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P Preface: Organizational Profile

P.1 ORGANIZATIONAL DESCRIPTION

Medrad develops, manufactures, markets and services equipment and sterile disposable products that enable or enhance diagnostic and therapeutic medical imaging procedures. Medrad's products are sold to hospitals and medical imaging centers worldwide and are used in Computed Tomography (CT) and Magnetic Resonance (MR) procedures, as well as in cardiovascular imaging performed in angiography and cardiology. Medrad 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 the liquid contrast agents used for cardiovascular imaging. In 1986, and again in 1992, Medrad created new markets for vascular injection systems, first for CT applications and then for MR. In 1988, in cooperation with an original equipment manufacturer (OEM) partner, 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.

Vascular Injection Products

Medrad's largest product area is vascular injection systems, which includes vascular injectors, compatible syringes and other disposable products, and applications support. Injection systems control the flow rate, volume, and pressure of contrast media injections and synchronize the injection with the creation of the medical images by MR and CT scanners and cardiovascular imaging equipment. Key product requirements for this equipment are ease of use, safety, reliability, and serviceability.

Sterile disposable products are primarily high volume syringes that are compatible with Medrad’s injector systems. Medrad also manufactures and markets syringes that are compatible with the injectors of other vascular injector manufacturers. In addition, Medrad supplies other related sterile disposable products including quick-fill tubes, and connector tubing. Product requirements for all disposables are primarily ease of use, safety, procedure cost effectiveness, and clinical capabilities.

Figure P.1-1 2002 Revenue by Product Type

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MR Accessories

Medrad designs and manufactures MR surface coils and internal coils (probes) for use with MR scanners manufactured by major imaging manufacturers. Surface coils are placed next to the part of the body being imaged. They detect radio frequency signals emitted by body structures and then transmit the signals to the MR scanner, which produces the image. Medrad’s surface coils are used in a number of specific applications including imaging of the brain, torso, shoulder, ankle, neck, prostate, and knee.

In 2000 and 2002, Medrad expanded its MR Accessories products to include MR-compatible patient monitoring and infusion products. Standard patient monitoring and infusion products cannot function in the high magnetic field created by MR scanners and can interfere with scanner operation. Medrad’s MR-compatible products enable safe management of sedated or medicated patients during the scanning procedure.

Equipment Service

Medrad has an established direct-service force in North America, major European countries, Australia, Japan and Brazil. Factory-trained service engineers support all Medrad products. Medrad dealers provide service in countries without direct service representation.

Through its service organization, Medrad offers a variety of service agreements designed to meet the needs of its customers. Customers have a variety of service options including training of their own on-site biomedical personnel.

Medrad achieves a competitive advantage through its customer support services including Technical and Application Training. To support the injector and MR Accessory products and equipment service, Medrad employs registered technologists, who provide on-site applications training to customers, which qualifies them for Continuing Education Credit. The training helps customers increase efficiency, improve safety, and optimize their use of Medrad’s equipment and disposables products.

In 2002, Medrad expanded its service products to include service of MR coils and ultrasound probes produced by other manufacturers.

Distribution

As a small company in an industry dominated by very large scanner and contrast manufacturers, distribution channel management is a key to Medrad’s success. Customers around the world purchase medical imaging devices like injectors and coils from a variety of distribution channels, exerting cost and commoditization pressure. Medrad’s distribution model, (Figure P.1-2), focuses on creating value for end-user medical imaging customers by maintaining direct contact with the customer, developing high quality products compatible with their imaging equipment, and then supporting customers with responsive field service and applications training. As a result, customers prefer Medrad products, which they can order through any of the common distribution channels: (1) Medrad’s sales force, including
direct representatives in major countries and authorized local dealers in smaller countries; (2) OEM scanner manufacturers; or (3) contrast manufacturers.

Customers often purchase through OEMs, buying Medrad equipment and using it as part of a full medical imaging suite. Medrad maintains direct contact with all customers, regardless of distribution channel. It has developed consulting and/or clinical site partnerships with leading medical centers both in the US and abroad.

P.1.a.2
Medrad values people: patients, customers, employees, and other stakeholders. This value is rooted in the Medrad Philosophy, which has guided the company since its was introduced in 1983:

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 fairness; (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) never lose our sense of pride in our company.

Medrad began its performance excellence quest in 1988. It adopted a Quality Policy at the annual employees meeting in 1990. The Quality Policy clarifies how Medrad values customers, suppliers and employees by clearly understanding their requirements and meeting those requirements on time, every time.

Medrad's Quality Policy

Medrad is dedicated to continually improving the quality of all our products and services such that our customers' satisfaction, loyalty, and respect are unsurpassed.

It is our policy to clearly understand and agree upon the valid requirements of the work we perform for our customers, both internal and external, and to pursue 100% conformance to those requirements...on time, every time.

We will:
- Empower, involve, and train each and every employee.
- Establish partnerships with our customer and suppliers.
- Foster Quality Improvement Teams.
- Eliminate defects through prevention.
- Ensure that employees are recognized for achievements.

Medrad’s mission continues to be a guiding principle for how it operates and how it will grow. The mission was revised in 2001 to reflect Medrad’s diversification strategy.

The Medrad Mission

It is our mission to be a worldwide market leader of medical devices and services that enable or enhance diagnostic and therapeutic imaging procedures.

We will accomplish this mission by achieving performance excellence across our five corporate goals.

Corporate Scorecard Goals

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 evergreen goals guide decision-making at all levels, providing focus for operations and growth beyond financial cycles:
- **Exceed the financials:** CMB (profit) growth greater than revenue growth
- **Grow the company:** Revenue growth greater than 15% per year
- **Improve quality and productivity:** Grow CMB per employee greater than 10% per year
• **Increase customer satisfaction**: Continuous improvement in Top Box customer satisfaction ratings
• **Increase employee growth and satisfaction**: Continuous improvement in employee satisfaction above best-in-class Hay benchmark

P.1.a.3
Medrad has approximately 1200 employees. Medrad does not maintain data on employee education levels.

Medrad tracks the percent of women and minorities in managerial positions on two levels: (1) the percent of women and minorities reporting directly to Executive Committee members and (2) the percent of women and minorities within two levels of the Executive Committee.

Job diversity reflects:
- Individual contributors: production, professional/technical, sales & service, engineering; contract or temporary, mostly in production and R&D
- Management: front line; executive

Safety requirements are typical for light manufacturing and meet or exceed state and federal regulations.

P.1.a.4
Medrad’s headquarters in Indianola, Pennsylvania, a small town near Pittsburgh, includes a facility housing administrative functions and the sterile disposables enterprise production unit. The electromechanical assembly enterprise and service operations reside in a nearby facility. The majority of Medrad’s employees are located in these two facilities.

The North American field team, primarily sales, service, and applications training, works from home-based offices. International offices in Europe and the Far East have primarily sales, service, and support staff. The European headquarters office and warehouse is located in Maasstricht, the Netherlands, and supports direct sales, service and applications, and the local dealer network in Europe, Africa, and the Middle East. The Japanese headquarters is in Osaka, Japan, and supports the direct sales and local dealer network in Japan. A sales and distribution center in Singapore supports the Pacific Rim, and regional offices in Brazil and Mexico support South America. Imaxeon is a small Australian subsidiary acquired in 2000 that designs and develops simpler, lower cost injector systems for international markets.

Medrad uses many advanced technologies in product design and development. In injector areas, these technologies include design for manufacture and assembly, Computer Aided Design (CAD), automatic assembly, automated functional testing, and wave soldering, as well as Lean Manufacturing and work cell manufacturing philosophies.

The Disposables Product Line utilizes clean room, automated and semi-automated assembly, Form-Fill-Seal packaging, and robotics in conjunction with Lean Manufacturing and business teams. This combination of improved technology and employee empowerment allowed Medrad to increase syringe production over 700% while increasing the manpower to produce them by less than 60%.

Medrad’s MR product line utilizes vacuum forming, CAD/CNC machine milling, Spectrum Analysis Testing, RF Electronics, and MR Physics technologies.

P.1.a.5
Medrad is subject to myriad international, federal, and state standards and medical device regulations including:
- FDA
- PADER (PA Dept. Environmental Resources)
- DOT
- Allegheny County Health
- OSHA
- European Community
- ISO
- Japanese Industrial Standards
- TUV
- Japanese Ministry of Health and Welfare

The FDA extensively regulates the manufacture, distribution, promotion, and sale of medical devices cleared for distribution in order to assure their safety and effectiveness for use. Medrad is registered as a medical device manufacturer with the FDA, which inspects the company from time to time to determine whether it complies with various regulations relating to such manufacturers. All devices must be manufactured according to Quality System Regulations (QSR) specified in the FDC Act. These practices control every phase of production including raw materials, components and subassemblies, manufacturing, testing, quality control, labeling, tracing of consignees after distribution, and follow-up and reporting of compliant information.

P.1.b ORGANIZATIONAL RELATIONSHIPS

P.1.b.1
Medrad was a publicly traded company until October 1995, when it was purchased by, and became a wholly owned subsidiary of, Schering AG, a $5-6 billion German pharmaceutical company headquartered in Berlin. Medrad employees represent less than 5% of the total employees of Schering AG. One of the Schering AG product lines is contrast media, which is used in conjunction with Medrad’s vascular injection systems.

As an independent subsidiary, Medrad provides its own business support functions. It follows parent governance rules and may be audited by Schering in areas like information systems and environmental compliance. The president and chief executive officer of Medrad meets semi-annually with the Medrad Board of Directors and annually with the Board’s Executive Committee, which is Schering’s legal governance of Medrad. He meets with Schering leadership annually as part of the budget cycle and participates in strategic business planning and in meetings of Schering’s U.S. entity, as needed.
P.1.b.2
As illustrated in Figure P.1-2, Medrad’s customers are end-user customers who use Medrad products for medical imaging procedures. End user customers are further segmented by imaging modality (CT, MR, Cardiovascular) for product definition and portfolio planning, and by geography for sales management. Customers often purchase through distribution channel sub-segments, including OEM scanner manufacturers, who may incorporate Medrad products into their value chain, and contrast agent manufacturers.

All customer groups have common requirements in addition to hygiene factors like basic product features and regulatory compliance: product reliability, on-time delivery, successful product installations, training and applications support, and prompt, efficient service support.

Medrad focuses on delivering customer satisfaction, and the ability to manage multiple, competing OEM scanner and contrast agent manufacturers as a means of its competitive advantage. Medrad’s competency in these areas is a critical part of building and maintaining its global market leadership.

P.1.b.3
Material suppliers are Medrad’s major supplier category. Since 1988, Medrad has reduced its list of material suppliers by one-third. More importantly, in 2002, over 3/4ths of Medrad’s production materials were purchased from a group of carefully selected “Scorecard” suppliers. Commodity Teams, organized around Medrad’s critical commodity categories (injection molding, electronic components, and mechanical parts) manage the relationships with these key suppliers using a Supplier Scorecard. The Scorecard assesses supplier performance on the basis of quality, delivery, price, and service. The list of suppliers managed using the Scorecard is updated annually based on criteria such as criticality to Medrad, type of supplier, past and projected spend analysis, and past supplier performance.

Important new material suppliers are identified and selected using the Systems Integration Transformation (SIT) process (see 6.1a-2 and figure 6.1-5). Design and development partners, while a small part of total supplier spending, are often selected using the SIT process due to their impact on design, development, and, ultimately, production processes.

P.1.b.4
The goal of all key supplier relationships is to develop partnerships that may include the following elements: co-development, capacity responsiveness, joint sharing of process improvement benefits, and open-book pricing. Commodity Teams manage communication for material partners; R&D is also significantly involved in managing communication with design and development partners. Communication mechanisms include regular face-to-face meetings, the Supplier Scorecard, frequent email and phone communication, and an annual Supplier Day conference. Key suppliers visit Medrad on a regular basis and others have program managers on-site at Medrad. Suppliers participating in joint design projects may also share project management websites with Medrad designers to facilitate communication and planning. Medrad develops partnering relationships with its customers through the seven-phase Sales Process (see 3.2a), one of five key Medrad processes that rely upon timely customer input (see Figure 3.1-1). With a large percentage of sales coming from existing customers, Medrad recognizes that partnering with customers is critical to its long-term success. The company communicates with its customers through the mechanisms shown in Figures 3.1-1 and 3.2-1.

