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National Quality Award Application

2010



GLOSSARY

Acronym	Definition	Comments
AB	Advisory Board	1.1a1
AED	Automated External Defibrillator	
ANSI	American National Standards Institute	
APQC	American Productivity and Quality Council	
ASQ	American Society for Quality	
BD	Business Development	Ì
BIC	Best-In-Class	
BSI	British Standards Institute	
Business	A business is responsible for its own strategy, objectives, and financial	
Dusiness	performance – Radiology, Interventional and International/Service are	
	business units	
		I
CAD/CAM	Computer-Aided Design and Manufacturing	
CAO	Chief Administrative Officer	
CAPA	Corrective and Preventative Action	6.2c
CAPAR	Corrective and Preventative Action Request	
CATCSE	Customer Satisfaction Excellence	3.2b2
CCO	Chief Compliance Officer	1.2a1
CDI	Corporate Development and Innovations	1.1a3
CEAB	Compliance & Ethics Advisory Board	1.1a1
CEO	Chief Executive Officer	
CFR	Code of Federal Regulations	
COINS	Communities of Interest	
CMDCAS	Canadian Medical Devices Conformity Assessment System	
CMDR	Canadian Medical Device Regulations	
COG	Cost of Goods	
COINS	Communities of Interest	
CPR	Cardiopulmonary Resuscitation	444
CSAB	Customer Satisfaction Advisory Board	1.1a1
CT	Computed Tomography	
CTSO	Chief Technology and Strategy Officer	2 11 2
CRM	Customer Relationship Management	3.1b2
DFGM	Design for Gross Margin	
DHR	Device History Record	
DOH	Days on Hand	
EB	Executive Board	
EBIT	Earnings Before Interest and Taxes	
EBITDA	Expenses Before Interest, Taxes, Depreciation, and Amortization	
EC	Executive Committee	
EFQM	European Foundation for Quality Management	
EHS	Environmental, Health, and Safety	1.2b1
EHSAB	Environmental, Health, and Safety Advisory Board	1.1a1
EM	Electromechanical	
EMBA	Executive Master of Business Administration	
EPA	Environmental Protection Agency	
ERP	Emergency Response Plan	6.1c
EXPAT	Expatriation	5.2a
FDA	Food and Drug Administration	
117/1	Food, Drug, and Cosmetic	
	TELEBRICA DE LA CONTRACTOR DE LA CONTRAC	1
FDC		6.2h
	Failure Mode and Effects Analysis Failure Reporting Analysis and Corrective Action	6.2b 6.2c

Acronym	Definition	Comments
Function	A department, typically a support department led by an EC member.	
	Corporate Services/CAO and Corporate Compliance are functions.	
CEAD/CECAD		1
GFAB/GFSAB GHX	Global Facilities/Sustainability Advisory Board	
GM	Electronic ordering vendor only available in the U.S. General Manager	
GPO	Group Processing Organization	
GPTW	Great Places to Work	
GPTW	Gleat Places to Work	
HR	Human Resources	
HRAB	Human Resources Advisory Board	1.1a1
IAC	Infrastructure Application Committee	
IEEE	Institute of Electrical and Electronics Engineers	
IFRS	International Financial Reporting Standards	
IMAGES	Identify-Measure-Analyze-Generate-Experiment/Execute-Sustain	
Inorganic	Externally focused efforts relating to business development opportunities	
morganic	outside the company, such as acquisitions or other third-party alliances that	
	strengthen MEDRAD's competitive position, diversify the product	
	portfolio, or provide significant sources of growth for the organization	
INPAT	Inpatriation – non-U.Snative employee working in the U.S.	5.2a
IPO	Internal Posting Opportunity	5.1b
ISO	International Organization for Standardization	
IT	Information Technology	
ITIL	Information Technology Infrastructure Library	
ITSM	Information Technology Service Management	
J-GMP		1
J-GMP JIS	Japanese Good Manufacturing Practices Japanese Industrial Standard	
112	Japanese muusitai Standaru	
KOL	Key Opinion Leaders	3.1a1
LAB	Legal Advisory Board	1.1a1
LEED	Leadership in Energy & Environmental Design	
LSS	Lean Six Sigma	
LT	Leadership Team	
LTIR	Lost Time Incident Rate	
MBG	MEDRAD Benchmark Group	4.1a2
MDD	European Medical Devices Directive	7.142
MEGA	MEDRAD Events and Group Activity	5.2b
MESA	MEDRAD Employee Satisfaction Association	1.1b1
MI	Molecular Imaging	1.101
MMR	MEDRAD Management Review	1.1a1
MR	Magnetic Resonance	1.141
MRM	Marketing Review Meeting	
MSCAR	Material Supplier Corrective Action Request	
MST	Manufacturing Strategy & Technology Department	
MTTR	Mean Time to Repair	
		1
NA	North America	
NPD	New Product Development	
NPS	Net Promoter Score, Satmatrix, published in <u>The Ultimate Question</u> by Reichold	
		1
OEM	Original Equipment Manufacturer	
OIG	Office of the Inspector General	
OPS	Operations	
Organic	Internally-driven product development opportunities focused on new	
	platforms and products that will help grow the company	l

Acronym	Definition	Comments
OTS	On-Time Shipment(s)	
OSHA	Occupational Safety & Health Administration	
OUS	"Outside U.S." indicates non-U.S. approaches or processes	Fig. 3.1-2
PA	Product Analysis	
PAD	Performance Assessment and Development	5.1a3
PADER	Pennsylvania Department of Environmental Resources	3.143
PC	Personal Computer	
PDM	Product Data Management	
PDT	Product Development Team	1.2b1
PE	Performance Excellence	
PEAK	Performance Excellence Award Kudos	
PEC	Performance Excellence Center	P.2c
PETL	Performance Excellence Through Leadership	5.1a
P&L	Profit and Loss	
PLM	Product Lifecycle Management	
PLP	Product Lifecycle Process, encompassing New Product Development and	
	support of existing products	
PM	Performance Management	5.1a3
PRTM	Pittiglio Rabin Todd & McGrath Inc.	
PTA	President's Team Award	
PWC	PriceWaterhouseCoopers	
QSR	Quality System Regulations	
Rationalized	To review all possibilities, eliminate redundancies, and create a	
D 0 D	manageable list of actions	
R&D	Research and Development	
Region	Geographic sales area, with scorecard and P&L targets. North America,	
RF	Europe, Latin America, Japan, Asia-Pacific are regions. Radio Frequency	
SAP	Enterprise Resource Planning software	
SAT	Strategic Action Team	2.1a4
Satmatrix	The company that originated the NPS metric	
SD	Sterile Disposables	
SFDA	State Food & Drug Administration (China)	
SIT	Supplier Integration Transformation	
SLA	Service Level Agreement	
SMART	Specific, Measurable, Agreed-upon, Realistic And Timely	
SPP	Strategic Planning Process	
STOP	Safety Training Observation Program	
STRIVE	Success Through Recognition, Improvement, Values, & Excellence Senior Vice President	+
SVP SWOT		+
	Strengths, Weaknesses, Opportunities, Threats	1
TRIR	Total Recordable Incident Rate	
Top 12	Short- and mid-term objectives	2.1a1
TUV	Notified body for verifying ISO compliance	
UW	United Way	
VIP	Value Improvement Program	6.2b1
VOC	Voice of the Customer	
VoIP	Voice over Internet Protocol	
VP	Vice President	
WLI	Women's Leadership Initiative	5.1a2
YTD	Year-to-Date	
עוו	100 0 000	1

PREFACE: ORGANIZATIONAL PROFILE

P.1 Organizational Description

P.1a1 MEDRAD develops, markets, and services medical devices that diagnose and treat disease. It began in 1971 with the introduction of the first "flow controlled" vascular injector, which improved pictures of the heart and blood vessels by precisely injecting liquid contrast agents. In 1986, and again in 1992, MEDRAD created new markets for vascular injection systems, first for Computed Tomography (CT) applications and then for Magnetic Resonance (MR). In 1988, in cooperation with scanner original equipment manufacturer (OEM) partner GE Medical, MEDRAD expanded into MR surface coils. MEDRAD's expertise in the design, manufacture, and sale of MR-compatible equipment led the company to expand into other MR Accessory products in 2000. In 2008, ME-DRAD expanded its product offering to include thrombectomy technologies with the acquisition of Possis Inc. and also introduced the first vascular injection system for Molecular Imaging (MI).

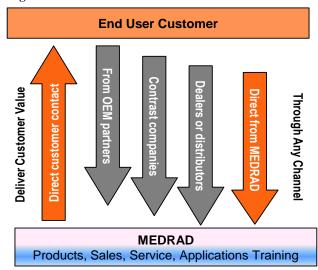
Figure P.1-1 MEDRAD's Razor/Razor Blade Business Model



MEDRAD's products are sold worldwide to hospitals, and medical imaging centers. They are used in **CT** and **MR** procedures and in **cardiovascular** imaging and therapeutic procedures.

MEDRAD's equipment products are the "razor" of a razor/razor blade business model (Figure P.1-1), with sterile

Figure P.1-2. MEDRAD's Distribution Model



disposable products, software, and service offerings providing annuity revenues that flow from the installed base of equipment.

MEDRAD's **delivery mechanisms** focus on making it easy for customers to purchase through their preferred distribution channel.

Figure P.1-3 Key Characteristics of MEDRAD's Culture

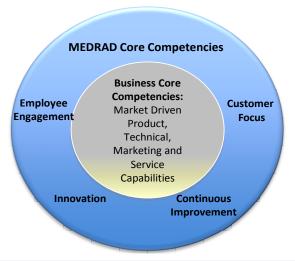
Characterist	c Areas of Focus
Performance Excellence	Commitment to delivering balanced results for customers, employees, and shareholders, including revenue and profit growth; continuous improvement; high-quality, innovative products and services
Customer Focused	Customer Satisfaction Net Promoter Score; Voice of the Customer
Employee Focused	Leadership focus on creating the environment for employee success; strong reward and recognition; great place to work
Teamwork / Process Oriented	Everything done by a team and through a process
Engaged / Aligned Workforce	Engaged employees; aligned with Philosophy, Corporate Scorecard Goals, and Top 12 Objectives; making a positive difference in millions of lives

P.1a2 The **key characteristics** of MEDRAD's **culture** (Figure P.1-3) reflect the MEDRAD Philosophy (Figure P.1-4), established in 1983, and drive improvement in structure, processes, and focus to support rapid growth without losing sight of any individual stakeholder group.

MEDRAD values **stakeholders: customers, employees, and its shareholder**. The importance MEDRAD places on these stakeholders is reflected in the MEDRAD Philosophy's Guiding Principles (**values**) and "Why We Exist" (**purpose**). The MEDRAD **Mission** was developed in 1991 to provide focus for sustainable growth. It continues to define how MEDRAD will grow, with revisions in 2001 and again in 2009. A focus on quality was needed when MEDRAD began its performance excellence quest in 1988; MEDRAD adopted its Quality Policy at the Annual Employees Meeting in 1990 and revised it in 2004 (Figure P.1-4).

MEDRAD's five Corporate Scorecard Goals arose from the enduring belief that continued growth and prosperity derive from balancing the interests of all stakeholders. These

Figure P.1-5. MEDRAD's Core Competencies



evergreen goals guide decision-making at all levels, providing focus for operations and growth beyond financial cycles.

At the corporate level, MEDRAD concentrates on developing a culture that enables ongoing growth and success. Underlying its culture are the MEDRAD core competencies depicted in Figure P.1-5, which are supported by processes used throughout all businesses and functional groups. In addition, each business systematically identifies its own core competencies including the product, technical, marketing, and service capabilities required to create strategic advantage in its specific market.

P.1a3 The MEDRAD workforce is comprised of >2,000 employees. MEDRAD employs workers with varying backgrounds and educational levels. Assembly and production workers include degreed and non-degreed workers and vocational school graduates. Nearly all professional and management employees have college degrees and many have advanced degrees.

MEDRAD uses research-based employee surveys to determine **key factors of employee engagement** (Figure 5.1-1) starting with the Hay Group survey in the '90s. After exceeding Hay best-in-class (BIC) for many years, MED-RAD wanted to raise the bar and selected the Great Places to Work (GPTW) survey, which addresses five dimensions of a great place to work. Research indicates that high scores in these five dimensions result in improved business performance.

MEDRAD tracks overall **diversity** as well as the percent of women and minorities reporting directly to Executive Committee (EC) members and at director-level positions or higher in the company. In 2009, 48 percent of new hires were women or minorities. MEDRAD has **no bargaining units**. Key employee **benefits** are listed in 5.2b2. Most of the **safety requirements** are typical for light manufacturing and are addressed through the processes described in 5.2b1. Unique safe-

Figure P.1-7 Regulations and Standards							
Area	Representative Regulatory / Standards Bodies						
Medical Device Manufacturing	 Food and Drug Administration (FDA) Canadian Medical Devices Conformity Assessment System (CMDCAS) State Food & Drug Administration (SFDA –China) 						
Employee Health and Safety	 Occupational Safety and Health Administration (OSHA) Japanese Ministry of Health and Welfare 						
Environmental Protection	 Environmental Protection Agency (EPA) PA Department of Environmental Resources (PADER) Allegheny County Health European Community 						
Industry Standards	 International Organization for Standardization (ISO) British Standards Institution (BSI) Japanese Industrial Standard (JIS) 						
Financial Standards	Sarbanes-Oxley (Voluntary compliance as com- pliance is not required of non-US parent.)						

ty requirements exist in some departments. MEDRAD meets or exceeds all applicable health and safety requirements.

P.1a4 [Confidential]

P.1a5 MEDRAD is subject to myriad international, federal, and state standards and medical device **regulations** as summarized in Figure P.1-7.

The FDA regulates all facets of the manufacture, distribution, promotion, and sale of medical devices cleared for distribution in order to assure their safety and effectiveness. ME-DRAD is registered as a medical device manufacturer with the FDA, which inspects the company from time to time to determine whether it complies with regulations relating to such manufacturers. All devices must be manufactured according to Quality System Regulations (QSR) specified in the Food, Drug, and Cosmetic (FDC) Act. These practices control every phase of production including raw materials, components and

Figure P.1-4 MEDRAD's Philosophy, Quality Policy, and Mission

The MEDRAD Philosophy

We the employees of MEDRAD, Inc. wish to preserve those basic values, which we believe have made our company the leader in its field and an enjoyable place to work. We want to express these values in the form of a MEDRAD Philosophy for all to see. . for the benefit of our future employees, for our customers, for our suppliers, for our investors, and for ourselves in the years to come. On this day of May 24, 1983, we the MEDRAD Team hereby state these basic values and pledge ourselves to them and thereby to the continued success of our company.

A. Why our company exists:

- · To improve the quality of health care
- To ensure continued growth and profit
- To provide an enjoyable and rewarding place to work

B. Those basic principles in which we believe

- (1) Treat all employees with dignity and faimess
- (2) Produce the highest quality products possible
- (3) Assure our company's future through new products
- (4) Maintain our company's leadership position through customer responsiveness;
- (5) Manage ourselves through sound planning and decision-making;
- (6) Preserve our ability to respond quickly to opportunities;
- (7) deliver on commitments we have made to ourselves;
- (8) Help fellow employees achieve their goals through teamwork;
- (9) Neverlose oursense of pride in our company.

The MEDRAD Mission

It is our mission to be a global market leader of innovative, high quality diagnostic imaging and therapeutic medical devices and services that improve healthcare for patients worldwide. We will accomplish this mission by achieving performance excellence across our five corporate goals.

The MEDRAD Quality Policy

MEDRAD is committed to enhancing customer satisfaction, employee satisfaction, and stakeholder value by continually improving the quality and reliability of our products and services. We achieve this by:

Meeting or exceeding our five corporate goals Satisfying customer and regulatory requirements Maintaining an effective quality management system. subassemblies, manufacturing, testing, quality control, labeling, tracing of consignees after distribution, and follow-up and reporting of complaint information.

MEDRAD has earned ISO 13485-2003 accreditation, CMDCAS accreditation, JGMP accreditation, and LEED certification. Its safety committees are certified by the Pennsylvania Department of Labor.

P.1b1 MEDRAD was an independent company until its purchase in 1995 by Schering AG. In 2006, MEDRAD and its Schering parent were acquired by Bayer AG, a \$44 billion global enterprise headquartered in Leverkusen, Germany.

MEDRAD has three business areas: Radiology, Interventional, and Service (1.2a2, 5.2a3). Three support functions, Human Resources, Information Technology, and Finance, were included within each business. Two **governance** bodies are in place and provide leadership: The Executive Board (EB) and the Executive Committee (EC). Membership and responsibilities are indicated in the in Figure 1.1-1.

MEDRAD has established Advisory Boards in a distributed **leadership model** (Figure 1.1-1) to provide direction and oversight on key cross-functional programs and processes, including initiatives to improve performance.

P.1b2 MEDRAD's key stakeholder groups are customers, employees, and Bayer. MEDRAD's customers are end-users segmented by imaging modality (i.e., CT, MR, and Cardiovascular) and call point (i.e., Radiology, Cardiology, and Vascular Surgery) for product definition and portfolio planning, and by geography for sales and support management. Customers may also purchase equipment through distribution channel sub-segments, including OEM scanner manufacturers that may incorporate MEDRAD products into their value chain, and contrast agent manufacturers like Bayer Schering Pharma and GE Amersham (Figure P.1-2).

All **customer groups have common requirements**: [Confidential].

To make it easy for customers to purchase from their preferred distribution channel, MEDRAD addresses **channel partner requirements**: [Confidential].

Key employee requirements are listed in Figure 5.1-1. MEDRAD focuses on the **key requirements of these three stakeholder groups through its five Scorecard Goals**.

P.1b3 Material **suppliers** are MEDRAD's major supplier category. Key material suppliers include "partnered product" suppliers that provide finished products and/or work with MED-RAD on **innovative** new designs. Partners include OEMs, GPOs (Group Purchasing Organizations), and contrast companies.

Key suppliers, partners, and collaborators are part of MEDRAD's work systems and the production and delivery of its products and services. MEDRAD uses a variety of approaches to manage communication and supplier relationships; these approaches are described in 6.2a and 6.2b1.

Key supply chain requirements, measured on supplier scorecards, are [Confidential].

P.2 Organizational Situation

P.2a1 [Confidential]

P.2a2 The principal factors that determine MEDRAD's success [Confidential]. Healthcare reform in the U.S. has been a **key trend** since 2007.

P.2a3 MEDRAD's global and regional competitors are either

small business units of large corporations, whose results cannot be discerned from the parent's reports, or small, privately-held companies that do not share information. As a result, competitor data is unavailable. MEDRAD collects what it can from field sources, analysts reports and conferences for use in the Strategic Planning Process (SPP) and for an assessment process, facilitated by Market Research, that addresses changes in competitor strategy outside the SPP cycle.

Available sources of comparative data for analogous processes outside the industry include non-competitive medical device companies, trade associations such as the American Society for Manufacturing, survey suppliers such as GPTW (HR), Gartner (IT), Baldrige, and other organizations identified as BIC.

P.2b [Confidential]

P.2c Performance improvement and innovation are the heart of MEDRAD's performance excellence culture, driven by the Scorecard. It establishes year-on-year improvement goals to deliver increasing customer, employee, and shareholder value, driving the incremental and breakthrough improvements required for growth. A decentralized philosophy of improvement ensures common tools are available while empowering departments to make improvements and innovate new approaches for improvement. Key elements of MEDRAD's performance improvement system are:

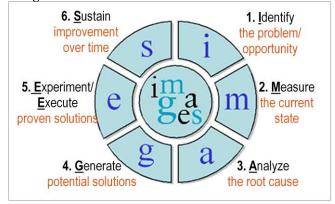
Resources:

- The Performance Excellence Center (PEC) is an internal consulting resource for process **evaluation** and **improvement**. It promotes organizational **learning** by crossfertilizing best practices throughout the company, uses a Lean Six Sigma (LSS) based process called IMAGES (Figure P.2-1) to help teams make improvements, and offers certification in LSS to employees throughout the company. PEC manages the Baldrige process organizational **evaluation**.
- Corporate Development and Innovation (CDI) manages strategic evaluation planning and innovation processes, including selecting critical improvement projects for longterm performance against Scorecard Goals and identifying strategic gaps.
- Individual departments throughout the company may also staff an improvement function.

Evaluation Tools and Approaches:

 The Scorecard is a common reference point for assessing performance. Departmental and individual scorecards and

Figure P.2-1 IMAGES Model



objectives, waterfalled from the Corporate Scorecard, drive evaluation of performance and identification of improvement needs.

- LSS tools and resources include the PEC's "IMAGES" Lean Six Sigma Toolbox, an Intranet-based resource of LSS tools based on the IMAGES process that is available to all employees.
- External award programs, including assessment-based programs like Baldrige, *Industry Week* Best Plant, and the ASQ Team Award, provide independent evaluation of performance.

Organizational Learning and Innovation Processes:

- The PEC IMAGES LSS Toolbox includes benchmarking process recommendations and resources. Some departments subscribe to benchmarking services or surveys like Gartner for IT, GPTW for HR, and APQC for PEC.
- Voice of the customer (VOC) approaches are shared by the PEC, CDI, and Market Research departments, ensuring input from key stakeholders for improvement and innovation.
- Customer Relationship Management (CRM) databases maintained by IT, a customer satisfaction database managed by Global Customer Satisfaction, and business and support function intranet sites provide information on MEDRAD customers and competitors.
- Knowledge and information sharing resources include the InfoCenter, the Market Research department, and the Regulatory Affairs group, which publish newsletters, maintain intranet pages, and provide in-person resources for information and knowledge. Teams and departments also share information and manage knowledge through team or department intranet sites.

1 LEADERSHIP

1.1 Senior Leadership

1.1a1 In 1983, an employee team commissioned by senior leaders established MEDRAD's Purpose (vision) and Guiding Principles (values) in the MEDRAD Philosophy (Figure P.1-4) to "preserve those basic values which we believe have made our company the leader in its field, and an enjoyable place to work... expressed...for all to see...for the benefit of our future new employees, for our customers, for our suppliers, for our investors, and for ourselves in the years to come." In 1991, senior leaders commissioned the MEDRAD Mission (Figure P.1-4) to focus growth. They sponsored an update of the Mission in 2009.

