE TO BE SURE THERE IS ADEQUATE TAPE - IF RED LINE APPEARS ON EDGE OF TAPE - REPLACE
PUSH CYCLE START BUTTON
COMPLETE STERILIZATION RECORD
• DATE RECORD
• RECORD CYCLE START TIME
• APPLY LOT LABEL IN SPACE PROVIDED FOR CYCLE
• RECORD PRESSURE AND TEMPERATURE
• INITIAL IN SPACE "CYCLE STARTED BY"
WHEN CYCLE COMPLETE BUZZER SOUNDS
UNLOCK DOOR
CRACK DOOR OPEN APPROXIMATELY 2"
DO NOT OPEN DOOR FULLY FOR 10 MINUTES
CHECK PRINTOUT TO ASSURE CYCLE PARAMETERS HAVE BEEN MET
• EXPOSURE TIME
• TEMEPRATURE
• PRESSURE
• DRYING TIME
PARAMETERS MET
No
UNWRAP AND REPROCESS ALL GOODS
IF CYCLE PARAMETERS SET INCORRECTLY RESET
Yes
COMPLETE STERILIZATION RECORD
• CHECK CYCLE START TIME
• RECORD CYCLE END TIME
• CHECK PRESSURE AND TEMPERATURE RECORD
• INITIAL IN SPACE "CYCLE COMPLETED BY"
IF THE CAUSE OF THE PROBLEM CAN NOT BE DETERMINED TAKE THE STERILIZER OUT OF SERVICE AND NOTIFY THE BIOMEDICAL DEPT AND THE SPD MANAGER


OPEN DOOR FULLY - LINE STERILIZER CARRAIGE UP WITH CHAMBER TRACKS LOCK IN PLACE
USING PROTECTIVE GLOVES REMOVE CAR FROM CHAMBER ONTO CARRAIGE
• MAKE SURE CAR LOCKS ONTO CARRAIGE
• RELEASE CAR AND CARRAIGE FROM STERILIZER AND PULL BACK FROM CHAMBER
BIOLOGICAL TEST PACK IN LOAD
Yes
• DON PROTECTIVE EYE WEAR & GLOVES
• REMOVE TEST PACK
• OPEN TEST PACK
• REMOVE TEST VIAL
• ALLOW VIAL TO COOL FOR 5 MINUTES
• CHECK INDICATOR ON TEST VIAL
• CAREFULLY PLACE TEST VIAL IN INCUBATOR SLOT
• PUSH VIAL INTO SLOT CRUSHING THE INNER VIAL
No
ALLOW GOODS TO COOL ON STERILIZER CAR FOR 15 MINUTES BEFORE OFF LOADING ONTO WIRE CART
• REMOVE GLOVES
• REMOVE PROTECTIVE EYE WEAR
• RECORD TEST AND CONTROL INFORMATION IN LOG BOOK
• DATE AND MARK CONTROL VIAL
• PLACE VIAL INTO INCUBATOR
• PUSH VIAL INTO SLOT CRUSHING THE INNER VIAL
• CLOSE INCUBATOR
CHECK PACKAGES AS THEY ARE OFF LOADED
• CHEMICAL INDICATORS CHANGED
• PACKAGES INTACT FREE FROM DAMAGE
• LOT LABEL ON PACKAGE
• LABELS LEGIBLE
ITEMS ACCEPTABLE FOR USE
No
UNWRAP ITEM AND REPROCESS
Yes
REMOVE IMPANTABLE ITEMS AND PLACE ON "QUARANTINE RACK" COMPLETE IMPLANT RECORD
TAKE GOODS TO THE CASE CART AREA OR THE O.R. FOR STORAGE AND/OR DISTRIBUTION

G. Ethylene Oxide Sterilization

❖ Physical Settings:

- There are three systems for ethylene oxide sterilization on the market today: a mixture of ethylene oxide and hydrochlorofluorocarbon (HCFC); ethylene oxide and carbon dioxide; and $100^{\%}$ ethylene oxide. Each has its own characteristics (see MSDS sheet), and the cycles are pre-set by the sterilizer manufacturer. Operating policies should be established based upon manufacturer's instruction which shall include the following:
  - Instructions for installation, storage and use.
  - Safety precautions to be taken during routine use as well as recommended sterilizer settings, safety precautions for terminating a cycle in progress, and explanation of how pressure recordings should be interpreted to detect chamber leaks.
  - Technical information about the chamber temperature and pressure ranges acceptable during operation.
  - Validation procedures used to establish that the recommended cycle parameters provide a 10^{-6} sterility assurance level.
  - Types of items for which EtO sterilization is appropriate.
  - Selection of appropriate packaging materials.
  - Environmental humidity control.
- Designate a specific area for Prep and Packaging

❖ Chemical Indicator/Integrator/Biological Testing

- Various types of external and internal chemical indicators/integrators are available, each with different response characteristics. The manager should obtain data from the manufacturer on the reliability, sterility assurance level, safety, performance characteristics, storage requirements and shelf life. This data will support the manager in developing specific polices for use, placement, and storage.
- Policies for the type of chemical indicator/integrator should establish placement, frequency of use, interpretation and actions taken in response to a non-responsive or inconclusive chemical indicator/integrator.
- An auditing system should be established to insure system compliance with chemical monitor procedures. This system may consist of a reporting system from the end user, or breaking down completed packs, or customer complaints.
- When selecting a biological monitor, the manufacturer's recommendations for storage, handling, use, and microbiological testing should be used to develop procedures.
- Policies for use of biological monitors should address testing upon frequency of use for installation of new equipment, after major repairs of sterilizers, implantable devices, and positive test results.

- Written documentation or a decision tree should be established as to the actions taken in response to a positive biological monitor.

    1. Key Players:
        a. EtO Supplier
        b. CS/SPD Manager/Director
        c. Department Heads
        d. CS/SPD Technician
        e. Safety/Risk Manager
    2. References:
        a. New Jersey State Regulations
            i. NJAC 8:43G-8.8(c)2
            ii. NJAC 8:43G-8.8(a)1
        b. AAMI Recommended Practices:
            i. ST 41 – Ethylene oxide sterilization in health care facilities: Safety and effectiveness
            ii. ST 21–RCO "Sterilization of Health Care Products-Biological Indicators, Biological Indicators for Ethylene Oxide Sterilization" Part II, 1999.
        c. ASHCSP "Ethylene Oxide Use in Hospitals".

❖ Aeration

- Sterilization by ethylene oxide leaves toxic residuals that must be removed by mechanical aeration. A departmental policy should take into consideration properties of the item being sterilized, the type and temperature of the aeration process, the characteristics of the airflow, and intended use of the item. The medical device manufacturer must determine proper aeration times and provide written recommendations, which are used to formulate department procedures.
- Some medical devices may require additional aeration than that provided by the pre-set cycle. A system should be developed to identify items requiring additional aeration.
- Temperature and duration of aeration shall be monitored and documented.

❖ Employee Safety

- The New Jersey Department of Environmental Protection requires licensing for those individuals working directly with ethylene oxide. Applicators' licenses and operating permits should be posted and expiration dates logged to insure that renewal licenses are obtained.
- OSHA established strict regulatory standards for the use of ethylene oxide, which also includes the development of an EtO Emergency Plan (A sample is provided in Appendix). Polices and procedures should be based upon federal standards. Monitoring and alarm systems records should be maintained and checked by management.

- There are specific requirements for retention of EtO records when employees are potentially exposed to EtO at or above the action level, or above the short-term excursion limit. Records may be kept in employee's health file and a master file for easy reference and auditing.