P.2 ORGANIZATIONAL CHALLENGES
P.2.a COMPETITIVE ENVIRONMENT
P.2.a.1
Medrad is the market leader in the three vascular injector modality markets—MR, CT, and cardiovascular (angiography/cardiac). Medrad has two global and several regional competitors in the vascular injection business and three global and several regional competitors in the magnetic resonance business.

P.2.a.2
The principal factors that determine Medrad’s success relative to its competitors are product reliability, customer support, intellectual property management, and distribution channel management.

The primary changes taking place that affect the competitive situation are managed healthcare and globalization.

Managed healthcare drives hospitals to seek cost-reduction and revenue enhancement opportunities. Some
U.S. hospitals participate in buying groups, which negotiate multi-year contracts for participating hospitals.

For several years, international expansion has been a key growth strategy, during which time international sales have quadrupled. International markets require local language labeling, documentation, and support. Medrad’s competitors are attempting to globalize by partnering with domestic competitors. In addition to building its international sales and service organization, Medrad has signed worldwide distribution agreements with the leaders in diagnostic imaging equipment.

P.2.a.3
Medrad’s competitors are either small business units of large corporations, making it impossible to delineate their results from the larger entity, or small privately held companies that do not share information. As a result, competitive data are not available. Information about competitors is collected from field sources and conferences and summarized in a competitive database on Medrad’s intranet.

The available sources of comparative data for analogous processes outside the industry range from non-competitive medical device companies to other organizations identified as best in class (see 4.1a). Medrad has no unusual limitations on its ability to obtain these data.

P.2.b STRATEGIC CHALLENGES
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P.2.c.1 PERFORMANCE IMPROVEMENT SYSTEM
Medrad’s performance improvement efforts began in 1988 with the formation of the President’s Quality Council, now known as the Performance Excellence Team (PET), comprised of senior staff. In 1997 the senior leadership team began using a balanced scorecard featuring five Corporate Scorecard goals [see P.1a(2)]. The specific targets are reviewed each year at the beginning of portfolio planning [see 2.1a(1)].

Medrad maintains an organizational focus on performance improvement by aligning the activities of functions, teams, and individuals with these corporate goals and the Top 12 objectives, as described in 2.2a(1). Medrad’s performance management system, which is explained in 5.1b, involves all employees in creating individual objectives and development plans that support corporate goals and individual growth.

At the corporate level, the annual strategic planning process identifies, selects, and allocates resources to critical projects to improve Medrad’s ability to achieve the corporate goals and objectives and to implement the portfolio plan.

As needed, employees and work groups form teams to implement improvements and address process problems. Teams identify sponsors for their projects, usually higher-level managers, who procure resources for the group and provide feedback and direction. A charter between the team and the sponsor is developed for projects that are typically cross-functional and large in scope.

A corporate Performance Excellence Center and productivity centers in selected departments provide resources for improvement initiatives and also look for opportunities to share best practices with other parts of the company.

At the organizational level, Medrad has been using the Baldrige Criteria to assess and improve its management system since 1994, and has received three site visits. Medrad’s senior management uses the Baldrige Criteria feedback report in the Performance Excellence Team meetings (PET) where improvement initiatives are reviewed and selected.

P.2.c.2
Medrad fosters organizational learning through the approaches described in 1.1a(2), most notably the quarterly Quality Forum (best practices sharing and introduction of performance excellence tools), the annual Performance Excellence conference (team best-practice sharing and training in team skills), and Learning and Development. The cross-functional Learning & Development Leadership Team identifies critical learning needs for the organization and designs and implements programs to meet them. Departments also have knowledge sharing forums, such as Q-First in Corporate Services and the OPS Quality Council in Operations.

Medrad uses existing systems to share knowledge assets including the Information Center, which puts knowledge capital such as standards, journals, and other business information, on the corporate intranet. The intranet is used to share policies and procedures, business results, new product information, and “darn good examples” of useful tools and approaches. Field sales and service representatives share customer information through Avenue. Earlier this year, Medrad launched a competitive database to formalize the collection and communication of competitive information.
1 LEADERSHIP

1.1 Organizational Leadership

1.1.a.1

At Medrad, leadership reflects the company’s team culture. The organization chart in this application shows reporting relationships in the Executive Committee (EC) and Senior Staff, while Figure 1.1-1 on the next page portrays Medrad’s model of distributed leadership. It includes senior leadership teams, their participants, and their responsibilities. Senior leaders use the cross-functional teams in this diagram to set and deploy Medrad’s vision, mission, and philosophy, and to set and review performance on the five corporate scorecard goals, Top 12 objectives (see Figure 2.1-5) and function plans that establish expectations to improve customer and employee satisfaction and to meet financial goals.

Advisory boards play a critical role in communicating the company’s values; developing and deploying operational strategy, policy, and plans; and managing operations. Each advisory board includes several members of Senior Staff and middle managers with expertise in the area being advised. The vertical and horizontal participation communicates key elements of Medrad’s basic philosophy including treating all employees with dignity and fairness, delivering on commitments of Medrad’s basic philosophy including treating all employees with dignity and fairness, delivering on commitments made to each other, and helping fellow employees achieve their goals through teamwork.

The Medrad Philosophy, presented in P.1a, expressed the company’s values when employees first signed it in 1983. A growing workforce affirms it every five years, most recently this year with the Philosophy’s 20th anniversary. As the foundation of the leadership system, the Philosophy establishes the importance of customers, employees, and shareholders. The Quality Policy defines the customer-related responsibilities by requiring all employees to “understand and agree upon the valid requirements of the work we perform for our customers, both internal and external.”

Alignment of values, directions, and expectations occurs through the corporate scorecard, which measures performance on five short- and long-term goals: (1) exceed the financial objectives; (2) grow the company; (3) improve quality and productivity; (4) improve customer satisfaction; and, (5) improve employee growth and satisfaction.

Through the strategic planning process, senior leaders confirm these goals, set one- and five-year financial targets, and establish targets for the annual planning cycle [see 2.1a(1)]. The planning process deploys directions and expectations through the leadership system and to all employees, as described in 2.2a(1).

In addition to the strategic planning process, senior leaders communicate Medrad’s values, direction, and expectations to all employees through the President’s monthly highlights, a memorandum that summarizes trends and performance on each of the five goals listed above and provides special recognition for teams and individuals. Other key communication methods include Quarterly Business Reviews (QBR), Quarterly Management Interaction (QMI) sessions, Quality Forums, advisory board and function leadership, cross-functional team participation, staff meetings, the performance management system, participation in training for new and existing employees, and the annual “all-employee” meetings. Senior leaders conduct five large communication meetings each year to share progress, recognize accomplishments, and reinforce Medrad’s mission, philosophy, and goals. The meetings reach all employees with one in Pittsburgh, one for the Americas field employees, one for European employees, one for Asian employees, and one for employees in Australia.

1.1.a.2

Senior leaders create an environment that reflects the company’s Philosophy and its nine basic principles and the Quality Policy listed in P.1a(2) through frequent formal and informal communication, interaction with key stakeholders, and participation in training and employee recognition. The basic principles emphasize agility (“preserve our ability to respond quickly to opportunities”) and innovation (“assure our company’s future through new products”), while the Quality Policy addresses empowerment and learning (“empower, involve, and train each and every employee”).

Senior leaders communicate these values through the methods described in (1) above.

Informal communication is part of senior leaders’ frequent interaction with employees. The president often works in various departments including on production lines, with facilities workers and front-line field representatives, to better understand the work employees do and to maintain contact. Senior staff communicates openly with employees about the company’s performance using the formal vehicles listed above, frequent emails, and the company intranet. Senior leaders also interact with employees through project reviews, employee small group lunches, one-on-one interviews, involvement with the Medrad Employee Satisfaction Association (MESA; see 5.3b), discussions with employees of employee satisfaction survey results, contact at employee events, and employee recognition [5.1a(3)].

The VP of global customer relationships, VP of global sales and service, and director of sales reinforce Medrad’s Philosophy and Quality Policy through quarterly meetings in the company’s sales zones with field sales and service representatives and managers. For international subsidiaries, Medrad adapts its approach to communicating the company’s vision and values to each country’s culture and business, improving the acceptance by international staff members.

Recognizing that an environment of empowerment, innovation, agility, and learning involves other stakeholders, senior leaders pursue frequent interaction with end-user customers and distribution partners on a global basis through the listening posts shown in Figure 3.1-1. Senior leaders meet with key suppliers to review their relationships with Medrad and interact with suppliers during the annual Supplier Day. They interact with Medrad’s parent company through operational reviews and the strategic planning process. They participate in community and industry activities as described in 1.2b.
1.1.b.

Medrad’s management is accountable to Schering for the organization’s actions. It provides accountability through ongoing dialogue with the Chairman of Medrad’s Board of Directors, monthly reports to the Board, semiannual Board meetings, Medrad Board’s annual executive committee meetings, and an annual meeting with Schering in Berlin.

Annual Schering audits and internal audits ensure fiscal accountability as well as accountability and systematic improvement of the quality system and such areas as hazardous materials and IT. An independent auditor conducts the Schering audits with reports to Schering and Medrad senior management. Independent audits by TUV for ISO compliance, the EPA for environmental systems, and other outside groups ensure 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 the schedule demands. The compliance group, which is a section of Medrad’s regulatory department, is independent of the production and service functions it audits. It reports audit findings to the regulatory department, the areas that have been audited, and to senior leaders responsible for those areas. Actions resulting from the audits are addressed through the corrective action system (CAPA) and tracked at the Management Review Meeting (MMR), which is also the forum for presenting the status of the quality system to management.

Medrad protects stockholder interests through the regular reporting and auditing processes described. It protects stakeholder interests through these processes and through perform-

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<table>
<thead>
<tr>
<th>Figure 1.1-1. Medrad’s Leadership Model</th>
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<tbody>
<tr>
<td>CEO</td>
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<td>VP Corporate Services</td>
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<td>VP Finance</td>
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<td>Dir. HR</td>
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<td>VP Global Sales &amp; VP Global Cust. Rel.</td>
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<td>VP Quality &amp; Reg.</td>
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<td>Dir. E-M Operations</td>
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<td>Dir. Perf. Excellence</td>
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<tr>
<td>VP R&amp;D</td>
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<tr>
<td>VP New Prod. Prog.</td>
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<td>Function Management</td>
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2003 Malcolm Baldrige National Quality Award

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Confidential
ance on its five corporate scorecard goals, three of which address financial performance, one that focuses on customer satisfaction, and one that addresses employee growth and satisfaction. Medrad identifies customer interests through the listening and learning approaches described in 3.1a and shown in Figures 3.1-1. It identifies employee interests through the internal listening posts described in 5.3b.

1.1.c.1

Senior leaders evaluate Medrad’s performance and capabilities during the reviews listed in Figure 1.1-2. Performance on the five corporate scorecard goals and Top 12 corporate objectives guides the assessment process for the EC and Senior Staff. Advisory boards and the other reviews assess performance in their areas, as indicated in Figures 1.1-1 and 1.1-2.

A summary of the scope and results of these reviews is communicated to all employees in the monthly report prepared by the CEO. The report summarizes review findings by highlighting performance on the five corporate scorecard goals. Medrad measures organizational success by how well it performs on these goals. The report also illustrates how Medrad constantly tracks and reports competitive performance and progress on short- and long-term goals.

For example, the March 2003 report communicated performance on CMB growth, sales, sales by region and product line, regional growth rates, units produced compared to plan, product introductions, competitive updates, standards compliance, customer satisfaction, customer satisfaction by region, shipment performance, employee satisfaction, IPO hirings, and more.

Each review listed in Figure 1.1-2 includes a process for acting on data, information, and analysis that indicates a problem or opportunity. Senior leaders address changing organizational needs through these reviews. They assess Medrad’s ability to respond during the annual portfolio and strategic planning processes, as described in 2.1a.

1.1.c.2

Key performance measures and recent findings are listed in Figure 1.1-2.

1.1.c.3

Advisory Boards and Senior Staff translate review findings into priorities for improvement and innovation. All senior leaders serve on one or more of these groups. Advisory Boards and Senior Staff identify and prioritize process improvement opportunities and commission action, either as part of iterative review and action [see 2.2a(1)], resource reallocation for action in the current year, or improvement planning [see 2.1a(1)] for longer-term initiatives. In each case, alignment with the five corporate goals is a criterion for selection.

Senior leaders communicate and deploy performance review findings and priorities throughout the company through the methods used to communicate values described in 1.1a(1), which includes the monthly CEO report to all employees.

