iii. Identification of data sources, data collection methods, and data collection personnel;

iv. Selection of appropriate statistical methods of measurement;

v. Establishment of an attack rate. An attack rate is defined as the total number of people who show infection from the total numbers of people exposed to the infection; and

vi. Preparation and distribution of conclusionary reports to appropriate quality assurance personnel and departments involved in the study;

2. Methods for the prevention and control of nosocomial infections shall be implemented and based on the most recently published guidelines from the Centers for Disease Control and Prevention as well as the recommendations from the Hospital Infection Control Practices Advisory Committee (that is, HICPAC), and any amendments or supplements thereto, incorporated herein by reference, as follows:

i. Guidelines for Prevention of Catheter–Associated Urinary Tract Infections, PB84–923402;

ii. Guidelines for Prevention of Intravascular Device–Related Infections, PB97–130074;

iii. Guidelines for Prevention of Surgical Wound Infections, PB85–923403;

iv. Guidelines for Prevention and Control of Nosocomial Pneumonia, PB95–176970;

v. Guidelines for Handwashing and Hospital Environmental Control, PB85–923404;

vi. Guidelines for Infection Control in Hospital Personnel CDC, PB99–105454;

vii. Guidelines for Isolation Precautions in Hospitals (Infection Control and Hospital Epidemiology 1996; 17:53–80 and the American Journal of Infection Control 1996; 24:24–52);

viii. Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis In Health Care Facilities (Morbidity and Mortality Weekly Report 1994; 43–11–22); and

ix. Hospital Infection Control Practices Advisory Committee Recommendations for Preventing the Spread of Vancomycin Resistance;

3. The guidelines listed in (b)2 above are available from the National Technical Information Service (NTIS) by calling 1–800–553–6847 or writing the NTIS, 5285 Port Royal Road, Springfield, Virginia 22161. The complete set of the seven guidelines for the Prevention and Control of Nosocomial Infections are listed under the publication number: PB86133022. Further information is available on the Centers for Disease Control and Prevention/National Center of Infectious Diseases' web site at: http://www.cdc.gov/ncidod/hip. The HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance is available on CDC web site at: http://www.cdc.gov/ncidod/vancom.htm;

4. An exception to the use of the guidelines referenced in (b)2 above is permitted, provided there is an infection control rationale which meets minimum acceptable standards within the industry and which shall be based upon scientific research and epidemiological data. (Example: CDC, Morbidity and Mortality Weekly Report (MMWR));

5. Review, at least every three years, of the hospital's policies and procedures related to infection control, including, but not limited to standard precautions/isolation of infected patients, aseptic technique, employee health, and staff training;

6. Identification and reporting of communicable diseases existing throughout the hospital, through information obtained from the clinical laboratory, medical records, and the medical staff, as specified in N.J.A.C. 8:57–1, Communicable diseases, also known as Chapter II of the State Sanitary Code; and

7. Identification and reporting of HIV/AIDS existing throughout the hospital, as specified in N.J.A.C. 8:57–2.7, Reporting of acquired immunodeficiency syndrome and infection with human immunodeficiency virus.

(c) The following concern infection prevention and control responsibility:

1. Orientation for all new employees shall include instruction on infection control practices related to blood and other bodily fluid precautions, education on safe isolation practices for infected patients, tuberculosis education, and use of protective vaccines. Additional infection control orientation shall focus on the employees' specific areas of service.

2. The infection control professional shall coordinate educational programs to address specific infection control problems.

3. The infection control professional shall develop policies and procedures to educate employees and patients on latex allergy management, in coordination with the hospital's employee health department.

4. The infection control professional shall report problems, data, and relevant recommendations to staff in the quality improvement program, nursing service, administration, and the medical department, and shall ensure corrective action.

5. A system of infection control and isolation procedures, including Universal/Standard Precautions, shall be developed and implemented using criteria which meet or exceed the criteria established by the Centers for Disease Control and Prevention and Occupational Safety and

Health Administration Publication, "29 CFR 1910030 Bloodborne Pathogens."