    1. Key Players:
        a. CS/SPD Manager/Director
        b. CS/SPD Technician
        c. Employee Health
    2. References:
        a. Occupational Safety and Health Administration (OSHA, 1984) 29 CFR 1910.20
        b. Occupational Exposure to Ethylene Oxide 1988. 29 CFR, Part 1910.1047
        c. Ethylene Oxide Gas Sterilization, Emergency Response Plan, Virtua-West Jersey Health System
        d. New Jersey State Regulations:
            i. NJAC 8:43G-8.11(g), (h)
            ii. NJAC 8:43G-8.2(d)

H. Low Temperature Gas Plasma

❖ Physical Settings:

- It is essential to follow all of the sterilizer manufacturer's instructions as the source for policies and procedures relating to its use. This will include:
    - Materials must be compatible with the process (e.g., plastic, compatible instrument trays; polypropylene/silicone wrap and pads). It is not recommended to use linen, paper, or foam. The manufacturer provides a complete list of recommended materials in their user manual.
    - Since this technology is relatively new, it is essential that new devices or devices in question have been validated in the process (See user manual or ask manufacturer to send the validation information).
- Chemical Indicator/Biological Testing: There are specific biological and chemical indicators with instructions for their use. The manager should obtain data from the manufacturer on the reliability, safety, performance characteristics, sterility assurance level (SAL), storage requirements, and location of the BI in the load, frequency and shelf life. This data will support the manager in developing specific polices for use, placement, and storage.
- Designate a specific area for prep and package.
    1. Key Players:
        a. Manufacturer
        b. CS/SPD Manager/Director
        c. CS/SPD Technician

2. References:
    a. New Jersey State Regulations:
        i. NJAC 8:43G-8.8(a)3
        ii. NJAC 8:43G-8.8(c)3
    b. IAHCSMM "Central Service Technical Manual" Chapter 10

I. Dry Heat Sterilization

❖ Dry Heat Sterilization is the method of choice for sterilizing talc. Policies and procedures shall be established to insure appropriate time and temperature.

- An alternative to processing talc is to buy it sterile. The FDA has approved for marketing sterile talc produced by the Bryan Corporation, Woburn, MA, telephone (800) 343-7711.
- Chemical Indicator/Biological Testing: There are specific biological and chemical indicators with instructions for their use. The manager should obtain data from the manufacturer on the reliability, safety, performance characteristics, sterility assurance level (SAL), storage requirements and shelf life. This data will support the manager in developing specific polices for use, placement, and storage.
    1. Key Players:
        a. CS/SPD Manager/Director
        b. CS/SPD Technician
    2. References:
        a. Purdue/IAHCSMM, "Self-Study Lesson on Dry Heat Sterilization"

J. Chemical Sterilants and High-Level Disinfection:

❖ Physical Settings:

- The conditions given on the product label for high-level disinfection or sterilization are determined by the manufacturer, using FDA-recommended testing protocols. The user should read and follow the label instructions to determine time, temperature, concentration, and use conditions.
    - It is important that the manager check with each device manufacturer of the devices to be processed for materials compatibility and device functionality data regarding the chemical sterilant or high-level disinfectant intended for use.
    - Chemical sterilants/high-level disinfectants vary in their toxicity. It is important to obtain the material safety data sheet (MSDS) from the manufacturer of the chemical in order to develop employee safety procedures.
    - If automated systems are used that circulate the sterilant around and through the medical device, it is important to follow the manufacturer's recommendations for control of exposure conditions and calibration.

- Polices and procedures for final rinse, drying, and storage must be established for each type of device being processed.

    1. Key Players:
        a. Manufacturer
        b. CS/SPD Manager/Director
        c. CS/SPD Technician
    2. References:
        a. AAMI Recommended Practices:
            i. TIR 7 – "Chemical Sterilants and High-Level Disinfectants: A Guide to Selection and Use" January 1999,
            ii. ST-58 – "Safe Use and Handling of Gultaraldehyde-based Products in Health Care Facilities,"
        b. Society of Gastroenterology Nurses and Associates, "Standards for Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes, 2000"
        c. Association for Practitioners in Infection Control, Inc, "APIC guideline for selection and use of disinfectants" AJIC, Vol. 18, Number 2,1999
        d. Centers for Disease Control and Prevention, "Draft Guideline for Environmental Infection Control in Healthcare Facilities" 2001
        e. New Jersey State Regulations:
            i. NJAC 8:43G-8.7(a), (b)

❖ Chemical Indicator/Biological Testing

- There are many variables that can affect the efficacy of the chemicals used to process medical devices. A system shall be established to monitor the efficacy of the chemicals being used. Chemical test strips are used to determine the use life of the product. Policies should be established for frequency and documentation of results.
- There are specific biological monitors for chemical sterilants. The manager should obtain data from the manufacturer on the reliability, safety, performance characteristics, sterility assurance level (SAL) storage requirements and shelf life. This data will support the manager in developing specific polices for use, placement, and storage
    1. Key Players:
        a. Manufacturer
        b. CS/SPD Manager/Director
        c. CS/SPD Technician

2. References:
    a. New Jersey State Regulations:
        i. NJAC 8:43G-8.8(a) 2
        ii. NJAC 8:43G-8.7(e)

❖ Quality Control
- Chemical sterilants/high-level disinfectant systems may be employed in several departments within the healthcare facility. It is important that all departments coordinate policies and procedures to insure a consistent standard of care throughout the facility.
    1. Key Players:
        a. Department Heads
        b. CS/SPD Manager/Director
    2. References:
        a. New Jersey State Regulations:
            i. NJAC 8:43G-8.1(c)

K. Processing Rigid and Flexible Fiberoptic Scopes

❖ Transport of Used Scopes:
- The initial steps in the reprocessing begin in the patient's room immediately after removal of the insertion tube from the patient and before removing the endoscope from the power source.
- Follow the scope manufacturer's written instructions for processing.
- Suction the solution through the biopsy/suction channel until the solution is visibly clean.
- Transport the endoscope very loosely coiled to the Decontamination Room in an enclosed container.
- Reprocessing should not take place in the procedure room.

❖ Decontamination
- Have the following equipment available:
    - PPE (based upon risk).
    - Leakage tester equipment.
    - Channel cleaning adapters (per manufacturer's instructions).
    - Sink filled with enzymatic detergent prepared according to manufacturer's instructions.
    - Channel cleaning brushes and lint-free swabs.
    - Lint-free cloth.

❖ Leak Testing
- Perform a leak test of the endoscope following manufacturer's instructions.
- Follow the manufacturer's instructions or third party repair service instructions if a leak is detected or the endoscope appears damaged for shipping instructions.

- Cleaning
  - Develop cleaning procedures for GI endoscopes before automated or manual disinfection. The following issues shall be included:
    - The use of enzymatic detergent.
    - Disassembly so that all surfaces may be reached for thorough cleaning.
    - Size and use of brushes.
    - A system to identify cleaning adapters for suction, biopsy, air and water channels for all scopes.
    - Define the use of cleaning adapters or pistols for special endoscope channels (e.g., elevator channel, forward water jet, double-channel scopes).
    - Flushing all channels with the detergent solution to remove debris.
    - Define rinsing, drying and purging the endoscope and all channels.

- Automated Reprocessing
  - The above cleaning and leak testing procedures must be followed before using automatic reprocessor.
  - Prepare the endoscope reprocessor according to the manufacturer's instructions.
  - Place the endoscope in the reprocessor and attach all channel adapters according to manufacturer's instructions.
    - Identify the scope manufacturer, type of scope (i.e., colonscope) for every adapter used.
    - A color-coded tape applied to adapters can be used to identify specific scopes.
  - Because elevator channels have small lumens, pumps or pistols can be added to automated equipment to facilitate cleaning. However, you should verify with the scope manufacturer on the compatibility of the water pressure.
  - If the machine has a cycle that uses detergent, it should be a product that is compatible with the reprocessor and the endoscope.
  - Verify cycle exposure time and temperature for the liquid chemical disinfectant in use.
  - The final step for all automated reprocessors is an alcohol rinse preceding purging all channels with compressed air.
  - A preventive maintenance program is recommended for automated reprocessing equipment and all flexible scopes.

- Manual High-Level Disinfection
  - The above cleaning and leak testing procedures must be followed prior to high-level disinfection.
  - Verify that the solution has been tested for Minimum Recommended Concentration (MRC).
  - Define the process to insure disinfectant reaches into all channels of the endoscope.

- Develop a method to insure soak time and temperature prescribed by the manufacturer of the disinfectant.
- Flush all channels completely with air before removing the endoscope from the disinfectant.
- Rinsing – Identify the type of rinse water to be used (i.e., tap, filtered, sterile) and how it is performed.