When appropriate, Medrad deploys priorities and opportunities to key suppliers through the communication mechanisms listed in P.1b(4), and to key customers and customer groups through the field sales and service force and the other mechanisms shown in Figures 3.1-1 and 3.2-1.

1.1.c.4

Medrad’s Board of Directors, which is comprised of members appointed by Schering-Berlin, Inc. and Medrad’s former CEOs, is responsible for evaluating the performance of Medrad’s CEO. The CEO is responsible for evaluating his staff’s performance.

The Executive Committee owns Medrad’s leadership system. Based on findings from the performance review meetings described in Figure 1.1-2, and employee interactions described in 1.1a(2), the EC and Senior Staff initiate immediate improvements in the leadership system or plan long-term changes as part of strategic planning. Inputs that shape the review findings and improvements include performance on key measures including the corporate scorecard and Top 12 objectives, employee satisfaction surveys, MESA, customer listening posts, Schering AG expectations, the competitive environment, OEM and partner discussions, ISO and FDA audit results, Baldrige feedback reports, benchmarking information, professional society membership, and training events.

Improvements in the leadership system through this approach include establishing Senior Staff meetings with specific performance excellence focus (PET), application for the Baldrige Award, the corporate scorecard, the creation of Advisory Boards, and “incubator” leadership structures for multi-vendor services and Imajeon.

1.2 SOCIAL RESPONSIBILITY

1.2.a.1

The medical device industry is heavily regulated in the United States and internationally. Regulations cover product safety and efficacy, environmental protection, and employee health and safety. Medrad’s policy is to develop and implement programs that are targeted to meet or exceed all national, national, state, and local regulations. The approaches to employee health and safety are described in 5.3a.

The EC is responsible for regulatory compliance, which is deployed through the product development teams (PDTs) and Operations for day-to-day management. The Regulatory Affairs department provides expertise in these areas, advising the Senior Staff, PDTs, Operations, and the Configuration Control Board. Regulatory Affairs also audits operations and provides input to each product development stage exit review of the iPDP [see Figure 6.1-1]. The regulatory requirements vary in other parts of the world, and Medrad has regulatory managers in its European and Japanese offices.

The Medrad Control of External Standards procedure directs management of regulatory standards. All standards management is centrally located within Medrad’s Information Standard.
Regulatory compliance, product safety, and environmental concerns are integrated into every stage of the iPDP, as shown in Figure 6.1-3.

The PDTs develop each product’s instructional manuals, warranties, service manuals, warning labels, and advertising materials as part of the iPDP. PDT members receive training based on their roles. Examples include hazard analysis, human factors training, and follow-up training on new product design, development, and remanufacturing. All production supervisors have attended a nine-session course in hazard control training to heighten their awareness of potential safety, health, and environmental issues.

Operations designs these factors into their processes during the production and delivery process design phase of the iPDP and during the manufacturing design process. Process performance, including performance on safety, health, and environmental issues, is monitored through in-process and end-of-process measures to ensure that they meet design requirements.

The FDA conducts a regular full audit approximately once every two years or in the event of a product recall, and can decide to visit unannounced at any time. Of the seven audits conducted since 1994, six had zero observations, which is better than the industry average of observations issued 46% of the time an audit is conducted.

Medrad’s last seven ISO audits, which included U.S. and international Medrad facilities, had no defects. Medrad’s quarterly Medrad Management Review Meeting addresses Quality System issues that have surfaced anywhere within the company. Prompt resolution supports Medrad’s positive relationships with regulatory agencies.

Risk Management is a staff function established in 1994 that is responsible for being the link between legal responsibilities and quality assurance. The risk manager is an expert in public safety and is involved with new product development and production as well as internal training on human factors and other issues. Medrad implements preventive risk management initiatives through the Environmental Health and Safety Advisory Board and Employee Safety and Health Committee.

Medrad also addresses the impacts of its operations on the community at the local level. In 2002, Medrad received recognition from Allegheny County’s EnviroStar program, for pollution prevention and responsible environmental stewardship. The company’s Indianola manufacturing facility recycles cardboard packaging and recovers and reuses sterilant gas mix. Medrad has been participating in the Pennsylvania Adopt-A-Highway program for 11 years, completing clean-ups regularly, most recently in May. Since 1997, Medrad has been actively involved in the Pennsylvania Fish & Boat Commission’s Adopt-A-Stream project. On Medrad property in Indianola, employee volunteers and community members conducted five annual stream clean-ups, created a bird box trail, and constructed four fish habitat enhancement structures in Deer Creek to preserve and improve the environment.

Medrad has a good environmental compliance record. It uses environmental audits to identify and prevent problems. Medrad eliminated CFC emissions in 1995. It has been recognized by Allegheny County for environmental responsibility for focusing on pollution prevention.

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### Figure 1.1-2 Senior Leader Performance Reviews

<table>
<thead>
<tr>
<th>Group</th>
<th>Frequency</th>
<th>Topics</th>
<th>Measures Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Committee</td>
<td>Monthly</td>
<td>Business and quality issues</td>
<td>• P&amp;L results: month &amp; YTD</td>
</tr>
<tr>
<td>Senior Staff</td>
<td>Monthly</td>
<td>Top 12 objectives. Corporate performance and business issues</td>
<td>• P&amp;L results: month &amp; YTD</td>
</tr>
<tr>
<td>Advisory Boards</td>
<td>Monthly</td>
<td>See Figure 1.1-1</td>
<td>• P&amp;L results: month &amp; YTD</td>
</tr>
<tr>
<td>Senior Staff’s PET Meeting</td>
<td>Quarterly</td>
<td>Performance Excellence issues</td>
<td>• Top 12 initiative proposals</td>
</tr>
<tr>
<td>Medrad Management Review (MMR)</td>
<td>Quarterly</td>
<td>Quality System Issues</td>
<td>• Action Item closure</td>
</tr>
<tr>
<td>Field Sales &amp; Service Meet-</td>
<td>Quarterly</td>
<td>Sales and service reviews in all global regions</td>
<td>• Process indicators</td>
</tr>
<tr>
<td>ings</td>
<td></td>
<td></td>
<td>• Complaint &amp; Reliability trends</td>
</tr>
<tr>
<td>Health &amp; Safety Committees</td>
<td>Monthly</td>
<td>Health and safety performance</td>
<td>• Sales-to-date</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Outlook for quarter and year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Lost Time Days Incidents</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• OSHA Incidents</td>
</tr>
</tbody>
</table>
1.2.a.2
Medrad anticipates and proactively prepares for public concerns with its products and services through the iPDP, as described in (1).

Senior Staff oversees Medrad’s overall approaches to anticipating concerns with products, services, and operations, principally through Advisory Boards. The Regulatory Affairs department, Risk Management office, Employee Safety and Health Committee, and Corporate Environmental Health & Safety Committee monitor their areas of responsibility and expertise and participate in evolving issues. Members of these groups, together with senior leaders, field sales and service members, applications personnel, and others identify evolving issues through participation in trade shows, meetings with key influencers, luminary sites, contrast media pharmaceutical partners, OEM partners, and future trends information from AdvaMed, a health industry manufacturers association.

Acquired knowledge and learning are shared and institutionalized through the strategic planning process, which is also the forum for proactively preparing for public concerns.

1.2.b.
Medrad first developed its Code of Business Conduct in 2001, deploying it to all employees worldwide early in 2002 in order to:

- Reaffirm Medrad’s commitment to being an ethical company in a visible way;
- Provide a consistent worldwide message to employees and business partners;
- Formalize the company’s process for handling matters that may arise.

The Code outlines the expectations for all employees regarding compliance with laws and regulations, company policies, and conflicts of interest. The Code also provides a confidential process for reporting situations that an employee thinks may violate the Code. As part of its philosophy of continuous improvement, Medrad is currently reviewing the ethics policy proposed by Adva Med, an independent trade group.

Medrad’s ethical values are embedded in the Medrad Philosophy, and are first introduced to employees during their orientation. The company’s legal and risk management staff members ensure compliance, and the Business Ethics Committee reviews status quarterly, initiating improvements as needed.

1.2.c
Medrad and its senior leaders and employees support and strengthen the company’s key communities through an approach comprised of three elements:

1. Sharing expertise and resources to improve the quality of life in communities with Medrad facilities through direct sponsorship and participation in company selected activities and organizations;
2. Support of employee-championed activities and organizations;
3. Participation in industry and professional organizations.

Senior leaders set the example with broad involvement in the community and the medical device industry. For example, the president and CEO is a board member for eight organizations. Four other senior leaders serve on outside boards.

The Corporate Giving Committee oversees the budget established to support Medrad’s key areas of emphasis: hospitals, education, cultural institutions, and non-profit sports groups in communities with Medrad facilities. Employees around the world serve their communities as firefighters, paramedics, scout leaders, church and school group leaders, youth team coaches, and volunteers.

Medrad Points of Light is a community outreach organization established by Medrad’s employees and supported by management. It allows Medrad to share its success with neighbors in need by donating funds and manpower. Hundreds of employees have participated in Points of Light activities and organizations.

Each year Medrad’s president asks and encourages employees to personally support the United Way. Medrad matches 70% of employee gifts as it moves toward matching 100% in 2014. The president is a member of the United Way board of directors and other Medrad employees participate on United Way committees.

To support the United Way Day of Caring, Medrad halts operations for a day so that employees can spend time doing volunteer activities. In 2002, over 700 employees in Germany, the Netherlands, Singapore, Japan, and Sweden participated in the Day of Caring, along with U.S. employees in the field and in Pittsburgh.
2 Strategic Planning

2.1 STRATEGY DEVELOPMENT

2.1.a.1

Medrad’s strategic planning process is shown in Figure 2.1-1. The portfolio planning stage of the process is illustrated in Figure 2.1-2 and the continuous improvement planning and budgeting stages are shown in Figure 2.1-4.

The Executive Committee owns the strategic planning process, which produces: (1) a five-year vision of Medrad’s markets and revenues; (2) an action plan for the coming year that includes short- and long-term initiatives required to achieve the five-year vision; and (3) organizational alignment of the vision and action plan.

The process begins each January when the Executive Committee (EC) sets one- and five-year targets based on the five corporate scorecard goals, industry growth rates, and parent company Schering’s financial goals for those timeframes. The financial goals become targets for the first two corporate scorecard goals: achieve financials and grow the company.

The portfolio planning process depicted in Figure 2.1-2 addresses the short- and long-term achievement of these scorecard goals. Through the process, Medrad identifies business development and product development initiatives to capitalize on significant business opportunities, prioritizes the initiatives, and creates alignment throughout the company to achieve them. Business Development looks outside at acquisitions or alliances that strengthen Medrad’s competitive position or diversify the product portfolio. Product Development focuses on new platforms and products that will help grow the company.

The portfolio planning process consists of two phases: product line planning and product portfolio selection.

Medrad’s product line platform teams (PLP) drive product line planning: CT, MR, Cardiovascular and Multi-Vendor Service, plus an incubation team that targets long-term or new market development opportunities. A marketing “champion” leads each PLP team, which is supported by Business Development, PIAD (Product Innovation & Ad-
advanced Design), representatives from Medrad’s European, Japanese, and U.S. sales regions, Finance, and others as needed. An EC sponsor assigned to each platform provides oversight and guidance.

The product line planning phase of the portfolio planning process begins in January when the EC and the marketing process manager create a kick-off package that includes the post-mortem from last year’s process, targets for the current planning cycle, and confirmation of the planning categories. PLP teams review the targets, action plans, and results from the previous year, analyze the current business environment, and create a platform strategy. The analysis of the business environment is guided by Medrad’s product line planning assessment guidelines (Figure 2.1-3) and other factors described in the next section.

The PLP teams identify opportunities, specific initiatives that will take advantage of them, and estimated resource requirements. In late May or early June, each team presents its findings and recommendations to the EC.

In the product portfolio selection phase, each EC member scores each suggested initiative on: commercial risk; technical risk; return on investment; impact to sales revenue (short- and long-term growth opportunity); market share distribution and stability; short- and long-term contribution to CMB; rate of technological change; basis of product competition; and overall value proposition to customer.

Open debate during a series of meetings between the EC and the PLP champions resolves scoring gaps or differences, with the marketing champions clarifying opportunities and risks as needed. The resulting prioritized list of initiatives feeds the remaining steps in the strategic planning process, including defining target markets as an input to the Business Development process.