MEDRAD's Philosophy forms an unchanging core that guides decision-making, a foundation that supports the constant adaptability required for organizational sustainability. The Executive Committee (EC) **reviews mission, vision and values** in Step 1 of the SPP (2.1a1). The distributed leadership model defined in Figure 1.1-1 is a key part of globally **deploying** the Philosophy and Mission, developing and deploying strategies and plans, and managing operations. Each Advisory Board (AB) includes several members of the EC as well as others with relevant expertise. Global vertical and horizontal participation in the ABs facilitates communication throughout the leadership system. Through this model, senior leaders ensure that policies and programs reviewed at the ABs align with the Philosophy and Mission and may introduce refinements to

them as a result. The introduction of the Quality Policy and revisions to that Policy and the Mission, described in P.1a2, resulted from these reviews.

Senior leaders **deploy** the MEDRAD Philosophy, Mission, and Quality Policy throughout the leadership system and **to all key stakeholders** through the communication methods shown in Figure 1.1-2. For example, selection for the Presidents Awards presented at Annual Employee Meetings is based on the Philosophy's Guiding Principles.

New employees are introduced to the Philosophy and Mission during orientation and the entire workforce reaffirms its commitment to the Philosophy every five years. Other key approaches used to **deploy** the Philosophy and Mission to employees include the waterfalling of the Corporate Scorecard (Scorecard) and Top 12 as shown in Figure 2.2-1 and recognition programs that reinforce the Philosophy or achievement of corporate, team and department objectives (Figure 5.1-3).

Senior leaders pursue frequent interaction with **customers** globally through the listening posts described in 3.2a1. Senior leaders meet with key **suppliers** to discuss their relationships with MEDRAD and interact with suppliers during the annual Supplier Day.

Senior leaders **demonstrate their commitment** to MED-RAD's Guiding Principles through their day-to-day decisions and actions on the EB, EC and ABs shown in Figure 1.1-1, their formal and informal communications, their sponsorship of and involvement in SPP, and their active participation in:

- Business reviews and PLP reviews
- Field visits and calls on customers
- The customer satisfaction follow-up process (3.2a1)
- Key Opinion Leader meetings and focus groups
- Departmental and corporate award programs
- Participation in training, such as New Hire Orientation Senior leaders decisions as they navigated the reimbursement reforms that hit the U.S. market in 2007, and then the economic crisis in 2008-09, exemplifies their **commitment to the Philosophy's unchanging core values**.

Senior leaders are held accountable for their decisions and actions in the PM process, which includes biannual assessments of performance on the competencies that reflect MED-RAD's Guiding Principles, and the code of conduct (5.1a3).

1.1a2 Senior leaders participate in the CEAB and LAB (Figure 1.2-1), ensuring ethics processes and practices (1.2b2) that foster, require, and result in legal and ethical behavior. Senior leaders personally complete and pass the same test on ethics training that employees do. They promote legal and ethical behavior through their daily decisions and actions and in all aspects of the business, as described above.

1.1a3 The platforms for organizational sustainability are the MEDRAD Philosophy and the Scorecard, the unchanging core that balances customer, employee, and shareholder interests. The Scorecard also supports constant adaptability, delivering short- and long-term performance improvement and excellence. The SPP (2.1a1) assesses future business and market environments, including technologies and areas for innovation, and their investment requirements. As part of this process, the EC identifies the Top 12, MEDRAD's priorities for the year, based on their contribution to delivering increasing value for customers, employees, and shareholders. The Corporate Development and Innovations (CDI) function

Figure 1.1-1 MEDRAD Distributed Leadership Model

Light orange box indicates AB chair.

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Group	Responsibilities	Values/Vision Deployment	CEO	CAO	CTSO	000	SVP Radiology	SVP Interventional	SVP Service & Int'l	General Counsel	VP HR	Function Members
Executive Board (EB)	Manage overall performance; set corporate goals; allocate resources; manage Bayer relationship	Sound planning and decision- making; teamwork, future through new products, dignity & fairness	•							•		
Executive Committee (EC)	Manage business unit strategy and operations; review business unit and region performance	Sound planning and decision- making; respond quickly to opportunities; teamwork	•	•	•	•	•	•	•	•		
Customer Sat. AB (CSAB)	Effectiveness of approaches to continuously improve customer satisfaction	High quality products; customer responsiveness; teamwork				•	•	•	•	•		•
Compliance & Ethics AB (CEAB)	Assess and address ethics issues; effectiveness of compliance and ethics approaches	Pride in our company • •			•	•	•	•	•	•	•	•
MEDRAD Mgmt Review (MMR)	Effectiveness of quality system	High quality products	• • •			•	•	•	•	•	•	•
Legal AB (LAB)	Manage patent portfolio, contracts, other legal matters	Respond quickly to opportunities, Pride in our company	•	•	•	•	•	•	•	•		
Human Resources AB (HRAB)	Effectiveness of HR policies and programs	Dignity and fairness; pride in our company; teamwork	•	•	•	•	•	•	•	•	•	
Marketing Review Meeting (MRM)	Coordination of global sales, marketing, and service initiatives	Customer responsiveness; respond quickly to opportunities; teamwork					•	•	•			•
Env. Health and Safety AB (EH- SAB)	Effectiveness of approaches to environmental health and safety	Dignity and fairness				•				•	•	•
President's Adv Council	Two-way communication between CEO and global field teams	Customer responsiveness; teamwork	•									•
Global Facilities/ Sustainable Dev (GFAB)	Best use of and planning for facilities and develop- ment. Governing and steering of sustainable devel- opment program.	Pride in our company, sound planning & decision-making	•	•	•	•	•	•	•	•		•

identifies new business and technological **innovations** to expand core technological competencies to new, adjacent markets. Throughout the year, the EB's region and business reviews assess current and near-term market and environment changes, adapting as needed.

Senior leaders create an environment for **performance improvement**, accomplishing MEDRAD's **Mission** and **strategic** Top 12 **objectives**, **performance leadership**, and

agility through the leadership model (Figure 1.1-1), the SPP, and the performance management system. They use communication mechanisms (Figure 1.1-2), Listening Posts (3.2a1) and reward and recognition programs (5.1a3) to understand challenges and encourage excellence. The SPP translates the Mission, Scorecard Goals and Top 12 into action plans that are deployed through ABs, departments, teams, and individuals. Each Scorecard Goal includes an expectation of year-to-year improvement.

Senior leaders ensure that resources are allocated to performance improvement through the SPP (Figure 2.1-1) and improvement processes described in P.2c and 6.2c. Participation in these approaches, and in reward and recognition programs (5.1a3), fosters a continuous improvement environment.

Senior leaders **create an environment for learning** through ownership of the AB system, strategic planning, and the Scorecard. The annual improvement goals built into the Scorecard create urgency for organizational learning and improvement. Reviews by the EB, EC, and ABs include evaluation of lessons learned. ABs and the Performance Excellence Center (PEC) may conduct benchmarking to identify **innova-**

tive best practices for sharing, such as CSAB's adoption of the NPS process (3.2b1). Senior leaders select the President's Awards and the President's Team Award (PTA) recipients (Figure 5.1-3). The PTA recognizes and communicates successful team approaches to learning and improvement. Senior leaders input in the Lessons Learned portion of the PTA judging session also contributed to an improvement in the Team Award process, being launched this year.

Through their participation in the HRAB and SPP (Figure 2.1-1), senior leaders ensure effective programs are developed and resourced for **workforce learning**, such as career ladders, tuition support, bench-strength assessment, succession planning, and coaching. As function leaders, they use the Performance Management (PM) (5.1a3) system to support their individual learning and development.

Senior leaders also use the PM system to **develop and enhance their personal leadership skills**. Opportunities for improving individual skills and the leadership system are identified through 360 feedback, competency assessment, the employee survey process, and feedback from formal and informal communication.

Senior leaders participate in organizational learning as leaders of ABs and through the SPP. As described in 5.1b4, they review candidates and select high-potential talent through the **succession planning process** and review progress. A senior leader sponsors development of each high potential individual and reviews developmental progress. Senior leaders also participate in the STRIVE **leadership development** program, as sponsors, speakers, and trainers (Figure 5.1-5).

1.1b1 Senior leaders **communicate with and engage the workforce and communicate** methods listed in Figure 1.1-2. **Two-way communication** occurs through the ABs, function leadership meetings, cross-functional team participation, staff meetings, and participation in training for new and existing employees. Senior leaders conduct annual meetings for all employees in each of MEDRAD's businesses and regions, visiting each major location to share progress, recognize accomplishments, and reinforce the Mission, Philosophy, and Scorecard Goals. They engage employees in business issues through regular business unit and regional reviews and the SPP, and assess their engagement through the Great Places to Work (GPTW) employee survey.

Informal communication is a key component of engagement. The CEO frequently works in various departments, including on production lines, with facility workers, and with local office and field representatives around the world, to better understand the work employees do and to promote communication. The President's Advisory Council meets biannually to provide direct, **two-way communication** between the CEO and the field teams. The CEO and VP of HR also meet regularly with the MEDRAD Employee Satisfaction Association (MESA), a team selected by U.S. employees to provide employee perspective on MEDRAD programs and policies (5.2b2). Internationally, working councils in Europe and Japan meet regularly with their regional senior leaders.

Senior leaders communicate openly with employees about

Figure 1.1-2 Communication Methods

	Purpose									Audience					
	Two-way	Deploy Philosophy	Encourage High Perf.	Deploy Ethics	Obtain Feedback	Update Progress	Share Information	Recognition	Employees	Customers	Suppliers	Community			
Scorecard		•	•			•	•		•	•	•	•			
Town Hall Meetings	•	•	•		•	•	•	•	•						
Annual Employee Meetings	•	•	•		•	•	•	•	•						
GPTW Survey	•	•	•	•	•				•						
Bulletin Boards & Posters		•				•	•	•	•	•	•				
Orientation	•	٠	•	•	•		•	٠	٠						
Emails	•			•		•	•	٠	٠	٠	•				
CEO Highlights / Progress Reports		•	•			•	•	•	•						
Newsletters			•			•	•	٠	•						
Department meetings	•		•		•	•	•	•	•						
AB/Review Meetings	•	•	•	•	•	•	•	•	•						
Ethics Hotline	•		٠	٠	•			•	٠						
Intranet	•	•	•	•	•	•	•	٠	•						
Internet	•	•		•			•	•		•	•	•			
MedNews & Insight		•	•			•	•	•	•						
Customer Surveys	•	•	•	•	•				•	•					
Marketing Materials		•		•			•			•					
Press Releases		•				•	•	٠		•	•	•			
MESA	•	•	•		٠	•	•	•	•						
Supplier Scorecard		•	•	•	•	•	•				•				

Figure 1.1-3 The Inverted Triangle



the company's performance using the Scorecard and meetings, frequent emails, and the Intranet. Senior leaders also interact with employees through project reviews, small group lunches, one-on-one meetings, discussions of employee survey results, and employee events and recognition.

The Inverted Triangle (Figure 1.1-3) illustrates MED-RAD's emphasis on creating a culture of open communication and high performance, in which the CEO and his direct reports are responsible for enabling employees to serve customers. The lack of hierarchy creates a culture of "we are all in this together" that is reinforced by providing the same benefits package and paying the same gainsharing amount to all employees. MEDRAD is open about its compensation methodologies, payout percentages in the variable incentive plans, salary ranges on job postings, and other compensation data.

All employees have access to all senior leaders and managers at any time. A biennial internal communications survey, annual employee survey results and other feedback are used to regularly improve. STRIVE leadership development emphasizes communication skills through curricula like FACT Coaching (Figure 5.1-5). Survey results (Figure 7.6-6) indicate that employees feel they can openly discuss issues and ideas with their supervisors or other leaders.

Senior leaders communicate **key decisions** through AB meetings, the monthly *CEO Highlights* report, business and departmental progress reports, department meetings, MedNews, the Insight video, and the Intranet. For programs that directly affect employees, MEDRAD uses detailed communication plans to ensure that employees receive timely information about how the change will affect them (Figure 7.6-6).

Senior leaders play an active role in employee reward and recognition, sponsoring, selecting, or presenting awards that reinforce high performance, customer, and business focus (Figure 5.1-3). They sponsor and present awards within their departments and nominate and select recipients of the President's Awards. As members of the HRAB, they ensure the effectiveness of compensation plans and the performance management system. Compensation includes gainsharing that rewards all employees when MEDRAD achieves its Scorecard Goals and short- and long-term bonus plans for managers and leaders tied to business and Scorecard Goals.

1.1b2 MEDRAD's **balanced** Scorecard requires **year-on-year improvement**, which is translated into specific actions

through the Top 12. These are waterfalled through strategic plan deployment and the performance management system to all employees, **creating a focus on action** throughout the organization (Figure 2.2-1). Monthly progress reports and AB (Figure 4.1-2) reviews provide forums for senior leaders to sustain an organizational focus on goals and objectives.

Senior leaders review the key performance measures shown in Figure 4.1-1 to assess progress and identify needed actions. As part of the AB agendas, senior leaders compare performance to targets and indicators to identify the need for mid-course corrections and determine corrective actions.

The MEDRAD Philosophy, Quality Policy, and Mission focus the organization on **creating and balancing value** for customers, employees, and shareholders, and the Scorecard establishes balance among these stakeholders by setting goals for each one and via annual targets that demand improvement. Through the SPP, senior leaders identify performance expectations that align with these goals.

1.2 Governance and Societal Responsibilities

1.2a1 Bayer manages the **process of selecting and managing governance boards**.

MEDRAD's management is accountable to its parent, Bayer, for the organization's actions, as described in P.1b1. It also ensures **fiscal and management accountability** through the ABs, organizational performance reviews (Figure 4.1-2), ethics practices (1.2b2), and the PM process (Figure 5.1-2).

Regular performance reviews, annual Bayer audits, and internal MEDRAD audits ensure **fiscal accountability** by confirming compliance with Bayer and MEDRAD financial control processes.

External audits and internal MEDRAD audits also ensure the accountability and systematic improvement of the quality system and areas like hazardous waste and IT. An independent auditor conducts the extenal audits and reports to the board and senior leaders. Independent audits by TUV/BSI for ISO compliance and other outside groups ensure **independence in auditing** and compliance with legal, regulatory, and organizational standards.

MEDRAD's compliance group performs internal audits of the entire quality system annually with assistance from outside auditors as needed. The Compliance group is **independent of the functions that it audits**. It reports findings to the Chief Compliance Officer (CCO) and EB, the areas audited, and the senior leaders responsible for those areas. Actions to be taken are addressed through the corrective action system and tracked at the MMR, which is also the forum for presenting the status of the quality system to management.

MEDRAD protects stakeholder and stockholder interests through these regular reporting and auditing processes, and through performance on its five Scorecard Goals, with a goal for customer satisfaction, one for employee growth and satisfaction, and the remaining three focused on shareholder measures and overall growth.

1.2a2 MEDRAD's CEO utilizes MEDRAD's 360 feedback process to further his development and leadership effectiveness (5.1a3). MEDRAD **evaluates the performance of senior leaders** through the PM system described in 5.1a3, which includes reviews against their objectives, Top12, and scorecard.

Senior leaders use the PM system to further their development and improve their leadership effectiveness in several ways using 360 feedback and the biannual competency

Figure 1.2-1 Legal and Ethical Behavior Approaches and Indicators								
Approach	Governance	Address Adverse Impacts	Anticipate, prepare, address current-future concerns	Achieve-surpass regulatory- legal requirements	Address Risks with Products & Operations	Promote/ Assure Ethical Behavior, Breach Response	Focus	Indicators
SPP (2.1-1)	EC/EB		•			•	Identify public concerns, key risks or oppor- tunities associated with current or future prod- ucts or operations. Example: sustainability	Mitigators identified for key concerns, risks, or opportunities. Example: Sustaina- bility Initiative
PLP (6.2b1)	Stage Gate Reviews	•	•	•	•		Product and product-operations risk assess- ments, including patient, user, and operator safety, operations impacts, legal & regulatory requirements	Product and process specifications meet regulatory, legal, safety, environmental requirements. RoHS compliance tracking.
Commercialization	Release Sign Off			•		•	Programs complete for launch, including legal, regulatory, and field training requirements.	Sign-offs complete
Risk Management	CEAB	•	•	•		•	[Confidential]	Conflict disclosures, contest and training results, CIA compliance results, hotline activity, ethical breach closure, export compliance
Kisk Wianagement	LAB	•	•	•	•	•		Status of legal matters, trends, actions closure
	GFAB & EHSAB	•	•	•	•		Sustainable operations and development projects.	Waste stream, Resource utilization, LEED certifications
Quality System	MMR	•	•	•	•	•	Compliance with global standards and regula- tions, adherence to Quality System standards and regulations	Internal and external quality system audit results, warranty failure rates, complaints, Supplier Scorecard, Adverse events
Employee Health & Safety	EHS & EHSAB	•	•	•	•		Compliance with global environmental and employee health and safety laws, regulations, and standards	Work-related injury and illness metrics; STOP training; audit findings

assessment to evaluate effectiveness and set developmental objectives. A third-party coaching program also provides opportunities for self-assessment and improvement (5.1a3).

Senior leaders use performance results, including input from ABs and from employee and customer satisfaction surveys, to identify opportunities to **improve MEDRAD's leadership system**.

1.2b1 MEDRAD assesses current and future adverse product and operations' impact via the approaches described in Figure 1.2-1.

In addition to audits by the Compliance department, the FDA conducts a regular, full audit approximately once every two years or in the event of a product recall. It may also conduct unannounced spot audits at any time. Other key audits include independent audits by TUV/BSI, and MEDRAD's ISO audits at U.S. and international facilities. The quarterly MMR meeting addresses regulatory and quality system issues. Prompt resolution reinforces MEDRAD's positive relationship with regulatory agencies.

Environmental and patient or user safety risk processes are described above. **Business risks** are identified during the SPP (2.1a2). Key indicators for compliance and risk management are listed in Figure 1.2-1.

1.2b2 MEDRAD's ethical values are embedded in the MED-RAD Philosophy and made explicit in its code of conduct. Developed and deployed in 2001, it has been refined and improved regularly, incorporating the AdvaMed code in 2004 and adopting Bayer's global Corporate Compliance Policy as its code of conduct in 2008. The code of conduct outlines expectations for all employees regarding ethical behavior, compliance with laws and regulations, company policies, and conflicts of interest. The CCO and CEAB oversee this process, which includes review and resolution of any issues that arise, assessment of broader trends, and corrective action. Corporate

Compliance investigates every report of an **ethical breach**, takes corrective action, and reports findings to the CEAB.

In 2004, MEDRAD established the Corporate Compliance department and the CEAB and LAB to align with the U.S. government's OIG guidelines for an effective compliance program. Figure 1.1-1 and 1.2-1 show their roles in assuring legal and ethical behavior.

Ethics & Values and Integrity & Trust are core competencies in MEDRAD's performance management system (5.1a3) Every employee is assessed biannually against these competencies. MEDRAD's approach to ethics is introduced to new employees on Compliance Day during orientation. Annually, every employee completes training and passes a test to demonstrate knowledge. Periodic global "Code Contests" keep skills fresh and top-of-mind. Suppliers are also required to sign the code as part of their contract. The CEAB and LAB ensure the integrity of interactions with customers and partners. Figure 1.2-1 shows key indicators of ethical behavior.

1.2c1 Societal well-being and benefit are embedded in the MEDRAD Philosophy, which identifies "improving the quality of healthcare" and "providing an enjoyable and rewarding place to work" as two of three reasons the company exists. Initiatives to improve societal well-being and benefit flow from this focus. MEDRAD employees and senior leaders participate on numerous boards, trade associations, and community associations, which provide insight into well being of relevant environmental, social, and economic systems (Figure 1.2-2). These insights are considered in strategy and operations in the same way that MEDRAD anticipates public concerns, described in Figure 1.2-1. Multiple programs to improve environmental systems have resulted, beginning in the '90s with a focus on waste. Energy use reductions (7.6a5) and LEED standards for new buildings (2007) and existing buildings (2009) are also examples. Sustainability was subsequent-

Figure 1.2-2 Senior Leader and Employee Involvement

Area	Association	Participant(s)	Support
Economic	Allegheny Conference Board		Board member
	Pittsburgh Regional Alliance		Past Chairman
	Pittsburgh High Tech Council		Chair/ Board member
	Japanese-American Chamber of Commerce		Board member
	Keystone Alliance for Performance Excellence		Founder, Judges, Examiners
	(Pennsylvania Baldrige-based award)		Monetary & in-kind support
	European Foundation for Quality Mgt (EFQM)		Member
Societal/	United Way		Executive Committee/ Past Chair
Educational	Pittsburgh Symphony		Board member
	World Affairs Council		Board member
	Life's Work		Board member
	American Productivity & Quality Center		Board member
	Point Park University		Board member
	University of Maastricht student competition		Sponsorship, Judges
	Habitat for Humanity		Project leaders
Environmental	Bayer Corporate Sustainability Council		Member
	Adopt-A-Stream		Project leaders
	Adopt-A-Highway		Project leaders
Healthcare	Pittsburgh Regional Healthcare Initiative		Board member
	West Penn Allegheny Health System		Board member
	St. Margaret Foundation		Board member
	UPMC Passavant Hospital		Board member
	Magee-Women's Hospital		Executive Committee
	Tissue Engineering/Hillman Cancer		Board member
	AdvaMed Medical Device Trade Association		Committee member
	VZI-Dutch Assoc. of Hospital Technicians		Member
	Internat'l Society of Pharmaceutical Engineers		Member, Best Practice Contributor

ly added as a strategic thrust this year. Other outputs of processes to incorporate social well-being and benefit into strategy and operations include:

• Distribution operations were consolidated to reduce the number of shipping legs, saving energy (7.6a5).

1.2c2 MEDRAD's Charitable Giving Committee defines key communities and determines areas for organizational involvement. Key communities are defined as those with major MEDRAD facilities—SW Pennsylvania, Minneapolis, the Netherlands, and Japan. Key areas for involvement align with core competencies, and are defined as hospitals, education and cultural institutions. As a past Baldrige recipient and market leader, MEDRAD shares best practices in its core competencies of employee engagement, continuous improvement, innovation, and customer relationships. Senior leaders set the example with their involvement, as shown in Figure 1.2-2, joining employees to support key communities by:

- Sharing expertise and resources to improve the quality of life through direct sponsorship and participation in company-selected activities and organizations
- Supporting employee-championed community activities and organizations
- Participating in industry and professional organizations to support employee development and industry information sharing
- Supporting local universities through internship and Coop programs and use of academic project teams.

MEDRAD's leadership in the United Way (UW) includes participation in UW boards and committees (Figure 1.2-2) donations to the annual UW fundraising drive, and a Day of Caring event during which employees around the world take a day to give back to their communities. Last year, MEDRAD coordinated 63 Day of Caring projects around the world.