❖ Drying (same for Automated or Manually Reprocessed Scopes)
- Define the limits for use of high air pressure. High-pressure air can damage the internal channels of flexible GI scopes.
- Flush all channels, including accessory channels, with alcohol.
- Purge all channels with air.
- Remove all channel adapters.
- Dry the exterior of the endoscope with a soft, lint-free cloth.
- Thoroughly rinse and dry all removable parts. Do not attach removable parts (valves, etc.) to the endoscope during storage.

❖ Storage
- Storage of endoscopes with the removable parts detached lowers the risk of trapping liquid inside the instrument and facilitates continued drying of the channels and channel openings.
- Define storage conditions to protect the scope from damage, dust free, and provide ventilation.

❖ Processing of Endoscopic Accessories
- Items that penetrate mucosal barriers (e.g., biopsy forceps) are considered critical and therefore must be sterilized before use.
- Only sterile water should be used to fill the bottle for endoscopic irrigation.
    - The water bottle and its connecting tubing should be sterilized or receive high-level disinfection at least daily.

❖ Documentation of Devices Processed
- All endoscopes reprocessed should be maintained in a log which includes:
    - Date
    - Patient Name
    - Medical Record number
    - Processor
    - Endoscopist
    - Serial number of the scope used

❖ Rigid Endoscopes
- Follow scope manufacturer's instructions for cleaning, disassembly, inspection, testing and re-assembly.

- Cleaning of scopes should include the following factors:
    - If recommended, disassemble scope's light guide adapter and eyepiece cup.
    - Do not lose pieces; keep together for re-assembly after cleaning.
    - Do not clean more than one scope at a time to avoid damage.
    - Do not place in mechanical washers - manual clean only.
    - Use neutral pH detergents.
    - Rinse well.
    - After cleaning, make sure threads are completely dry before re-assembly.
- Inspection of scopes should include the following factors:
    - Should have unobstructed view with no black spots, cloudiness or other imperfections. If noted, send the scope for repair.
    - If smudges are noted, clean eyepiece and distal tip with 70% alcohol.
    - Check for bends, dents in shaft.
    - Check eye piece sealing cup for damage
- Sterilize per the scope manufacturer's instructions;
    - EtO or low temperature gas plasma are commonly employed for reprocessing.
    - Some rigid scopes are labeled steam-autoclaveable only.

1. Key Players:
    a. CS/SPD Manager/ Director
    b. Endoscopy Manager/Director
    c. OR Manager/ Director
    d. Endoscopy Technician
    e. CS/SPD Technician
2. References:
    a. Society of Gastroenterology Nurses and Associates, "Standards for Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes," 2000
    b. Association for Practitioners in Infection Control, APIC Guidelines for Infection Prevention and Control in Flexible Endoscopy," 2000
    c. IAHCSMM, Central Service Technical Manual, Chapter 7

V. Sterile Storage

A. Handling of Sterile Product

❖ Develop clear and concise procedures for rotation of stock

- First in, first out (FIFO)
- Fill from right, pull from left
- Fill from back, pull from front
- Check packaging integrity and outdates

- Monitor compliance
    1. Key Players:
        a. CS/SPD Manager/Director
        b. Materiel Personnel
    2. References:
        a. IAHCSMM, "Central Service Technical Manual," Chapter 12
        b. AAMI Recommended Practice:
            i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
        c. ASHCSP "Training Manual for Central Service Technicians", Chapter 8
        d. New Jersey State Regulations:
            i. NJAC 8: 43G-8.1(b)

❖ Evaluate stock on hand:
- Inventory control methodologies.
- Delete obsolete stock/trays.
- Review par levels for stock and floor trays.
- Work with Materiel Management in developing and adjusting inventory.
- Purchase plastic bins for storage of supplies.
- Look at shelving configurations – maximize space utilization.

    1. Key Players:
        a. Department Manager
        b. Materiel Manager
    2. References:
        a. AAMI Recommended Practice:
            i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"

❖ Environmental storage conditions can have a significant impact on sterile storage. The following issues should be addressed:
- Involve Infection Control and Engineering to maintain temperature and humidity range for area.
- Purchase and install thermometer/hygrometer and monitor/document temperature and humidity daily.
- Post signs and enforce restriction to area to indicate authorized personnel only.

    1. Key Players:
        a. CS/SPD Supervisory Staff
        b. Infection Control
        c. Engineering
        d. Administration
        e. CS/SPD Staff

2. References:
    a. AAMI Recommended Practice:
        i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"

B. Physical Environment

❖ Organization of space within sterile storage is important and the following issues need to be addressed:

- All storage locations need to be clearly labeled.
- Use label guns; remove old adhesive tape residues.
- Communicate new items added to stock and location; items removed from stock
- Provide a tool for replacement of stock before last item is issued.
- Assign responsibility for checking stock and ordering items on continual basis.
- Ensure all items dispensed and received are accurately documented.
- Perform cycle counts to verify accuracy of inventory information.
- Reconcile stock discrepancies.
- Use signs to identify equipment out for repair or "stock outs" and anticipated date of availability.
- Develop and maintain a locator file.
- Maintain a tracking system so items can be located in a timely manner.
- Maintain storage space as per the local fire code.

1. Key Players:
    a. CS/SPD Supervisory Staff
    b. Materiel Manager
    c. CS/SPD Staff

VI. Distribution

A. Systems

❖ Usually a combination of systems is used in order to provide optimum efficiency and cost effectiveness. Meet with Materiel Management and user departments to assess their needs and the needs of the facility.

- Type of system(s) selected needs to:
    - Provide supply history and usage.
    - Provide control and documentation of all medical/surgical supplies.
    - Be timely and accurate.
    - Meet the needs of the customers.
    - Provide for off-hour acquisition and accountability of supplies and patient care equipment.
- Factors influencing the type(s) of system(s) selected are:
    - Needs of the customers.
    - Elevator constraints.
    - Types of services the facility provides.

    - Size of the facility.
    - Physical design and age of the facility.
    - Financial resources.
- Types of Distribution Systems:
    - Demand (Requisition & Delivery System).
    - Par-Level Stocking (including automated par level stocking; e.g., Pyxis, Omnicell).
    - Exchange Cart.
    - Case Carts.
    - Specialty Carts.
    - Stockless or Just in Time (JIT).

B. Work Practices

❖ All systems require accurate selection, careful handling, and timely delivery of needed items.

❖ Arrange stock efficiently either alphabetically, numerically by stock number, or functionally by related groups, so it can be easily found when needed.

❖ Label all storage locations. Place heavier items on lower shelves and lighter items on higher shelves.

❖ Develop departmental par levels. Inventory either manually or with a hand held computer. Par levels need to be reviewed at least annually and revised as needed or appropriate.

❖ For unique specialty supplies, develop a requisition form that contains a list of all the items along with par levels.

❖ For specialty carts, bins, procedure carts, etc., develop a list of the supplies with their location on the cart for restocking.

❖ Develop a system to differentiate storeroom items vs. special order items.

C. Quality Assurance

❖ Develop a QA system for tracking receiving errors:
- As stock is received, it should be checked against the packing list.
- Report discrepancies to designated supervisory personnel.
- Advise Materiel Management.

❖ Develop a QA system for tracking distribution errors:
- Monitor compliance with par levels.
- Monitor compliance with restocking case or specialty carts.

- ❖ Develop a QA system for identification, documentation and reporting damage:
  - Package integrity upon receiving.
  - Package integrity due to in-house handling.

D. Delivery

- ❖ Develop Policies and Procedures defining the distribution process, route and frequency.

- ❖ A schedule for cleaning and disinfecting transport devices must be established:
  - Transportation carts and/or containers should be cleaned between uses.
  - Carts should be dedicated for transport of clean/sterile items.

- ❖ Clean or sterile medical/surgical supplies should be protected from contamination, damage, or loss during transport.

- ❖ Distribution carts must have solid bottoms.

- ❖ Distribution carts should not be left unattended.

- ❖ Develop a system to insure that manufacturers' recommendations for processing must remains with the device to end user and CS/SPD.

1. Key Players:
   a. Materiel Manager
   b. CS/SPD Manager/Director
   c. Finance
   d. Customers
   e. Supply Distribution Manager
2. References:
   a. New Jersey State Regulations:
      i. NJAC 8:43G-8.1(c)
      ii. NJAC 8:43G-8.5(c)5
   b. AAMI Recommended Practice:
      i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"
   c. IAHCSMM "Central Service Technical Manual" Chapter 17
   d. ASHCSP "Training Manual for Central Service Technicians", Chapter 9

VII. Inventory Control

A. Methodology:

- ❖ All systems must meet the facility's needs and minimize the overall cost of acquiring, handling, and maintaining supplies in storage.