Corporate improvement planning, the next step in the strategic planning process, uses inputs from portfolio planning, function planning, and advisory board and function reviews to identify needed improvements in key processes (Figure 2.1-4). Function planning is a subset of strategic planning that may be conducted by a function or sub-function any time during the year to assess capability and plan improvements using planning tools such as Hoshin planning, Baldrige assessment review, and traditional strategic planning tools.

The Performance Excellence Team Advisory Board (PETAB) requests proposals for cross-functional initiatives, which are screened using criteria established by Senior Staff at a PET meeting. One of the criteria is impact on corporate scorecard goals. Senior Staff selects the final list at the June PET meeting.

The first two steps in the strategic planning process conclude with the assignment of a Senior Staff sponsor and a leader to each Top 12 corporate objective, and their prioritization. Top 12 objectives include the product and business development initiatives from portfolio planning and the cross-functional initiatives from corporate improvement planning. The twelve objectives for 2003 are listed in Figure 2.1-5.

During the action plan budgeting step, project managers of initiatives and programs supporting the twelve objectives develop budgets and schedules with their project teams, which include representatives from all stakeholder departments. Each functional manager (who is also an EC member) works with his/her staff and a financial representative to prepare a budget that is rolled up into an EC-level function budget and, ultimately, to a corporate P&L statement. Cross-functional teams plan budgets for their initiatives with individual expense lines addressed in the relevant function budget. The EC reviews overall budget roll-ups twice...
before the final budget is approved and forwarded to Schering for approval.

“Waterfalling” is Medrad’s term for cascading corporate objectives from the corporate level to the functional and team levels to the individual employee level. The response to 2.2a(1) describes the waterfalling process.

Strategic planning ends with the completion of the objectives waterfalling. The entire organization is now aligned to corporate goals, corporate objectives, and individual function objectives. The resulting action plan is executed using the iterative process described in 2.2a(1) and performance is assessed as described in 1.1b(1).

At the completion of the portfolio strategic planning processes, process owners, using input from process stakeholders, evaluate effectiveness, efficiency, and cycle time. Throughout the year, they also evaluate the effectiveness of the entire process by comparing actual progress on the Top 12 objectives to the strategic direction and plans. The process owners use this evaluation, self-assessments, Baldrige feedback, and external best practices to identify and implement process improvements. The strategic planning process has undergone eight cycles of improvement.

2.1.a.2

During the product line planning phase of the portfolio planning process, product line platform (PLP) teams analyze the current business environment in order to develop platform strategies and specific initiatives. The product line planning assessment guidelines (Figure 2.1-3) provide a structure for gathering information by product and business about market and customer needs and opportunities, the competitive landscape (by product/business and geographic region), organizational strengths and weaknesses through the opportunities and issue analysis, and financial and other risks through issue analysis, financial justification, and resource requirements. Each area within the “Business Environment” category (Figure 2.1-3) considers technological and other expected and potential changes. Supplier strengths and weaknesses are addressed during Operations’ functional strategic planning phase of the strategic planning process (see Figure 2.1-1). Operations and the New Product Development departments use the Strategic Integration Transformation (SIT) methodology to select and integrate material and design suppliers and partners that will support the corporate goals and initiatives.

A critical factor in product line planning is timely knowledge of existing and potential customers. PLP teams acquire this knowledge through the listening posts shown in Figure 3.1-1 and use it to complete a formal competitive update that presents information on current competitors and market shares, potential competition, and, for each competitor, its overall marketing strategies, SWOT analysis, and how Medrad currently competes and plans to compete moving forward. A centralized source of online competitive information, introduced this year, will also provide competitive information to the PLP teams.

As part of the cycle of improving the strategic planning process, this year introduced an approach to assessing the probability of success and translating that into a hurdle rate for financial projections that are part of portfolio planning. The approach, taken from an IEEE journal article, begins when a product planner and team assess technical and commercial success risk factors using a weighted scale, then discuss the results to produce an overall risk factor which is translated into a hurdle rate in the financial model. The risk factors considered include technical, proprietary position, organizational competencies and skills, complexity, access to external technology, commercial risk, manufacturing capability, customer/market need, market/brand recognition, distribution channels, raw materials supply, and environment, health, and safety.

The acquisition and use of critical data and information continues throughout the planning cycle. As action plans are executed, Senior Staff, advisory boards, and functional man-

<table>
<thead>
<tr>
<th>Corporate Goal</th>
<th>Target</th>
<th>Corporate Objective</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceed financials</td>
<td>CMB (profit) growth &gt; revenue growth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grow the company</td>
<td>Revenue growth &gt; 15 % per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve quality and productivity</td>
<td>Grow CMB (profit) / employee &gt; 10% per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve customer satisfaction</td>
<td>Continuous improvement in Top Box ratings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve employee growth and satisfaction</td>
<td>Continuous improvement in employee satisfaction above best-in-class Hay benchmark</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Confidential*
agers assess the external and internal environments and initiate corrective actions.

2.1.b.1

Medrad’s key strategic objectives are the five corporate scorecard goals, which are long-term goals that rarely change from year to year. The Top 12 corporate objectives are short- and longer-term programs critical to achieving the corporate goals. The first two rarely change while the remaining ten are product development and improvement initiatives that have milestone rather than numeric targets (Figure 2.1-5).

Contribution Margin B (CMB) is the profit measure used by Medrad’s parent, Schering, as a consistent measure of Schering’s varied operating entities.

2.1.b.2

Figure 2.1-5 shows how the Top 12 objectives, which are short-term objectives with a one-to-three year time frame, support achievement of the long-term corporate scorecard goals. Medrad ensures that short- and longer-term challenges and opportunities are balanced through the long-term goals and shorter-term objectives and through the portfolio and strategic planning processes, which identify and address such challenges and opportunities.

Specific goals and objectives that focus on customers, employees, and Schering’s shareholders balance the needs of Medrad’s key stakeholders.

2.2 STRATEGY DEPLOYMENT

2.2.a.1

During the objectives waterfalling step in the planning process, managers and staff members at all levels create objectives and plans that support the corporate scorecard goals, Top 12 objectives, and function plans. They combine these objectives, initiatives, and plans with an analysis of the function’s performance based on elements that include process indicators, customer and supplier listening posts, employee listening posts, benchmark and comparative studies, ISO and FDA findings, and Baldrige feedback. They use SWOT and gap analyses, affinity diagrams, and Hoshin planning tools to identify opportunities for improvement.

Staff and team meetings and discussions refine and align these objectives, which all employees then use to create supporting individual objectives during the performance management process [see 5.1b].

Resource needs are balanced through an iterative process among functions, cross-functional teams, process teams, PDT teams, and executive teams. The process involves developing objectives and plans that align with the corporate goals and objectives, sharing them with the functions and teams that must execute and/or support the plans, requesting and considering their input, and finalizing the objectives and plans after input from all affected groups. This iterative process continues through plan execution, involving the functions and teams in performance reviews and course corrections on the year’s objectives and plans.

Before submitting the final budget to Schering, resource conflicts are resolved at the lowest possible level. Resources are allocated to support the Top 12 objectives first and then to fulfill the function plans. A fine-tuning cycle occurs in the fourth quarter after Schering approval and when the entire year’s results are more visible.

The EC and Senior Staff review progress and make course corrections on the Top 12 objectives at the senior leadership team meetings described in Figure 1.1-2. Function and team leaders evaluate progress on function and team objectives. Employees and their managers track performance on individual objectives through the performance management process, which includes two formal one-on-one reviews each year and informal reviews as needed.

The objectives waterfalling process links and aligns teams and individuals across the company with the corporate goals and objectives. The process includes several methods of communicating the plan including the employee meetings and displays of related information throughout the facilities.

Medrad ensures that changes resulting from action on the Top 12 objectives can be sustained by reviewing progress on them throughout the year (see Figure 1.1-2) and during the annual strategic planning process.

2.2.a.2

Medrad’s Top 12 corporate objectives are its key short- and longer-term action plans (see Figure 2.1-5).

2.2.a.3

Human Resource plans support specific corporate scorecard goals (see Figure 2.2-1).

2.2.a.4

The Top 12 objectives represent action plans that support achievement of the corporate scorecard goals. Medrad monitors progress on Scorecard goals. Advisory Boards track progress on initiatives that address Top 12 and functional goals. Senior Staff reviews Top 12 objectives on a rotational basis. In addition, department scorecards track progress on department objectives or initiatives that address scorecard goals. Figure 2.2-2 shows Medrad’s key performance indicators and their projections.

The alignment of corporate goals and objectives with function and team objectives and plans and with individual development plans through the waterfalling process ensures that all functions, teams, and employees are working toward the same goals, that the strategic plan and key indicators are deployed throughout the company, and that the needs of all stakeholders are addressed.

2.2.b. PERFORMANCE PROJECTION

Figure 2.2-2 lists Medrad’s short-term (this year) and long-term (2007) performance projections for its key performance indicators.
Medrad compares current and projected performance with past performance on all corporate scorecard goals and measures, which have been in place for several years, as shown in the results on those measures in Category 7. Internally, departments and functions throughout Medrad benchmark against internal best-in-class performance indicators.

The only available competitive benchmarks in an industry that does not share confidential information are market share, a customer satisfaction survey question asking how Medrad rates versus competitors, and the annual Medical Imaging magazine customer ranking.

**Figure 2.2-1. Human Resources Team Top Initiatives/Link to Corporate Scorecard**

<table>
<thead>
<tr>
<th>CY 03 Top HR Initiatives</th>
<th>Corporate Scorecard Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Achieve Financials</td>
</tr>
<tr>
<td>Develop a 3-Year HRIS Strategy</td>
<td></td>
</tr>
<tr>
<td>Raise Awareness &amp; Effectiveness of Medical Spend</td>
<td></td>
</tr>
<tr>
<td>Sustain Global Based Compensation Benchmarks &amp; Processes</td>
<td></td>
</tr>
<tr>
<td>Raise the Level of L&amp;D Program Effectiveness</td>
<td></td>
</tr>
<tr>
<td>Adopt a Customer Satisfaction Philosophy for HR Customers</td>
<td></td>
</tr>
</tbody>
</table>

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**Figure 2.2-2. Key Performance Indicators and Projections**

<table>
<thead>
<tr>
<th>Corporate Goal</th>
<th>Key Indicator</th>
<th>2003 Goal</th>
<th>2007 Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceed financials</td>
<td>▪ Grow CMB faster than sales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grow the company</td>
<td>▪ Sales growth &gt; target</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve quality and productivity</td>
<td>▪ CMB/employee</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Reduce new product cycle time</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Reduce defects per million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve customer satisfaction</td>
<td>▪ Corporate/Regional Top Box customer satisfaction scores &gt; prior year</td>
<td></td>
<td>Confidential</td>
</tr>
<tr>
<td>Improve employee growth &amp; satisfaction</td>
<td>▪ Survey scores &gt; Hay benchmark</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3 CUSTOMER AND MARKET FOCUS

3.1 CUSTOMER & MARKET KNOWLEDGE

3.1.a.1 Marketing product line and marketing managers define market and customer segments through the Portfolio Planning Process shown in Figure 2.1-2 and described in 2.1a(1). The managers and other members of the platform teams determine customers and their needs according to three factors:

1. End-user clinical modality
2. Geography
3. Distribution channel

In the Product Line Planning (PLP) phase of the Portfolio Planning Process, PLP teams, using product line planning assessment guidelines (see Figure 2.1-3) analyze information that is gathered through the listening posts described in 3.1a(2). PLP teams focus on Medrad’s product platforms—CT, MR, and Cardiovascular Products—with an Incubator team dedicated to new products and markets. The nature of the analyses conducted by PLP teams, which includes detailed information about competitors’ and potential customers, is described in 2.1a(2).

3.1.a.2 Medrad listens to and learns from current, former, and potential customers, as well as customers of competitors, through the listening posts shown in Figure 3.1-1. The listening posts apply to both of Medrad’s basic customer groups: end users and distribution channel customers.

Field teams comprised of representatives from the sales and service organizations and technical applications specialists interact with customers worldwide. Team members enter information about these contacts into the Field Force Automation (FFA) system. Field or corporate sales and service, as well as marketing personnel, access FFA to find current information on equipment performance, customer requirements and satisfaction, sales opportunities, shipments, product orders, customer profile information, and other customer information.