MEDRAD Points of Light, a group established and managed by employees with leadership support, allows MEDRAD to share its success with neighbors in need by donating funds and manpower. A few examples of Points of Light activities and organizations include Habitat for Humanity, Youth Center, Veterans' Center, food banks, women's shelter, and elderly assistance. MEDRAD has been an Adopt-A-Highway

and an Adopt-A-Stream sponsor for 16 and 20 years, respectively.

2 STRATEGIC PLANNING

2.1 Strategy Development

2.1a1 MEDRAD's **Strategic Planning** Process (SPP) has **three time horizons**. The ten-year horizon focuses on longer-term vision and strategy, market development, and revenue forecasting. The five-year horizon focuses on portfolio planning, product lifecycle management, and [confidential]. Annual planning translates longer-term plans into an **action plan** for the coming year and includes identification, prioritization, and resource allocation for Top 12, SATs, and initiatives required to achieve the ten-year vision.

Corporate Development and Innovations (CDI), facilitates the **key process steps** (Figure 2.1-1.) Other **participants** include the EC and their designated strategic champion and project teams, who represent all businesses, functions, and regions. SPP outputs **address the time horizons** with a tenyear vision of the company's strategy; markets and revenues; a budget that details human and capital resource alignment to support the plan; strategic thrusts, an action plan for the coming year that includes short and mid-term objectives (Top 12) required to achieve the ten-year vision; SATs formed to address strategic gaps identified during the planning process; and an overall corporate **workforce** capacity plan

Step 1 (Figure 2.1-1) begins mid-year with a kickoff and participant training session. A review of the MEDRAD Philosophy and Mission, and the prior year's plan provides a backdrop on strategic direction. Each business and function champion uses common planning templates and workbooks designed to ensure that **blind spots** are addressed, **SWOTs** are analyzed, **core competencies are defined** and **early indications of major shifts** are considered. Technical, business, and functional representatives from across the organization participate on these teams, facilitating cross-functional alignment throughout the organization.

MEDRAD's SPP identifies initiatives to capitalize on significant business opportunities. They then take separate paths until they come together for the analysis of their impact on MEDRAD's ten-year plan (Step 5).

Figure 2.1-1 Strategy Development and Deployment

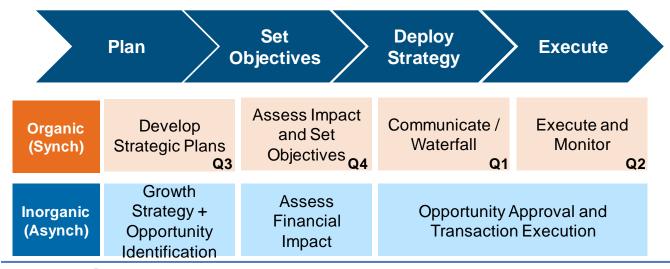


Figure 2.1-2 Top 12 Integration with Scorecard Goals, Strategic Advantages, Challenges and Thrusts

[CONFIDENTIAL]

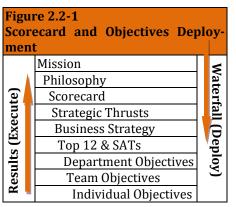
The organic effort (Steps 2A-4A) includes Voice of the Customer (VOC) inputs (Figure 3.1-1) and growth analysis. Teams whose plans require R&D investment conduct business strategy and product line portfolio planning. These groups, plus the staff functions, also assess requirements and improvements in technical and/or workforce capability and competencies needed to achieve the plan.

In Step 5, outputs of reviews are linked, to determine the impact on MEDRAD's ten-year overall performance plan, and to balance growth needs and objectives. Strategic champions present their initiatives to the EB using planning templates that require discussion of opportunities and risks. EB members use defined criteria to score the initiatives, and open debate resolves scoring gaps or differences by clarifying risks and opportunities. The EB develops a rationalized list of initiatives that feeds the remaining steps of the process, including defining target markets, identifying strategic gaps for further investigation, and budgeting.

Significant gaps in growth rates are prioritized and targeted for corporate growth initiatives by CDI. These growth initiatives are reviewed when significant acquisition investment or capital expenditure is included.

The Rationalization and Consolidation phase (Step 6) ensures the alignment, resourcing, and oversight necessary to **execute the strategic plan**. The EB develops a rationalized list of initiatives that feeds the remainder of the process, including performance targets, programs, and investments. They also set budgets and finalize objectives, including performance expectations for each of the businesses, regions, and corporate functions. The EB finalizes the Scorecard Goals, including the financial targets for two Scorecard Goals: Exceed Financials and Grow the Company.

This step's key output is Top 12 identification and prioritization for the coming year, including the assignment of an EC sponsor and leader for each project. The Top 12 are product and business development programs as well as cross-



functional improvement projects to support core competencies or ensure long-term organizational sustainability.

During Budgeting (Step 7), the Top 12 project leads create SMART objectives and develop

budgets and schedules with project teams, which include representatives from all stakeholder departments. Each EC member works with their staff and a financial representative to prepare their final budget and, ultimately, a corporate P&L statement. For non-Top 12 initiatives, cross-functional teams plan

budgets with individual expense lines in the relevant budget. The EB reviews the overall budget before it is forwarded to Bayer for approval.

Each business uses the SPP templates and worksheets which specifically request information for identifying **potential blind spots**. In Step 6, CDI analyzes each plan, providing an assessment to the EB. CDI also recommends actions and strategic initiatives that will contribute to **organizational sustainability**. These initiatives are screened using SAT criteria and selected by the EB. Created to address each initiative, SATs develop charters, which the EB uses to monitor progress.

The process for deploying the plan (Step 8) is described in 2.2a2. A lessons learned process gathers and selects improvements for the next cycle. Examples are provided in 2.1a2.

MEDRAD identifies its core competencies, strategic challenges and advantages through the SPP. The templates used by each business, region, and corporate function ask for core competencies that exist, are in development, or are needed for continued success (Step 3A). Strategic challenges and advantages are identified through a SWOT analysis, as well as a strategy summary detailing competitive advantages by each business, region, and corporate function. These analyses are an input for MEDRAD's overall strategic advantages and strategic thrusts (challenges), which are introduced as part of the strategic direction in Step 1 and reiterated in Step 7.

2.1a2 As described in 2.1a1, templates and worksheets **ensure** that planning teams **address key factors and analyze relevant data and information to do so.** These guidelines provide a structure for gathering information about **market** and **customer preferences** and opportunities, the competitive landscape, organizational **SWOTs**, and risks. Each business assesses risks and other expected and potential **shifts** in their **markets**, **including regulations**. Functions use the same SPP templates and process.

Planning teams acquire in-depth knowledge of existing and potential **customer's preferences and shifts** in their markets through listening posts (Figure 3.1-2). They use this data to complete a competitive update.

The final plans presented by each business and function specify the **capabilities** required for successful **execution** and **organizational sustainability**. The EB validates that the proposed plan and functional requirements will **sustain near-and longer-term success**. Where adjustments are required, the planning group adjusts requirements and modifies the required resource budget appropriately.

CDI evaluates the **effectiveness**, efficiency, and cycle time of the planning process using survey and other input from

process stakeholders, making improvements for the next planning cycle which are discussed during the kickoff and training. The EC evaluates the **effectiveness** of the entire process by comparing progress on the Top 12 (Figure 7.6-2) and SATs to the strategic direction and plans.

2.1b1 MEDRAD's key **strategic objectives** are the five Scorecard Goals, which are evergreen. The **targets** for each Scorecard **Goal** change annually and are a key driver of organizational improvement. Strategic thrusts provide additional strategic direction for planning.

2.1b2 Strategic objectives address strategic challenges (thrusts) and advantages and they guide business and function planning, as well as the selection of the Top 12. Each business also analyses their own competencies, strategic challenges and advantages in their strategic plan development (2.1a1), identifying opportunities for product, operations and business model innovation, and defining and prioritizing initiatives for discussion with the EB.

The planning processes fuel **innovation** through their focus on **product** and **business** development opportunities.

The SPP specifically asks participants for existing, developing, and needed competencies necessary to achieve their plans, including those for the **workforce**.

During the SPP, each business identifies the trends and drivers in its market, along with specific challenges and opportunities, and creates a set of strategic **objectives** and project portfolios that address the **challenges** and take advantage of **opportunities** over the plan period.

In addition to reviews by leaders of each business, the Portfolios are reviewed by the EB and CDI to ensure that the business plans address the challenges and the opportunities each business faces over the near- and longer-terms. During the rationalization process (Step 6), the EB is specifically asked to rate the plans on the **ability of the plan to support the Scorecard over the entirety** of the planning period.

The Scorecard Goals balance the needs of customer, employee and shareholder stakeholders. During the rationalization and budget steps (6-7), the EC ensures a balance of Top 12 objectives across the Scorecard Goals.

Cross-functional teams from across the organization participate in the SPP to ensure both business and functional representation and the communication of **employee** needs.

End user **customers** are MEDRAD's other key external stakeholder. All business teams use VOC data (Figure 3.1-1) in the development of new product and business portfolios for strategic planning. Customer-facing functions also use VOC in creating their strategic plans.

2.2 Strategy Deployment

2.2a1 MEDRAD's Top 12 define the key short- and longerterm **action plans** critical to achieving Scorecard Goals. The first two are evergreen while the remaining ten are product, strategy, and improvement initiatives that indicate **key planned changes in products, customers, markets or operations**. SATs also address key organizational gaps important to resolve for MEDRAD's success. SMART goals that incorporate key milestones and performance targets are established for Top 12 and SATs.

2.2a2 The action planning process (Steps 7-8) begins with rationalizing budgets and assigning program leads to each Top 12 and SAT. Project leaders and sponsors create SMART objectives which are reviewed at EC meetings to ensure that overall **deployment** is on track and meeting expectations.

The strategic plan is waterfalled throughout the company in several ways (Figure 1.1-2). **Deployment** (Figure 2.2-1) flows from the Top 12 and SATs to managers, who create group objectives and plans. These objectives are refined and aligned through team meetings and discussions and used by **employees** to create individual objectives in the PM process.

Senior leaders review progress and make course corrections on the Top 12. SAT objectives, and **sustainability of**

action plan outcomes at EB, EC and relevant ABs (Figure 4.1-2). Department and team leaders evaluate progress on their objectives, using process indicators; customer, supplier, and employee listening posts; benchmark and comparative studies; ISO and FDA findings; and EC feedback. Employees and their managers track performance on individual objectives through the PM process (5.1a3). Relevant elements of the plan are **deployed** to suppliers at the annual Supplier Day and through discussions with commodity managers. Plans requiring **deployment** to distribution channels are discussed in meetings with channel representatives.

MEDRAD ensures that **changes resulting from action on the Top 12 can be sustained** by reviewing progress throughout the year during team and staff meetings, organizational performance reviews (Figure 4.1-2) and the annual SPP. Targets established for new products and acquisitions are monitored and corrective action taken as needed. Corporate Development also identifies areas in which implemented changes are not being sustained and communicates them to the EB.

2.2a3 As described in 2.2a2, Top 12 project leaders and their EC sponsors develop the **project** (action) plan and work with stakeholders to identify financial and human **resource requirements**. SPP steps 6-7 include rationalization of projects and their investments to **balance near- and longer-term needs**. The resulting diversified portfolio balances risk with return on investment in each project's plan.

Prior to submitting the final budget, resource conflicts are resolved (Steps 7-8). Top 12 objectives are top priority for resource allocations. Throughout the year, the EB and EC review progress (Figure 4.1-2) and ensure resource availability while meeting current obligations. Each initiative is analyzed for commercial, technical, or financial risks. Program risk is managed at many levels by individual program teams, steering teams, senior business leaders, and, ultimately, through the EC and ABs (Figure 1.1-1). Product programs must comply with rigorous requirements in the PLP (6.2b1), which contains multiple stage gates with program review and analysis, to mitigate and manage risk. Strategic programs are monitored closely by business leaders, the EC and the EB, as required. Businesses and functions review Top 12 and department-specific initiatives at their leadership team meetings.

2.2a4 Changes affecting progress on **action plans** are discussed during progress reviews and escalated as needed based on project priority and shift magnitude. Top 12 program shifts require senior leader guidance and are addressed during the monthly EB meetings, if not sooner. Once approved, the modified plan is immediately **deployed** or, if a new opportunity or issue arises, a new SAT is established. Annually, as part of the planning process, the past year's objectives are reviewed and results compared with what was anticipated to provide a macro-level review of performance on planned objectives.

2.2a5 Workforce capability plans and competency needs assessments are explicit in the SPP templates, and HR and the HRAB also develop plans as an output of CAO participation in the SPP. Key workforce plans to accomplish short- and long-term objectives are included in the Top 12. Potential impacts on employees and changes in capability and capacity are addressed through communications plans, workforce capability and capacity assessments. The PM process (Figure 5.1-2) and learning and development system

(5.1b) also support that the individual workforce plans support Scorecard Goals and the Top 12. Individuals set objectives that align with and support the corporate goals and objectives, as shown in Figure 2.2-1. MEDRAD development programs and career ladders (5.1b4) support the company's short- and longer-term strategic objectives.

2.2a6 Figure 4.1-2 lists **key performance measures for tracking action plan achievement and effectiveness.** Performance measures for the Top 12, SATs and business, region, function and individual objectives are **aligned** with the Scorecard measures through the waterfalling process (Figure 2.2-1) and the PM system. This ensures that all functions, teams, and employees are working toward the same goals, that strategic plan and key indicators are **deployed to key areas**, and all **stakeholder needs** are addressed.

2.2b Figure 4.1-1 **lists short and longer-term projections for MEDRAD's key performance indicators**. The projections are **determined** during strategic planning and rationalized by the EB. Figure 7.6-1 summarizes MEDRAD's performance in achieving its projections from 2004 to 2009.

MEDRAD compares current and projected performance with past performance on all Scorecard Goals and measures (Figure 7.6-1). MEDRAD consistently raises the bar on scorecard goal benchmarks, most recently to NPS for Customer Satisfaction and GPTW for employee engagement.

Based on these comparisons, **current or projected gaps** in **performance are addressed** during several stages of the SPP, as described in 2.1a and 2.2a4, or by the ABs as an outcome of organizational performance reviews (Figure 4.1-2).

3 CUSTOMER FOCUS

3.1 Customer Engagement

3.1a1 MEDRAD uses several processes (Figure 3.1-1) to identify and innovate product or service offerings that meet or exceed customer expectations, attract new customers or expand relationships with existing customers.

In step 3A of the SPP (2.1a1) Innovations, Marketing and

Figure 3.1-1 Customer Processes & System

PrimarySecondary	SPP (2.1)	PLP (6.2b1)	Sales (& all field) (3.1b2)	Satisfaction (3.2b1)	Commercialization	KOL (3.1)	VOC (3.2c2)	Logistics/Perfect Order	Complaints (3.2a3)
ID & Innovate Product or Service Offerings	0	0	•	•		0	0		
Determine Support Needs & Mechanisms	0		•	0	•		0		
Deploy Support Requirements			0	0	0				
Build & Manage Relationships			0	0		0		•	•
Determine Satisfaction & Dissatisfaction			•	0				•	•
Handle Complaints			•	•					0
Keep Customer Approaches Current	0			0					
Governance	CS	SAB	, MI	MR,	Bus	sines	s R	eviev	WS

Figure 3.1-2 Support Mechanisms & Listening Posts

Figure 3.1-2 Suppo	1101	VIC	ciiu.	11101	ns & Distern	ig i obto
	Seek Info	Use Products	Conduct Business	Listening Post	Varies by	Deployed to
Customer Support	•		•	٠	Language	Global
Inside Sales	•	•	•	•	Business	U.S.
TAC Center	•	•	•	•		Global support
Sales	•	•	•	•	Region	Global
Service Support	•	•	•	•	Region, SLA	Global
Installation Support	•	•	•	•	Business	U.S.
Applications Support	•	•	•	•	Business	U.S.
Complaints			•	•	Language	Global
Trade Shows	•		•	•	Business	Global
Credit & Collections	•		•	•		Global
Email Newsletter	•	•		•	Language	U.S., U.K.
Web	•	•		•	Language	By country*
VOC Research				•	Language	Global
Key Opinion Leaders				•	Business	Global
Trade Associations				•	Region	Global
Manager 'Ride-alongs'	•		•	•		Global
Channel Partners	•	•	•	•	Region	OUS
Customer Sat	•	•	•	•	Language, method	Global
Patent Watch				•		Global
* Major languages and co	ount	ries				

Market Research use the Voice of the Customer (VOC) process to identify new markets or customers, and translate **customer expectations** into product or service specifications in the design stages of the PLP. Radiology's identification of Molecular Imaging as an offering to attract new customers is an example. The same step also identifies new products or product extensions that expand relationships with existing customers, as with Radiology's Informatics product, and Service's Remote Connectivity platform.

New products may also be identified and innovated in the Full Production stage of the PLP, based on complaint (3.2a3) or warranty data, or ideas for cost reductions that benefit customers. The MVS business and pressure rated extension set are examples.

New offering ideas can also come through listening posts (Figure 3.1-2). Relationships with Key Opinion Leaders (KOL) are a significant source. Marketing works with KOLs, located at teaching centers in MEDRAD's four regional markets, to understand the capabilities of new imaging equipment under development and to identify new imaging opportunities expected to emerge over the next five years. MEDRAD's engagement with KOLs delivers innovative ideas and solutions to problems as they appear. For example, the technology for the Stellant DualFlow, which was inspired by a physician from Europe and validated by a U.S. university, is the standard for imaging the complete heart in Cardiac CT Angiography.

For inorganic products (i.e. company acquisitions), CDI conducts a target company analysis in SPP step 4B (2.1a1), including an assessment of product fit with market needs. The acquisition of Possis in 2008 is an example of that process at work, to attract new customers.

3.1a2 MEDRAD determines customers key support mechanisms and requirements through processes outlined in Figure 3.1-1. For new products, SPP plans include consideration of new support mechanisms. In the PLP process, Marketing uses the Commercialization process to determine if new support mechanisms are needed for the new product, and enlist the function responsible for their development. Product development teams create a Service and Support strategy document in the PLP process, outlining how the product will be supported in relevant regions of the world so that appropriate technology and process solutions can be designed to meet service and support requirements. The Commercialization Process also includes deployment of new customer support requirements to all people and processes involved in customer support for new products.

Key support and communication mechanisms and variations across customer groups or segments are listed in Figure 3.1-2. Functions responsible for key support mechanisms, (Service, Customer Support, etc.) use listening posts (Figure 3.2-1), trade associations, benchmarking, and input from field teams and ABs (Figure 1.1-1) to anticipate or identify changing support requirements. In SPP step 3A (2.1a1) they assess their approaches and recommend improvements and innovations. GHX electronic ordering improvements and 2009 web enhancements (7.5a2) are examples.

MEDRAD's Field teams work together, addressing onthe-spot or emerging needs through team meetings, CRM databases, and other tools so that customer requirements for support, installation, training, and service are met. During and after product installation, customer contact employees ensure that customer requests, needs, expectations, questions, and comments are handled accurately and rapidly so that customers can maximize the quality of care and patient throughput in their imaging departments. Service's Technical Assistance Center (TAC) is available 24/7 for customers needing immediate support, and often resolves issues without dispatching a Field Service rep, increasing response time and reducing customer costs. One service organization supports all of ME-DRAD's direct customers, including the customers of Possis, MEDRAD's recent acquisition. MEDRAD trains its own service reps and distributor network to ensure consistent service and support to all customers in all markets.

Web-based technology also enhances customer access. A Sales Support Locator on MEDRAD's Web site gives customers worldwide access to their Sales reps, frequently asked questions, downloadable brochures and other product and clinical information. Direct updates on products and a quarterly education bulletin containing clinical and industry information are e-mailed to customers who subscribe.

Customer support requirements are deployed to customer-facing employees in their Role Profile, which defines role competencies. Employees learn these competencies through classroom or on-the-job training; their performance on them is evaluated through MEDRAD's PM system (5.1a3), including assessment of the employee's "Customer Focus," a core behavioral competency for all employees. In addition, Field Team managers use competency checklists to assess skills and determine gaps to be addressed, and service engineers' territory management training covers customer expectations. Customer contact employees receive formal and on-the-job training in product knowledge, customer satisfaction, customer needs assessment, and complaint handling.

3.1a3 Process owners, and CSAB and MMR (Figure 1.1-1) keep approaches for identifying and innovating product offerings and for providing customer support current through the approaches described in Figure 3.1-1. Listening posts, SPP analysis, or AB findings may signal a change is needed. Teams then form and use IMAGES (P.2c) or department-specific approaches to close the gap or tap the opportunity. Recent examples include Remote Connectivity that allows Service to diagnose issues or upgrade software remotely, the Install Coordinator Process that features a "point person" who coordinates new equipment installation and customer training, updates to the VOC process, and addition of clinical subject matter experts to Field Teams to support certain modalities.

3.1b1 MEDRAD cultivates a culture that ensures a consistently positive customer experience and contributes to customer engagement starting with its unchanging core – the Philosophy, Scorecard and Quality Policy (Figure P.1-4). The Philosophy reinforces the importance of producing high-quality, innovative products and creating a leadership position through customer responsiveness. The Scorecard sets the ex-

Figure 3.1-3 Sales Process

Sales Process Step	Purpose	Listening/Relationship Building
1. Earn the Right	Generate interest.	Listen and understand previous experiences with MEDRAD.
	Establish credibility.	Build confidence and trust in representative and MEDRAD.
2. Qualify the	Qualify opportunity.	Listen and understand customer's needs and buying criteria.
Opportunity	Define customer needs.	Listen and identify competitive issues.
3. Establish Buying	Establish buying	Understand decision makers and influencers.
Influences & Criteria	criteria.	Work with customer to create action plan.
4. Satisfy Buying	Satisfy buying criteria.	Execute action plan.
Criteria		Offer proof sources, reference lists, site visits, and product demonstrations
5. Gain Commitment	Agreement to Purchase.	or evaluations to build customer confidence.
6. Implement	Deliver, install, and	Field Teams work closely with customer to ensure defect free installation
	provide training on	and provide training to ensure positive usage experience.
	products.	Installation Coordinator provides single point of contact.
7. Customer	Ongoing contact.	Field Teams provide coordinated, direct contact with the customer to
Enhancement		promote satisfaction and loyalty.
		Follow-up satisfaction surveys (3.2), relationship surveys, targeted web-
		based programs and email educational bulletins.

pectation for continuous improvement in customer satisfaction by requiring improvement year on year. A portion of the annual gainsharing payout is based on achieving the corporate customer satisfaction target.

The waterfalling process (Figure 2.2-1), and **PM system** "customer focus" competency, gainsharing, recognition programs like CSAB's Personal Promoter, and individual and leadership development (5.1a3) ensure focus on customer priorities. For customer contact employees, individual NPS customer engagement (3.2b1) scores are tied to variable compensation and rankings for reward and recognition.