B. Instrument Inventory:

❖ Surgical instruments represent an asset that needs to be managed.

- It is recommended that a physical inventory of surgical instruments and devices be performed. Often this will be performed at no cost as a value-added service when a prime-vendor agreement for surgical instruments is negotiated.
- The inventory should be provided on a disk.
- For facilities without prime vendor agreements, knowing tray values and the number of trays can provide a rough instrument inventory value for reference.
- It is essential that the inventory be maintained by amending additions/deletions as they occur.
- The inventory list becomes an important management tool to identify tray contents, costs for replacement and accountability of sets to prevent loss.

C. Administrative Considerations:

❖ Staffing – CS/SPD needs to have sufficient staffing to permit processing of equipment and trays for the OR in a timely manner to avoid case delays and impacting on successful patient outcomes. Monitoring staff productivity will assist in documenting staffing levels. A career ladder should be established to help encourage professional growth and retention of personnel. There is no national standard that is available to assist in developing staffing levels.

❖ Budget – There needs to be adequate dollars for CS/SPD staffing and overtime as needed to support the OR schedule and emergency cases. Monies need to be budgeted for instrument replacement (for lost instruments), repairs, and additional instruments as determined by flash sterilization records and other indicators (i.e., new surgical services). Productivity and volume need to be tracked because increases in either will impact on operational expenses and staffing.

❖ Regulatory impact – Compliance with all regulatory issues regarding employee safety, Blood Borne Pathogens, and Sharps injuries must be ensured.

❖ Develop a joint Peri-Operative/CS/SPD Policy and Procedure that addresses scheduling conflicts. The OR Booking Department needs to be provided with a current equipment/instrument list to prevent scheduling conflicts (i.e., schedules 3 Arthroscopies at 7:30 AM in different rooms but only 2 Arthroscopy sets are available for use).

❖ CS/SPD needs to determine realistic turn around times for limited instrument sets and make sure the OR is aware of the turn-around time. Develop a procedure to communicate the need for quick turn around and involve booking personnel in process (See sample Priority Processing form in Appendix of this document).

- ❖ Some instrument manufacturers will provide instruments and devices (i.e., endoscopic cameras, light cords, and instruments) on a fee-per-use basis. There are advantages to this system because the facility can request any amount of instrumentation and is billed only when the system is used. The instrument manufacturer assumes all responsibility for repairs and additional equipment needs. The facility has the further advantage of up-to-date technology that can be replaced as needed since the equipment is not owned by the facility. This process also encourages standardization of systems which facilitates in-service and processing issues for both the OR and CS/SPD staffs.

D. Patient Care Equipment

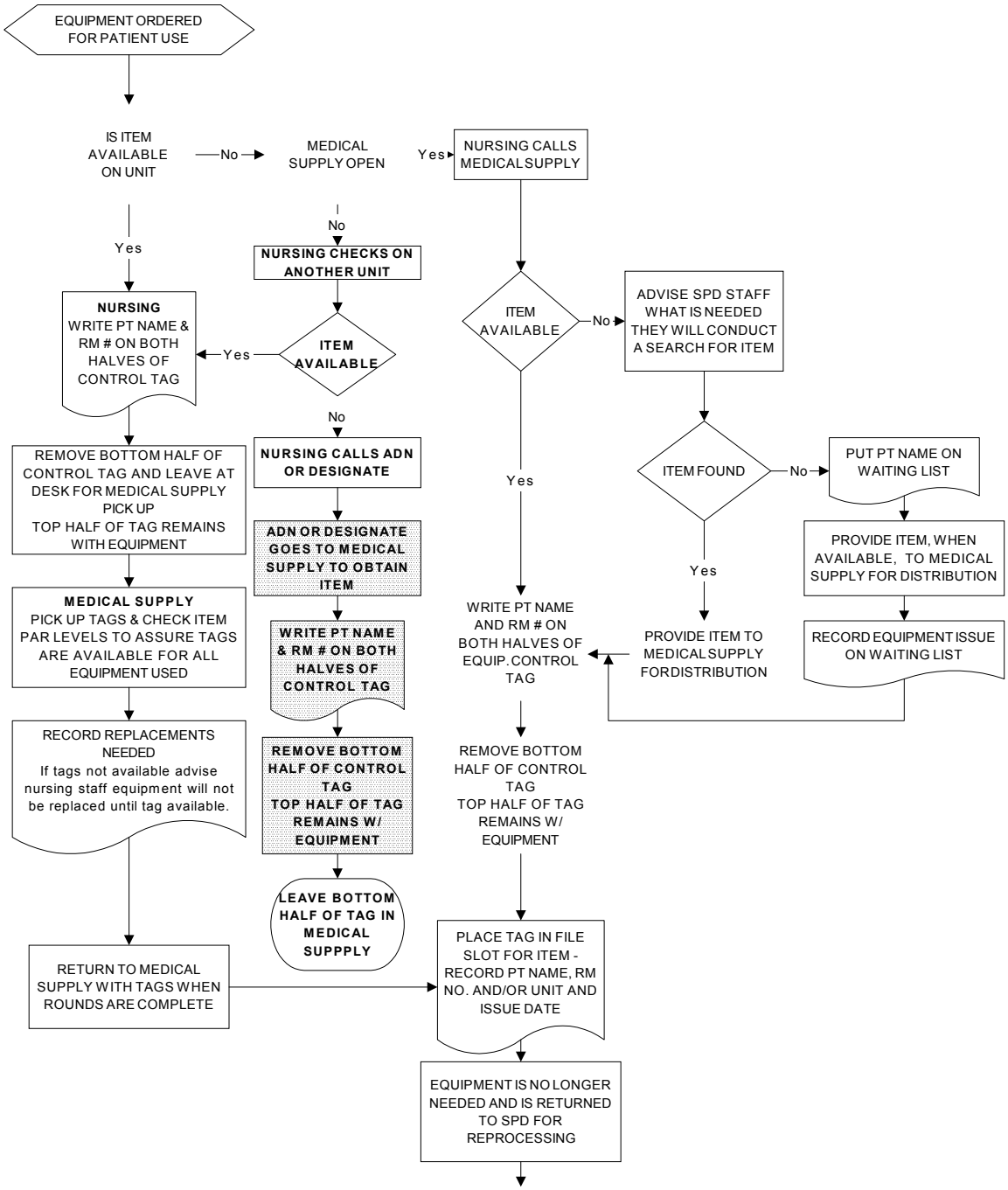
- ❖ All patient care equipment must be inspected by the biomedical department/service prior to being placed into service.

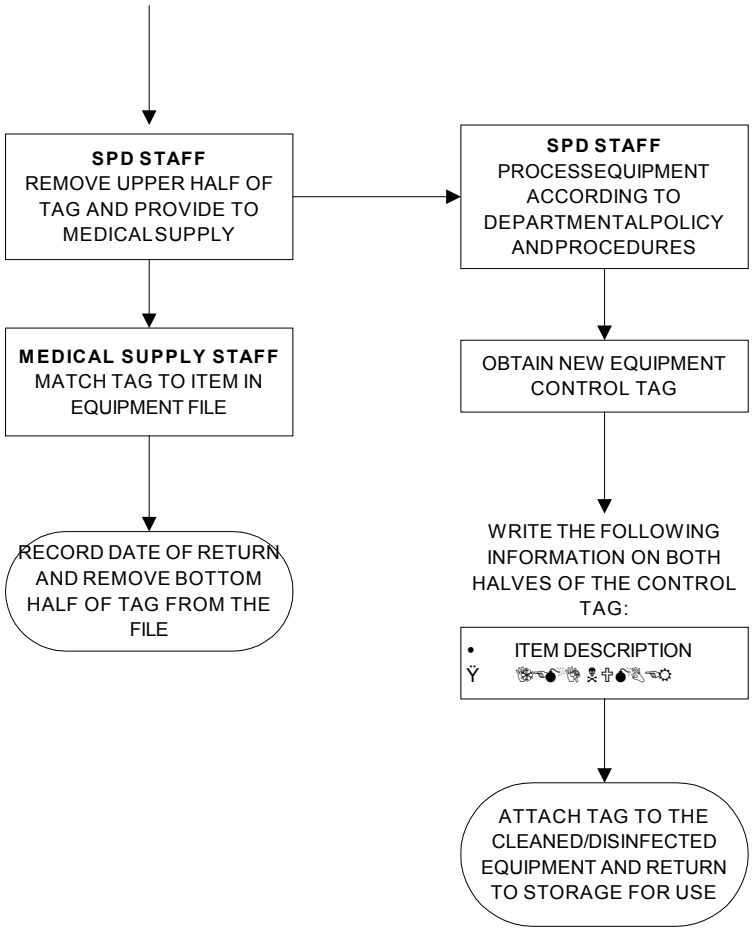
- ❖ The biomedical department is responsible for the Preventative Maintenance (PM) on Patient Care Equipment.