The sales, marketing, field management, reliability, and customer satisfaction departments use reports generated from FFA data and customer satisfaction surveys to determine key customer requirements and expectations and to analyze and improve customer satisfaction, product performance, and sales.

As needed, managers generate tracking reports on equipment performance, customer satisfaction, and opportunities won or lost. In addition, reports using FFA data are created for all regional meetings of functional groups—sales, service, and applications.

The reasons for losing any customer are entered into FFA where they are available for analysis by marketing and sales managers. The Customer Satisfaction Advisory Board communicates progress on resolving top customer issues. This year, CSAB is piloting a program to create a 3-in-1 Opportunity Map that identifies what will be done to win the lost customers back and address issues as they relate to all customers.

Sales representatives and managers rely upon listening post information to evaluate sales process efficiency and track customer retention. Sales uses the “sales funnel” to quantify the efficiency and effectiveness of the Sales Process (see 3.2a) and to better understand it (see example for one product line in Figure 3.1-2). Funnels are also used as forecasting tools to predict likely revenues from customers at different stages in the pipeline. In addition, Sales uses the funnels and FFA data on lost customers to identify the reasons they were lost.

Marketing managers are responsible for analyzing listening post information to assess product and service requirements and to improve forecast efficiency. Product planners determine product and service features using the listening posts shown in Figure 3.1-1. Each of the product lines has a product planner assigned to determine customer and product requirements and set a five-year product roadmap. The requirements and roadmaps feed the strategic planning process and are used to define the direction for each modality and for the company.

Those requirements or opportunities that extend beyond Medrad’s current capabilities go to Business Development (BD). BD managers determine which organizations have the resources to capture the opportunity and then, with the approval of the BD Advisory Board, contact them about acquisition, joint venture, alliance, or a distribution agreement.

Product Development Teams (PDT) use extensive customer input from several listening posts to design and validate new product feature sets that respond to customer needs. In Stage 1 of the Integrated Product Development Process [IPDP; see 6.1a(2)], the product planner and PDT use listening posts to define the product and check product development. Clinical partnering with end users is used to initiate market development, confirm product features, and perform Beta site testing.

As part of Medrad’s ongoing customer relationship enhancement (CRE) initiative, a project team assessed customer relationships along multiple dimensions that included product attributes, service, applications support, interactions, intimacy, information provider, and innovation. The assessments included all major customer groups across several geographic regions.
3.1.a.3

Medrad keeps its listening and learning methods current with the company’s needs and directions primarily through zone manager meetings, European and Asian managers meetings, the Customer Satisfaction Advisory Board, the Market Research department and the Global Customer Satisfaction department.

Zone managers in North America meet formally every quarter, after which they meet with sales, service, and applications representatives in their respective zones to share information. Cross-functional team members attend the zone meetings and participate in discussions about customer preferences and requirements and the methods of determining and meeting them. Field team members use the customer information to develop and refine individual and team support strategies that enhance customer value and satisfaction.

Sales managers in Europe and Asia meet quarterly to discuss sales progress versus objectives and to exchange information on the market dynamics. Twice yearly, corporate executives and marketing managers join these meetings.

The Customer Satisfaction Advisory Board (CSAB) leads improvement of the Customer Satisfaction Process described in 3.2b(1). Representatives of IT, Field, Customer Support, Engineering, Operations, Marketing, and international subsidiaries participate on the CSAB, bringing diverse information about business needs and trends to the group. Improvements include refinement of listening posts, such as improvements in customer survey questions.

The Global Customer Satisfaction department manages and improves Medrad’s customer surveys to keep them current with the company’s directions.
3.2 CUSTOMER RELATIONSHIPS AND SATISFACTION

3.2.a.1
Medrad builds and maintains customer relationships primarily through the Sales Process. With the help of Xerox Learning Systems, the North American Sales and Service departments adopted the process in 1993, which has since been improved and deployed to the European and Japanese direct field organizations. The Customer Process represents the complete integration of the sales, service, and support processes, providing a single company perspective for customers while allowing Medrad to know where it is with a customer at any point in time.

The Sales Process has seven phases, each of which is the umbrella for many activities that may or may not be used with a customer depending on the customer’s needs and situation. The seven phases are:

- **Earn the Right.** Medrad sales, service, and applications representatives establish contact with a customer or potential customer and generate interest in doing business with Medrad. When a field representative “earns the right” with a customer, credibility has been established. The customer trusts the Medrad employee based on perceived knowledge of the business, products, and applications, and trusts in Medrad’s commitment to deliver. All front-line employees are trained in communications and customer handling skills.

- **Qualify the Opportunity.** During this phase Medrad determines whether there is a qualified opportunity with the customer by asking questions about timeline, funds availability, impending event, decision maker identification, buying criteria, need, and competition or substitutes. Once at least four of these questions are answered positively, the opportunity is considered to be qualified. Continuous training of Medrad’s customer contact employees ensures steady improvement in the company’s ability to understand the customer’s business situation and needs. Medrad refined this phase in 1999 with the Conceptual Selling Process, a tool to help sales and service representatives effectively assess customer needs and requirements.

- **Establish Buying Influences and Criteria.** Medrad clarifies the decision makers and influencers and establishes the criteria (i.e., required information, support documentation, functionality proof) that each of them will use to determine their choice of product. Medrad representatives then create an action plan with the customer to satisfy their criteria.

- **Satisfy Buying Criteria.** The action plan is executed. Medrad offers its customers proof sources, reference lists, site visits, and product demonstrations or evaluations as means to satisfy their criteria. Customer contact employees receive product, service, applications, business, market, and customer training as needed to continuously improve their ability to offer the best solutions to the customer’s problems and needs.

- **Gain Commitment.** Medrad obtains verbal commitment, negotiates a deal, provides a written quote, and obtains a purchase order.

- **Implement.** Upon agreement, Medrad field teams deliver, install, service, and provide training on the products to ensure defect-free implementation and to continue building customer relations and satisfaction.

- **Customer Enhancement.** With a large percentage of sales from existing customers, maintaining customer satisfaction and loyalty is critical to Medrad. This phase of the Sales Process focuses on continuous follow-up and support. Medrad maintains routine contact through direct customer contact and follow-up satisfaction surveys. Medrad improved this phase in 1999 by implementing the Large Account Management Process for building relationships with OEM, GPO, and national account customers.

Medrad’s Opportunity Management Process maps to the Customer Process. The Opportunity Management Process monitors opportunities with a customer as they progress from casual interest to a “won” or “lost” resolution. A probability of winning is assigned based on customer interest, satisfaction of buying criteria, and the competitive situation. Opportunity maps and sales “funnels” provide input to sales projections and help guide the sales cycle.

Key process performance measures are on-time deliveries, acceptance rates, and customer satisfaction surveys.

Field team members use timely, comprehensive customer information to implement the Customer Process. The information is available through the Field Force Automation (FFA) system, which Medrad deployed in North America in 1996, in Europe in 2000, and in Latin America, Australia, and Japan in 2001. With FFA, field team members use laptop computers to document and track customer contacts, check the status of orders and shipments, check account-receivable status, review customer satisfaction results, track the status of complaint and inquiry responses, get current product information, review customer equipment service history, get leads, schedule installations or training, send and receive email, and get product promotions and training materials from the corporate office.
Field team members enter contact information, installation status, maintenance actions, competitive information, and notes on customer preferences, requirements, and expectations. A built-in report writer capability allows field teams and management to use individual and territorial customer data in customized reports to identify territorial/zone opportunities.

3.2.a.2

After Medrad “earns the right” to “implement” product solutions, it ensures that customer requests, needs, expectations, questions, and comments are handled accurately and rapidly. Customer contact employees understand that Medrad can “lose the right” to serve its customers at any time.

Customer contact employees include corporate accounts, field sales, service, and applications representatives, and internal team members in customer support, telemarketing, and marketing. Medrad provides all customer satisfaction support personnel with formal and on-the-job training in product knowledge, customer satisfaction, customer needs assessment, and complaint handling. Service standards are set and reviewed to align with current customer expectations. Medrad ensures that contact requirements are fully deployed through training, instruction and observation by field and corporate management, and key performance measures such as the customer surveys.

Key access mechanisms for customers to seek information, conduct business, and make complaints are shown in Figure 3.2-1. Customer contact processes and subprocesses are measured for response timeliness and the nature of the outcome. End-of-process measures include late shipments, installations, warranty calls, and customer credits.

Medrad is also using Web-based technology to enhance customer access. Permission marketing efforts provide direct e-mail updates on products. A Sales Support Locator on Medrad’s Web site gives customers worldwide access to their sales representatives. Frequently asked questions and the ability to download brochures and other product and clinical information make access easy for customers.

3.2.a.3

All customer complaints are entered into a home office Complaint Tracking System to ensure timely follow-up and resolution and to support future analysis of the causes of problems and opportunities for improvement. Field team members, sales and service managers, the manager of global customer satisfaction, and regulatory personnel systematically investigate these complaints to resolve them in a timely and satisfactory manner and to identify and address root causes.

Field team members and/or field managers follow up with customers to address dissatisfaction and resolve issues. During the follow up, these field representatives draw upon whatever resources are necessary to return the customer to satisfied status. Additional follow-ups will be conducted until the customer’s needs have been met.

During monthly Medrad Management Reviews (MMR), issues raised by customer complaints and their recommended product and process improvements are tracked for closure. The vice president of operations also leads a weekly Operations Customer Satisfaction meeting that involves the department heads for all operations including QA/RA, manufacturing, shipping, supply chain, and customer support/customer satisfaction to discuss and respond to shipping issues and customer complaints. Repetitive product customer complaints are escalated to the Customer Satisfaction Advisory Board (CSAB) for tracking and resolution. A Failure Analysis Team (FAT) meets routinely to determine the precise technical cause of a problem/complaint and ensure that the proper organizations are involved in resolving it. Both the MMR and FAT teams assign Life Cycle Engineering, comprised of engineers and quality assurance representatives, to investigate issues and recommend improvement actions. Actions are prioritized and assigned to the appropriate department or team for implementation.

Problems and complaints related to patient safety are documented and acted upon according to FDA medical device reporting guidelines. When Medrad receives such a complaint, a field service representative is immediately dispatched to the customer’s location. The representative fully inspects and tests the equipment and replaces any defective components. The representative then provides written and

Figure 3.2-1. Customer Access Mechanisms
verbals feedback to the customer through the Field Service Report (FSR). The representative returns any defective items to Pittsburgh for analysis by the Quality Assurance department, which reports the results of its testing to the FAT. The FAT identifies, prioritizes, and implements appropriate field procedure modifications and product improvements. Medrad Regulatory Compliance follows up with all parties including technologists, physicians, biomedics, and dealer contacts, to verify satisfactory resolution of the issue.

3.2.a.4

Meadrad sales, service, and marketing own the processes for building relationships and providing access to customers. Cross-functional and functional improvement teams form to work on specific improvement activities. Inputs include the listening posts shown in Figure 3.1-1, Medrad’s business results, management and employee ideas, and comparison and benchmark information. FFA (1997) and the Conceptual Selling Process (1999) are two examples of improvements in building relationships, as is the addition of strategic selling to the sales process in 2001, expansion of FFA and strategic selling to European and Japanese sales teams in 2001, and refinement of the Customer Process in 2002.

3.2.b. & 3.2.b.1

The Customer Satisfaction Advisory Board monitors current trends in customer satisfaction and develops strategies and approaches to improve them. Improving customer satisfaction, one of five Corporate Scorecard goals, is a major focus for the CSAB.

The CSAB determines customer satisfaction and dissatisfaction through information from listening posts shown in Figure 3.1-1 and through surveys. The Global Customer Satisfaction department designs and improves third-party customer satisfaction surveys based on listening post information [see 3.1a]. Key listening post information from field representatives, focus groups, customer visits, and complaints helps shape and interpret Medrad’s customer satisfaction surveys. In addition, the global customer satisfaction survey process owner visited customers and field managers in North America, Europe, and Japan to refine the surveys so that they ask about what is important to customers. All customer surveys are reviewed annually to make sure they are addressing the customer and market requirements revealed through listening post information. Marketing, sales, product planners, and field teams access survey results through a shared database.

All surveys are conducted by third parties and are administered monthly or bimonthly. The surveys have been continuously improved since being introduced in 1992. Questions were added in 1999 to determine repurchase intent and to allow comparisons with the competition. In 2001, Medrad began setting performance objectives and measurements based solely on the company’s ability to receive a “5” or “Top Box” rating from the customer. When customers assign a score less than “5,” the surveys ask what Medrad could do differently to receive a “5” on future surveys.