The Inverted Triangle (Figure 1.1-3) emphasizes the importance of customer-facing roles, and the roles of support teams and leadership. Sales and service training helps develop the skills required to serve and build relationships with customers

3.1b2 MEDRAD's customer-facing employees in Sales, Service, Clinical Support, Customer Support, Inside Sales, and Marketing are responsible for building and managing customer relationships to acquire new customers, meet or exceed their expectations in each stage of the life cycle, and increase their engagement with MEDRAD. The MEDRAD Sales Process (Figure 3.1-3) is the primary vehicle. Other customer relationship processes are the Customer Satisfaction, Complaint, and Listening processes described in 3.2.

MEDRAD's North American Sales and Service departments adopted the Sales Process from Xerox Learning Systems, in 1993. Each of the seven process steps is an umbrella for many steps that may or may not be taken depending on customer needs and situation. It integrates Sales, Service, and Clinical Support into one ongoing process, ensuring a **consistently positive customer experience**, while apprising MEDRAD of the status of each customer across the lifecycle.

Multiple improvement cycles include deployment to European and Japanese direct field organizations and to the newest business, Interventional last year. Radiology's 2009 introduction of the Mind of the Customer (MOC) approach includes listening to customer's business goals and challenges, to identify how MEDRAD products and services can improve the customer's business. Customer Relationship Management (CRM) databases ensure timely, comprehensive customer information to implement the Sales Process. Field teams use these databases to document and track customer contacts; check order and shipment status; review competitive information and notes on customer preferences, requirements, and expectations; review customer satisfaction results; track complaint and inquiry response status; get current product information; review customer equipment service history; get leads; and schedule installations or training.

MEDRAD makes it easy for customers to buy from any distribution channel (P.1-2). While the vast majority purchase directly from MEDRAD, processes to support customer engagement with MEDRAD also address these channels:

 Some products or markets use scanner manufacturers (OEMs) and Group Purchasing Organizations (GPOs) as distribution channels. Field Teams work closely with OEM and GPO reps to coordinate sales, service, and clinical support and equipment installation. Field teams build relationships with these customers, using the same sales process and customer satisfaction approaches used for customers who purchase directly from MEDRAD. •In some countries, dealer representatives sell MEDRAD products to customers. For this distribution channel, the Global Distribution Network (GDN) works with dealers to develop market plans, and provides sales, service and product training, and sales, promotional, clinical and service support, to help dealers build customer relationships and grow business. Regular distributor meetings and participation in annual regional employee meetings also build relationships.

3.1b3 MEDRAD uses the approaches described in 3.1a3 to keep its customer relationship building approaches current with business needs and direction and to sustain its customer-focused culture. A recent example is the total redesign of MEDRAD's web site in 2009 (7.5a2). This initiative originated in strategic planning and was endorsed by the CSAB as a project, who reviews progress. Another example is the 3 cycles of improvement in MEDRAD's customer satisfaction approaches, described in 7.2a1.

3.2 Voice of the Customer

3.2a1 Listening builds trust. MEDRAD listens and **obtains actionable information and feedback on products and customer support** (Figure 3.1-1) through multiple listening posts, which may **vary** based on region or segment (Figure 3.1-2). Systematic collection, dissemination, and analysis of VOC information ensure that employees have the information they need to make customer-focused decisions and improve customer engagement.

As described in (3.1b.2), Field Teams interact with customers daily and capture information in CRM databases. At regular field team meetings, customer insights are discussed and programs created to address them.

Information from customer surveys (3.2b1) and complaint analysis (3.2a3) are aggregated with CRM database information. MEDRAD relies on other listening approaches to provide actionable information for new product development, portfolio planning, and business development. These include

Figure 3.2-1 Complaint Process

Step	How	Who
1-Originate	Complaint received via phone, email, FSR, Web, Survey, Field interaction	Customer contact employees, Customer Sat Catchers or Champions, Complaint Handlers
2-Capture	Complaint entry into CRM, Customer Sat or Complaint database	Same as above
3-Investigate and Resolve	Complaint evaluation workflow	Complaint Handler
4-Follow up	Per customer request	Complaint Handler
5-Analyze	Weekly reports, team meetings	Compliance, Service, Operations, Customer Support, Logistics or Perfect Order team
6-Improve	CAPAR/MSCAR tracked to closure Complaint review meetings	MMR members, Suppliers as needed Complaint team, Field Logistics or Perfect Order teams

primary and secondary market research and the Key Opinion Leader program (3.1a1), as well as customer visits and focus groups, to gain in-depth understanding of product requirements. Luminary sites, which are customer sites used to demonstrate products to potential buyers, provide valuable product feedback and improvement ideas from both current and potential customers.

MEDRAD follows up with customers on the **quality of its products, support, and transactions through** direct questioning in every phase of the Sales Process. Field Teams have primary responsibility for these follow-ups. The CRM database gives them information about products, support, and transactions. They report the results of their follow-ups including issues, problems, and/or action items via the CRM system to Engineering, Operations, Marketing, and other departments.

Post-transaction surveys provide immediate and actionable feedback from customers (3.2b1)

3.2a2 MEDRAD listens to former and potential customers and customers of competitors through the listening posts described in Figure 3.1-2. The VOC process (Figure 3.1-1) includes these customers in studies to identify or improve products and services, or determine support requirements and mechanisms. Marketing and Field Teams gather information on products and services from former customers and customers of competitors, in addition to potential customers, at Trade Shows and in their work with Key Opinion Leaders, capturing the information in CRM databases for aggregation and use in product or process improvement.

MEDRAD captures the reasons for lost sales from **former customers and customers of competitors**, and inputs them into the CRM system, for aggregation to uncover lost-sales trends and address issues. The CRM account contact list identifies existing customers by department and **potential** users of MEDRAD products in related departments so that Field Teams can begin to develop new relationships within existing customer organizations and learn about their needs. In addition, the Relationship Customer Satisfaction Survey (3.2b1) includes **competitor and potential** customers in the sample, which provides opportunities to listen to competitor and future customers.

3.2a3 MEDRAD's **customer complaint process** (Figure 3.2-1) begins with receipt of the complaint, proceeds with evaluation or investigation of the issue, and ends with resolution of the issue and follow up to ensure satisfaction. The process **recovers customers' confidence and enhances their satisfaction and loyalty by**:

- Capturing complaints from any channel (Step 1-3)
- Ensuring prompt and effective resolution (Step 2-3)
- Following-up to recover customer confidence, enhance satisfaction and engagement. (Step 4)
- Aggregating and analyzing complaints to make improvements internally, and with suppliers (Step 4-6)

Global field or other customer contact employees enter complaints into CRM, Survey, or complaint databases, which route complaints to complaint handlers for action. Product complaints are managed according to FDA Quality System requirements to ensure timely follow-up and resolution. Actioners may follow up with customers to provide customer relationship enhancement by addressing dissatisfaction and resolving issues promptly, drawing on whatever resources are

necessary to recover customer confidence. Additional followup occurs as needed until the customer's needs are met.

Regularly scheduled complaint review meetings include business representatives and the heads of Manufacturing, Shipping, Supply Chain, and Customer Satisfaction to ensure cross-functional alignment.

Issues identified from customer complaints and related product/process improvements are presented to senior leaders at MMR or CSAB and tracked to closure. Critical and repetitive complaints are escalated to the CSAB for monitoring and resolution.

Complaints related to patient safety are documented and acted upon according to FDA medical device reporting guidelines with an added degree of speed and rigor.

In MMR, CSAB and weekly meetings of department heads (Step 5, Figure 3.2-1), complaints are **aggregated** by business and product category and **analyzed** by issue and frequency. **Suppliers** participate in analysis or resolution as needed. When trending and analysis identifies a higher frequency or severity, the issue is assessed through the Corrective and Preventive Action Request (CAPAR) to determine if a CAPAR is warranted. Resources are assigned to manage the CAPAR, which is tracked until root causes are identified and the corrective actions validated as effective.

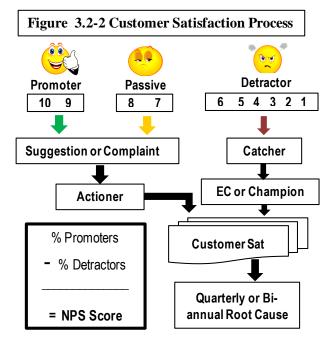
The Customer Satisfaction process' "detractor" focus (3.2b3) proactively **anticipates customer complaints.**

3.2b1 Determining and improving customer satisfaction and engagement is the major focus of the CSAB (Figure 1.1-1), responsible for continuous improvement in customer satisfaction, a Scorecard Goal. CSAB measures, tracks, and improves the customer experience, sponsoring improvement initiatives and tracking their progress. CSAB sponsored three major improvement cycles of MEDRAD's approach to customer satisfaction and engagement (7.2a1), each establishing a higher standard for satisfaction.

In 2007, the Global Customer Satisfaction department completed a total reengineering of the customer satisfaction process, moving to Satmatrix' Net Promoter Score (NPS), the most sensitive metric in the industry (Figure 3.2-2). It is calculated as the percentage of Promoters, minus the percentage of detractors, and is more sensitive to dissatisfaction than past Top Box or Percent Positive metrics. Research shows that Promoters are extremely loyal and engaged, and that an NPS score of 10% is average, and 50% or higher is best in class.

The Global Customer Satisfaction department designs and improves customer satisfaction surveys based on customer feedback gathered from users of the survey results and through MEDRAD's various listening posts. The process is deployed to all major regions, markets and **partners** and aligns with the Sales Process (Figure 3.1-3).

Three types of surveys cover **key customer groups** and **market segments**: 1) The monthly Relationship Survey measures customers' overall perception of MEDRAD. 2) The Purchase Transaction Survey measures the satisfaction with Sales, Service, Clinical and Support related to equipment purchases in each region. 3) The Field Service and Multivendor surveys address service customers receiving service. All surveys use the approach described below, with a "likely-to-recommend" question, as well as what MEDRAD does well and recommendations for improvement.



Special project surveys are conducted as needed to determine the satisfaction of specific customer groups or with specific products or services.

Based on their responses to a "likely to recommend" question included in all surveys, the NPS process segments customers into three categories (Figure 3.2-2). Detractors are automatically assigned to a regional Catcher, a field manager responsible for reviewing the response and assigning an actioner. Actioners are EC members, Customer Champions, or team leaders who increase **engagement** by resolving issues and capture **actionable** information for improvement. Promoters or Passives with suggestions or concerns are also assigned to appropriate Actioners. Catchers and Actioners complete their follow-ups within a specified time, to increase engagement. They capture root cause, issue resolution, and any further action needed in the Customer Sat database for action, **aggregation** and **analysis**.

Customer Champions from every business, region, and support function aggregate and analyze data from the survey and from actioners. They present causal analyses to the CSAB at least once annually, with business units and regions reporting three times/year. Business units' causal analysis includes satisfaction results, product complaints, and warranty and service results. The Global Customer Satisfaction department aggregates and analyzes global data monthly, and trend reviews quarterly, presenting results and recommendations to CSAB. Through these reviews, MEDRAD aligns its customer approaches with customer expectations, to build engagement.

3.2b2 MEDRAD compares its scores with those of **other organizations** and **industry benchmarks** using the NPS methodology (7.2a1). Customers surveyed include past customers who purchased **competitor** products; responses to openended survey questions also may reflect satisfaction with features or benefits of **competitors**.

MEDRAD benchmarks best practices of companies in the medical devices industry, especially distribution channel partners who share the same customer base globally and provide competitors' products. Sharing best practices with these companies helps MEDRAD understand what customers expect from their best suppliers. MEDRAD shares lessons learned throughout the organization through the CSAB meetings and, globally, through email, training, videos, and Field Team meetings.

In 2006 MEDRAD joined the benchmark group Competitive Advantage through Customer Satisfaction Excellence (CATCSE), a diverse group of non-competing companies. Members meet three times a year to share best practices in customer focus strategies.

3.2b3 The focus of the NPS process is to convert **dissatisfied** customers to **loyal** customers. It uses the approaches described in 3.2b1 to **capture and analyze information** from dissatisfied "detractors" **for use in improving the customer experience throughout the organization, and by partners**. Follow-up is required for all detractors, as well as for any customers that request follow-up on the survey. The system automatically generates causal analysis graphs segmented by Promoter, Passive and Detractor, to understand and address dissatisfaction. Information captured in the Complaint process (3.2a3) is also used to understand root causes of customer dissatisfaction.

3.2c1 MEDRAD uses the SPP (2.1) and the PLP to identify current and potential customer, product, and market groups and determine which to pursue. Both processes use VOC information gathered through MEDRAD's listening posts (Figure 3.1-2) which includes competitor and other

Figure 3.2-3 Data Used in Segmentation

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potential customers.

An open feedback channel established by Field Teams and **partner** organizations captures feedback from current and potential customers and customers of competitors. This feedback is documented and becomes an input to the SPP and PLP. MEDRAD uses this information to understand specific benefits of products, services, and customer experiences with competitor offerings, evaluates how these benefits compare with equivalent MEDRAD offerings, and **determines** what products or services will close the gap. In some cases, MEDRAD may choose not to close the gap if the action does not fit its strategic framework.

Product development teams use VOC and market information in the PLP to determine customer **requirements**, and design and develop new and updated products. VOC primary research is conducted to plan the next product offerings and feature sets. Throughout the PLP, additional VOC is conducted worldwide to ensure that the product will meet the needs of the targeted customer groups and market segments, which include the customers of competitors.

During SPP (Figure 2.1-1), customer groups and market segments are identified.

All of the data groups are used for each targeting activity, but the degree of usage varies depending on the stage. SPP relies more on market trends while product improvements via PLP rely more on customer satisfaction and sales information. Data usage also depends on whether customers are being targeted for current or future offerings.

The Marketing Excellence process is used to **define markets, buying process, and identify relevant brand positions**. Once the relevant segments are identified, they are prioritized and sequenced based on attractiveness criteria. VOC is frequently used in this process.

3.2c2 MEDRAD's VOC Process includes detailed steps, templates, and "darn good examples" of how to gather, analyze, and prioritize customer information to **determine customer requirements** and **changing expectations, and their importance to customers.** All of the customer information gathered by Marketing through this process is fed into the PLP, which includes a Marketing Requirements Document and Product Requirements Document that drive the detailed design. Advisory Boards or thought leaders may be engaged, to review the design and ensure that it meets customer requirements and **changing clinical and regulatory practices**.

Through the VOC process and PLP, MEDRAD identifies different customers, customer groups, market segments, and customer life cycles for each new and updated product. The processes are used to determine **requirements** for **each segment** and group. Marketing uses customer information to understand how customers perceive MEDRAD's products and services and how they are being used during clinical procedures worldwide. Regional differences and market segment characteristics are identified. Analysis of the differences in how a product is used and the frequency of use help MEDRAD **understand and anticipate differences in customer groups** and market segments through the product life cycle.

3.2c3 Sales reps and managers use listening post information captured in CRM systems to track customer retention and evaluate product performance. They use data from the win-loss analysis to **understand and quantify the efficiency and effectiveness of the Sales Process** (Figure 3.1-1), predict revenues, and identify the reasons for lost customers, which are captured in the CRM system.

Marketing managers analyze customer information to assess product and service requirements and improve forecast efficiency. Each product line has a marketer assigned to determine customer and product requirements and set a five-year product roadmap. The requirements and roadmaps feed the SPP and are used to define the direction for each modality and for the company. The resulting plans drive improvements and innovations in products, features, and work processes. Market research and strategic planning assess effectiveness, cost, and accessibility of market research used in

development, planning and forecasting and make **improvements**, like the Marketline newsletter.

The Customer Satisfaction department and CSAB assess overall approaches as part of the SPP, and in their regular reviews, to build a more **customer-focused culture**. The three cycles of improvement described in 3.2b1 arose from these reviews. When customer satisfaction survey data indicated customers wanted more contact with their Sales reps, an improvement team was formed to analyze best practices, and the Email Education bulletin was created.

3.2c4 The owners of each listening post identified in Figure 3.2-1 **keep their approaches for customer listening current with business needs and directions** through periodic reviews of the listening posts and the SPP. Zone Managers meet quarterly with cross-functional team members to discuss customer preferences and requirements and the methods of determining and meeting them. Sales Managers meet quarterly to discuss sales progress compared to objectives and to exchange information on market dynamics. Twice a year, senior leaders and marketing managers join these meetings to help align regional findings with a global perspective.

The CSAB improves the use of survey data by leading improvement initiatives using IMAGES or other improvement processes (P.2c). It also leads improvement of the customer satisfaction process to keep current with business direction with customer needs. The CSAB and Global Customer Satisfaction department review surveys annually to make sure they are addressing appropriate customer and market segments, asking about relevant customer and market requirements, collecting the right data from the right customers, incorporating effective analytical methods and measurement scales, and recording and communicating results. Internal survey customers help determine the appropriateness of the questions, which are added, deleted, or revised as part of this process.

4 MEASUREMENT, ANALYSIS, AND KNOWLEDGE MANAGEMENT

4.1 Measurement, Analysis, and Improvement of Organizational Performance

4.1a1 Senior leaders **select key organizational measures** (Figure 4.1-1) to **align** with MEDRAD's Philosophy, Mission and Scorecard Goals (P.1a2). Working with relevant functions and teams, the EC uses the waterfalling process (Figure 2.2-1) to deploy the Top 12 and associated measures throughout the organization. Teams **select measures** that **align** with the Sco-

Mission	Scorecard	Measure	Enganonar	Target	Projections			Danahmault
MISSION	Goal		Frequency		2010	2012	2014	Benchmark
	Exceed the Financials	Gross Margin	Monthly					
Ensure continued growth and profit	Grow the Company	% Revenue Growth	Monthly					
	Improve Quality & Productivity	Operating Income per Employee	Monthly					
Improve the quality of healthcare	Improve Customer Satisfaction	NPS	Monthly					
Provide an enjoya- ble and rewarding workplace	Improve Employee Satisfaction	GPTW Overall Score (Fig. 7.4-1)	Yearly					

Figure 4.1-3 Cascading Performance Measures

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recard and facilitate assessment or prediction of performance. The depth of measures and reporting frequency is based on each function's needs, with **collection** and reporting processes established to enable reviews and course correction. Each business aggregates its performance results in a monthly Scorecard aligned with the Corporate Scorecard. Strategic Measures **align** to Operational Measures and are then cascaded throughout the organization (Figure 4.1-2).

Scorecard results are published monthly on the Intranet. ABs (Figure 1.1-1) track progress on the **strategic objectives** and overall **organizational performance** and communicate performance through the methods listed in Figure 1.1-2. Performance on Top 12 objectives is reviewed regularly by sponsors, in depth on a rolling three-month basis by the EC, and more frequently by exception.

MEDRAD **collects, integrates**, and delivers data and information from all sources through an extensive IT network. The core system for managing **daily operations** is SAP. All SAP information is housed in one instance of the application globally to maximize the comparability and rapid dissemination of information. **Operational and financial data** reside in the system, with information integrated from other sources including PDM and CRM systems. Over 800 employees have SAP access, with all major operations in the world connected to one global instance.

MEDRAD focuses on sharing data critical to achieving the Scorecard Goals.

Departments deploy and maintain work-group level systems such as PLM and CAD tools. The focus is on data that helps achieve Scorecard Goals. CRM systems are used in regular meetings to **align** sales projections with forecasting and production planning.

In-process measures are used in a wide variety of functions. The CSAB assesses measures like cycle time and champion follow-ups in the NPS process (3.2b1). Support organizations like the IT HelpDesk track customer satisfaction scores. An integrated ITSM system used for managing HelpDesk incidents monitors performance against established Service Level Agreements (SLA) and escalates issues that have breached their SLA.

The measures in Figure 4.1-1 are the company's annual operating **performance metrics**. For **longer-term performance metrics**, the SPP sets measurable goals and objectives (2.2b). Three of the Scorecard Goals - gross margin, revenue growth, and operation income per employee - are **key financial measures** that are used for tracking performance and inputs for longer-term planning and projection (Figure 4.1-1).

When commissioning new initiatives, proposals are supported by a common financial justification. Key **data** are measured and reported to track progress. Within IT, the monthly status report includes metrics related to performance versus target on the timing, budget, quality, and customer satisfaction for key initiatives. At the close of all major IT projects, the responsible program manager presents a "Business Case Realization" explaining whether the project

achieved its original aims, to what degree, and the source of any shortfall. A business case analysis has recently been completed on the three-year project, showing that the team realized more than 80% of the original benefits. The Steering Committee then worked with the project team on a strategy to capture some of the as yet unrealized benefits.

4.1a2 The selection of comparative data (P.2a3, P.2c) begins with the Scorecard Goals, which reflect benchmark data. With respect to financial metrics, MEDRAD focuses on medical device organizations that are in the top quartile of performance. Employee and customer benchmarks are selected based on achievement of best-in-class results, across industries. Benchmarking is part of MEDRAD's approach to continuous improvement (P.2c). Work groups select organizations and practices to benchmark for learning and to drive innovation, most notably for processes considered critical to MEDRAD's competitive success. Senior leaders ensure effective use of measures by requesting benchmarks and comparative analyses for SPP and proposed targets for the Top 12 and by reviewing and sharing results at monthly department and AB meetings.

Some functions obtain benchmarking information through sources such as HR's use of GPTW and Hewitt Associates, IT's consultations with the Gartner Group and SAP, and the Electromechanical (EM) facility's affiliation with *Industry Week* and the Kennametal Center for Excellence. NPS provides comparisons to other organizations that use the NPS methodology, and the Point, a QuickBase market research database, provides key market comparisons.

MEDRAD collects competitive information (Figure 4.2-2). The information is also a key input to the SPP (2.1a2). MEDRAD conducts competitor research and includes this

Figure 4.1-2 Key Organizational Performance Reviews

Group (Frequency)	Topics	Key Measures and Indicators Reviewed
Executive Board (Monthly)	Strategy & resource allocation	
Executive Committee (Monthly)	Business performance and key initiatives	
ABs (Monthly)	See Figure	
• CSAB	1.1-1	
• HRAB		
• CEAB		
• LAB		
• IAB		
• EHSAB		
• GFAB		
MEDRAD Management Review (MMR) (Quarterly)	Quality System Is- sues	
Business Reviews	Business	
(Quarterly)	performance	
Health & Safety	Health and	
Committees (Monthly)	safety per- formance	

information in decisions.

Functions, teams, and individuals use different benchmarking approaches, from surveys or acquisition of secondary research to formal and informal third-party analyses. These benchmarking efforts are shared as part of objective and project reviews, through department and team meetings, and through communication channels such as CEO *Highlights*, MedNews, and status reports.