- ❖ Develop Policies/Procedures for tracking patient care equipment from distribution to return:
    - Track equipment to each patient and return after each patient use.
    - Use serial number or inventory control number.

- ❖ Develop Policies and Procedures for handling damaged/broken or malfunctioning equipment:
    - Mechanism to identify malfunction/problem, specifying problem and unit.
    - Decontamination.
    - Send to Bio-Medical Department/Service for evaluation and/or repair.
    - Retention of service/repair records.
        - Use as documentation for replacement of non-repairable equipment.

Equipment Tracking Process




SPD STAFF
REMOVE UPPER HALF OF TAG AND PROVIDE TO MEDICAL SUPPLY
SPD STAFF
PROCESS EQUIPMENT ACCORDING TO DEPARTMENTAL POLICY AND PROCEDURES
MEDICAL SUPPLY STAFF
MATCH TAG TO ITEM IN EQUIPMENT FILE
OBTAIN NEW EQUIPMENT CONTROL TAG
RECORD DATE OF RETURN AND REMOVE BOTTOM HALF OF TAG FROM THE FILE
WRITE THE FOLLOWING INFORMATION ON BOTH HALVES OF THE CONTROL TAG:
• ITEM DESCRIPTION
ATTACH TAG TO THE CLEANED/DISINFECTED EQUIPMENT AND RETURN TO STORAGE FOR USE

VIII. Loaner Instruments/Equipment

E. Lending/Borrowing

- ❖ Develop policies and procedures for consignment or borrowing surgical instrumentation from other healthcare facilities or vendors to include the following:
    - Acquisition
    - Accountability
    - Disposition

F. Acquisition

- ❖ A system should be established to identify each employee's role for handling loaner instrumentation/equipment.
    - Designate people within the healthcare facility that can accept request.
    - Designate people within the healthcare facility that can process and make arrangements with vendors or other healthcare facilities to fill the request.

- ❖ Designate people responsible for transport of instrumentation/equipment to central service.

- ❖ Develop a communication chain for loaner instruments/equipment. When loaner instruments are requested from a company, CS/SPD must be advised of the following**:** (see sample forms in appendix)
    - What is ordered?
    - What is needed?
    - How is it arriving (e.g., Fed-X; sales representative)?
    - When is it arriving?
    - Written manufacturer's recommendations for processing requirements including decontamination, preparation and sterilization (exposure times and temperatures).
    - Where will it be received?
    - When is it needed (time/date of case and surgeon)?
    - How/when will it be returned?

G. Accountability for Non-Hospital Owned Instrumentation/Equipment

- ❖ Includes:
    - Physician owned
    - Manufacturer loaners
    - Borrowed from other institutions
    - Consignment

- ❖ Identify accountability for lost or damaged instruments/equipment.

- ❖ Develop documentation form for the acceptance of instruments from vendors or other healthcare facilities. (See appendix)

- ❖ Non-Hospital owned instrumentation poses issues of financial and liability ramifications. All instruments brought into the institution for a particular case should comply with ASHCSP/IAHCSMM Position Paper on Loaner Instrumentation (See samples in Appendix).

- ❖ The facility should develop a "count sheet" or "packing list" to be used from receipt of the instrumentation to pick-up for return back.
    - Assure complete processing directions are on file for staff reference (including flash sterilization instructions).
    - Assure that in-servicing has been completed for all staff that will be using or handling instruments or equipment.
    - Develop policies and procedures to assure that all loaner instrumentation is cleaned before sterilization and after use before leaving the facility.

- ❖ If instrumentation is lent to/borrowed by another facility, document the process, usually on the Lender's facility's Lend/Borrow form (See Appendix).
    - It is essential that trays/instruments are not released without the consent of the Peri-Operative Director or designate and that all information is communicated, documented and posted.

H. Disposition

- ❖ Develop policy to insure return of items to vendor or other healthcare facility.

IX. Repair of Instruments

- ❖ Inadequate, inconsistent repair/maintenance of surgical instruments/devices can be best addressed by the following actions:
    - Obtain information from several repair/maintenance companies with on-site repair capability.
    - Perform evaluation of services.
    - Determine pricing.
    - Contact clients for references/satisfaction.
    - Obtain contract.
    - Verify loaners available (for cameras/scopes).
    - Consider pay-for-use program for scopes/cameras.
    - Develop schedule for routine maintenance (i.e., sharpening of curettes, gouges, etc).
    - Establish budget line for repairs.

- ❖ Surgical instruments need to be kept in good repair. Develop a policy/procedure to ensure instruments are repaired in a timely manner and that there is an ongoing preventive maintenance program for sharps:

- Identify which department budget will be responsible for the repairs.
- Develop a process for identifying instruments needing repair (i.e., tag instrument - safety pin; repair tags; use colored plastic tags). Make sure all OR and CS/SPD Staff aware of the mechanism being used.
- Decontaminate or follow repair company or manufacturer instructions for return of damaged soiled devices.
- Once identified, the instrument should be removed from the tray and set aside, usually in a predetermined area (i.e., Repair box/bin).
- Identify who is responsible to coordinate the repairs - be specific in responsibilities.
- Before sending instrumentation to other than the original manufacturer, check the manufacturer's warranty (some instruments are warranted for five years and will be repaired/replaced for free during that time).

❖ Select a repair company (jointly between OR, CS/SPD and Materiel Management) and establish a process for sending instruments for repair (or repair on-site which reduces downtime of instruments).
- Identify acceptable turn-around times for instruments being sent out for repair. Replace with back-up instrument supply when possible.
- CS/SPD needs to have a back-up supply of instruments on hand.
- Determine what quantity and whose budget will be billed for replacements.

❖ When repaired instruments are returned, they should be inspected for functionality and then decontaminated before sterilization.

❖ If the instrument needing repair is a one-of-a-kind or is in limited quantity, determine if a loaner needs to be obtained. Make sure to determine with the OR if the tray can be used without the instrument, used on a limited basis, or take the tray out of circulation until the instrument is repaired/replaced:
- Develop a repair log to identify what is out, if a loaner is brought in (identify loaner with serial # and possibly a specific color instrument tape to make retrieval easier) and update when repair complete.

❖ Develop policy/procedure for use of loaner instruments provided by the original equipment manufacturer (OEM) while the facility's instrument is being repaired. Track the loaner device to ensure prompt retrieval for return to the manufacturer:
- One suggestion is to use surgical instrument-marking tape in a color specific to loaner instruments.

❖ When the loaner device is received, the serial number should be noted on a Log Form for Loaner Instruments indicating the date received, name of the instrument, serial number of the device (if known) and tray/set/service.
- When the facility's device returns from repair, the loaner can be easily retrieved by the serial number and tape identification.

- Document on the Log form the date the loaner device was retrieved and returned

1. Key Players:
    a. OR Manager
    b. CS/SPD Manager/Director
    c. Materiel Management
    d. CS/SPD Staff.
2. References:
    a. AORN Recommended Practices: " Preparation of Surgical Instruments & Power Equipment"
    b. IAHCSMM, "Central Service Technician Manual" Chapter 17
    c. New Jersey State Regulations:
        i. NJAC 8:43G-8.11(b)
        ii. NJAC 8:43G-8.10

X. Automated Documentation Systems

❖ There are a number of automated systems to manage the instrument processing process, such as instrument tracking systems, sterilizer documentation systems, computerized count sheet programs and OR scheduling systems to name a few.