The CSAB and the Global Customer Satisfaction department use survey feedback to identify and address areas to improve.

The Global Customer Satisfaction department collects, aggregates, and analyzes data from the third-party surveys. It forwards key information to all field, marketing, and operations management personnel and to members of the CSAB. It also identifies negative comments or low ratings for follow-up and resolution by field management using the Customer Satisfaction Follow-up Process. For North America, Europe and Australia customer comments are color-coded. Yellow highlighted comments indicate a high level of negative customer perception and require management follow-up, resolution and documentation in the FFA database within 10 business days of receipt. Follow-up performance is reviewed quarterly by the CSAB. Blue font comments indicate an unmet need or some level of negative customer perception and should be followed-up by a field representative or manager. Orange font comments indicate a high level of customer satisfaction and provide recognition for the field representative.

The department publishes positive comments to recognize employee performance and reinforce customer expectations and requirements. Survey results are maintained within the FFA database for use by field teams in future customer interactions.

The CSAB reviews customer satisfaction trends monthly and initiates improvements as needed. All Customer Satisfaction Exceptional Care surveys ask if customers would be willing to recommend Medrad to others. Recognizing that customers unwilling to recommend Medrad may be at risk, field managers contact them to better understand the source of their dissatisfaction. The goal is to address the customer’s perception and to clarify future expectations and requirements.

The monthly Field Service Customer Satisfaction Surveys, which is conducted by an independent firm, asks customers who received emergency service in the previous 30 days to rate their on-site service. All calls are made within two weeks of the service interaction and customer contacts are provided weekly. The survey also asks what Medrad could do differently to receive a “5” overall on future surveys to help field service management identify and correct problems.

The recently implemented monthly application in-service survey administered by a third party asks up to one half of customers who received product in-service training in the previous 30 days to rate the training they received. As with the other surveys, the application in-service survey asks what it will take to receive a “5” overall in order to help application management improve the team’s performance.
Special project surveys are conducted as needed to determine satisfaction of specific customer groups and markets or with specific products or services.

3.2.b.2
Medrad’s field team members have primary responsibility for following up with customers on products, services, and transactions. The FFA database provides them with information about these events and they report the results of their follow-up, including issues, problems, and/or action items, through the database to engineering, operations, marketing, and other departments. In addition, the Field Service Customer Satisfaction Survey follows up with customers who have received recent emergency service [see 3.2b(1)].

3.2.b.3
Medrad compares its customer satisfaction to that of competitors through competitive account surveys, a syndicated market research study, and a customer satisfaction study conducted by Medical Imaging.

Field team members identify candidates for competitive account surveys and report their findings in the FFA database. The field uses the information to assess a competitor’s strengths and weaknesses and to better understand the capabilities of Medrad and its competitors.

Medrad purchases the results of a quarterly syndicated market research study of market size and share in selected markets. A third-party administrator validates the objectivity of the survey data.

The industry magazine Medical Imaging conducts an annual North American customer satisfaction survey of 57 medical imaging companies. Magazine readers evaluate the companies on ten categories including product quality and service and support. Medrad finished third overall in 2002 after finishing fifth in 2000 and 2001. The parent company of one of Medrad’s major competitor’s finished in the top 30 International, which finished 27th in 2002. Medrad is the smallest company in the top ten with far fewer resources than the large companies that populate it.

3.2.b.4
The manager of global customer satisfaction has day-to-day responsibility for managing customer satisfaction approaches. In conjunction with the manager, the CSAB leads the evaluation and improvement of the surveys and other approaches described in this section. Senior managers and field, marketing, and operations personnel also participate in the evaluation and improvement process.

The CSAB and Global Customer Satisfaction department review and update all surveys annually to make sure they are addressing appropriate customer and market segments, asking about relevant customer and market requirements, collecting the right data, incorporating effective analytical methods and measurement scales, and recording and communicating results. Internal customers of the surveys help determine the appropriateness of the questions, which are added, deleted, or revised as part of this process. The addition of the “top box” questions in the 2001 surveys is one example of the results of this process.
4 MEASUREMENT, ANALYSIS AND KNOWLEDGE MANAGEMENT

4.1 MEASUREMENT & ANALYSIS OF ORGANIZATIONAL PERFORMANCE

4.1.a.1

Medrad gathers, integrates, and delivers data and information from all sources through its extensive IT network, which includes core information systems, desktop systems with email, and the Medrad intranet. Approximately 85% of employees have individual computers to access the network, while the balance have access through common stations. All employees worldwide can access the network 24x7.

The core system for managing daily operations is SAP, an integrated enterprise resource planning (ERP) system. Business transactions and financial data reside in the system, with information integrated from other sources including product design and field comments (Field Force Automation or FFA). SAP is highly regarded as an outstanding transaction processing system for data integration. Medrad has all major operations in the world working off SAP servers in Pittsburgh. To enhance reporting of mission critical information, Medrad has developed reporting and analysis tools such as the ALV and 3D, which extend the value of information in SAP well beyond using it for transactions. Since the establishment of SAP in the mid-1990s, Medrad has gone through several cycles of improvement aimed at increasing data availability and ease of analysis. Examples include converting the financial tracker from paper to web pages on the intranet; adding ALV reporting via VAFA (value added financial analysis project); and business intelligence based reporting via 3D.

Medrad intentionally gives extra attention to sharing data critical to achieving the five corporate scorecard goals. For example, data on revenues and margins critical to growth and profitability have been made available in real time in the easy-to-use 3D Analysis capability released in 2003. The information stored in this “data warehouse” can be sorted and totaled in numerous ways, thereby enabling Finance, Marketing, and Sales to track and analyze performance and plan and initiate effective field actions. Daily reports are published from 3D to the intranet, updating revenue and margin data globally for analysis of the very latest results.

Departments such as Operations, Sales and Service, Marketing, and New Product Development deploy and maintain workgroup level systems and applications as well as support major systems such as FFA, product data management (Product Center), project management (TOPS), and Computer Aided Design tools. The focus is on data that helps achieve scorecard goals, such as daily production, on time shipments, or those critical to ensuring prompt response to out of bounds conditions, such as quality levels.

In-process measures are used to effectively manage a wide variety of functions. Field service uses statistics on preventative maintenance services due and average on site labor per repair to assure proper customer service. QA monitors trends in warranty repair. HR uses data to manage filling of open positions including the number of days jobs have been open, number of resumes and interviews, and more.

The selection of overall organizational performance measures begins with the five corporate goals and the Top 12 corporate objectives identified and updated during the strategic planning process (see 2.1b).

Finance publishes the five corporate scorecard goal results monthly on the intranet. As described in 2.1a, the scorecard displays five primary measures that support the achievement of the strategic plan. Figure 4.1-1 displays the corporate scorecard goals, their alignment with Medrad’s mission and strategic plan, the benchmarks used to assess performance, and the reporting frequency. Results are shown in Figure 7.5-8 through 7.5-12. The President’s Letter, emailed monthly to employees worldwide, also presents the latest scorecard results.

In its Performance Excellence Team meetings (PET), the Senior Staff annually confirms and prioritizes the Top 12 objectives and sets targets and measures. Since these objectives support corporate scorecard goals, Medrad approves only those proposals that project substantive improvement and innovation.

The Top 12 objectives are reviewed regularly by the objective sponsors, in depth on a rolling three-month basis by Senior Staff, and more frequently by exception. Executives responsible for each objective waterfall objectives and progress measures throughout the organization, working with relevant sub-functions and teams. At both the corporate and sub-function/ team level, measures are selected based on their ability to predict performance or measure results, with collection and reporting established to enable course correction at appropriate time intervals. Figure 4.1-2 shows how measures align with Medrad’s philosophy, mission, and strategies.

Functions and sub-functions also identify challenging continuous improvement objectives and measures that align with the corporate goals through the waterfall objective process. Support of the Top 12 objectives demands improvement and innovation in these functional level goals. The depth of measures and frequency of reporting is appropriate to the needs of the functions, as described in (1) above.
The measures and waterfalling can be quite extensive. For example, Operations has a detailed Operations Scorecard through which aggregated results are reported monthly. Figure 4.1-3 shows the alignment of goals from the corporate objectives to the operator level in Operations.

4.1.a.2

As with the selection of measures, the selection of comparative data begins with the five corporate goals, all of which reflect benchmark data or derivatives of benchmarks. Process teams, departments, and work groups identify meaningful and cost effective comparative data to set targets and assess performance. Senior Staff promotes effective use of measures by challenging the proposed targets of the Top 12 objectives, and to drive improvement and innovation, most notably for processes considered critical to Medrad’s competitive success. For example, benchmarking input from a past Baldrige recipient led to changes in the prioritization of improvements during strategic planning, and benchmarking studies with APQC and PRTM triggered improvements in supply chain management. The Electromechanical Enterprise’s Medflow team benchmarked lean manufacturing systems at other companies.
to develop innovative production processes at Medrad’s new facility. Medrad is also a corporate member of APQC.

As noted in the Profile, Medrad has difficulty obtaining certain basic benchmark information on direct competitors such as financials because they are either: (a) small units within large corporations; or, (b) small, privately held companies. However, to compensate for the lack of information on direct competitors, Medrad has identified a group of successful publicly traded medical equipment and device companies of similar product scope and size which we refer to as the “Medrad Dow” for benchmarking core financial information. This information is effectively used to verify that Medrad’s overall financial goals of sales growth and profitability are targeted toward the top quartile of this group of peers, and that various aspects of Medrad’s financial performance are of high quality as well.

Medrad gathers information on its direct competitors’ new product releases (quality, price, frequency and regulatory approvals), the technology and design approach used in their products, and field force size and composition, and monitors their press releases. Medrad also obtains market share information through audit surveys. Much information is stored in the newly created Competitive Edge database. Medrad ensures effective use of this competitive information by incorporating it into the annual Portfolio Planning exercise where key product strategies critical to the company’s competitive direction are established.

Functions, teams, and individuals use different benchmarking approaches, from informal fact-finding via the Internet to formal third-party analyses, based on the estimated cost/benefit value of the research. These benchmarking efforts are frequently shared as part of objective and project reviews.

Medrad’s Disaster Recovery (DR) program is an example of innovation arising from benchmarking. When the DR team benchmarked alternate top quality approaches, they realized the costs to implement “right” would be beyond budget. However, by developing an innovative approach the team saved substantial money while meeting Best-in-Class timeframes during a full DR test in April.

4.1.a.3

The PET reviews Medrad’s performance measurement system annually as part of the strategic planning process described in 2.1a. The system remains current with Medrad’s needs and directions by supporting the corporate and business objectives established each year. PET confirms these objectives and reviews proposed measures and goals to verify alignment, focus on desired results, and ensure their ability to project performance improvement. The PET promotes effective use of measures by challenging the proposed targets of the Top 12 objectives and by reviewing and sharing results at monthly PET meetings, QMIs, and Quality Forums.

Medrad ensures that its performance measurement system is sensitive to rapid or unexpected change through the daily measures generated through the worldwide, highly integrated SAP system. Related reporting tools such as the 3D data warehouse provide timely information to areas that might be affected most by market changes such as sales, orders/backlog/prospects, margins, production, and on time shipments. These measures and Medrad’s many listening posts help the company react very quickly to change. In addition, the “watch list” of potential financial and operating issues and Medrad’s regular operating forecasts give a future orientation that helps the company react quickly as circumstances merit.

4.1.b.1

Medrad relies on project and objectives trackers, scorecards, and forecasts at the corporate, departmental, and process levels to aggregate data that are analyzed by senior leaders, departments, and process teams. Analyses are also presented at Advisory Boards for discussion and review.

Senior managers meet regularly at EC, Senior Staff, Advisory Boards, and staff meetings to review analyses including:

- Root causes of variations on corporate scorecard measures
- Correlations of on-time delivery and service and customer complaints
- Evaluation of product features and the trade-off with product launch schedule
- Sales and wins/losses illustrated in the “sales funnel” with Sales Process improvements and forecasting
- Benchmarking analyses for targets or process changes
- Financial comparisons
- Market share and gains/losses of customers, customer satisfaction survey data, and GPO and geographic issues
- Projections of revenues, costs and return on investment of new or expanded marketing or Business Development projects
- Trend analyses on sales, market, financial, and reliability data
- Resource usage and project slip rate on NPD and IT projects
- Cycle time, defect levels, production/delivery costs, customer satisfaction, warranty costs, and customer satisfaction with new product lines
- Employee satisfaction, training, compensation, turnover, and other HR measures
- Resource allocation among strategic planning projects and plans

The Corporate Financial Tracker shows performance in a consolidated financial performance report. The report is widely distributed and serves as the basis of all financial reviews. The alignment of analyses with key business results is also promoted by compensation plans that link achievement of all five corporate goals with team and individual pay [see 5.1b].

