HACKETTSTOWN REGIONAL MEDICAL CENTER
Administrative Policy & Procedure
Novamed Risk Based Medical Equipment Inspection Program

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Effective Date:	**February 2009**	**Policy No:**	**MM16A**
Cross Referenced:		**Origin:**	**Materials Management**
Reviewed Date:	**1/10, 4/12**	**Authority:**	**Chief Financial Officer**
Revised Date:		**Page:**	1 of 3

PURPOSE:

This policy is implemented to ensure that all of the equipment on the medical equipment program gets an inspection at the proper frequency. If the device is not exempt from the medical equipment program, an inspection will be scheduled and performed.

POLICY:

All patient care or patient care related equipment including; therapeutic, monitoring, diagnostic, or analytical equipment will be evaluated for inclusion in the hospital's biomedical equipment management program before it is put into use. The program inclusion criterion evaluates equipment function, clinical application, maintenance requirements and equipment incident history to determine if the device is included in the program.

All equipment, regardless of ownership or purpose, which meets the program inclusion criteria, will be put on the preventative maintenance schedule before it is put into use. Each piece of equipment selected for inclusion in the program will have written performance assurance inspection and maintenance procedures on file in the department. User training programs on medical equipment use are the responsibility of the Nursing Education Department, but will be provided by Biomedical Technology Services on an individual device or departmental basis as needed upon request.

PROCEDURE

Equipment inclusion criteria have been developed to evaluate each piece of equipment in use at the hospital. A numerical value has been assigned to each device type by classifying its equipment function, clinical application and required maintenance. Adding the number from each subgroup yields an Equipment Management Number (EM#) as follows:

EM # = Function # + Application # + Maintenance # + History #

Those devices that have an EM number greater than or equal to 12 are included in the program.

The calculation for Inclusion/Exclusion shall be made as part of the Incoming Equipment Inspection form.

Equipment Function

Equipment, based on its function, is first categorized into one of the four following sub-categories and assigned a risk assessment values as follows:

Classification	Description	Function Value
Therapeutic:	Life Support	10
	Surgical & Intensive Care	9
	Physical Therapy Treatment	8
Diagnostic:	Surgical & ICU Monitoring	7
	Other Physical Monitoring & Diagnostic	6
Analytical:	Analytical Laboratory	5
	Laboratory Accessories	4
	Clinical Equipment Computers & Related	3
Miscellaneous:	Patient Related & Other	2

Physical Risk

Based on the possible consequences to the patient and/or operator in the event of equipment failure or malfunction, equipment is then assigned a risk assessment value as follows:

Classification if a device malfunction could result in:	Risk Value
Patient Death	5
Patient or Operator Injury	4
Inappropriate Therapy or Misdiagnosis	3
No Significant Risk	1

Maintenance Requirements

Based on the type and level of routine maintenance, equipment is then assigned a risk assessment values as follows:

Classification	Description	Maintenance Value
Extensive	Routine Calibration & Part Replacement Required	5
Average	Performance Verification & Safety Testing	3
Minimal	Visual Inspection & Safety Testing	1

Equipment Incident History

The following criteria regarding service history will be considered when evaluating the device type to determine an EM number. Service history information will be reviewed periodically to determine if a device type should be considered for upgrade into or downgrade out of the program. Individual classes of equipment, including model #, will be evaluated for number of failures per year averaged over the past several years. The following table is used to evaluate each device type:

Classification	Average Equipment Failures	History Value
Significant	More than one in 6 months	+2
Moderate	One in 6 - 9 months	+1
Average	One in 9 - 18 months	0
Minimal	One in 18 - 30 months	-1
Insignificant	Less than one in 30 months	-2

Included Devices

All devices with EM # of 12 or greater will be included in the program and scheduled for inspections and preventive maintenance. During the incoming inspection, any new device will be included in the program if the same device type has been previously evaluated and classified for inclusion. If the device has not been previously evaluated a new device classification will be created, it will be evaluated according to the outlined PROCEDURE to produce an EM # and it will be included in the program if appropriate. If it is included, a performance assurance inspection and preventive maintenance PROCEDURE will be written for the new device type.

Maintenance Interval

The maintenance requirement values are also used to determine the interval between the inspection and maintenance procedures for each device type. All devices classified as extensive (characteristic value of 4 or 5) are given a preventive maintenance interval of six months. All devices classified as average or minimal (characteristic values of 3, 2 or 1) are scheduled for inspections annually.

Additionally, devices with an EM # of 15, 16, 17 or 18 will be scheduled for inspection at least semiannually. Devices with an EM # of 19 or 20 will be given an inspection interval of three times per year.

Devices Not Included in the Program

All patient care related equipment including; therapeutic, monitoring, diagnostic, or analytical equipment not included in the program because it did not receive an EM number of 12 or above will still be included in the hospital's biomedical equipment inventory and will be covered on a repair only basis.