❖ Any system must be evaluated for an institution's requirements and must include:

- Compatibility with IT&S
- Costs relating to the following:
    - Basic system
    - Upgrades
    - Additional stations
    - Wiring
    - Education time
        1. What is included
            a. On-site
            b. Off-site
        2. Time frames allotted
    - Licensing agreement
    - Technical support
    - Implementation time frame
        1. Number of hours from company
            a. Additional time charges
        2. Facility man hours required
- Number of FTE's needed to support the system
- Evaluation of system
    IX. User friendly
    X. Data retrieval available
    XI. Ease of making changes

XI. Linen Processing

A. Develop Standards/Expectations for linen supplies used by CS/SPD

❖ Set par levels for each type of linen product required on a daily basis – gowns, wrappers, drapes, towels etc.
- Establishing inventory levels and maintaining them requires the cooperation of suppliers and users.

❖ Develop a system to notify linen services of discrepancies

❖ Delivery specifications to include but not limited to
- Delinting
- Holes/Tears
- Repair
- Stains
- Reject policy
- Thread wear
- Emergency back-up inventory
- Protection during delivery

❖ New linen needs to be laundered before use.

❖ Determine if a back up of paper products will be necessary for emergencies

1. Key Players:
   a. CS/SPD Manager/Director
   b. Linen Services Manager/Director
   c. CS/SPD Staff
2. References:
   a. AAMI Recommended Practice:
      i. ST65 – "Processing of Reusable Surgical Textiles for use in Healthcare Facilities" 2000
   b. OSHA (29CFR) 1910.1030
   c. New Jersey State Regulations:
      i. NJAC 8:43G-8.7(c)

B. Inspection

❖ Develop policies/procedures that define acceptable level of quality the facility wishes to maintain.
- Include how unacceptable items will be handled.
- Include proper rotation of stock.

❖ Using the quality standards established, inspect each linen product before use, looking for:
- Stains
- Residue
- Holes/Tears
- Chemical/Thermal Damage
- Lint/Debris

❖ If using a tracking system, scan or mark item as received.

1. Key Players:
    a. Linen Services Manager/Director
    b. CS/SPD Manager/Director
    c. Peri-Operative Manager/Director
    d. CS/SPD Technicians
2. References:
    a. AAMI Recommended Practices:
        i. ST65 – "Processing of Reusable Surgical Textiles for use in Health Care Facilities" 2000
    b. OSHA (29CFR) 1910.1030
    c. AORN Recommended Practices, "Surgical Attire" "Gowns and Drapes".

C. Repair

❖ Holes/Tears/Cuts
- Use heat-sealed patches.
    - Use vulcanized material.
    - Durable
    - Allow for effective sterilization.
    - Applied according to manufacturer's instructions or a validated process.
- No sewing patches or cross-stitching.

❖ All items that have been repaired need to be carefully inspected to assure area has been correctly repaired.

1. Key Players:
    a. CS/SPD Manager/Director
    b. Linen Services Manager/Director
    c. CS/SPD Technicians

D. Rewash

❖ Elect to request because of:
- Stains
- Debris
- Residue (Detergent and/or bleach)

❖ Counts as an additional life cycle for the item

❖ Assure items are replaced when sent for rewash to avoid shortages.

1. Key Players:
    a. CS/SPD Manager/Director
    b. CS/SPD Technician
2. References:
    a. AAMI Recommended Practice:
        i. ST65 – "Processing of Reusable Surgical Textiles for use in Health Care Facilities" 2000

E. Preparation/Packaging/Storage

❖ Physical Environment
- Space allocation should be based on the processes and responsibilities of linen handling. Based on your specific responsibilities, the following equipment may be needed:
    - Light and work tables
    - Transport carts
    - Patch Machine
    - Bins for rewash; repair and discard
- If responsible for repairs and/or delinting (except for towels), a separate room is required
- Recommended temperature: controlled and monitored to a range between $20^{o}C$ – $23^{o}C$ ($68^{o}F$ – $73^{o}F$).
- Relative humidity to be maintained and monitored at $30^{\%}$-$60^{\%}$.
- 10 air exchanges per hour will minimize lint particles in the air.

❖ Traffic should be restricted to authorized personnel only. Controlled best with walls or partitions to separate functions

❖ Develop policies/procedures that bring consistency to how products are wrapped each and every time.
- Manufacturer's instructions for use should be the basis of the packaging policies and procedures in order to achieve successful sterilization, maintain sterility until opened, and provide for the removal of the contents without contamination.

❖ CS/SPSD staff assigned to linen processing should follow policies/procedures for cleaning table surfaces at the end of each shift, and shelving and carts on a scheduled basis.

1. Key Players:
    a. CS/SPD Manager/Director
    b. Plant Engineering Manager/Director
    c. Infection Control Coordinator
    d. CS/SPD Technicians
2. References:
    a. New Jersey State Regulations:
        i. NJAC 8:43G-8.7(c)
    b. AAMI Recommended Practice:
        i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance"

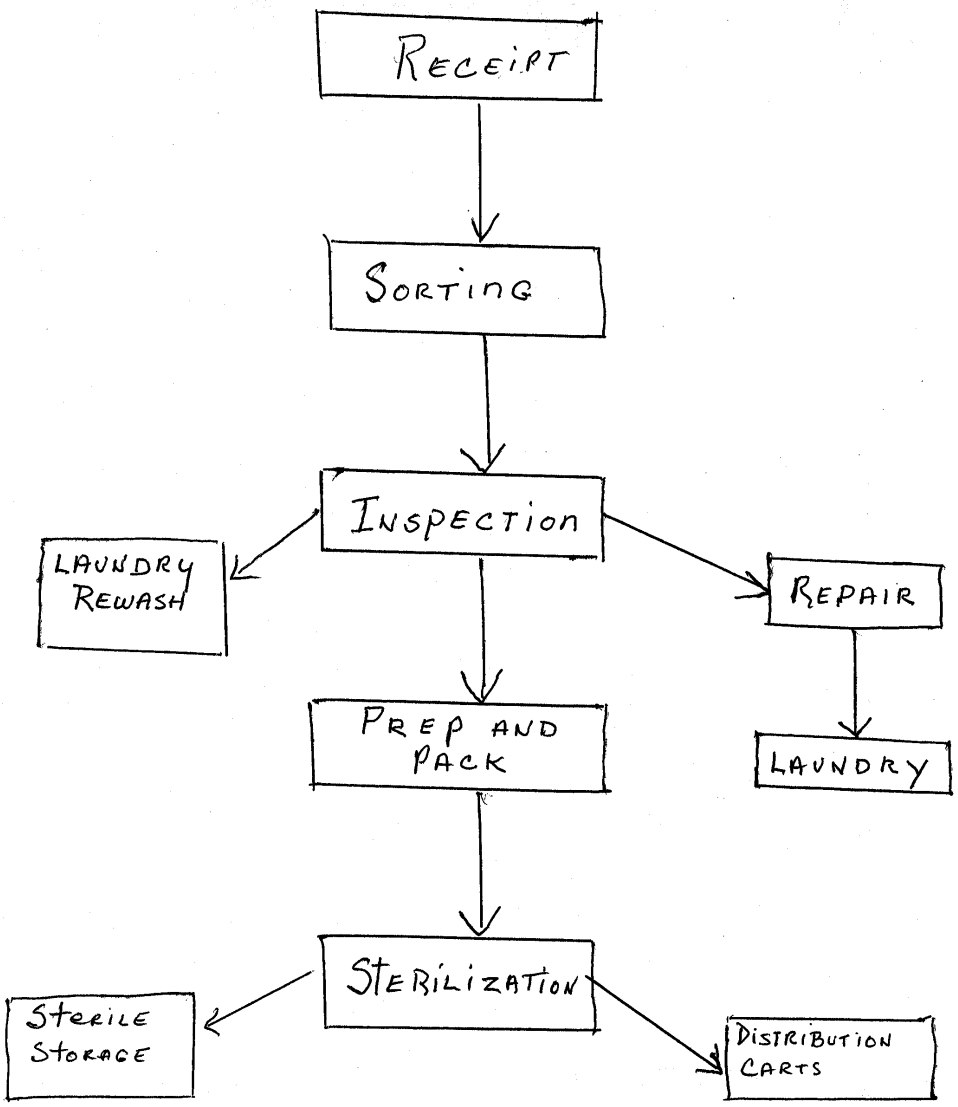
F. Training

❖ Training is based on procedural responsibilities and may include:

- Principles and methods of linen processing.
- Principles and methods of Infection Control.
- Procedures for sorting, inspecting, folding and preparing surgical packs.
- Sterilization methods.