4.1a3 MEDRAD systematically evaluates its **performance** measurement system annually as part of the SPP. The system is kept current with MEDRAD's needs and directions through the process of aligning the measures with Scorecard, Top 12, business, and function objectives. There is a defined process for improving the performance measurement system based on reviewing trends in data and its usefulness in decisions over time. Examining trends led to cycles of improvement in measuring both employee satisfaction and customer satisfaction measurement systems. The EC confirms objectives and reviews proposed measures and goals to verify alignment with desired results and to ensure their ability to project performance improvement. IT and Finance assess performance measurement and propose improvements either through the SPP or in response to benchmarking findings or input from ABs. Each business and function modifies its measures to align with Scorecard goals and with changes in the organizational structures and external environment.

MEDRAD ensures that its performance measurement system is sensitive to rapid or unexpected change through reporting tools that provide timely information to areas that might be affected most by market changes. These measures and MEDRAD's many listening posts (3.2a1) help the company react very quickly to change. On a quarterly basis, there is a defined process of reassessment of the strategic and operational plans for all businesses that results in adjustment of goals and updated forecast for the company. AB reviews and input help keep the organization attuned to changes.

4.1b Senior leaders evaluate MEDRAD's **performance and capabilities** during organizational performance reviews (Figure 4.1-2). MEDRAD relies on project and objectives trackers, scorecards, and forecasts at the corporate, business, departmental, and process levels to aggregate data that are **analyzed** by senior leaders, departments, and process teams. This includes financial data as well as other key metrics such as Customer Satisfaction and Employee Satisfaction results. Senior managers meet regularly at EB, EC, MMR, AB, and staff meetings to review and discuss **analyses** and detailed operational measures.

The alignment of **analyses** with key business results is also supported by compensation plans that link achievement of all Scorecard Goals with team and individual pay (5.1a3).

Businesses prepare **performance analyses** that typically include both actual versus plan/objectives and historical trend information. MEDRAD is future oriented in these **analyses** with a heavy emphasis on forecasting the results compared to plan, prior year, and prior forecast. Senior leaders use these forecasts and **analyses** by the groups listed in Figure 1.1-1 to detect actual variations and anticipate issues, enabling management to initiate actions to meet objectives and improve performance.

Leaders require comprehensive **analyses** to support the

SPP (Figure 2.1-1) to develop short- and longer-term plans. As part of the SPP, teams analyze market and customer characteristics, competitive landscape, SWOTs, resource requirements, and acquisition landscape.

As described in 2.2a2, business and functional groups develop their own strategic plans with common elements such as: linking all initiatives to the Scorecard Goals and Top 12; performance measures; and interdependencies with other parts of the organization. These plans are reviewed by the EC and with the peer managers of other functions to ensure alignment, consistency, and support.

The goal of each **review** listed in Figure 4.1-2 is to act quickly on data, information, and **analysis** that indicate a problem or opportunity. SMART objectives and specific measures are set for each key initiative under review. Monthly, the governing bodies in Figure 4.1-2 review quantitative and qualitative results against the SMART Objectives, and make short-term course corrections as necessary. Long-term results and trends flow back into the SPP and portfolio planning process.

4.1c Findings from organizational reviews that require action are tracked and resolved by SATs. ABs and functions translate review findings into priorities for improvement and innovation. Leaders of the review body identify and prioritize process improvement opportunities and commission action, either as part of iterative review and action (2.2a2), resource reallocation, or during improvement planning (2.1a1) for longer-term initiatives. In each case, alignment with the Scorecard Goals is a criterion for selection.

The communications vehicles described in Figure 1.1-2 are used to **deploy priorities and opportunities** throughout the organization to **support decision-making**. Strategic and corporate-level priorities are waterfalled from the EC through their organizations. Senior leaders summarize the progress of their areas in progress reports and the CEO aggregates this information and analyses in his monthly *Highlights* report, which is distributed to all employees. Additional channels through which information is **deployed** on a business-, region-

Figure 4.2-1 Approaches to Ensure Data, Information, and Knowledge Quality

,	7	, y	SS	tiality
Approach	Accuracy	Integrity Reliabilit	Timeline	Security/ Confiden
Full audit trails	•	•		•
Backup and restore procedures		•	•	
Authorization process	•	•		•
Change management process	•	•		•
Disaster recovery plan		•	•	
Software validation process	•	•		
Global SAP instance		•	•	
Application integration	•	•	•	
Real-time application error checks	•	•	٠	
Review of audit logs		•		•
Master data management processes	•	•		
ETL tools	•	•		

, function-, or team-level include EC meetings; AB and business reviews (Figure 4.1-2); MMRs; annual employee meetings; department and project team meetings; town hall meetings; and Intranet sites.

MEDRAD **deploys priorities** and opportunities **to key suppliers** through the communication mechanisms outlined in 6.2b1; to **key channel partners** through regular meetings (3.1b1); and to **key customers** and customer groups through Field teams (Figure 4.2-2).

4.2 Management of Information, Knowledge, and Information Technology

4.2a1 MEDRAD's **data**, **information and knowledge** are housed in one of three global, integrated enterprise systems.

MEDRAD developed a reporting and analysis tool that extends the value of information in accounting systems beyond its use for transactions. 3D accesses data from multiple source systems. MEDRAD has completed several cycles of improvement based on systemic analysis of user feedback related to management reporting. MEDRAD's SharePoint Intranet platform has enabled the creation of more than 600 department and team websites for reporting and tracking projects and measures.

MEDRAD's approaches to the accuracy, integrity, re-

liability, timeliness, security, and confidentiality of its data and information are shown in Figure 4.2-1.

MEDRAD eliminates potential lags in data availability and **integrity** by maintaining one instance of each major enterprise system globally.

The primary goal for data **security and confidentiality** is to ensure that access to data and transactions is appropriate. MEDRAD has a defined process for approving non-standard software and related authorization to major systems that includes manager approval, review by an IT domain expert, review by specific functional leaders for certain levels of access, and review by an IT Authorizations manager prior to rights being granted (4.2a2).

The company's code of conduct requires each employee to respect the **confidentiality** and **integrity** of information. In addition, the End User Security policy outlines the specific responsibilities of each end user with respect to systems and data

4.2a2 IT has established processes and tools that enable departments to create and maintain data and information that meets their requirements. MEDRAD's global locations have local networks and support to provide quick, quality responses to employees.

4.2-2 Knowledge Management Creation, Deployment and Measurement

Category	ry Creation		Method of Knowle	dge Transfer	Scorecard Goal
Philosophy, Values, Ethics	• Philosophy (P.1-4) • Defined Mission (P.1-4)	• Quality Policy (6.2a) • Code of conduct (1.2b2)	 New employee orientation Corporate intranet Annual Employee meetings Highlights Reports 	 MMR Reports Ethics training Code Challenge Integrity Hotline	Improve Employee Satisfaction
Strategy	• Scorecard goals (7.6-1) • SPP (2.1-1) • SATs (2.1a1)	• Strategic Thrusts(2.1-2) • Top 12 (2.1-2)	EC meetings / reviews Compensation structure Annual employee meetings Corporate Intranet Team/individual Objectives	PM systemBusiness reviewsBudget proposalsCEO HighlightsStatus reports	Grow the Company
Customer & Market	• NPS scores (7.2-1) • Market share data (7.3a2) • Competitive data (7.3a2) • CRM tool notes (3.1a2)	• Industry/economic data (7.3a2) • Government and regulatory trends • Emerging market trends	Email campaign Thought-leader programs Intranet/extranet sites Knowledge databases MarketLine newsletter Regulatory Newsletter Distributor surveys Distributor regional meetings	Employee briefings InfoCenter resources Third party research Channel reports MEDRAD.com Customer site visits Distributor Clinical and Service training	Improve Customer Satisfaction
Process Excellence	• SPP (2.1-1) • ITIL, PLP (6.2-1) • Incident Mgt / Disaster Recovery (6.1c) • Sales process (3.1-3) • Forecasting process	Customer sat. process (3.2b) Emerging market and new business integration processes Processes in key enterprise systems: SAP, PLM, CRM HR processes: Comp, PM (5.1-2)	New employee orientation Validated policies/procedures Intranet resources Disaster Recovery Tests Visual work instructions	• Training • Intranet team sites • IMAGES • COINS • Lessons Learned	Improve Quality & Productivity
Employee Develop- ment	• STRIVE (5.1-5) • Mandatory training for key positions • Training courses (5.1b1)	 Defined career models (5.1b4) Web-based content and skill training MEDRAD competencies (5.1-4) 	 Annual development plans Employee training sessions Web-based training tools Tuition reimbursement Job rotations/cross-training 	 Intranet team sites PM system WLI Learning Management System 	Improve Employee Satisfaction
Best Practices	• IMAGES (P.2-1) • LSS program (5.1b1) • VIP program (7.4-6/7)	 President's Awards (5.1-3) Internal/External Audits External benchmarks (4.1a2) 	Reward and recognition Certification programs Training	Web-based tools Performance Excellence Conference	Improve Quality & Productivity
Suppliers & Partners	• Inventory management • Supplier Scorecard (P.1b 3, 6.2b3) • Supplier agreements		Extranet sites for collaborate Daily emails on Inventory and projected demand	Supplier DaysQuarterly meetingsDesign change triggers	Improve Quality & Productivity

Figure 4.2-3



Most **employees** have individual computers to access the network, while the balance can access the network through common workstations. Business areas are responsible for granting access to company-wide information and for information content. IT can manage access centrally or allow the application owner to manage access. Critical business systems require manager approval through a formal process for access and licensing.

MEDRAD uses an Intranet to share corporate and local business information. The Intranet also hosts numerous team sites that allow for real-time collaboration among smaller workgroups. To ensure quality Intranet content, IT implemented a content management process that allows for distributed publishing, approval controls, and version control. Average daily page hits on the corporate Intranet have increased from 4,400 in 2007 to more than 7,800 in 2009.

At each of its major locations, MEDRAD maintains a physical information center with relevant company information, industry information, books, and periodicals. The Info-Centers are staffed with dedicated library science professionals to assist with specific research requests. The centers also have PC kiosks for **employees** who do not otherwise have access to computers. The vast majority of InfoCenter resources are also available to **employees** online for remote and international **employees**.

In 2009, MEDRAD conducted a systematic evaluation of the value its external website provided **customers**. This data resulted in a project to improve its public Internet site to a more user-centric model, which provides **customers** with product information, white papers, application information, and a complete Field Directory, as well as email newsletters. Marketing manages site content, communicates relevant information, and uses site statistics to make improvements. Since the launch, the number of monthly inquiries has increased 11 times versus the previous site.

MEDRAD has worked to expand its communication and collaboration capabilities with **suppliers** as indicated in 6.2b1.

MEDRAD utilizes SharePoint extranet capability to establish collaboration forums with key **partners** and outside organizations, including suppliers and OEMs.

To assess the **availability** of data and information, IT monitors usage, tracking logons in SAP and hits on information items on the Intranet. IT uses this data to manage software license costs, identify opportunities to improve information availability, and promote IT's capabilities.

4.2a3 Knowledge Management at MEDRAD begins with defining what knowledge is most critical to the organization; creating assets that capture that knowledge; utilizing multiple deployment channels to ensure the dissemination and reinforcement of the knowledge; and defining measures to check the effective use of the knowledge (Figure 4.2-2).

ABs and functional groups guide the collection and

transfer of organizational knowledge through crossfunctional meetings, the Intranet, various databases, training courses, job rotations, and other communication approaches and tools. The biweekly MedNews newsletter provides employees with a channel for sharing key business information. The newsletter is available online and in hard copy.

Databases and tools for **collecting and transferring workforce knowledge** include CRM for field sales and service, PLM for product development, InfoCenters, and others (Figure 4.2-2). Additionally, knowledge transfer is enabled through the use of "team sites" on the Intranet. These sites allow users to form a specific community around a project, issue, or area of interest and collaborate and share knowledge in real-time (4.2a1).

Within MEDRAD's customers, suppliers, and distributors, multiple two-way mechanisms are established to promote effective knowledge transfer (Figure 4.2-2).

The identification and sharing of best practices is done by teams and functional departments in a variety of regularly scheduled sharing forums. MEDRAD's global IT, Finance, and HR organizations meet annually for training and to share best practices. Field personnel attend regional meetings to share information and best practices. Product development leaders meet regularly on a cross-Business basis to share perspectives and to promote domain specific knowledge sharing. Operations hosts cross-plant learning sessions. The annual Performance Excellence Conference is a showcase for best practices, at which teams present their practices and results to compete for the President's Team Award (Figure 5.1-3). As a result of systematic evaluation, an IMAGES team recently improved the President's Team Award process to increase the identification and sharing of best practices across the organization.

Additionally, specific analyses are performed as inputs to the **SPP** (Figure 2.1-1). Business and functional groups are responsible for completing a pre-defined set of deliverables, including analyses of industry trends, competitive assessments, comparative analyses of key benchmarks, historical and projected financial data, and internal assessments of capabilities and SWOT analysis. These analyses ensure common knowledge and grounding of all parties in discussion of strategic alternatives, as well as ensuring that strategies have the supporting data to justify conclusions and recommendations.

4.2b1 MEDRAD ensures hardware and software reliability, security, and user friendliness. By maintaining a global Enterprise Resource Planning system, IT provides a reliable, secure network that supports the operation of all business systems. Hardware and software reliability and userfriendliness are also ensured by maintaining outstanding service processes. IT HelpDesk tracks response to incidents by time and severity, based on service level agreements (SLAs), and the percentage of incidents rated as "Top Box" by the customer (Figure 7.5-7). MEDRAD benchmarked the Help-

Desk Institute to understand best practices, creating a structured development and career path for HelpDesk employees.

IT follows a formal process to review and approve requests for access to systems. IT requires user IDs and passwords to access major systems and control information availability. **Reliability** is promoted by having a well-defined change control process. MEDRAD has adopted the ITIL framework and designed processes around Incident, Problem, Change, Release, and Configuration. For major implementations, each project follows a defined stage-gate review process (Figure 4.2-3) that includes cross-functional peer reviews before it can advance to the next stage. Each project team consists of a core team with a representative from each major IT function. This ensures that solutions are designed for long-term reliability, and supportability.

System tools are used to ensure that no change can be promoted to a production environment until approved by the Change Control Board. All change control processes have been incorporated into an IT Service Management Tool, which is modeled on ITIL benchmarks and best practices.

Reliability is also promoted by thorough Quality Assurance processes. IT relies on validation plans and test protocols to make sure systems meet user requirements, which is critical for QSR/Part 11 compliance. A member of the QA function is dedicated to IT and signs off on all changes before they move to production.

Ease of use is promoted by strong user involvement throughout the development process. Users are required to sign off on all requirements and designs as a precondition for moving to the Build phase. Users are enlisted to participate in conference room pilots and to help create and execute test cases, which optimize the usability and furthers understanding of the solution. The Deployment stage-gate requires that the project team present a training and deployment plan for all users. The Support stage-gate requires that the solution be formally "accepted" by both the user sponsor and IT before the initial project team can consider the project complete (Figure 4.2-3).

4.2b2 MEDRAD's first priority in **emergency** management is prevention. Tools are used to monitor the status of critical systems and provide proactive alerts if systems approach a breach of availability or performance. IT maintains an emergency response and disaster recovery plan that supports the company's Emergency Response Plan (6.1c) and enables rapid decision-making when an incident occurs. MEDRAD has identified the critical processes, resources and utilities required for **continuity availability of systems and data and information**. For example, MEDRAD has installed a permanent back-up data center at a different site than the main data center.

In the event of a declared disaster, the IT Disaster Recovery Plan is implemented. It outlines service recovery goals for critical systems, the specific roles of each individual, and contains a work plan for restoring key systems. IT tests its disaster recovery plan annually through an unannounced simulated emergency. IT takes down key systems and restores them in disaster mode at a remote back-up data center, tracking the timing and effectiveness of the recovery, an innovation developed in 2003. The results of testing are communicated to the

EC, who are responsible for monitoring effectiveness of the emergency management plan and sponsoring related continuous improvement activities.

4.2b3 MEDRAD has established roles and processes to ensure that its **systems remain current with changes in both business and technology**. Process leads are aligned with particular processes. They are responsible for domain expertise in their processes and for remaining current on technology advances within those domains. Designated IT directors in each of the businesses take a more strategic view of IT for their business and using IT as a competitive advantage in their business. These roles converge in an annual and ongoing IT portfolio planning process in which proposed projects create business cases and are evaluated against various strategic priorities. The outcome of this process is an approved portfolio of initiatives which drive process and technology improvements. This portfolio is monitored and updated on a monthly basis.

The Infrastructure Application Committee (IAC) is responsible for monitoring changes in technology and emerging trends and for translating that information into near- and longer-term infrastructure and innovation opportunities. The IAC recently championed an initiative to move to a virtualized server environment, resulting in reduced hardware costs and greater flexibility.

5 WORKFORCE FOCUS

5.1 Workforce Engagement

5.1a1 The GPTW survey (5.1c1) is based on twenty years of research to determine the factors that define the best places to work. These **factors**, listed in Figure 5.1-1, are highly correlated with **workforce engagement and satisfaction**, and business performance. MEDRAD validates these factors as it implements its global action planning process related to the survey results. While the factors are consistent across the

Figure 5.1-1 GPTW Key Engagement Factors

Key Engagement Factors and Related Survey Dimensions

1. Employees trust the people they work with Credibility

- Communications are open and accessible
- Competence in coordinating human and material resources
- Integrity in carrying out vision with consistency *Respect*
- Supporting professional development and showing appreciation
- Collaboration with employees on relevant decisions
- Caring for employees as individuals with personal lives *Fairness*
- Equity balanced treatment for all in terms of reward
- Impartiality absence of favoritism in hiring and promotions
- Justice lack of discrimination and process for appeals

2. Employees have pride in what they do *Pride*

- In personal job, individual contributions
- In work produced by one's team and one's group
- In the organization's products and standing in the community

3. Employees enjoy the people they work with *Camaraderie*

- · Ability to be oneself
- · Socially friendly and welcoming atmosphere
- Sense of "family" or "team"

Figure 5.1-2. Performance Management Process



company, survey results vary across workforce groups and segments. This process enables the organization to make specific determinations of engagement and satisfaction for different work groups and segments (Figure 7.4-2). MEDRAD also considers performance on key indicators of employee engagement and satisfaction including retention, productivity, gainsharing performance, and safety records. Analysis of the reasons for any significant change in these indicators includes the impact on employee engagement and satisfaction.

5.1a2 MEDRAD creates a **culture of open communication**, **high performance**, **and engagement** through many communications approaches (Figure 1.1-2) and extensive use of functional and cross-functional teams on a global basis. These teams cut across locations, businesses, and levels, facilitating horizontal communication and collaboration at all levels:

- The EB, EC, and ABs (Figure 1.1-1) exemplify crossfunctional teamwork at the highest level, setting strategy, corporate policy, and direction, and establishing priorities.
- Top 12 Teams and SATs drive the organization's key strategies and initiatives. SATs can also be assigned to quickly address specific problems.
- Quality or process improvement teams solve problems and pursue breakthrough improvements, often with crossfunctional participation.

MEDRAD encourages employee participation on teams at all levels. Teaming approaches include planning, role definition, goals and measures, reviews, reporting, Intranet team sites, and training as needed.

MEDRAD's waterfalling and performance management processes (Figures 2.2-1 and 5.1-2) **encourage high performance and engagement** by aligning team and individual objectives with the Top 12, Scorecard, and, ultimately, MED-

RAD's Philosophy (P.1a2). In turn, these processes are supported by development of behavioral competencies that drive performance, experiential training and learning opportunities, a safe and supportive culture, and numerous services and benefits, including employee-planned events and community outreach programs that foster employee engagement.

The MEDRAD Philosophy **fosters diversity** by encouraging employees to interact honestly and openly while treating each other with dignity, respect, and fairness (Figure P.1-4). MEDRAD's culture of cross-functional teams further reinforces the value of diversity, **capturing the diverse ideas and thinking** of team participants. "Managing diversity" is a leadership competency (Figure 5.1-4), and all employees are required to participate in the Leveraging Differences course about inclusion.

5.1a3 MEDRAD promotes **high-performance work and workforce engagement** through its global Performance Assessment and Development process (PAD) for hourly employees and the Performance Management process (PM) (Figure 5.1-2) for all other employees. Both include a self-review and manager's evaluation, and focus on development and dialogue. They are managed through an internally designed system customized for MEDRAD's PM processes.

For both PM and PAD, employees and their managers set annual objectives aligned with the Scorecard Goals, Top 12, and department goals through the waterfalling process (Figure 2.2-1). In PAD, these objectives are team-based to be more conducive to driving performance in manufacturing. All employees create written development plans that address areas to improve and the knowledge and skills they need to move into other roles. In addition, PM includes a 360 process that provides feedback from peers, customers, and direct reports, as applicable. Employees self-select to receive 360 feedback, and

Figure 5.1-3 Recognition Program Examples

11gure 3.1-5 Recognition 110gram Examples						
Award	Focus		Ind.	Target Group		
President's Leadership Awards	Accomplishments reflecting the Guiding Principles		•	All		
President's Team Awards	Performance improvement projects	•		All		
Spirit Award	Supporting/encouraging coworkers; performance beyond expectations		•	All		
PEAK Award (Performance Excellence Achievement Kudos)	Exemplifying performance excellence		•	All		
Personal Promoter Power	Exemplifying customer excellence		•	All		
Sharpshooter Gross Margin Award	Increasing gross margin	•	•	Employees focused on gross margin		
Inventors Award	Key innovations and patents		•	Innovations		
Field Awards	Customer satisfaction, teamwork, sales, service	•	•	Sales, Service, Support		
New Product Development Awards	Exceptional contributions to new product development		•	NPD		
Personal Notes from the CEO	Employee anniversaries		•	All		
Examples of Departmental Awards						
Ops (Operations) All Stars	Positive internal customer satisfaction		•	Primarily Operations		
Steering for Success	Behind the scenes support award and project excellence award		•	HR		
Finance SCORE Award	Significant contribution to meeting one of the Scorecard Goals		•	Finance		

must solicit feedback at least once every three years. Focusing on behavioral competency feedback, this process is for development and is not linked to the performance assessment.

Each year, managers review employee performance against objectives and discuss performance plan goals. They use skills learned in the "Performance Excellence Through Leadership" (PETL) program, "How to Conduct a Collaborative Performance Review" course and in STRIVE (5.1b1).

