Supply Chain Management	**Subject:** New Product Introduction Policy	
	Effective: 01/01/2007 **Revised: 01/08/2007** **Supersedes:** none	**Policy No.**: **Page**: 1 of 9
	Approved by: Henry Ford Health System Executive Administration	

1.0 Philosophy/Purpose:

1.1 Henry Ford Health System is devoted to quality care and has determined that there is a need from a quality and patient safety perspective to establish a formal product evaluation process that will cross disciplines.

1.2 The intent of this policy is to provide a clear and understandable set of rules governing the introduction of products into Henry Ford Health System.

1.3 The purpose of this policy is to provide a process by which all new products, proposed product changes, and product replacements are reviewed and known prior to their use.

2.0 Scope:

2.1 This policy applies to all employees at all business units and Corporate Offices of Henry Ford Health System, including Henry Ford Hospital, Henry Ford Wyandotte Hospital, Henry Ford Bi-County Hospital, Henry Ford West Bloomfield, the Henry Ford Medical Group and Behavioral Health Services and Community Care Services.

2.2 This policy directly applies to vendors that provide services and medical/surgical supplies for HFHS.

3.0 Responsibility:

3.1 Supply Chain Management and staff throughout Henry Ford Health System who deal with vendors and their representatives, will be held accountable to these standards of conduct.

3.2 It is the responsibility of Henry Ford Health System department managers and clinicians to adhere to company policies when committing the System's financial resources for the purchase of goods, services, and equipment.

3.3 HFHS leaders are responsible for communicating these policies to all of their employees and ensuring that they are adhering to these policies.

3.4 Vendors are responsible for understanding and adhering to this policy as it relates to new products they wish HFHS to purchase or utilize on a test, loan, or consignment basis.

4.0 Policy:

4.1 This Policy Statement has been created to:

- 4.1.1 Establish requirements for Vendors seeking to have new products utilized at any HFHS location.
- 4.1.2 Provide guidelines for staff when seeking new goods and services for use in clinical care.
- 4.1.3 Establish a formal evaluation process for patient related products, new equipment, and new clinical technology.
- 4.1.4 Establish guidelines for standardization when possible; evaluate products for their effectiveness, safety, cost effectiveness, and compliance.
- 4.1.5 New equipment and technology will be formally evaluated through a trial process prior to purchase or change.

5.0 Procedure/Requirements:

5.1 Request for New Product

5.1.1 With the permission of the respective HFHS department leader, vendors may inform physician or staff of new products.

5.1.2 Subsequent to product/equipment evaluation, vendor-provided assets shall not be left at a HFHS facility unless a purchase order is issued or approval is given by the respective departmental leader.

5.1.2.1 Under no circumstances will HFHS pay for any product or equipment item that is not supported by an approved HFHS issued Purchase Order.

5.1.2.2 Any invoices submitted to HFHS for payment of such product or equipment items will be immediately returned to the vendor. See the Supply Chain Management Policy.

5.1.2.3 All products if used by HFHS with permission from vendor must adhere to the Consignment/Loan Policy.

5.1.3 HFHS staff must complete a Request for New Product Form (Appendix A) on all new products and forward to the requesting department Clinical Leader or administrator for approval. This form is available on Henry. Once completed and signed by requesting department leader it should be forwarded to the SCM Compliance department.

5.1.4 If this is a new technology the request should go through the New Technology Assessment Committee via Supply Chain Management.

5.1.4.1 New technology is defined as requiring significant individual user training and capital investment by HFHS. An example would be the DaVinci robot.

5.1.5 It is the responsibility of the team member that sponsors a new product to ensure collaboration as appropriate with HFHS' Bio-Medical Department, Information Systems Department, any department that the product crosses over (along continuum of patient care), and Supply Chain Management to ensure compliance with current system/directives.

5.1.5.1 Equipment provided by a vendor for product evaluation must be tested and approved by the HFHS Bio-medical Department prior to the product evaluation.

5.1.6 New products shall be vetted through the respective HFHS Value Analysis Team once they have passed through the evaluation process.

5.1.6.1 The team shall be made-up of representatives from the respective department(s) and a Supply Chain Management representative.

5.2 New One-Time Use Product

5.2.1 Supplies or equipment brought to the facility for one-time use on a specific patient may not have to go through the formal evaluation process.