1. Key Players:
    a. CS/SPD Manager/Director
    b. In-service Education Department
    c. Human Resource Department
    d. CS/SPD Staff
2. References:
    a. AAMI Recommended Practice:
        i. ST65: "Processing of Reusable Surgical Textiles for use in Healthcare Facilities" 2000
    b. OSHA (29 CFR) 1910.0130
    c. IAHCSMM Central Service Technical Training Manual, Chapter 13

Work Flow of Linen Processing



XII. Off-Site Processing

A. Soiled Instrument Transportation

- ❖ Coordination between the institution and reprocessing facility is paramount in developing policies and procedures for instrument shipment.

- ❖ Develop polices and procedures for the transportation of soiled instruments to an off-site processing facility:
    - Transporting soiled instruments:
        - o Soiled instruments, which cannot be cleaned or disinfected due to the lack of functional CS/SPD facilities, may be transported only if they are properly contained in a sealed rigid container:
            1. Develop criteria for transport container.
            2. Develop preconditioning standards (i.e., moisture foam or gel) for instruments prior to and during transport.
        - o Training of transport personnel which shall include but not limited to:
            1. Handling
            2. Emergency situations
    - Sending clean instruments for sterilization only:
        - o The sending facility must notify the receiving facility that the transport is underway and the estimated return date/time.
        - o All items slated for transport must be properly cleaned/decontaminated when possible and placed in a sealed rigid container prior to transport.
        - o If the facility decides to pre-package cleaned instruments prior to shipment for sterilization, then all appropriate internal/external indicators must be in place.
            1. Packaging must be compatible with the sterilization process.
        - o Policies and procedures for cleaning, disinfection and processing all items to be transported shall be based on manufacturer's recommendation.
        - o The major exception to pre-cleaning instruments prior to shipment for reprocessing and/or repair is regarding shipment of scopes that have failed a leak test.

            1. Key Players:
                a. CS/SPD Manager/Director (Processing Facility)
                b. CS/SPD Manager/Director (Sending Facility)
                c. Transportation Department
                d. CS/SPD Staff (Both Facilities)
                e. Infection Control
            2. References:
                a. AAMI Recommended Practices:
                    i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings."
                b. New Jersey State Regulations:
                    i. NJAC 8:43G-8.5(c)1, 2, 3

B. Processing

- ❖ Receiving facility must have the following:
    - For pre-packaged instruments, the receiving facility must inspect all packages and pouches for abrasions, tears or damage of any kind prior to beginning the sterilization process.
    - The receiving facility shall appropriately label for outdates or event related sterilization.
    - All load and processing records should be maintained at the processing facility for a period agreed to by risk management of both facilities.
    - A recall system shall be established to notify the off-site facility of a positive biological result.

- ❖ Policies for processing instruments by ethylene oxide (EtO) shall be established and include the following.
    - Items received from any department which must, (by manufacturer's recommendation), be processed by EtO sterilization, shall be transported off-site to the nearest facility having the license and capabilities accordingly, provided that the sending facility has no capabilities for EtO.
    - The sending facility shall have a written agreement for such services.

- ❖ CS/SPD personnel must inspect all items being returned from an out-sourced venue for the following:
    - The items are properly wrapped.
    - The items are appropriately labeled.
    - The items are appropriately contained in plastic.
    - External and internal indicators are intact.
    - External indicator autoclave tape is intact.
    - Packages have no tears or abrasions.
    - Rigid transport container is locked or sealed.

- ❖ All items received back from an out-sourced venue must be properly logged with verification of the log (See Appendix)

C. Receipt of Finished Product

- ❖ Sending Facility must have:
    - Policies for receiving finished product from an off-site processor.
    - The facility must inspect all packages and pouches for abrasions, tears or damage of any kind prior to beginning the sterilization process.
    - The receiving facility will then notify the sender that the load(s) is(are) ready for pick-up by authorized personnel.
    - Only official facility personnel may transport items.

- ❖ All sterile items being returned to sender must be wrapped and placed in a sterilization-maintenance/dust cover large enough to accommodate the item.
    - This might include large clear and clean plastic trash bags, which may be utilized only if sterilization maintenance/dust covers are not available.

- ❖ It shall be the responsibility of the receiving department to inspect all packages returned for any kind of damage prior to use. Although items or packages might show outdates or an event related sterilization label, this inspection is most important due to any incident that might occur in transit.

1. Key Players:
    a. CS/SPD Manager/Director (Reprocessing Facility)
    b. CS/SPD Manager/Director (Sending Facility)
    c. Staff (Both Facilities)
    d. Transportation Staff
    e. Infection Control
2. References:
    a. AAMI Recommended Practices:
        i. ST46 – "Good Hospital Practice: Steam Sterilization and Sterility Assurance."
        ii. ST41 – "Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance."
    b. New Jersey State Regulations:
        i. NJAC 8:43G-8.5(c)4, 5

XIII. Administrative Considerations

A. Training

- ❖ It is essential that each employee receive standardized departmental orientation, which is documented and contains the following components:
    - Dress Code
    - Attendance Expectations (time, requests, call-in)
    - Departmental Policies
    - PPE
    - Work Flow
    - Institutional Tour
    - Staff Introductions
    - Departmental Hazards
        - o High-level Disinfectants
        - o EtO
        - o Steam under Pressure
        - o Noise Hazards
        - o Chemical Sterilants

B. On the Job Training

- ❖ This training should include at a minimum the following components (each step should be expanded to include the key components of the process):
    - Review of policies and procedures.
    - Compliance with the device manufacturer's written instructions for cleaning, packaging and sterilization.
    - Identification of all regulatory issues and compliance.
    - Basic infection control and microbiology.
    - Intensive Decontamination methodologies, including selection and use of proper chemicals and cleaning methodologies.
    - Principles of instrument identification, testing and assembly into sets.
    - Use of appropriate chemical and biological indicators specific to the sterilization process selected.
    - Use of preceptors throughout the duration of the orientation process.
    - Return demonstrations to validate competency.

C. Continuing Training

- ❖ When new procedures and/or changes occur, an in-service should be done and documented to assure all staff have the necessary information.

- ❖ Staff meetings used for education should be documented and provided to all staff.

- ❖ The use of infection control practitioners, sales representatives, OR service leaders, surgical instrument manufacturer's catalogs and professional journals can be used to assist in the educational process.
- ❖ A good way to educate OR/CS/SPD staff is through use of a task force for instrument and process issues.

- ❖ Weekly/monthly in-services are essential. In the beginning, the meetings will probably be weekly then move on to monthly:
    - Alternate the location - OR/CS/SPD Neutral.
    - Hold meetings to time frames established.
    - Set topics (agenda) and keep to it.

- ❖ Cross training of OR/CS/SPD Staff is recommended to improve the communications between the departments:
    - Should be started as part of orientation for personnel (both OR and CS/SPD).
    - Should include a tour of the respective departments.
    - Assign personnel to respective departments for (minimally) a full day.

- ❖ Continuing education programs and courses provided by professional associations should be encouraged by management to insure that staff keeps current with the changes in regulations, technology, and materiel management.
    - Continuing Education Credits are required for maintaining manager and technician certifications.

- ❖ It is important to encourage staff to get involved with their local or national professional associations.
    - The experience will build pride, self-esteem, and leadership.

D. Competency

- ❖ Competencies should be developed for all key processes in the department.
    - Each employee should be required to meet the competency level each year.
        - Confirm competency with oral/written test and/or observation as identified

- ❖ Competencies should be focused on activities falling into one of the following categories:
    - High Risk
    - High Volume
    - Prone to Error
    - Identified Problem Areas

E. Process Improvement

- ❖ The CS/SPD Manager/Director should be an active member of the facility's Process Improvement & Infection Control committees.