Functions including Finance, Sales, Marketing, R&D, and Operations prepare performance analyses that typically include both actual versus plan/objectives as well as historical
trend information. Medrad makes a conscious effort to be future oriented in these analyses with a heavy emphasis on forecasting the results at least through the balance of the quarterly or annual period (compared to plan, prior year, and prior forecast). Senior leaders use these forecasts and analyses in the groups shown in Figure 1.1-1 to detect actual variations and anticipate issues, thereby enabling management to initiate actions to increase chances of meeting objectives and to improve performance.

Leaders require that comprehensive analyses support the strategic planning process, integrating it with the work of the product line platform teams to develop short- and longer-term plans [see 2.1a(2)]. For example, as part of the Portfolio Planning process for each product area, teams analyze market and customer characteristics, competitive landscape, SWOTs, resource requirements, and the acquisition landscape.

As described in 2.1a, various groups such as Operations, IT, and Service develop their own functional strategic plans. They typically include an analysis of current situation, anticipated future demands to support corporate objectives, available new ideas and technologies in their fields, and benchmark information from similar functions in top performing organizations.

4.1.b.2

Mered’s successful experience to date has proven that its system of aligned objectives throughout the company, in combination with extensive communication of appropriate business results and analyses and networked availability of information, gives managers and employees the foundation for effective decision-making.

Functional leaders who participate in senior leadership meetings of the EC, Senior Staff, and advisory boards initiate communication of the results of the organizational-level analyses described above by sharing what they learn at meetings with their staff. Staff members disseminate key results to teams and workgroups. Information is thus waterfalled through the organization.

The CEO aggregates functional and organizational information and analyses in his monthly report, which is distributed to all employees.

Mered also communicates the results of high-level analyses through cross-functional, organization-wide forums such as the Quarterly Business Review, Quarterly Management Interaction (QMI), Quality Forums and other groups listed in Figure 1.1-1, as well as email and intranet communication by the CEO and other senior leaders, as appropriate.

4.2 INFORMATION & KNOWLEDGE MANAGEMENT

4.2.a.1

Mered’s SAP network makes data and information available to all employees worldwide 24-hours a day, seven days a week. Corporate IT has established processes that enable departments and process teams to create and maintain data and information that meets their local requirements. A corporate intranet communicates company news, performance information, how-to concepts, human resource information, and other information to all employees.

Mered’s global locations have local networks and support to provide quick, quality responses to employees. The ERP system, SAP, is hosted in Pittsburgh and provides real-time data for any business transaction in the world, as described in 4.1a(1).

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 within the Meder domain. Critical business systems require manager approval through a formal process for access and licensing. To ensure quality content, IT implemented a content management process that allows for distributed publishing, approval controls, and version control.

IT utilizes an intranet to share corporate and local business information including policies, industry news, Information Center resources, company financial data/reports, competitive database, and the R&D project command center.

In the past year, IT has extended Meder’s customer Internet site, which provides customers with product information, white papers, application information, and newsletters emailed with the customer’s permission, as well as a complete directory of field personnel. Marketing manages site content, monitoring and communicating relevant information, and uses statistics such as traffic on the site to make improvements in what is offered.

Mered has focused on extensive communication with a group of just over 30 top parts suppliers, including sending them monthly emails of results of the supplier scorecard performance taken from the SAP system, holding periodic audits and planning sessions, and inviting them to an annual Supplier Day in Pittsburgh where additional information is shared and recognition awards are given. Meder is also extending its communication with suppliers. A new initiative to develop a product with a partner vendor includes use of regular telecommunications and PC-based visual communication along with white board capability.

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.

4.2.a.2

Mered ensures hardware and software reliability, security, and user friendliness through its SAP system, which provides critical data and information to those employees who need it, as they need it.

By maintaining a company-wide ERP, Corporate IT provides a reliable, secure network that supports the operation of all business systems 24x7. IT conducts annual vulnerability assessments to validate the quality of system security. IT follows a formal process to review and approve requests for access to systems or functions within an application. IT requires
user IDs and passwords to access major systems and control information availability.

A formal Disaster Recovery Program was completed and successfully tested in spring 2003 after a six-month design process that included a business impact study and that involved all impacted functions. During the simulated disaster, Medrad proved that critical information and telecommunications functions could be made operational within target time frames.

Reliability is promoted by having each project manager responsible for developing a testing plan to review information inputs and outputs, and the owners of the new application review the test information. To make the test real, IT utilizes its production database in a test environment, employing scramble techniques to maintain confidentiality. An IT person dedicated to quality reviews the testing process for quality assurance. IT relies upon validation plans and test protocols to make sure systems and data meet user requirements. MIDAS software tracks all system changes and provides audit trails of what happens.

Ease of use is a regular focus of the IT Advisory Board (ITAB) and IT Leadership Team (ITLT), which act as functional consultants to IT and help translate business requirements into technical specifications. The deployment of systems and applications typically includes end users as part of the project team to make sure user requirements are met. Making it easy for the end users includes paying attention to training and providing needed Help Desk support during system roll out. The leadership group reviews projects monthly.

Corporate IT follows a software selection process when it selects new software. The process has five evaluation categories: (1) business requirements; (2) technical requirements; (3) vendor viability; (4) costs; and (5) support. The technical requirements focus strongly on reliability and user friendliness based on the needs of the business and the user community.

For new business applications or enhancements to packaged software, IT solicits business requirements that typically include user interface requirements such as navigation and reporting, and then uses those requirements to evaluate reliability and user friendliness.

4.2.a.3

IT developed and implemented a five-year IT strategic plan in 1996 and a three- to five-year plan in 2001. Medrad’s business needs drove the strategic plans, which reflected benchmarking information.

The ITAB aligns IT strategies with business needs and directions based on recommendations from the IT function. Annually and throughout the year as needed, departmental steering committees identify information needs and technology solutions. The sponsors in each departmental steering committee serve on the ITAB and are responsible for establishing policy, aligning data and information availability mechanisms with business needs and directions, and managing investments. The leads in each committee serve on the ITLT and provide leadership, program management, and resource management. The ITLT meets monthly to coordinate resources on cross-functional initiatives and to review the status of “Top Projects.”

The ITAB and ITLT also keep Medrad’s information management system current with business directions through a formal prioritization process that is part of the strategic planning process (Figure 4.2-1). Functional strategic planning (see Figure 2.1-2) identifies IT projects and initiatives in preparation for budget planning, during which resources are allocated to these projects and initiatives. The ITLT conducts resource planning and makes final recommendations on the projects and initiatives. Working with their ITLT members, the ITAB reviews and approves the recommendations.

4.2.b.1

The collection and transfer of employee knowledge is guided by the advisory boards and functional groups and facilitated by use of the cross functional meetings, the expanding intranet, various databases, training courses, job rotations, and numerous communication approaches (such as progress reports) and tools.

These databases and tools include FFA for field sales and service, iPDP for product development, the Competitive Edge database, human resource database, an Information Center, and others. Information posted on the intranet by numerous departments and functions is also playing an increasingly important role in knowledge management. The usage of these various databases is described throughout this application. A Community of Interest Network (COIN) approach to knowledge management is being piloted by the PEC to spread benchmarking knowledge.

The primary transfer of relevant knowledge about all customers and customer groups occurs through FFA, as described in 3.1a(2). A regular series of sales and marketing

![Figure 4.2-1. Cross-Functional IT Leadership System](image)
meetings throughout the year provide forums for sharing information about customers.

The transfer of supplier knowledge occurs through the Procurement and Supplier Quality Management group, which posts supplier performance on scorecard and other measures through the SAP information system [see 6.1a3 and 6.1a(5)].

The identification and sharing of best practices is done by teams and functional departments. Process teams, functions, and work groups are encouraged to file the results of their benchmarking activities in the Information Center to make them accessible to all employees. Regular meetings also ensure sharing of best practices. For example Medrad’s Pittsburgh based IT, Finance, and Human Resource organizations are held accountable to be worldwide centers of expertise for their functions. They meet annually in Pittsburgh for one week for training and to share best practices. Departments also use the intranet to document practices and build off them. Quality Forums and the annual Performance Excellence Conference is a showcase for best practices, at which teams present their results and practices to compete for the President’s Team Award.

4.2.b.2

Medrad recognizes the value of its information investment, purchasing reliable disk drives with appropriate redundant systems to reduce hardware risk.

IT ensures integrity with audit trail processes that record data and provide for follow-up. Medrad also engages an audit firm to provide an annual audit of reliability and controls on financial information.

Most of the data on the SAP system is available in real time with two exceptions, which are updated nightly.

The approaches to ensuring reliable and secure hardware and software [4.2a(2)] also ensure the reliability and security of data, information, and organizational knowledge. Reliability and accuracy are attributes assessed by the functions, teams, and work groups that use and refine the data, information, and knowledge. In addition, Medrad’s performance measurement system aligns data, information, and knowledge as shown in Figure 4.1-2, providing a framework for evaluating reliability and accuracy.

Medrad ensures confidentiality by controlling access to major systems and information. IT follows a formal process to review and approve requests for access to systems or functions within an application. The company also has a formal Ethics Policy that requires each employee to respect confidentiality and integrity of information.
5.1 WORK SYSTEMS

5.1 WORK SYSTEMS

5.1.a.1

Medrad achieves high performance by organizing in functional and cross-functional teams, understanding employee needs through the employee satisfaction survey process, aligning efforts through strategic planning, promoting innovation and creativity through VIP and PIAD, motivating employees through performance management, training for individual and company needs, and providing a safe and supportive environment for all employees.

Medrad’s functional organizational structure serves the company’s philosophy, mission, values, and strategies by aligning key activities such as sales, marketing, and manufacturing with the corporate objectives and strategic plan. Examples of functional innovation and excellence are presented in other parts of this application, including Sales and Service’s Sales Process, IT’s delivery of data and information through SAP, Human Resources’ initiatives to train and staff a growing company, and manufacturing’s Medflow lean production process.

At the same time, Medrad promotes cooperation, initiative, empowerment, innovation, and agility through extensive use of cross-functional teams. The Executive Committee and Senior Staff teams exemplify cross-functional teamwork at the highest level, setting corporate policy and direction and establishing Medrad’s priorities (see Figure 1.1-1). Eight cross-functional advisory boards direct and advise the areas they serve. Process teams manage key cross-functional processes. Quality improvement teams (QITs) often have cross-functional participation to solve a problem or pursue breakthrough improvements.

Business teams centralize resources to get a product manufactured. Representatives from production, quality, equipment maintenance, and engineering are co-located to work as a cohesive team. Enterprise teams on the production lines operate much like self-directed work teams. A team leader reports to the process manager or supervisor and is responsible for coordinating daily activities, building and maintaining harmony among team members, and communicating to and from the team. Each team member is expected to act according to the Medrad Philosophy. The rules each team must follow are called boundaries and exist at three levels: corporate (i.e., FDA regulations); enterprise (i.e., perform within budget); and team (i.e., Medrad Quality Policy). Each team participates in training in such areas as regulatory requirements, standard operating procedures, and communication. Each team uses a scorecard for planning and for guiding performance improvement.

Cross-functional teams are also formed to tackle the objectives “waterfalled” from the strategic plan [see 2.2a(1)]. The cascading process leads to individual objectives developed as part of Medrad’s performance management process [see 5.1b]. The connections between corporate objectives, strategic plans, functional plans, cross-functional team objectives, and individual objectives shape an organizational culture that values teamwork as essential to high performance.

In addition to the work of functional and cross-functional teams, four processes promote initiative and innovation and contribute to effective communication and knowledge and skill sharing across work units, jobs, and locations: VIP, PIAD, the Rack, and FFA.

VIP is a systematic approach to generate project ideas and to measure, track, and provide visibility for improvements. Launched in Operations in 1998, VIP encourages teams and individuals to submit primarily cost-saving ideas that support the five corporate goals. An idea is first screened by a VIP representative against criteria for acceptance, and then entered into the database. The VIP review board evaluates ideas and commissions implementation. The process for and involvement in initiating and acting upon ideas is shown in Figure 5.1-1.