5.2.1.1 An evaluation form will be completed on these items for future decisions.

5.2.1.2 Any item to be used on a patient will have a signed Consignment/Loan agreement and follow the process stated in the Consignment/Loan Policy.

5.3 Product Evaluations/Trials

5.3.1 All evaluations or trials of supplies or equipment must be arranged through Supply Chain Management Vendor Compliance & Management department.

5.3.2 A Request for New Product Form must be filled out and signed by the Department Chairperson or Administrator in their respective field prior to being submitted.

5.3.2.1 If the Form is marked that the new item will be transported or utilized in the continuous care of the patient across multiple areas or departments, then an interdisciplinary evaluation team needs to be created to evaluate its use beyond the immediate department.

5.3.2.2 This interdisciplinary team should include a member of the Clinical Quality & Safety Department, a physician in the inpatient and/or outpatient setting, an inpatient nurse and/or clinic nurse, an education representative, and other clinicians as needed.

5.3.3 The Product Evaluation Form (Appendix B) will be available on Henry.org for ease and confidentiality and will be sent directly to Supply Chain Management Compliance department.

5.3.3.1 The form is required to be filled out on each patient that the product is used on by several different types of clinicians. i.e. physician, registered nurse, operating room technician, nurse assistant.

5.3.3.2 A physician/surgeon is required to fill one out on every patient that has been impacted by the product/equipment.

5.3.3.3 If the product crosses disciplines it will be necessary for the other disciplines to participate in the evaluation process.

5.3.3.4 The form can be utilized to report any actual or potential concerns, issues, or patient complaints **foreseen** with the product, using the comment section.

5.3.3.5 The forms will be sent to and reviewed by Supply Chain Management Compliance.

5.3.4 Department chairs and management team will be notified when an item is being considered for trial or a new piece of patient care equipment is being evaluated. It is the responsibility of the departmental chair and management team to provide a suitable representative from their discipline to evaluate the product if it will be used in their discipline.

5.3.5 Items and/or equipment will be evaluated for a specific period of time depending on the frequency of its use and interaction with other disciplines, which will be defined by SCM.

5.3.6 If there are any results or comments on the evaluation that could affect patient safety or quality, then the clinical department leader, Supply Chain Management, and/or the Clinical Quality & Safety department will halt the evaluation and investigate the concerns.

5.3.6.1 If there was a direct impact to the patient's care the patient care team should fill out an online Red form in RadicaLogic. The evaluation will be terminated until the members of the evaluation review team, which include Clinical Quality & Safety, have assessed the problem and determined if the cause was directly related to the product.

5.4 Vendor Evaluation Participation

5.4.1 Vendors must provide information on product effectiveness, safety, previous trial results, scientific evidence, and failure modes and effects analysis when available.

5.4.2 Vendors will be required to provide education and demonstrations on initial product use and training for the evaluation period.
5.4.3 It is required that product representatives are certified by their employers to be able to train medical staff on the specified products' use. This requires a statement or certificate from their employer.
5.4.4 Vendors may be required to provide education/demonstrations on several occasions depending on the number of individuals involved in the trial, the level of detail in the training, and during implementation of product use.
5.4.5 Vendors may be asked to be present or available in the department during the first few trials to facilitate safe and effective patient care.
5.4.6 Vendors will provide training competencies for HFHS staff.
5.4.7 Results of the evaluation may be shared with the vendor.
5.4.8 If product has patient safety concerns or problems have been identified the vendor will be contacted immediately.

5.5 Evaluation Results/Selection
5.5.1 SCM will summarize the evaluations and report back to the requesting department.
5.5.2 Justification for potential purchase will be based on the evaluations' effectiveness, ease of use, duration of learning curve, compatibility with other products, safety, and improved patient outcomes and results.
5.5.3 If the requesting department recommends moving forward on the product change, the evaluations will go to the area's Value Analysis Team for further review.
5.5.4 The Value Analysis Team will evaluate the product, review and determine cost/benefit analysis, and make recommendations.
5.5.4.1 The Value Analysis Team will be made up of Supply Chain Management staff, the departmental chair and discipline staff.