- ❖ Develop an OR/CS/SPD CQI/Process Improvement Committee
    - Committee membership should include staff representation from both departments and all shifts.
    - Co-chairs should be representative from both departments.
    - Identify an administrative liaison for support.
    - Identify tools to measure issues with current processes (i.e., Instrument survey, case cart accountability forms, flash documents, etc.).
    - Prioritize process improvement initiatives based upon their impact on patient care and customer satisfaction.
    - In the beginning, try to select an issue that is not complex and will result in noticeable change and/or improvement so that team members are not frustrated.
        - For example – development of a back-up instrument cart to provide a supply of back-up instruments, thereby preventing case delays and opening entire sets for needed instruments.
        - Communication issues being resolved by walkie-talkies or separate "hot line" for OR.

- Focus on the process – not the people.
  - Personality issues and turf wars – This can be the demise of effective communications between the departments.
  - Much is dependent on the educational levels of management and staff of each department.
  - The length of service of both department managers may be an asset or liability - address these "turf" issues up front.
  - Prior experiences with each department play a large role to resolve perceived "bad" experiences.
- Utilize a CQI approach to resolving issues - don't assign blame - look for realistic solutions, which may include compromise on both sides!

❖ CS/SPD Manager reviews and oversees high-level disinfection and sterilization practices for the facility.

F. Hospital Purchasing Policy

❖ CS/SPD Manager/Director must be included in the pre-purchase decision making for:
- Processing equipment
- Instruments/devices requiring reprocessing

❖ Develop a policy and procedure that is to be followed by all departments with regards to notification of CS/SPD of new devices being considered that require cleaning, disinfection and/or sterilization.

❖ Develop a policy regarding reuse of single-use medical devices
- In-House reprocessing
- Third Party reprocessors
  1. Key Players:
     a. Processing Manager
     b. Administration
     c. Operating Room Management
     d. CS/SPD & OR Staff
     e. Materiel Management
     f. Vendor
     g. Surgeon
     h. Infection Control
     i. Risk Management
     j. Staff Development
     k. Radiology
     l. Respiratory Therapy
     m. Cardiac-Cath Lab
     n. Endoscopy
     o. All other user departments
     p. Patient Advocate
     q. Finance
  2. References:

a. AAMI Recommended Practice:
    i. TIR12 – "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."
b. FDA "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties or Hospitals", Aug 14, 2000
c. IAHCSMM "Central Service Technical Manual", Chapter 14
d. ASHCSP "Training Manual for Central Service Technicians"

G. Environmental Sanitation

❖ Policies for housekeeping should specify areas to be cleaned, frequency of cleaning, chemicals to be used, employee health concerns, and designate who is responsible. These policies should include:
- Care of environmental surfaces, such as floors, walls, counter tops, sinks.
- Cleaning of processing equipment.
- Use of protective attire (Gown, Hair Cover, Shoe Cover, Mask, Gloves, Eye Protection).
- Use of specific utensils such as hand brushes:
    - Develop procedures for care of reusable brushes.

❖ Environmental Services has the responsibility of reducing the bio-burden in CS/SPD.
- Meet with Infection Control and Environmental Services to develop cleaning protocols for department; develop rationale for 7-day cleaning schedule.
- Determine which departments are responsible for specialty cleaning (i.e., vents); develop schedule.
- Develop schedule where cleaning is done in hourly segments (i.e., on weekends), rather than entire area at once.

❖ Maintenance of environmental surfaces and plumbing is a function of Plant Operations and work orders should go through a designated employee and records maintained.

❖ The pest control program should include:
- A logbook with all pesticides used within the department.
- A logbook for staff to identify the location of activity within the department.
- Maintenance work orders to seal openings, repair water leaks or eliminate potential harborage areas.

❖ Policies and procedures must be established for the collection, storage, and disposal of Regulated Medical Waste, Solid Waste, and Recyclable Waste.

1. Key Players:
    a. CS/SPD Manager/Director
    b. Infection Control
    c. Engineering
    d. CS/SPD Staff
    e. Pest Control Operator
2. References:
    a. AAMI Recommended Practices:
        i. ST35 – "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Non-Clinical Settings"
    b. ASHCSP "Training Manual for Central Service Technicians"
    c. IAHCSMM "Central Service Technical Training Manual," 5th Edition

APPENDIX

Automated Documentation Tracking Systems

1. **Materiel Management Microsystems, Inc**.
   1031 East Circle Drive
   Milwaukee, WI 53217
   Phone: (262) 240-9900
   www.mmmicrosystems.com

Sterile Processing Microsystem (SPM) is a comprehensive asset management computer system. Using bar code technology, SPM tracks instrument sets and equipment throughout the processing cycle. Among its many functions, SPM allows the user to monitor employee productivity levels, track instrument replacements and repairs, identify sterilizer-set incompatibility, view instrument set usage rates, view total value of instrument and equipment inventory, print updated count sheets and numerous reports which provide solutions to staffing levels, productivity, inventory allocation and financial status.

2. **3M Health Care**
   15 Henderson Drive
   West Caldwell, NJ 07006-6689
   Phone: (973) 575-2042
   FAX: (973) 575-2678
   RKS system Catalog # 1213

Software database product for maintaining sterilization assurance and related records. Replaces traditional paper forms, log books, and envelopes.

3. **Rosebud Solutions**
   411 East Washington Street
   Ann Arbor, MI 48104
   Phone: (888) 980-8255
   FAX: (734) 996-2069

Tray Master is a complete management system for sterile processing of instruments and trays. The technician uses a wireless palm-top scanner to document all tray activity such as: decontamination, packing, sterilizing, stocking, issuing, and returning. Users have the option to define sterilization settings. You can specify minimum, maximum, and current quantities for each tray type in each storage location. Use pictures of completed trays and individual instruments to help technicians pack trays accurately.

4. Census Technologies, Inc.

113 Seaboard Lane
Suite B200
Franklin, TN 37067
Phone: (615) 963-3872
FAX: (615) 963-3847

CENSIS© Technologies, Inc. harnesses patented laser inscripting methods coupled with state of the art scanners and proprietary Internet-based software concerned with managing expensive surgical inventories. CENSIS© provides the only system that can accurately and efficiently measure the utility of individual surgical instruments and also the containers they reside in. It provides management and staff with the tools to optimize inventories, monitor productivity and enhance training, evaluation and quality assurance.

5. Healthcare Systems Management, Inc

95 Old Short Hills Road
West Orange, NJ 07052
Phone: 973-322-0296
FAX: (973-322-4217)
Email: contactus@htmtrilogy.com

Trilogytm is an integrated state of the art computer assisted *Training/Testing/Tracking* system. Its interactive multimedia productivity software uniquely combines self-paced, self-testing programs of mission critical training, which encompasses hundreds of interactive exercises with unlimited competency test questions that lead to certification. The tracking system provides Real-Time instructional tools customized according to client needs. Count sheets and Tray Sets are created for individual surgical procedures that also highlight surgeon preferences, sterilization practices, reprocessing guidelines, decontamination procedures and surgical services procedures as identified by user requesters. The instrument and tray update library allows the creation of thousands of additional instruments and images to be integrated into yet the most user-friendly and efficient tracking software available. This system meets the educational needs of the OR and sterile processors by its unique software that permits downloading of digital photos of all instrumentation. In addition, procedures can be downloaded for in-services, competency testing and reminders.

6. Getinge / Castle Inc.
1777 East Henrietta Road
Rochester, NY 14623-3133
Phone: (800) 475-9040 ext. 5701

T-DOC stands for TOTAL DOCUMENTATION. It is the fast and easy way to collect, organize, analyze and archive sterile processing and mobile equipment data. Bar code technology lets you know exactly where all of your goods are, all the time.

- Hand-held scanner records information and stores it electronically.
- Easy to read screen display lets you view and manage information you've never accessed before.
- Available on-line connection facilitates off-site monitoring, archiving, system upgrades and service diagnostics.

OFF-SITE PROCESSING LOG

The department of CS/SPD hereby attests that all out-sourced items logged below have been received in proper condition (wrapped, sealed, in plastic) with all appropriate labels and tape intact. Also, the sterilizer tape and biological testing results have accompanied all items returned from the out-sourced venue.
This form shall be maintained according to State and/or Federal regulations.

Date Sent	Item No.	Description	Sent to	Date Received	Initials