To strengthen alignment with corporate goals and objectives and promote a "we are all in this together" attitude, MEDRAD provides a gainsharing payout each year based on achieving the corporate objectives minus the employee satisfaction objective, which ensures accurate responses to the employee survey. All employees worldwide receive the same amount.

MEDRAD's variable **compensation** program for managers **reinforces a customer and business focus** by linking payouts to achieving the Scorecard Goals. The program is designed to ensure that managers have a balanced focus on achieving results for all stakeholders.

A wide variety of formal **recognition** programs reinforce MEDRAD's Philosophy and achievement of its Scorecard Goals, as illustrated by the examples in Figure 5.1-3. These are supplemented with frequent informal recognition including gift certificates; tickets for sports events and other entertainment to recognize special contributions and extra effort; and team celebrations when key milestones are reached.

5.1b1 MEDRAD's learning and development system focuses on meeting the business needs of the organization and the development needs of employees. This system incorporates an integrated approach to identify and assess organizational and employee needs, determine associated actions, and ensure continuous learning and improvement. MEDRAD identifies learning and development needs through the SPP, business and functional planning, identification of competencies critical to achieving organizational objectives, and the GPTW survey. Learning and development needs are translated into actions that fall into either platform level activities (STRIVE), skill building and functional specific initiatives (Marketing Excellence, PETL courses, LSS), or individual development plans and job rotations. The above activities are supported by a continuous learning and improvement culture driven by PEC and reinforced through our PM system.

Workforce Development delivers programs that support and drive improvement on the Scorecard Goals and Top 12, which address MEDRAD's **strategic challenges** and capitalize on the **organization's core competencies** (Figure P.1-5). As described in 2.2a5, it also identifies capability gaps and develops workforce plans to build **core competencies**.

Workforce Development addresses the **development needs** of employees through programs and initiatives that support career growth and leadership development and contribute to organizational success. These include leadership, coaching, diversity, performance management, finance, communication, collaborative teaming, productivity, quality, and customer satisfaction programs.

Over the past decade, MEDRAD has developed and refined a set of behavioral **competencies** (Figure 5.1-4) to drive individual and organizational success and foster the MEDRAD culture globally. These competencies are linked to the

skills, abilities, and expertise needed to achieve the Scorecard Goals and Top 12 in a way consistent with the MEDRAD Philosophy (P.1a2). They are divided into a core set for all employees, a required set based on level, and selected competencies that are manager and employee driven. These competencies are embedded in the PM and PAD processes (5.1a3) and are used extensively for employee development. The competencies are also used to evaluate job candidates, assess employee potential in the Benchstrength and Succession Planning processes (5.1b4), create Role Profiles that define the duties and responsibilities of different jobs, and drive development planning.

Development needs and opportunities are identified through individual development planning and through the Succession Planning and Benchstrength processes. Individual development plans, developed as part of the PM and PAD processes (5.1a3), establish goals for developing the skills needed in current and future positions as well as development goals for personal improvement. Development planning is a joint responsibility of the manager and employee.

A Development Planning Toolkit clarifies the roles and responsibilities, process, and SMART goal development. Six months after the goals are set, employees meet with their managers to review progress and make corrections. Managers are also encouraged to discuss objectives on a regular basis.

MEDRAD is currently involved in a development strategy focused on developing leadership talent, building capability, and expanding workforce knowledge and skill. Core development programs are STRIVE (management development), critical functional skills (e.g., marketing excellence, project management), and critical thinking and decision quality (fact-based coaching model).

STRIVE (Figure 5.1-5) is a leadership development program with three progressive stages that include classroom training, on-the-job assignments, roundtable discussions, interviews with HR, journaling, development planning, and networking for cross-functional knowledge. Participants are evaluated during the first two stages to determine who will move on to stage three. As part of STRIVE, MEDRAD has implemented a coaching model for managers and supervisors that helps them coach employees through numerous situations including the reinforcement of new knowledge and skills.

The PEC helps build a culture of continuous **improvement** (P.1a2) through coaching, training, project support, and recognition. It supports MEDRAD's Lean Six Sigma (LSS) approach, IMAGES (P.2c), with LSS training including:

- Excelerating Excellence Fundamentals, a four-hour course required for all new employees that introduces the fundamentals of MEDRAD's continuous improvement culture and methodologies.
- LSS Green Belt Wave and Black Belt Frameworks, blended approaches that use e-learning, classroom work, peer-sharing, and project execution to get successful Green Belt- or Black Belt-level project results and Lean Six Sigma certification for chosen candidates.

These programs are supplemented with Operations' training focused on Lean manufacturing including initial training, 6S training and implementation, order fulfillment, refresher training, problem solving, and STOP safety training (5.2b1).

LSS, STRIVE (Figure 5.1-5), and other management de-

Figure 5.1-4 Behavioral Competency Model

Core: Customer Focus, Drive for Results, Integrity and Trust, Ethics and Values						
Team Contributors Supervisors/Managers Leaders						
Action Oriented	Decision Quality	Managing Vision and Purpose				
Perseverance	Developing Direct Reports & Others	Global Business Knowledge				
Dealing with Ambiguity	Motivating Others	Innovation Management				
Learning on the Fly	Managerial Courage	Developing Direct Reports and				
Problem Solving	Business Acumen	Others				

velopment training promote **innovative** thinking to **improve** processes, solve problems, and make effective decisions. In addition, training programs such as Innovator's Dilemma and Six Hats teach participants how to generate new ideas and approaches when existing approaches have been successful.

MEDRAD's commitment to **ethics** (1.2b2) is reinforced by ethics training delivered during new employee orientation and annually thereafter. Ethics training covers ten areas including commitment to fair competition, integrity in business dealings, and commitment to fair and respectful working conditions. All employees participate in compliance training and certification that is focused on areas of direct dealing with customers. In addition, all employees have an objective to promote and adhere to the company's ethics and compliance programs in our PM system.

MEDRAD offers several approaches, including training, coaching, mentoring, STRIVE, job rotation, and work-related experiences, to support **workforce and leader development**. These are used with MEDRAD's 70-20-10 learning and development model: 70% of learning occurs through experience, 20% from others (coaching and mentoring), and 10% through classroom instruction. The development planning template provides direction and examples of how to link development objectives to annual goals, which reinforces the model.

Employees are encouraged to pursue outside education and coursework at accredited universities with support from MEDRAD's tuition reimbursement program.

5.1b2 As described in 5.1a3, all employees identify their learning and development needs jointly with their managers during the PM and PAD processes. Each employee's individual development plan establishes development goals for the skills needed in current and future positions as well as for personal improvement. The employee and manager

determine how to accomplish these goals and review progress during performance reviews. During these reviews, managers bring perspectives from benchstrength sessions and assessment of performance related to skills and competencies, while employees bring insight from the 360 process as well as career interests and desires. This joint approach fosters buy-in and ensures learning and development opportunities satisfy both developmental needs and employee desires.

As described in 5.1.b1, at the organizational level, assessments are based on a review and analysis of workforce learning and development needs to support the Top 12, SATs, GPTW survey results, and input from the businesses.

In addition, MEDRAD's bench strength and succession planning process (5.1b4) is also an important component to determining **learning and development needs and knowledge transfer** opportunities globally. At a macro level the process provides an assessment of the overall depth of our talent base; identifies areas where knowledge transfer may be important due to single incumbent jobs or the changing demographics of our workforce; and identifies key positions / competencies important to achieving organizational objectives. At a micro level the process identifies strengths and opportunities for improvement for each employee culminating in specific development actions to help employees build skills for career advancement or map out potential career moves.

MEDRAD uses several methods to **reinforce new know-ledge and skills on the job**. A development planning template

Figure 5.1-5 STRIVE Process

Stage 3: Back to the Business Stage One: Basic Training Stage Two: Building Competency **CMU Management Program Building Business Acumen** Coaching High Performance Teams Understanding Human Behavior Critical Thinking/Decision Making Creating Star Performers Employment Law & MEDRAD Mgr. Generation Management Critical Thinking/Dec. Making Leading at the Speed of Trust Critical and Difficult Conversations Change Management Strategic Cost Mgmt. Managerial Communication Value Chain Mgmt Leveraging Internal Networks Strategy & Renewable Advantage Global Business Curriculum **Employees Business** The Mgmt Game STRIVE, Community of Practice (CoP)

provides guidance on how to link development objectives to annual goals, encouraging the use of new knowledge and skills to accomplish the goals. Toolkits available on the Intranet provide reinforcement and refresh learning. MEDRAD's coaching model (5.1b1) helps managers **reinforce new knowledge and skills** through coaching. For managers of STRIVE participants, a PETL course called "Making Training Pay Off" teaches managers how to help employees get the most from training experiences. Participants in STRIVE, Decision Making and Critical Thinking, and FACT Coaching journal how they are using the training and how to improve their use of it while developing action plans to apply the skills they learn and measuring the impact it has on business performance.

5.1b3 MEDRAD measures the **effectiveness and efficiency of its learning and development** efforts through post-training survey results or tests. For certain types of training, including service training, compliance and ethics, and LSS, participants must pass a written test. STRIVE participants document how they've applied supervisory techniques on the job in journals, and their immediate manager is interviewed to determine if changes in skill are apparent. Customer Survey (NPS) or Employee Survey (GPTW) scores may also be indirect indicators of learning and development effectiveness.

5.1b4 A partnership of HR and business functions has developed several Career Opportunity Models to define and guide **career progression**. The models establish expectations for the technical, behavioral, educational, and experience requirements necessary to perform in current and future roles. It links technical and behavioral skills to the Behavioral Competency Model. Together, a manager and employee use the models to create the employee's development plan, with progression within or across functions. The models are also used to assess performance and determine readiness for promotion.

To ensure that the Opportunity Models are **effective** at meeting the organization's needs, employees and managers are surveyed annually to determine strengths and opportunities for improvement. The models are refined based on this feedback and on an analysis of future role requirements to support MEDRAD's Scorecard Goals and Top 12.

The Internal Posting Opportunity (IPO) process communicates job opportunities and skills that MEDRAD needs, identifies employees with specific skills and competencies, leverages the knowledge employees have, helps recruit more quickly and effectively, and reinforces the value MEDRAD places on treating employees consistently by making jobs transparent and open for internal bid.

MEDRAD identifies and develops employees for management and leadership positions through **Succession Planning** and Benchstrength processes. In 2005, MEDRAD partnered with Lominger Inc. to develop a Leadership Competency Model that identified the competencies required for continued growth and success (Figure 5.1-4). The formal Succession Planning process is used to evaluate senior managers for potential in broader leadership roles. The process begins with a manager assessing an individual's performance over time and in relation to the leadership competencies, learning agility, and readiness for development. Next, senior leaders and managers collectively discuss the talent and identify a few high-potential individuals, for focused development. The development status of these individuals, who are targeted for future positions in

either functional or cross-functional leadership roles, is reviewed at least annually. Leaders not targeted through the succession process are developed through the PM system.

A similar Benchstrength process is used at other levels to identify and target individuals for promotion into management roles and other key jobs. The Benchstrength process feeds the Succession Planning process by identifying key talent at all levels of the organization. Based on organizational competencies, it is also used to identify collective strengths and gaps of a particular group.

5.1c1 For over 15 years, MEDRAD has been utilizing a company-wide employee survey to **assess global workforce engagement and satisfaction** (P.1a3). In 2007, MEDRAD switched from the Hay Group survey to the GPTW survey also used by Fortune magazine to determine the 100 best places to work. This change was driven by the fact that MEDRAD was consistently exceeding the benchmarks in the Hay Group survey and in the spirit of continuous improvement made the decision to benchmark itself against the Top 100 companies as delineated in the GPTW survey. The survey measures three factors and five dimensions that define the best workplaces (Figure 5.1-1), based on GPTW's twenty years of research on employee engagement.

Although the questions are different, the GPTW survey is consistent with the Hay Group survey it replaced. The GPTW categories and questions were compared to the MEDRAD philosophy and the Hay survey to ensure alignment with factors that had been validated over a long period of time.

Survey results are segmented to help identify and meet the needs of multiple segments of the employee population. Any group can access the GPTW database to learn from the Top 100 companies and best-in-class practices.

The structure of the GPTW survey affords respondents the opportunity to assess engagement and satisfaction factors for both MEDRAD overall and the specific department in which the respondent works. This enables the organization to determine drivers of engagement and satisfaction for specific work groups and segments. Each work group utilizes a consistent action planning process (review results, interpret results, communicate results, develop action plans, rollout, check progress) to identify and address those factors that are most important to satisfaction and engagement for that particular group or segment. For example, at a MEDRAD level, programs are developed to address a corporate wide focus area while at a work group / segment level there are specific initiatives to address opportunities for improvement that are unique to that work group / segment. These initiatives are communicated and reinforced through corporate top 12, business top objectives, monthly reports, and ultimately management accountability for future survey results.

MEDRAD obtains input on major policies, issues, and events that affect the workforce, such as flexible work arrangements, the drug and alcohol policy, vacation accrual, and the healthcare benefits program, through focus groups and MESA and international working councils. The move to the Global Center was coordinated by work teams that gathered employee input and addressed employee concerns. Focus groups, work teams, and project teams enjoy enthusiastic participation, an indication of MEDRAD's culture of high employee engagement.

The methods and measures for assessing workforce engagement and satisfaction do not **differ across groups**. Each group determines how it will respond to the survey and focus group findings to address opportunities for improvement. Employee teams recommend and implement changes they believe will increase engagement and satisfaction. Management reviews the recommendations for insight into the factors affecting morale. Bottom-up solutions ensure that the voice of the employee is heard and that actions taken are likely to be effective and to support improving engagement and satisfaction.

In addition to survey and focus group results, MEDRAD uses several **other indicators to assess and improve work-force engagement** and business results including employee retention, productivity, customer satisfaction, gainsharing performance, and safety records. All of these items are indicators of employee engagement and are monitored for any changes in trend. Changes are investigated to determine root causes and whether or not causes are related to **employee engagement**.

5.1c2 MEDRAD relates **workforce engagement** and satisfaction to key **business results** through the Scorecard (Figure 4.1-1). Employee satisfaction, as measured by the GPTW survey, is one of five Scorecard Goals. In addition, GPTW provides analysis and correlations of employee survey results and business performance.

5.2 Workforce Environment

5.2a1 MEDRAD assesses workforce capability and capacity needs during the SPP and as part of reviews of the Opportunity Models, Succession Planning, Benchstrength process, and Competency Model. During the SPP, each department's leadership, which includes an HR partner, determines the objectives and projects and human resource requirements including skills, competencies, and staffing levels necessary to achieve the plan. These plans are aggregated and analyzed to determine overall capability and capacity needs, including numbers, levels, and skills.

5.2a2 MEDRAD translates the longer-term strategic planning needs into annual staffing plans during the budgeting cycle for its global workforce. New positions are first offered to internal candidates through the IPO process (5.1b4); however the IPO process is also MEDRAD's best source of outside referrals due to engaged employees who encourage outside candidates to apply.

MEDRAD has implemented the Talent Acquisition Process, which includes an online applicant tracking system that speeds the **sourcing and hiring** of qualified candidates. Teams of five to ten members assess candidates, using a behavior-based selection process focused on MEDRAD's competencies and aligned with the workforce planning process. This ensures a thorough evaluation of candidates and supports strategic staffing for the future.

MEDRAD has established specific **recruiting** strategies to meet key staffing needs. To "seed" the organization, especially in hard-to-fill engineering and business positions, it developed a college recruiting process that has been continually refined since 2000. For example, MEDRAD has a college ambassador program to focus on engineering and business students. The organization estimates its need for future engineers based on the budget and strategic planning process. It uses these estimates to adjust its college recruiting goals. To

support growth in a global marketplace, MEDRAD identified four areas of international focus this year

To compete in the challenging medical device market while improving performance, MEDRAD must have access to and attract qualified and **diverse** candidates. MEDRAD's outreach recruiting strategy focuses on developing partnerships with diversity-focused recruiting agencies, participating in diversity-focused organizations, sponsoring diversity-focused events, and building relationships with local colleges and universities to attract and hire a diverse group of interns, co-ops, new college graduates, and ambassadors. MEDRAD's college relations program identifies college societies and organizations that have a diversity focus or diverse groups of students.

Interviewers are trained to ask questions that encourage **diverse hiring** (P.1a3). Staffing reports reviewed by the EC show the ratio of new hires versus terminated women and minorities to help assess the full impact of hiring strategies.

In addition to the **recruiting** and selection approaches outlined above, MEDRAD's talent management processes also play an important role in achieving a diverse workforce. Annually objectives are set to achieve our diversity goals in identified areas based on the desired demographics of our workforce. Actions to achieve these goals are accomplished through our Succession Planning and Benchstrength processes where high potential females and minorities are identified for development, movement, or promotion. For example, this year a key focus area for MEDRAD is increasing female representation in leadership (5.1a2) as well as sales and marketing positions. Specific placement goals are established for each area and action plans in place. To ensure accountability, progress on these actions is presented to the HRAB. MED-RAD also actively supports EXPAT/INPAT assignments, which encompasses assignments from the U.S. to another country or from another country to the U.S respectively, to bring together employees with diverse backgrounds and share experiences broadly throughout the organization.

MEDRAD welcomes new employees with its orientation program, which encompasses two days and includes an introduction to the MEDRAD Philosophy and Mission (P.1a2), review of HR programs, introduction to MEDRAD's Performance Excellence and Customer Satisfaction approaches, and a full day of quality, legal, and compliance training (1.2b2) to help them quickly become contributing members of their teams. The CEO kicks off each orientation session with his views of MEDRAD's culture and performance. Field-based employees receive an additional two days of training. Individual department orientations and job-specific training supplement the corporate orientation program. Thereafter, MEDRAD relies on its processes for employee development and engagement to retain employees.

5.2a3 MEDRAD manages and organizes its workforce utilizing its inverted triangle philosophy (Figure 1.1-3). This philosophy conveys that leaders support employees in accomplishing the work of the organization. It empowers those departments that directly serve customers and promotes the innovation and agility needed to respond quickly to changing business needs.

MEDRAD's waterfalling process (Figure 2.2-1) drives organizational **performance** and **aligns employee actions by linking the mission, vision, and strategic goals** of the organ-

Figure 5.2-1. Key Measures of Workforce Health and Safety

Category	Practices	Measures (Goal)
	STOP Behavior-based Safety Training	
Operations	State-Certified Plant Safety Committees	
	Emergency Response Teams/Medical Responders	
	• Ergonomics training (Orientation)	
Office	Ergonomic furniture standards	
Office	Lighting studies/white noise	
	Wellness rooms	
	Radiation Badge Monitoring	
	On-line Radiation and MR Safety Training	
	MR Safe Toolkits	
Field	On-line Safety Training for blood-borne pathogens	
	Hepatitis Vaccinations	
	Driver Safety Training	
	Field Safety Committee	

ization to those **competencies** most important to achieving Scorecard Goals. The competencies are embedded in the PM system and the creation and assessment of objectives and competencies **reinforces the customer and business focus** necessary to **address strategic challenges and successfully execute the objectives** of the organization.

At an organization level, MEDRAD achieves **the agility to address changing business needs** through determining where the organization needs to go and how to get there within the SPP. This **agility** is achieved by preparing employees for future organizational requirements through Succession Planning and Benchstrength assessments, learning and development initiatives, job rotations, and development planning.

5.2a4 Once MEDRAD determines **capacity and capability needs** (5.2a1), the decision is made to develop the capability/capacity internally or to obtain it externally. When the talent will be developed internally, the solution is developed through the workforce planning process, using turnover trend data and processes such as PM and PAD, succession planning, STRIVE, management coaching sessions, IPO, and the competency curriculum. When external talent is needed, a recruiting forecast and strategy are developed to predict what skills are needed and when. The recruiting group uses this information to recruit the needed talent.

Although MEDRAD experienced rapid growth for several years, it intentionally chose to grow headcount slower than revenue, focusing on improving productivity to meet growing demands. By pursuing this approach to sustainable, responsible growth, MEDRAD has been able to conserve jobs.

Job rotations and Lean job flexibility also help **prepare the workforce for changing capability and capacity needs** by giving employees experience in different roles so that they can move from jobs that may be eliminated to jobs the organization needs. MEDRAD also uses contract employees on a line or in a process that is being redesigned to **prevent workforce reductions** once the improvements are implemented.

As a result of the above, MEDRAD creates an agile workforce that can be redeployed to other opportunities in anticipation of changing business needs.

5.2b1 The EHS Policy defines MEDRAD's commitment to responsible **environmental**, **health**, **and safety** management. It addresses compliance, risk identification and mitigation, performance improvement and proactive communication with stakeholders. The EHSAB (Figure 1.1-1) evaluates, provides

direction and input, and guides improvement on corporate initiatives and key EHS issues.

The EHS Department **improves health and safety** by identifying issues, hazards, and incidents through several sources of information including third party auditing, accident/incident review, and Employee Safety Committee observations. The department participates in each plant's leadership staff meetings to ensure that EHS topics are represented and addressed and that the department stays current with each plant's operating strategies. In addition, the department is involved in the processes for choosing and purchasing new manufacturing equipment, which helps ensure that EHS issues are addressed early and/or eliminated by vendors.

The Employee Safety Committee is a cross-functional group of employees responsible for making recommendations to improve overall safety, periodic auditing of MEDRAD's accident and illness prevention program, and managing medical response teams. STOP, the Safety Training Observation Program, is a multi-unit training package purchased from DuPont. Using a behavior-based approach, it teaches production supervisors, managers, and employees how to identify safety concerns and promote safe work practices. Deployment began in 2008 and continues at all locations.

Physical **security** and access control systems are installed at facilities and the access points are controlled and monitored to allow only authorized personnel into the buildings. The system also limits access to hazardous areas to prevent injuries and facility outages.

5.2b2 MEDRAD **supports it employees** through a comprehensive approach to health, well-being, and satisfaction incorporating the needs of a **diverse workforce** that involves employees in designing, deploying, and refining key programs. MEGA is a group of employees who plan, coordinate, and execute corporate-wide events for employees and their families. Company-sponsored and MEGA-organized events that are specific to a range of **diverse** needs include annual celebration parties, annual picnic, children events, athletic events, amusement park/field trips, and annual all-employee meetings.

MESA is a cross-functional team that provides a formal avenue for communication on significant employee issues as well as potential policy changes. MESA representatives bring unique perspectives to management and policy creation from the vantage points of their individual departments. In addition to eight holidays, MESA designates a ninth holiday to be celebrated company-wide each year with two personal holidays also provided to each employee.

MEDRAD **supports its employees** with health plans, 401(k) plans, career counseling, and tuition reimbursement, and by sponsoring participation in an EMBA program. A flexible benefit program allows employees to **customize their benefits and coverage levels to fit their needs**. MEDRAD also manages the Wilson Scholarship awarded annually to recipients, who are dependents of employees.