5.6 Product Implementation
5.6.1 Define Implementation Process
5.6.1.1 The Value Analysis Team will determine the best implementation process for the particular product
- Facility by facility
- Department by department
- Inpatient vs. Clinics

5.6.1.2 Supply Chain Management will execute the defined plan.
5.6.2 Determine distribution plan
5.6.2.1 The Value Analysis Team will suggest a distribution plan focused on the departmental acceptance & education methods used by the affected areas.
- Place a new product side by side with the current product
- Place a fixed number of products side by side with current product
- Replace existing product with the new product

5.6.3 Communication Plan
5.6.3.1 Supply Chain Management will work with the respective departments to determine a suitable communication plan.
5.6.4 Educate/demonstrate to all staff users

5.6.4.1 Supply Chain Management or the department leader will develop an education plan with assistance from Nursing Education, Clinical Quality & Safety, and medical education.

5.6.4.1.1 Education will be based on the type of change required with the product and using the guidelines provided in the Education Tiers Defined document (Appendix C).

5.6.4.2 Attendance documents will be created to be signed by all staff completing the training. This would include even minimal training (communications) with a sign-off that employees received it.

5.6.4.3 Vendors will supply staff training competencies where necessary.

5.6.5 Feedback on product

5.6.5.1 It is suggested that feedback on the product be continued after implementation, through the Product Evaluation Form on Henry. This is to ensure that the product is just as effective in other departments and to get their feedback.

5.6.5.2 Based on the level of complexity of the product change and at the direction of Supply Chain Management, post -implementation evaluation may need to occur one year after system wide use.

5.6.5.3 Patient safety concerns will be filed on-line with the Red form on RadicaLogic.

6.0 **Compliance Monitors and Audits:**

6.1 Staff Responsibilities

6.1.1 All staff involved with new products are responsible for complying with this policy for patient quality and safety.

6.1.2 Department leaders and chairs are responsible for the evaluation of new products.

6.1.3 Supply Chain Management Compliance department is responsible for tracking the introduction of new products and the continuous monitoring of product evaluations.

6.2 Compliance

6.2.1 The area of Vendor Compliance & Management within the department of Supply Chain Management will investigate any reported violations of this policy.

6.2.2 Staff found not to be in compliance with this policy will be reported to their supervisor for action.

6.2.3 Continuous trended monitoring will take place through this new process.

7.0 **Definitions:**

7.1 *Vendor* is any representative of a manufacturer or company who visits for the purpose of soliciting, marketing, or distributing products or information regarding the use of medications, products, equipment and/or services.

7.2 *Supply Chain Management (SCM)* is Henry Ford Health System's purchasing department.

7.3 *Value Analysis Team:* Clinical common product/equipment/service teams that will coordinate and unify procurement processes across the system.

10.0 References:

10.1 Please refer to the following additional Supply Chain Management policies:

Business Associate Agreement Policy
Consignment/Loan Policy
Emergency Procurement Policy
Supply Chain Management Policy
Vendor Policy and Procedures

APPENDIX A

Henry Ford Health System
Request for New Product Form

Please attach any related literature for this product to this form.

Part 1: Product Information: (to be completed by Person requesting evaluation)	
Product to be evaluated:	
Manufacturer:	Catalog Number:
Person requesting evaluation:	
Facility and Department:	Phone Number:
Person requesting product:	Phone Number:
Product Description and Function:	
Product Use Frequency Per: Day:_____ Week:_____ Month:_____ Year:_____	
Will Product Travel with Patient? ☐ Yes ☐ No	
What departments may be exposed to product: ☐ ER ☐ OR ☐ Clinic ☐ IPD ☐ Interventional Cardiology ☐ Radiology ☐ Rehab ☐ Dialysis ☐ Hemo/Onc	

Part 2: Reason for Request: (to be completed by Person requesting evaluation)		
Reason for request: (Check all boxes that apply).		
☐ Contract Compliance Issue	☐ Savings Opportunity	☐ Single-Use Item
☐ New Technology	☐ Physician's Request/Preference	☐ Supplier Design Change
☐ Safety Requirement	☐ Regulation Requirement	☐ Other:_____
☐ Improves Efficiency	☐ Improves Patient Outcomes	

Currently Used Products or Equipment being used and PeopleSoft Numbers
Supply Chain Management will write in PeopleSoft Number

Product Name	PeopleSoft Number	Product Name	PeopleSoft Number

Part 3: Sales Representative Information: (to be completed by person requesting evaluation)	
Company Name:	Phone number:
Sales Representative:	Phone number:
	Pager number:

Part 4: For Value Analysis Team Use Only	
Old product on Contract: ☐ Yes ☐ No	New product on Contract: ☐ Yes ☐ No
Number used last F/Y:	Projected Use new product for this F/Y:
Old Product Cost (each): $	New Product Cost (each): $
Annualized Cost Impact: $	Annualized Cost Impact: $
Evaluation Request Approved: ☐ Yes ☐ No	If "No" give reason
Further information needed? ☐ Yes ☐ No	If "Yes" referred to:

Disposition of current product	
☐ Addition to current inventory	☐ Replacement to current inventory
☐ Reduces use of an existing product line	☐ Special Order item
☐ Stocked in Materials Management	☐ Stocked in OR inventory
☐ Other:	

Evaluation will be done at: (Check all appropriate boxes below)

Facility	Start Date	Stop Date	Facility	Start Date	Stop Date
☐ HFH			☐ HFBCH		
☐ HFWH			☐ HFWBH		
☐ CHS			☐ HFMG		

Chairperson Signature: **Date:**

Please provide completed form to Supply Chain Management- Compliance – fax number 313-874-9565.

APPENDIX B

Henry Ford Health System
Product Evaluation Form

Date:	**Revenue Center:**	**MRN:**

Facility

☐ HFH ☐ HFBCH ☐ HFMG ☐ HFWBH ☐ HFWH ☐ CHS ☐ Other: _____

Product Information	**Personnel and Procedure**		
Product Name:	**Procedure:**		
Manufacturer:	Evaluator Name:		
Catalog Number:	☐ Evaluator Expert User	☐ Evaluator Novice User	
Product Description as Needed:	**Evaluator Position**		
This product will replace:	☐ Physician	☐ Nurse	☐ Nurse Assistant
Hours of Training on Product:	☐ OR Nurse	☐ Technician	☐ Surgeon
☐ 15 min. < ☐ 30 min. < ☐ 1 hr. < ☐ 1 hr. >	☐ Other: _____		

Please check appropriate box related to the below issues where they apply.	**N/A**	**Very Poor**	**Poor**	**Good**	**Very Good**	**Excellent**
Patient Safety						
Team Member Safety						
Ease of Use						
Infection Control Concerns						
Durability of Product						
Product Effectiveness						
Perceived Impact on Technique or Use During Procedure						
Device Compatibility with Other Products						
Ease of Device Removal (if necessary)						
Packaging						
Patient Satisfaction						
Clinical Outcome						
Adequacy of Training on Product						
Ease of Training on Product						

I believe this product to be: (check only one) ☐ **Clinically Superior** ☐ **Clinically Acceptable** ☐ **Clinically Unacceptable**

If deemed to be Clinically Unacceptable, please write a comment stating why it was not clinically acceptable.

Comments: _____

_____

_____

Additional Comments on any Aspect of the Product: _____

_____

_____

Please Return Form to Supply Chain Management Compliance – fax number 313-874-9565.

APPENDIX C

EDUCATIONAL TIERS FOR NEW PRODUCTS

Education Structure	Definition	Education Strategy	Level of Evaluation
Tier I	• Change- **Minor** to Process, procedure, policy, or product. • Simple product substitution • Change is easily transmissible; concepts are simple • No history of quality problems, risk, or issues	• Staff meeting • UGC • Poster • Flyer • Web Newsletter Easily fits into daily routine with little training.	• Comment Sheet • Product Evaluation Form
Tier II	• Change – **Significant** to policy, procedure, or process, but not all three. • Change affects quality of product; processes used with product, or heighten risk of harm if used incorrectly.	• In-service • Handouts • Job aide (point of service) • Video • Demonstration • Quiz • Self-study material • Web Notification • Skill Check • Skill Practice • Train the Trainer • Product Representative Requires Manpower on the unit.	• Written tests • Skill observation • Attitude/rating scales

Tier III	• Change – **Multifaceted** in policy, procedure, or process.
	• Change involves a learning curve.
	• Concepts are complex.
	• Requires an assurance of staff competency to decrease/eliminate patient risk.
		• Scheduled time for participation
		• Skill Check
		• Skill Practice
		• Test with passing score identified.
		• Test repeated if not successful
		• Train the Trainer
		• Video
		• Web Testing
		• Requires significant manpower.
		  o Scheduling staff
		  o Providing the education
		  o Performing the tracking
			• Surveys/questionnaires
			• Interviews
			• Performance appraisals
			• Audits
			• Incident/variance reports

http://henry.hfhs.org/documents/HFH%20Nursing/Shared_Governance_Councils/Education_Council.pdf