(d) Between October 1, or earlier if the vaccination is available, and February 1 of every year, provided a patient's medical condition permits, every patient aged 65 or older shall be provided the opportunity to receive vaccination against influenza, in accordance with the recommendation of the Advisory Committee on Immunization Practices of the Centers for Disease Control in effect at the time, incorporated herein by reference. Receipt of the vaccination shall be documented on the patient's chart and made a part of the patient's permanent hospital record. Prior to administration of the vaccination, diligence should be exercised to determine whether the patient has already received the influenza vaccination for the year in question.

1. Centers for Disease Control publications can be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402

(e) As soon as a patient's medical condition permits, every patient aged 65 years or older shall be provided the opportunity to receive vaccination against pneumococcal disease, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control in effect at the time, incorporated herein by reference. Receipt of the vaccination shall be documented on the patient's chart and made a part of the patient's permanent hospital record. Prior to administration of the vaccination, diligence should be exercised to determine whether the patient has received the pneumococcal vaccination within the preceding 10 years. Centers for Disease Control publications can be obtained from the address in (c)1 above.

(f) Patients refusing either or both the influenza and/or pneumococcal vaccine(s) shall be requested to sign a form indicating that the vaccine was offered, but refused. The form shall contain all relevant patient identification information. In the event the patient refuses to sign the form, the form shall so indicate. The refusal shall be documented on the patient's chart and made part of the patient's permanent hospital record. The refusal form shall also become a part of the patient's permanent hospital record.

(g) Hospitals shall collect data regarding patient influenza and pneumococcal immunization and shall report that data to the Department on an annual basis, beginning July 1, 2000, for year 1999 data. The data shall be limited to the number of patients aged 65 and older receiving the influenza vaccine and the number of patients aged 65 and older receiving the pneumococcal vaccine.

Amended by R.2001 d.287, effective August 20, 2001.
See: 32 N.J.R. 4073(a), 33 N.J.R. 2893(a).

Deleted former (a); recodified former (b) as new (a); inserted new (b) and (c); and recodified former (c) through (f) as new (d) through (g).

8:43H-20.3 Environmental aspects of infection control

(a) Disinfection and sterilization of patient care items or equipment shall be implemented as follows:

1. Critical items, that is, objects that enter sterile tissue or the vascular system, shall be sterilized by a process that can demonstrate a kill rate of 10^6.

2. Semicritical items, that is, objects that come in contact with mucous membranes or with skin that is not intact, require high level disinfection or intermediate level disinfection; at a minimum, the disinfectant shall inactivate Mycobacterium Tuberculosis.

3. Noncritical items that come in contact with intact skin but not with mucous membranes require low level disinfection; emphasis shall be placed on cleaning of appropriate surfaces.

(b) Methods for processing reusable medical devices shall conform with the following standards; if revised or later editions are in effect, they are incorporated herein by reference:

1. The Association for the Advancement of Medical Instrumentation (AAMI) requirements for good hospital practice steam sterilization and sterility assurance, AAMI, St (Standard) 46, Steam Sterilization and Sterility Assurance, 3rd Edition, 1993, AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201; and

2. The Association for the Advancement of Medical Instrumentation (AAMI) requirements for safe use and handling of gultaraldehyde-based products in health care facilities, AAMI, St. 58, Safe Handling and Use of Gultaraldehyde Based Products in Health Care Facilities, 1996.

(c) Single-use items shall be reused or reprocessed only if the manufacturer provides written documentation of validation of processes related to reuse or reprocessing, or if the hospital has scientific validation of the safety of reprocessing and reuse of the item. Procedures for reprocessing and reuse shall conform with these recommendations or validation studies.

1. The validation studies shall demonstrate that the sterilization process is efficacious, and the integrity of the item is not compromised; the number of reuses that can safely be performed shall be specified.

2. Should the hospital outsource the reprocessing of a single-use item to a third party reprocessor, a certificate of registration with the Food and Drug Administration shall be provided to ensure compliance with good manufacturing practices.