MEDRAD's Employee Assistance Program offers free, confidential help to employees with job stress, emotional difficulty, legal concerns, or family issues. MEDRAD offers a variety of flexible work arrangements including flextime, re-

duced work hours, and job sharing. Membership in a local health club is promoted by paying part of the monthly fee and arranging special discounts on extra-cost services.

MEDRAD's **employee benefits** are managed based on a set of principles which state that employee benefits should be competitive and cost-effective and promote wellness, and that MEDRAD is responsible for providing tools and employees responsible for using them. The benefit program is evaluated and improved on annually, based on these principles, the Scorecard Goals, and Top 12, as well as experience, marketplace conditions, data analysis, and employee feedback.

In 2007 MEDRAD introduced a branded wellness program to employees called "Thrive!" A cross-functional team of Wellness Ambassadors serves as advisors to help identify, implement, and drive programs. Thrive! offers proactive outreach, coaching, health education programs, condition management, onsite health fairs, and free flu shots on company premises. The University of Pittsburgh Medical Center is MEDRAD's wellness partner. To date, more than 87% of employees have participated in the program, which compares to an expectation of 45% (Figure 7.4-14).

To address workforce **demographic needs**, Thrive! was expanded to include financial wellness. The program gives employees the opportunity to participate in onsite programs on topics ranging from investing to identity theft. One-on-one sessions are offered with a reputable outside firm to help employees get assistance with a variety of needs such as financial planning, college education, or a new family addition. MEDRAD's work / life balance philosophy also address the needs of a **diverse workforce** with programs such as summer work hours where employees are encouraged to take off Friday afternoons; 4x10 workweeks in our operations environment allow for an additional day off work; and the telecommuting policy affords employees the opportunity to work from home to be closer to family and other personal needs.

6 PROCESS MANAGEMENT

6.1 Work Systems

6.1a1 MEDRAD's **work system is designed** to optimize achievement of its Scorecard Goals (Figure 7.6-1) by building on existing core competencies and identifying needed competencies through the SPP (Figure 2.1-1). Figure 6.1-1 summarizes the factors that drive work system **design and innovation**. Senior leadership ensures that the **work system** responds to MEDRAD's mission and strategies, changing stakeholder requirements, integrating best practices of role model companies, and continuous improvement.

In order to determine which core competencies to streng-

Figure 6.1-2 Dynamic Partnership Model

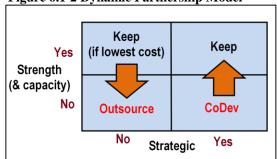


Figure 6.1-1 Work System Design



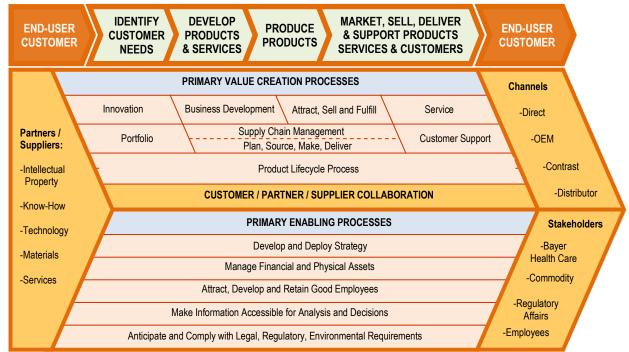
then or add and which processes will be internal or external (Figure 6.1-2), several key factors are analyzed during the annual SPP. If a process gap is identified, additional factors are evaluated. Decisions to develop a new competency or process and to develop it internally or externally are always made cross-functionally. Once a decision is made to develop a new competency or process, budgets and action plans are established. MEDRAD may earmark a new competency or process as critical to the organization by making it a Top 12.

Breakthroughs in our work systems are derived from externally driven strategies and listening posts located across our supply chain and customer base (3.2a1). MEDRAD performance results and goals require vigilance on work system performance through governance forums (Figure 1.1-1) that take regular measurements, and externally focused lessons learned processes that seek to gather the best ideas from internal and external experts. This is done routinely during normal business and ad hoc in response to a missed goal or off-track measure. Changes to work systems are processed and executed through a variety of mechanisms including advisory boards, work process leadership teams, and self-directed work teams, and without fail, they are cross-functional.

6.1a2 MEDRAD's **core competencies** (Figure P.1-5) must differentiate it from its competitors. To accomplish this, each business assesses its **competencies** against customer and market needs during the SPP (2.1a1). Business leaders use the results to identify processes that need to be created or improved to achieve market success.

6.1b1 MEDRAD's **key work processes** are included in Figure 6.1-3. The processes are designed to provide end-to-end customer support and full coverage throughout product life cycles. MEDRAD defines value creation processes as those that help produce value - products and services - for its customers. These processes generate revenue and **deliver** high levels of **customer value and satisfaction** and repeat business, while **contributing to profitability, organizational success, and sustainability**. Enabling processes contribute by enabling a high level of customer focus, employee engagement, continuous improvement, and innovation, and by supporting the value creation processes.

Figure 6.1-3 Key Processes



6.1b2 MEDRAD **determines the key requirements** for value creation **processes** through VOC information that feeds the portfolio planning process described in 2.1a2. This process produces a product development roadmap that incorporates **customer** and **operational** requirements.

Cross-functional involvement and formal procedures ensure input is obtained as a key consideration in work process design. As new products are developed, Product Development Teams (PDT) use VOC information (3.2a1) to gain a more indepth understanding of **customer** product and support **requirements**. PDTs translate these requirements into process requirements for value creation and enabling processes collaboratively during the course of the product lifecycle through the Product Lifecycle Process (PLP). Input from partners and other **stakeholders** is systematically incorporated through the involvement of experts who are responsible for ensuring that these requirements are met (3.2c1, 3.2c2). Key **supplier** participation in PDTs ensures their requirements and competencies are considered in new product designs.

6.1c MEDRAD **ensures its work system and workplace preparedness for disasters or emergencies** through it Emergency Response Plan (ERP), which defines how each type of disaster or emergency should be managed. The goal of the plan is to ensure the safety of employees and business continuity. The plan provides initial response procedures, contact information (internal and external) for response teams, needed resources, information about the level of responses required, steps to take in each situation, procedures for communication, and steps to close out the response.

All business functions develop and maintain ERPs, which are designed to function together if an emergency/disaster affects multiple areas. (The IT Disaster Recovery Plan is described in 4.2b2.) The plans are tested annually. Following each test, a report summarizes the events, what went well, and what needs improvement. The lessons learned are incorporated as part of the continuous improvement process.

For example, to ensure that all employees understand the proper evacuation procedure at their building, they are given evacuation direction cards to put with their badges; these cards are placed in visitor badges as well.

Prevention begins with planned maintenance of all utilities and facilities as part of ongoing operations. All items designated as critical to MEDRAD's operations and product quality are managed by a 21 CFR Part 11 compliant software package that schedules planned maintenance, records performed maintenance, and documents the specific work performed during the planned maintenance.

The **management** of MEDRAD's ERP includes an emergency team that includes a Command Coordinator, Evacuation Coordinator, and First Responders. These individuals, who have backups at each site, would take control and manage the emergency situation with regard to the safety of employees while also containing spills, etc., until the necessary external responders arrive. They receive outside training on these topics as well as training specific to their role. For example, First Responders receive First Aid, CPR and AED training, as well as training on the ERP.

MEDRAD has identified the critical processes, resources and utilities required for **continuity of operations**. For these critical items, MEDRAD has installed permanent back-up systems either on site or at remote locations. For example, the IT back-up data center is located at a different site than the main data center, while back-up electrical power generators are installed at the sites to ensure a continuous power supply.

Communication plans embedded in each ERP outline communications needs and responsibilities for all emergency situations as well as routine interruptions (e.g., snow emergencies). Phone trees, a hotline and a Web site allow senior man-

Figure 6.1-4 Key Work Process Requirements and Performance Indicators
[CONFIDENTIAL]

agers and employees, specifically MEDRAD First Responders, to be notified of an emergency or disaster quickly and efficiently. If the ERP is modified through an evaluation and improvement cycle, affected employees are notified via a number of different communication channels, including email or television communication at the plants.

6.2 Work Processes

6.2a The overarching foundation of MEDRAD's work processes flows from the FDA Quality System Regulation (QSR) and from ISO-13485, which sets standards for work system capability for medical device companies. MEDRAD designs and innovates its work processes to meet and exceed these standards and all customer, regulatory, compliance, and business requirements. The MEDRAD quality system establishes process ownership and a procedural framework that allows each business and function to define its processes. Linkages to the strategic plan are made through core, developing, and required competencies (2.1a1), which in turn focus investments in improvement efforts.

MEDRAD is highly focused on bringing the VOC into its product designs. This is also the centerpiece for how MEDRAD has **designed its value creation processes**. MEDRAD has designed these processes to provide an end-to-end support network, inclusive of responsibilities, deliverables, procedures, "darned good examples," stage-gates, and process threads that are focused on delivering customer value.

Functional and cross-functional teams design and **innovate** processes using MEDRAD's IMAGES methodology (Figure P.2-1). The **design** begins with alignment with Scorecard Goals and financial plans. Inputs to the **design** process include competitor information, VOC data, market conditions, global growth requirements, new business opportunities, current critical improvement initiatives, benchmarks, business development needs, product performance in the field, and assessment of the process.

MEDRAD incorporates new technologies (P.1a4) and organizational knowledge into process designs through steering teams, ABs, benchmarking, and technology forums and roadmaps. All processes have assigned owners and most are designed and improved by cross-functional teams. MEDRAD encourages lateral, cross-functional assignments to **share knowledge** from different areas in functional and cross-functional teams.

MEDRAD partners with external organizations to identify and explore the application of **new technologies**. MEDRAD also learns about new technologies from suppliers, new employees, benchmarking visits, conferences, seminars, and trade shows. MedFlow, a Lean system tailored for electromechanical manufacturing, is one example of this approach (Figure 6.2-2).

The CDI and MST teams develop technology roadmaps (P.1a4) to track, learn about, and adopt **new technologies** in current and future product development initiatives. They work with NPD to understand product development portfolios well in advance to be ready with **new technologies**, which are typically identified in Stages 1 and 2 of the PLP.

The **incorporation of new technologies** is not limited to manufacturing.

To promote agility in process design, MEDRAD makes

virtual collaboration possible through instant messaging, video conferencing, VoIP phone system, Intranet tools, a PDM system, and a variety of other tools (4.2a2). Virtual collaborators rely on information technology to simulate the experience of physical proximity and create a virtually co-located environment in which internal teams, partners, and suppliers can communicate. The freedom to shop the world for design expertise and manufacturing capacity promotes **agility**, **new technologies**, and the ability to add the greatest value.

IMAGES requires efficiency and effectiveness factors, including **cycle time, productivity, and cost control**, to be addressed during **process design**. The PDT translates customer requirements into product specifications. As designs evolve, Manufacturing Strategy & Technology and the Global Sourcing Group work with Design Engineering to estimate costs and model and analyze the design to identify opportunities for

Figure 6.2-1 Product Development Model [CONFIDENTIAL]

component cost reduction, ease of assembly, and overall production feasibility.

6.2b1 The implementation and management of work processes to meet design requirements is accomplished through a range of approaches. The MMR oversees MED-RAD's quality system, which establishes process ownership. AB's oversee all primary work processes. Stage-gate processes maintain alignment to objectives for NPD and IT processes. Process FMEA evaluates potential failure modes and addresses them during the design phase of the PLP. ME-DRAD's Installation Qualification/Operational Qualification/Process Qualification process, an FDA requirement for Good Manufacturing Practices, ensures robust manufacturing processes for new and improved products. Project and process reviews provide oversight, and in-process and sampling measures are used to monitor process capabilities and identify areas to improve.

The PLP guides the **implementation and management** of new products.

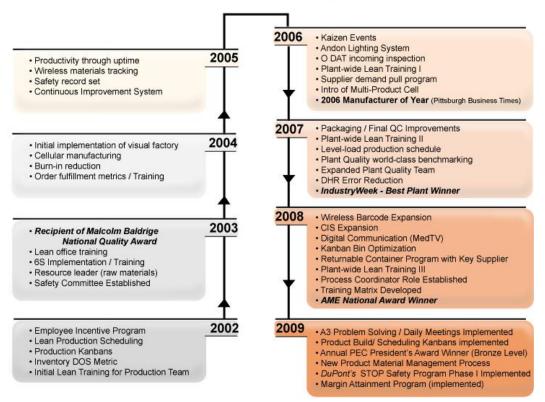
Process and test equipment is designed concurrently to facilitate the timely introduction of products and services. The design of automated manufacturing processes and test equipment adheres to the same design control process as product design and includes requirements, verification and validation activities, and design reviews. Manufacturing processes are validated or qualified before commercial product launch. New production processes are tested in the new process prototype lab before moving online to ensure processes are performing as designed and documentation is ready.

Operations utilizes visual work instructions to communicate product specifications to operators. MedFlow is used to drive a lean focus into manufacturing to improve cycle time, inventory control, on-time delivery, and quality (Figure 6.2-2).

When elements of production or delivery require outside support, MEDRAD involves key **suppliers** in process design through the PDT to maximize cost efficiency and process quality. Suppliers participate with PDTs through the Supplier Integration Transformation (SIT) process. A cross-functional team selects suppliers using the Supplier Selection and Certification Policy. The Procurement and Supplier Quality Man-

Figure 6.2-2 MedFlow: A World-Class Lean System





agement group ensures that suppliers meet requirements through supplier scorecards that provide performance feedback on key supply chain requirements, including quality, delivery, price, and service. Other communication mechanisms include regular face-to-face meetings, strategic business reviews, Quality Summits, technology and capacity reviews, online collaboration portals, frequent email and phone contact, and a Supplier Day conference. Key suppliers visit MEDRAD regularly and several have a program manager on-site. MED-RAD also uses a supplier risk matrix to manage suppliers not on the scorecard (P.1b3).

Functional and process teams implement and manage enabling processes through process indicators, process capacity or failure analysis, complaints, and analysis of process trends. Process improvement teams use IMAGES to develop processes that meet customer, quality, and operational performance requirements, gathering information at each key point in their processes.

MEDRAD ensures that the **daily operation of processes meets key process requirements** by tracking daily measures. In Operations, a process performance tracker is waterfalled to make sure key steps in all key processes are being measured and managed. All steps are controlled by documented procedures

Workforce input in process management begins with the instrumental role production operators play. Operators also offer suggestions and ideas through the continuous improvement system, VIP, and regular communication meetings. Participants in all value creation and enabling processes are trained and empowered to track performance, initiate correc-

tive action, and suggest improvements. Supplier scorecard trends are one element used by Global Strategic Sourcing to develop strategic & tactical supplier plans. These plans are reviewed during the environmental scan phase of Operation's SPP, which is a component of the overall SPP. Customers provide input on process performance through Field reps, surveys and other listening posts (3.2a1). Suppliers and partners are selected early in new product development, as described above, and integrated into the ongoing management of relevant processes. **Supplier** feedback is captured through multiple channels including process validation reports, engineering change orders, supplier audits, quality agreements, Supplier Corrective Action Requests (MSCAR), supplier scorecards, and regular Strategic Business Reviews.

6.2b2 Overall costs of ME-

DRAD's work processes are controlled through the SPP (Figure 2.1-1), which identifies growth and profit targets for the longer-term, with annual goals for revenue, profit, gross margin, head count, and capital spending. The annual budget cascades budget targets by functional area, which includes project budgets for key improvements and innovations, new product development, and strategic investments for both value creation and enabling processes.

Capital spending is managed by the Capital Acquisition Request process, which requires business case justification and post-acquisition analysis to ensure that return on investment targets are achieved. **Costs are also controlled** by a corporate spending policy that dictates spending authorization levels for every kind of expenditure. In conjunction with cross-functional groups, Finance analyzes revenue, cost, and forecast metrics monthly and advises the EC on actual, projected versus budgeted spending.

MEDRAD **prevents defects, service errors, and rework** through several approaches. It uses only approved suppliers. During product development, lessons learned from products in the field are incorporated into new product designs. When possible, PDTs leverage common components and platform systems from existing products in new products.

The FRACAS database centralizes data. The system is routinely queried by New Product Engineering, Manufacturing, and Service Operations in order to **prevent defects**, **improve reliability**, **and minimize warranty costs**.

Verification and validation testing in the PLP helps refine the design and **prevent defects**. MEDRAD minimizes the costs of inspections, tests, and audits through several preventive measures described above, beginning with a supply chain management process that involves suppliers in the design process and continually certifies more suppliers and materials. Operators follow controlled procedures for testing critical performance characteristics throughout the production process.

All manufacturing equipment is maintained and calibrated to ensure proper manufacturing control and product quality. Equipment Maintenance maintains a comprehensive preventive maintenance program. Regular internal process audits ensure compliance with the FDA, QSRs, and ISO 9000. Regulatory Affairs performs random audits to ensure compliance.

6.2c Continuous improvement is embedded in MEDRAD's culture. It is the first point in MEDRAD's Quality Policy, the goal of its Mission (Figure P.1-4) and a core competency (Figure P.1-5). All employees receive training and are expected to identify and support process improvement.

MEDRAD improves its value creation and enabling processes through IMAGES, which integrates Lean, Six Sigma, Quality for Life, and other related problem solving and improvement methodologies (P.2c). Process improvement and innovation is aligned with Scorecard Goals and the Top 12 through the waterfalling process (Figure 2.2-1). ABs and functional leaders systematically review key processes to determine if process improvements are needed and make their recommendations to the EC, which analyzes the recommendations and selects key strategic process improvement initiatives to include in the Top 12.

Improvements that can be addressed by a single function or team are prioritized, planned, and allocated resources as part of functional planning and budgeting. For major or crossfunctional projects and initiatives, steering committees oversee process improvement. Project Charters codify continuous improvement goals and ensure cross-functional alignment. Engaged employees at all levels of the organization ensure that improvement occurs as close to the work as possible. Other approaches that contribute to **process improvement** include:

- VIP, a ten-year program led by Operations to identify cost savings and avoidance opportunities
- CAPA, a closed-loop process of quality system audits that identify gaps that require corrective and preventive action
- · FRACAS database
- Strategic Planning, which drives improvement in enabling processes and provides a forum for sharing best practices
- External feedback on assessments such as the Baldrige Award, *Industry Week* Best Plants, and Advanced Manufacturing Excellence awards

The President's Team Award and PEAK Award recognize teams and individuals for performance excellence and continuous improvement (Figure 5.1-3). The Performance Excellence Center supports process improvement through training in approaches such as IMAGES and LSS, best practice sharing, and instruction on the use of process improvement tools including kaizen events, Pareto analysis, FMEA, 6S, value stream mapping, and control charts (P.2c).

At each level of organizational review described in 4.1b, relevant measures and goals are established and communicated through scorecards, dashboards, and progress reports. These measures and goals are communicated to process own-

ers, ABs, steering teams, process improvement teams, and work groups for incorporation into the **evaluation and improvement of their work processes**.

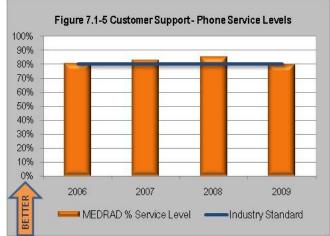
Work improvements and lessons learned are shared through the communications approaches listed in Figure 1.1-2 and a variety of other approaches including business, regional sales and service, plant, work group, and dealer/distributor meetings; a knowledge base of best practices in service delivery; lessons learned sessions; COINS in key areas; benchmarking visits by other companies that help MEDRAD learn about itself; and the President's Team Award, which is aimed at sharing best practices.

7 RESULTS

7.1 Product Outcomes

7.1a The process indicators used to monitor performance on customer requirements are key indicators of product and service performance that are important to our customers. Continuously innovating our products to better serve our customers is a cornerstone of MEDRAD's business model.

MEDRAD tracks a number of key metrics that measure the fulfillment of customer needs, including on-time shipments and product quality. Since 2005, MEDRAD's results for these metrics have improved significantly due to the use of Perfect Order teams for on-time shipments and through the IMAGES process and tools in the case of product quality and error rates.

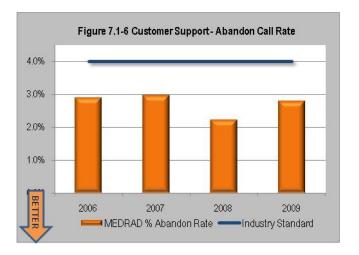


MEDRAD is committed to ensuring ease of access for its customers via field response and by phone support. Figures 7.1-5 and 7.1-6 are indicators of MEDRAD's responsiveness to customer calls. Customer Support measures phone service levels as the percentage of total calls answered within 20 seconds and call abandon rate as the percentage of calls abandoned by the customer before the call is answered. MEDRAD consistently outperforms the industry standards determined by the Global Benchmarking Council.

The improvement **trends** in the **three key MEDRAD products** during their warranty period are the result of continued work with our FRACAS, CAPA, and PLP processes.

Finished product quality within EM is measured in the product release error rate. Global ISO audit results are a **leading indicator for product quality**.

Order accuracy effectiveness is a **customer support** requirement. In 2007, an IMAGES team assessed the process, determined root causes and took action.



7.2 Customer-Focused Outcomes

7.2a1 Continuous improvement in **customer satisfaction** is one of MEDRAD's five Scorecard Goals. There have been three cycles of "raising the bar" for customer satisfaction standards. MEDRAD started with the "% satisfied" measure, achieving BIC levels. In 2001, they moved to the more rigorous Top Box, measuring only the most delighted. In 2007, NPS, the most demanding standard, was adopted (3.2b1) to increase the focus on "detractors" or dissatisfied customers (3.2b3). NPS scores for **competitors** are not available, so MEDRAD assesses itself against industry BIC. According to Satmatrix research, best-in-class is 50% or higher. MEDRAD demonstrates leadership NPS levels similar to the MBNQA program (53%), and Google (63%), a Satmatrix-designated "NPS Leader". Cultural differences affect NPS scores - for example, European and Japanese segments are generally lower. MEDRAD demonstrates leadership levels of engaged customers in all regions, indicating effectiveness in exceeding customer requirements and building relationships.

MEDRAD tracks "Detractors" (3.2b3) and Product Complaints as **measures of customer dissatisfaction**. Customer dissatisfaction with the purchase experience and service support is at leadership benchmark levels.

In addition to root cause reviews by region and business (available onsite), responses to the question "what would increase your overall score" are pareto'd, and improvements initiated.

The effectiveness of CSAB root cause analysis and PLP processes is indicated by the downward trend of complaints. **Product safety** (user or patient) is tracked through the same system, to an even higher degree of rigor and speed.

7.2a2 Satmetrix' NPS research indicates that Promoters are the most engaged and loyal customers, who bring repeat business and referrals. MEDRAD uses the NPS survey to **measure the effectiveness of relationship-building and engagement across the lifecycle**, tracking the percent of promoters. MEDRAD's best-in-class performance against the NPS (calculated as the % of highly engaged promoters less the % of detractors), indicates **BIC engagement**. Further segmentation by individual customer-contact employees, teams, region and product are available on-site.

MEDRAD also **measures engagement across the lifecycle** by evaluating performance against customer requirements (P.1b2). Fast resolution of customer complaints increases customer engagement. Similarly, **accessibility** to MEDRAD increases engagement. Figures 7.1-5 and 7.1-6 indicate **BIC** levels of call answering rates.

Improving customers' business by **reducing their operating costs** also increases customer engagement.

Prompt, efficient service is a customer requirement. Results **improved** over three years.

Customers may purchase directly from MEDRAD, or through a Distribution Channel. MEDRAD conducts annual surveys of its Distribution Channel partners, a leading indicator for satisfaction in the customer life cycle. Survey results and improvements are available onsite.

MEDRAD measures customer satisfaction by transaction and overall relationship, segmenting the data.

7.3 Financial and Market Outcomes

7.3a1 From the Scorecard's inception in 1997 to the imaging reimbursement downturn in 2007 MEDRAD achieved its "Grow the Company" Scorecard Goal of doubling **revenues** every five years. When market growth slowed in 2007, MEDRAD set a new target, while maintaining leading profitability metrics for a medical device company. Two other key **financial performance** indicators are also Scorecard Goals: "Exceed Financials" and "Improve Quality & Productivity", which is measured by operating income/employee.

MEDRAD continues to seek **profitability** improvements through product and process efficiencies, indicated by BIC levels for VIP (Figure 7.4-6) and OPScore results.

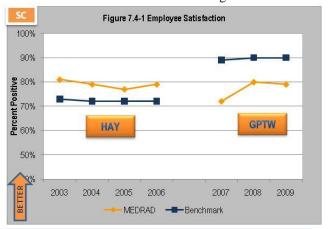
7.3a2 MEDRAD's strategic planning and customer focus processes enable sustained **market leadership**.

Market Share comparisons are to MEDRAD's strongest competitor, and to market leaders in related scanner and contrast markets (benchmark leaders), indicating the success of MEDRAD's product development and customer relationship approaches.

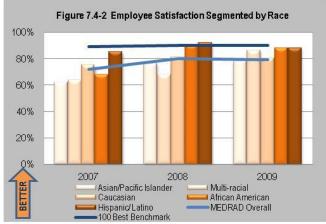
Sales **growth faster than market** growth is an indicator of product development and customer approaches. Service contract attachment rates are a **market share indicator** for the service business.

7.4 Workforce-Focused Outcomes

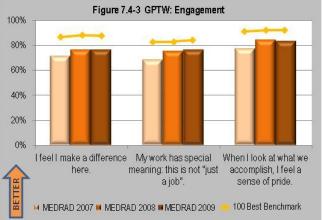
7.4a1 For over 15 years MEDRAD has been utilizing a company-wide survey to assess **workforce engagement and satisfaction**. Improving performance on this survey is one of MEDRAD's five Scorecard Goals. Figure 7.4-1 illustrates



results for 2003 through 2009 of employees responding positively to the summary statement in the survey regarding the overall strength of the workplace.



Since 2007, MEDRAD has utilized the GPTW survey while prior to 2007, MEDRAD utilized the Hay survey. MEDRAD decided to transition to the GPTW survey in 2007 as a



cycle of continuous improvement because of consistently exceeding the Hay benchmark in prior years. The GPTW survey gauges five key employee engagement factors: Credibility, Respect, Fairness, Pride, and Camaraderie (Figure 5.1-1). The GPTW and Hay surveys pose questions differently, making it difficult to crosswalk results from both surveys.

MEDRAD segments its **employee satisfaction** survey data to capture results for different workgroups and segments including race, gender, departments, world regions, and age, among others. An example of diversity results is shown in

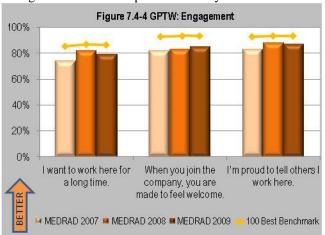
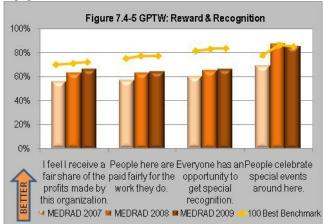
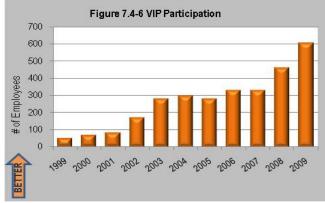


Figure 7-4.2 with BIC results in several segments.

As discussed in 5.1a2, MEDRAD uses a number of approaches to foster **employee engagement**. Annually MEDRAD assesses and improves **workforce engagement** through it action planning process related to survey results. Cross functional teams made up of Senior Leaders, Managers, and Employees are formed to address identified focus areas. The GPTW survey results in Figures 7.4-3 and 7.4-4 reflect the success of those approaches and relate to the key employee engagement factors of Pride and Camaraderie.



MEDRAD's reward and recognition processes are designed to be competitive, to reinforce that "we are all in this together," and reflect the **key employee engagement factors** of Respect and Fairness. It offers recognition to individuals and teams through numerous types of formal and informal programs and celebrations of success also contribute positively to these results (Figure 5.1-3). Our market based pay philosophy and continued improvements in various components of pay based on employee input are also key drivers. MEDRAD uses results from the GPTW survey to assess their overall effectiveness (Figure 7.4-5).

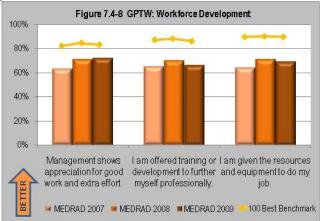


A key measure of **workforce engagement** and Pride is how active employees are in the improvement of the business. Figures 7.4-6 measures the level of employee participation in MEDRAD's VIP Program. This program captures, measures, tracks, and recognizes improvement ideas and is a leading indicator of success in the "Increase Quality and Productivity" Scorecard Goal. MEDRAD knows that it is performing at an exceptional level by comparing its performance to the Industry Week's "Best Plant" benchmark.

7.4a2 Figure 7.4-8 illustrates the results of GPTW survey questions related to **workforce development**, which reflect

the key employee engagement factors of Credibility and Respect. MEDRAD has embarked on a two-year cycle of improvement effort related to employee perceptions of career development.

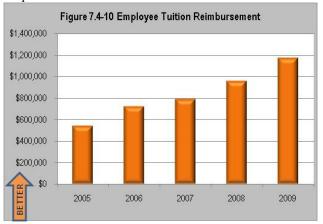
Figure 7.4-9 illustrates the number of managers attending **management development** training through STRIVE or PETL training. This reflects the cycle of improvement through the initiation of the STRIVE **leadership development** platform, as discussed in 5.1b1.



MEDRAD's commitment to the growth and **development of the workforce** through its tuition reimbursement is demonstrated by the growth in organizational expenditures for employee educational pursuits (Figure 7.4-10).



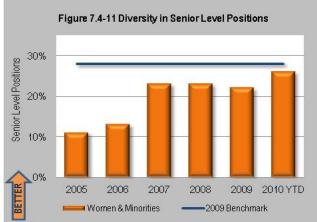
MEDRAD tracks the percentage of senior level positions filled by females and minorities (Figure 7.4-11) as an indicator of Fairness as a **key employee engagement factor**. MEDRAD uses the benchmark of 28% established by Fortune magazine's "Top 100 Best Places to Work." The data indicates annual



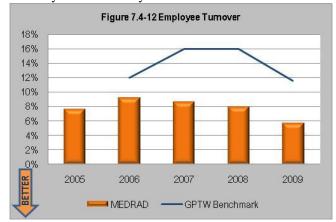
improvement as a result of the MEDRAD philosophy.

7.4a3 When assessing **capacity** needs, MEDRAD improves its Scorecard Goal of "Improving Quality and Productivity" by growing headcount slower than operating income.

MEDRAD's commitment to creating an agile work-force to respond to **capability and capacity needs** is evidenced by the number of internal placements and job rotations.

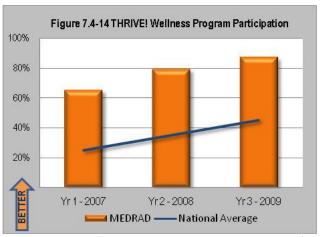


A key measure of **workforce capability and capacity** as well as **satisfaction and engagement** is turnover (Figure 7.4-12). While the GPTW benchmark includes only voluntary turnover in its calculation, the MEDRAD rate includes **both** voluntary and involuntary turnover.

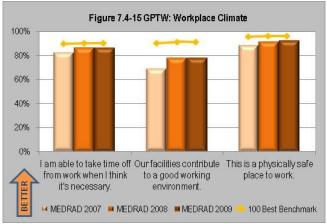


As an indicator of the **key employee engagement factors** of Fairness, Respect, and Credibility, and as a key measure of **workforce capability and capacity**, MEDRAD strives to conserve jobs through all economic conditions.

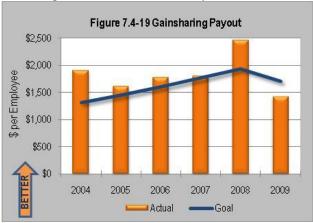
7.4a4 A key indicator of **workforce health and the key employee engagement factors** of Pride and Camaraderie is participation in THRIVE!, MEDRAD's branded wellness program available to all U.S.-based employees. MEDRAD tracks participation (Figure 7.4-14) and specific results. MEDRAD's participation trend is very positive, far outpacing the industry average benchmark. This was achieved through camaraderie of teams in events such as the weight race, financial incentives in the form of reduced healthcare premiums, and promotion of the benefits of self improvement. For example, in the most recent Wellness Challenge, **85 MEDRAD teams** stepped on the scale to join the Weight Race. Together, they lost over two thousand pounds over the twelve weeks of the challenge.



MEDRAD strives to create a **healthy workplace climate**. GPTW results relating to **safety**, work/life balance, and the working environment (Figure 7.4-15) shows positive results and trends due to programs related to employee health, safety, and wellness.



Employee safety and well-being processes are producing leadership levels for TRIR and LTIR. The results show successful implementation of STOP safety train-



ing in production facilities, the most critical area for workforce safety. As STOP training hours increased re-view activity increased, reinforcing safe behavior on the job. The total number of observations and total STOP training hours are reviewed in EHS as leading indicators of workforce safety.

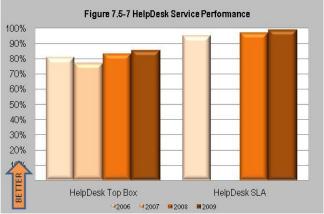
MEDRAD's gainsharing program is a **benefit** that is designed to reinforce achievement of the Scorecard Goals and the **key employee engagement factors** of Credibility, Respect, Fairness, Pride, and Camaraderie. (The Employee Satis-

faction goal is not included in the calculation.) All employees worldwide receive the same annual payout (Figure 7.4-19).

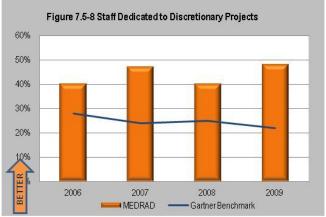
7.5 Process Effectiveness Outcomes

7.5a1 IT annually tests its disaster recovery plan through an unannounced simulated emergency. IT takes down six separate key systems and then restores them in disaster mode at the remote back-up data center, tracking the timing and effectiveness of the recovery. Based on benchmarking with Gartner, a widely-recognized research firm, MEDRAD understands that only 70% of companies run a similar large-scale test on at least an annual basis.

7.5a2 Key measures of support **process performance** include indicators for IT, HR and Finance. An internal provider to the entire organization, IT uses a scorecard to track its service of internal users' information needs. It has maintained one of its



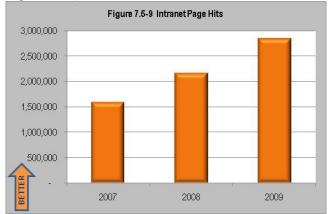
key measures, Systems Availability, at a high rate for the past four years. Two additional measures track service performance of the Help Desk: Top Box ratings by internal customers (5 on a 1-5 scale) and the percent of responses made within the targeted Service Level Agreement (SLA) time (Figure 7.5-7). The Top Box rating dropped in 2007 due to the addition of two new facilities that year without hiring additional Help-Desk staff. MEDRAD found the volume of HelpDesk issues was much higher than was initially



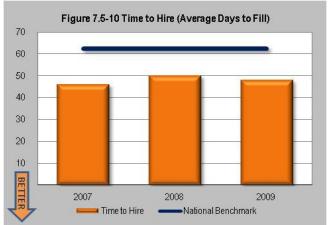
anticipated as the workforce became more geographically dispersed (e.g., supporting people with collaboration tools). Also, several experienced individuals within the HelpDesk were able to assume new roles through MEDRAD's IPO process, which left the HelpDesk with some short-term skill gaps and a higher mix of contractors than normal. The lessons learned from this situation lead to the establishment of the "Best of the

Desk" program. 2007 data for SLA performance is unavailable due to the implementation of a new measurement system.

MEDRAD dedicates IT staff to discretionary projects in order to create new systems or enhance existing ones at a rate significantly higher than that of the benchmark set by Gartner (Figure 7.5-8). IT and MEDRAD's Intranet business owners



use the number of Intranet page visits to assess the effectiveness of the Intranet and its content. The number of Intranet Page Hits has increased from just over 1.5M in 2007 to nearly 2.8M in 2009 (Figure 7.5-9).



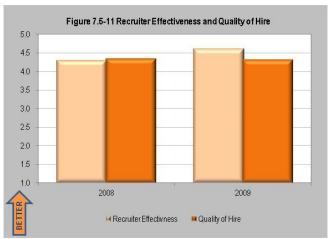
In 2009, MEDRAD conducted a systematic evaluation of the value its external website provided customers. This data resulted in a project to improve its public Internet site to be a more user-centric model.

HR measures support process performance such as average time to hire, which is equated by the number of days from the day a requisition is opened to fill a position until a person accepts an offer for that position (Figure 7.5-10). It is important to MEDRAD to get talent onboard in a timely manner in order to give businesses the resources they need. The benchmark is a compilation of information from a number of sources including GPTW, ERE, and Staffing.org.

Figure 7.5-11 shows both the effectiveness of internal HR recruiters and the quality of the new hire as rated by the ME-DRAD hiring manager using the Likert scale.

MEDRAD manages working capital to help it achieve its Scorecard Goal for operating income per employee.

MEDRAD has used a Supplier Scorecard since the mid-1990s to rate suppliers on quality, delivery, cost, and ser-vice. To be considered an "outstanding supplier", a supplier must meet or exceed specific requirements. In 2005 and again in 2008, the criterion for the Supplier Scorecard was made more



stringent, causing fewer suppliers to achieve "outstanding supplier" status. The trend line from 2007 to 2009 is improving. This is primarily due to regular supplier development and engagement through Sustaining Supplier meetings, Quality Summits, and Strategic Business Reviews as well as though expectation alignment and training. MEDRAD has also trained its key suppliers on important deliverables such as validation activities.

7.6 Leadership Outcomes

7.6a1 MEDRAD's Scorecard Goals show **accomplishment of its strategy and action plans** for the majority of goals over the last six years (Figure 7.6-1). Checkmarks indicate goals achieved or exceeded, and numbers indicate the percentage of goal achieved. Each goal is **benchmarked** (Figures 4.1-1), and the scorecard is **segmented** by business and region. MEDRAD's listening posts (3.2a1), the SPP (Figure 2.1-1), and workforce approaches (5.2a4) enabled the company to anticipate the impacts, reduce costs, and redeploy resources to critical areas, while conserving jobs and meeting shareholder commitments.

Top 12 Objectives completion is assessed annually, with **50% in '09, exceeding** the objectives completion rate of Midway, **a fellow Baldrige recipient** (Figure 7.6-2).

7.6a2 No control issues have been identified from that process. MEDRAD audits by Bayer's external auditor, PWC also indicate financial accountability. No significant audit

Figure 7.6-1 Accomplishment of Scorecard Goals

Scorecard Goal	Performance Indicator	2004	2005	2006	2007	2008	2009
Exceed the Financials	Gross Margin %	$\sqrt{}$	99%	$\sqrt{}$	√		99%
Grow the Company	Sales Growth Rate	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	96%	83%	96%
Improve Quality & Productivity	Operating Income/ Employee	V	V	V	96%	√	88%
Improve Customer Satisfaction	Customer Sat. Results	98%	√	91%	√	√	99%
Improve Employee Satisfaction	Employee Sat. Results	99%	99%	99%	94%	√	99%

Figure 7.6-2	Top 12	op 12 Achievement		
		2007	2008	2009
Achieved	0	42%	42%	50%
Partial	0	41%	41%	33%
Missed	0	17%	17%	17%
"% Achieved" Benchmark			21%	

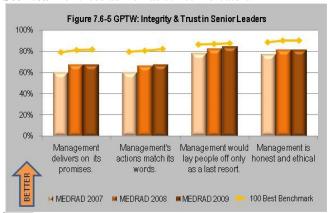
findings, over 5 years, confirms the soundness of fiscal controls.

7.6a3 Global audit results from regulatory agencies are MEDRAD's **key indicators of regulatory and**

legal compliance and effectiveness of Quality System improvements (1.2b1). TUV and BSI have been MEDRAD's ISO registrar/Notified Body, performing annual audits of MEDRAD's Quality Management System to the requirements of ISO 13485:2003, European Medical Devices Directive (MDD 93/42/EEC), the CMDR, and the J-GMP. Audit findings are classified as major or minor depending on the auditors' judgment of significance. Since 2002, none of the annual ISO audits in Europe or the U.S. identified a major nonconformance. These **BIC results** are in line with 2005, 2006, and 2009 Baldrige recipients with smaller, U.S.-only operations. Decreases in minor non-conformances also indicate improvements and overall effectiveness of the quality system. These same figures also show FDA inspection results. For each issue noted during an FDA inspection, a "483" is issued, requiring corrective action. No "483s" have been issued from any of the six FDA inspections since 2002, reflecting improvements in MEDRAD's quality management system. Distribution channel partners also audit MEDRAD, as discussed in P.1b2. MEDRAD's "strategic partner" status with channel partners results from strong audit scores.

Subscriptions to the Compliance department's **worldwide** "Regulatory Newsbrief" electronic newsletter **increased** 166% indicating effective approaches to **anticipating adverse impacts and legal and regulatory concerns.**

The CEAB and LAB (Figure 1.2-1) review and act on key controls and indicators of legal and regulatory compliance. See 7.6a4 for these as well as ethics indicators.

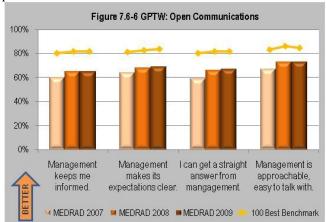


7.6a4 Employee perceptions are important **indicators of stakeholder trust in senior leaders, governance, and ethical behavior.** Figure 7.6-5 shows survey questions that indicate trust in senior leaders, an indicator of **confidence in ME-DRAD's leadership and governance**. Figure 7.6-6 demonstrates the effectiveness of leadership communications approaches, a leading trust indicator.

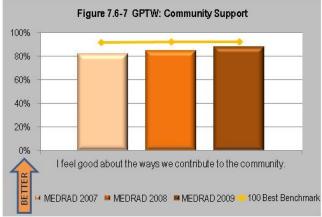
Other stakeholder confidence indicators are the variety of awards MEDRAD received as a result of its high level of accountability and ethics (Figure 7.6-11).

MEDRAD's CEAB and LAB (Figure 1.2-1) review other **indicators of legal and ethical behavior**, as well as indicators

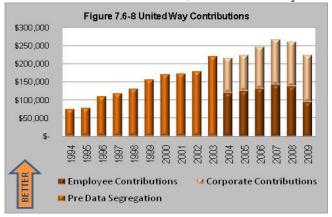
of **ethics breaches**. Global hotline and other inquiries, their resolution, and progress on remedial actions and training are reviewed. Due to their confidential nature, results are only provided on-site.



7.6a5 Figure 7.6-11, describes MEDRAD's numerous recognitions for its **fulfillment of societal responsibilities and support of key communities.** United Way (UW) contributions have more than tripled since 1995. When employees reacted to downturn fears by reducing donations, MEDRAD increased its contribution (Figure 7.6-8). Corporate donations



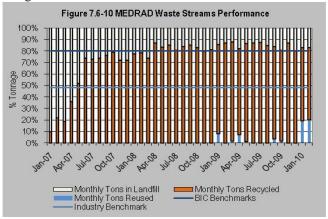
were 12% and 20% higher than the UW benchmark average in 2008-9, and total donation per employee exceeded Baldrige recipient AtlantiCare's benchmark. MED-RAD's UW Day of Caring is the largest single-company participation in the history of the Pittsburgh UW, a record set by ME-DRAD in 1998. Worldwide participation increased from 720 in 2005 to 1183 in 2009. These, and related survey results



(Figure 7.6-7), indicate that employees recognize MEDRAD's **support of key communities**.

The results described in 1.2c1 demonstrate MEDRAD's focus on **environmental responsibility**. LEED standards for sustainable buildings require waste to be diverted from landfills – MEDRAD diverts **a best-in-class result** among EPA WasteWise participants. LEED "**Gold**" and "**Certified**" designations for the Global Center and Saxonburg facilities also indicate environmental responsibility.

Recycling programs in manufacturing facilities **significantly improved waste and energy reduction**. With waste diverted from landfill at **best in class levels**, MEDRAD initiated tracking of reuse, in addition to recycling (Figure 7.6-10). Distribution operations were consolidated to re-duce the number of shipping legs, **reducing mileage** between manufacturing and the distribution center.



Over the last 10 years, MEDRAD has received a number of awards and recognitions (Figure 7.6-11) in the categories of Leadership, Ethics, and Accountability; Community and Environmental Responsibility; and Innovation, Industry, and Manufacturing Excellence. Details regarding specific awards are available on-site.

Figure 7.6-11 Awards and Recognition

Awards	Category
15	Leadership, Ethics, and Accountability
12	Innovation, Industry, Manufacturing Excellence
6	Community and Environmental Responsibility