The Rack is a team-focused idea generation system that encourages team members to identify problems and issues that affect quality, safety or efficiency. For example, in 2002, the Rack system in Sterile Disposables averaged approximately 22 ideas per month, more than half focused on facilities and equipment maintenance improvements. Ideas are also related to processes, forms and labeling, supplier quality, procedures, safety and other issues. Each Rack has a cross-functional team that meets weekly to review submittals, assign actioners, investigate ideas, and consider implementation. Since its inception, several submissions have been converted to VIP improvements.

Product Innovation and Advanced Design (PIAD) evolved from the Advanced Development Department to focus on new technology and innovation. PIAD’s mission is to:

- Foster product innovations that expand our business by addressing market needs
- Investigate and develop technologies that align with market needs
- Define develop, refine and advance core technologies to minimize technical risk in new product development
- Build an intellectual property portfolio to support business growth
- Support marketing, business development, and product development with technical research and expertise

Members of PIAD are formally involved in portfolio planning, with one PIAD representative on each of the portfolio planning teams. PIAD conducts quarterly project reviews that include representatives from Marketing and Business Development.

Field force automation (FFA), which is described in 3.1a(2), promotes communication and knowledge sharing on sales opportunities, sales orders, field service reports and information on customer contacts, complaints, satisfaction and other data.

Other avenues of cross-functional knowledge sharing include:
• Corporate and departmental intranet sites
• Quality Forums, where quality and productivity best practices are shared
• Performance Excellence Conference, which focuses on sharing team best practices
• Quarterly Business Reviews, which communicate marketing status throughout the company
• Quarterly Management Interaction, which involves supervisors, managers, and executives in discussing new and interesting major initiatives
• Monthly Progress Reports published and distributed to functional stakeholders and the customers of cross-functional efforts
• Monthly Progress Report by the CEO, which shares knowledge and information relating to the corporate scorecard goals, functional performance, and recognition with all employees

5.1.a.2
Medrad welcomes diverse ideas by rewarding a “values driven” competency that encourages employees to interact in an honest, ethical, trustworthy, and dependable manner, treating each other with dignity, respect, and fairness. It measures action on this competency through a question on the employee satisfaction survey. The company also systematically searches for diverse candidates in the hiring process.

Interview training provides coaching on how to ask questions that encourage diverse hiring. Medrad has identified certain colleges and student societies that have diverse student groups and diversity organizations so that it can be more involved with them when hiring. Letters to hiring agencies communicate Medrad’s commitment to diversity. As a result, the diversity of new hires at Medrad has increased 20% since 2000. Staffing reports regularly reviewed by the Executive Committee show women and minorities by level in the company. As a result of these and other efforts, Medrad has increased the percent of women and minorities in management-level or higher positions by 25% since 2000.

5.1.a.3
By their nature, cross-functional teams communicate across business units, jobs, and locations, both horizontally and vertically from work groups to the executive level. The strategic plan and the senior leadership reviews listed in Figure 1.1-2 ensure effective communication by focusing cross-functional interaction on the corporate goals and on the corporate objectives that include both strategic and performance improvement initiatives.

Medrad also achieves effective communication and skill sharing across work units, jobs, and locations through VIP, PIAD, the Rack, and FFA [see 5.1a(1)]. The SAP information system and other methods of communication described in 4.1a promote effective communication and skill sharing.

5.1.b.
Medrad supports high-performance work through the performance management (PM) and performance assessment and development (PAD) processes, and through the growth and development components shown in Figure 5.1-4. The only major difference between PAD, which is for hourly production employees, and the PM process (Figure 5.1-2), which is for all other employees, is that PAD does not have 360-degree feedback.

Both processes involve all employees worldwide in creating individual development plans. Employees and their managers/supervisors set individual objectives that align with the corporate scorecard goals and Top 12 objectives, which support a customer and business focus. The PM/PAD “objective setting” form completed by each employee and his/her manager lists the five corporate goals and the departmental goals that support corporate goals, followed by a space to list individual objectives that support the corporate and departmental goals.

The second piece of the PM and PAD processes involves identifying behavioral competencies to improve during the year, while the third piece is the Individual Development Plan (see 5.2b). The final piece is performance evaluation, which includes a self-review and manager’s evaluation in both processes and 360-degree feedback in the PM process. The 360-degree feedback process has been modified to focus the feedback on the employee’s development plan and not his/her pay or incentives, which has also accelerated and improved the process.
As part of PM and PAD, every employee receives feedback on his/her performance in the competencies that drive Medrad’s performance (Figure 5.1-3). Medrad’s competencies are also the basis of feedback on employees’ performance and behaviors in the 360-degree process. Medrad also uses the competencies to evaluate candidates for jobs, assess the potential of employees in the benchstrength process [see 5.1c(3)], and create Role Profiles that define the duties and responsibilities of different jobs.

Medrad bases its pay range on market pricing rather than on an internally focused job evaluation process. In 2001, a cross-functional project team worked with the HRAB to develop a market-based compensation system that reinforced the goals and objectives of the company and pays base pay in the top quartile of similar positions in the market. The team re-designed the pay structure to:

- Retain and attract high performance individuals at all levels of the company;
- Align individuals and teams with corporate goals;
- Support Medrad’s culture and employee growth and development; and,
- Maintain the view of base pay as one component of total compensation that also includes variable incentive pay, gainsharing, benefits, and other rewards and programs.

The company uses the Role Profiles to match all jobs to market salary data. The new pay equation combines market value for a given job with the unique qualities of the individual. Every job now has a market range with a target zone. Medrad’s goal is to move employees to their target zone over time, based on their performance and experience.

In 2001, the project team also changed the metrics used to make gainsharing payments to all employees globally. Previously, Medrad divided a percentage of profits above a specific level and distributed it to employees. Starting in 2001, the company aligned gainsharing with all corporate scorecard measures except the employee satisfaction survey, which was omitted to ensure an accurate read of employee satisfaction levels. In addition to this program, Medrad’s variable compensation programs for managers align individual objectives to the needs of the business and all five of Medrad’s corporate scorecard goals.

Several forms of recognition also honor achievements that support the corporate objectives, including the President’s Individual and Team Awards, Spirit Awards, Patent Awards, Service Awards, and departmental awards such as the OPS All-Star program, Admin’s APE award, and the NPD awards.

To further recognize superior performance, Medrad introduced the PEAK (Performance Excellence Achievement Kudos) Award in 2002. Employees worldwide nominate co-workers for the semiannual award. An employee committee chooses two winners.

The OPS All-Star program is an informal recognition program that rewards Operations employees for exceptional performance that continually makes a difference. Through the program, anyone in the company can recognize anyone in Operations, and anyone in Operations can recognize anyone outside the department who has gone “above and beyond” to provide assistance. With each “Thank You” submitted, the recipient receives a copy along with a coupon to enter into a quarterly drawing. The tenth recognition and twenty-fifth recognitions earn awards also. Each business team leader, manager, and supervisor receives a monthly report of the recognitions received by his/her employees that month.

Informal recognition is also widespread through such things as gift certificates to recognize extra effort or performance, personal notes from the CEO on employee anniversaries, and special recognitions for teams when milestones are reached.

The technical career opportunities model (TCO) applies to most engineers, scientists, designers, and technicians in Operations, New Product Development, and Global Service. The model provides them with a set of expectations for the technical, behavioral, educational, and experience requirements necessary for career progression. It gives technical managers a consistent, defined set of responsibilities for assessing employee performance levels and staffing needs. It links technical and behavioral skills to the Medrad Competency Model [see next section 5.1c (1)]. It provides an inventory, called the TCO Attributes Matrix, of the requirements necessary for job level. The model also details the technical depth and scope of engineering and technician positions through a Technical Differentiation Grid, which helps employees see how the tools and techniques for technical positions differ among Operations, R&D, and the field.

5.1.c.1

The competencies listed in Figure 5.1-3 are at the center of all HR processes, as shown in Figure 5.1-4. Medrad uses
the Role Profiles described in 5.1b, which are built upon the competencies, to identify the characteristics and skills needed by potential employees.

Medrad began identifying the competencies in 1996. The HR department, working with Senior Staff, came up with the first list of core behavioral/management competencies through an analysis of future leadership requirements based on Medrad’s vision and an assessment of the company’s current capabilities. In 1997, Medrad hired a consulting company to help refine and expand the definition and use of core competencies. The consultants worked with the HRAB and Senior Staff, conducted extensive interviews of high potential, high-performing companies, and made recommendations based on their analysis and industry experience.

5.1.c.2

To recruit talent, Medrad takes a proactive approach to anticipating the need for new employees. New anticipated headcount for the upcoming year is identified as part of the budgeting cycle and then fine-tuned in January. On a monthly basis, HR reviews the budgeted headcount list and collaborates with the Executive Committee to determine sequence and timing for releasing key positions for posting.

In 2000 to “seed” the organization, Medrad developed a college recruiting process and guidelines for supporting international technical talent working in the United States. Demographic studies show that fewer engineers are graduating now than in the past, making it increasingly difficult to find talent. Medrad estimates the company’s need for future engineers based on an assumed growth rate and turnover and on historical data, and uses the data to adjust its college recruiting goals. Employees involved with college recruiting communicate Medrad’s policy to students.

The IPO process communicates job opportunities and the skills Medrad needs, identifies employees with specific skills and competencies, leverages the knowledge that resides in employees, helps recruit “better and faster,” and reinforces the value Medrad places on treating employees consistently. Under IPO, all full-time positions are posted as they become open, with a few exceptions approved by Senior Staff and the Executive Director of Human Resources. HR communicates the openings through email, intranet, bulletin boards, Medrad staffing news and the Info Center. All full-time and part-time employees can apply for the open positions by completing an IPO form or submitting a résumé. Through IPO, Medrad filled 30% of its open positions in 2002 with existing employees. The IPO process is also Medrad’s best source of outside referrals by employees, helping it fill 17% of its positions in 2002.

5.1.c.3

Medrad addresses succession planning through a formal benchstrength process deployed throughout the company. With the benchstrength process, senior leaders identify employees with high potential and focus specific attention—such as mentoring, training, or job rotations—on them. The Executive Committee reviews the performance and potential of prospective leaders regularly and identifies opportunities for their development. The goal of the process is to identify and groom the company’s future leaders.

Functions and departments also use the benchstrength process to identify high potential, discuss what they need to do to maximize that potential, and get cross-functional input on employees’ performance. Operations is best-in-class at Medrad: At the conclusion of the benchstrength process, a template for each management position in the organization is updated, listing potential successors with information about
each including the time in their current position, a readiness assessment, and a PM rating. This “candidate slate” is used during the creation of each candidate’s individual Development Plan to identify growth and development opportunities that will prepare him/her for promotion. Senior managers also use the slate to identify potential successors for vacant positions.

5.2 EMPLOYEE LEARNING & MOTIVATION

5.2.a.1

Medrad designs and delivers education and training that serves the company’s objectives and needs. Learning & Development (L&D) determines those needs by validating requirements through departmental focus groups, Learning & Development Leadership Team, HRAB, and Senior Staff, as part of the first step in the learning and development process shown in Figure 5.2-1.

During the prioritization process, L&D balances employee requirements with the needs of the business and alignment with corporate goals (see Figure 2.2-1). A key L&D objective for 2003 is to support all five corporate objectives and their associated action plans by providing a training curriculum and key development programs that match business needs (see 2.2a(3)). L&D conducts a training needs assessment of the Top 12 objectives to help determine priorities; it supported seven of the Top 12 objectives in 2002.

The HRAB and Senior Staff approve training programs based on the recommendations of Learning & Development, which gathers information from managers, employees, corporate objectives and priorities, the L&D Leadership Team, and Senior Staff through documented needs assessment and valid requirements processes. The L&D Leadership Team is comprised of ten functional leaders who advise L&D throughout the learning and development process.

A parallel process involves determining the education, training, and development needs of individual employees. L&D determines these needs through the performance management process (see Figure 5.1-2) and validates them through meetings and conversations with employees. Individual needs are aggregated and communicated to L&D to support decision-making. Employees and managers can also use external training as part of a PM/PAD development plan. By conducting task, learner, and environmental analysis and combining these analyses with business and performance strategy assessments, L&D balances organizational goals and objectives with employee learning and development needs.

L&D contributes directly to the achievement of Medrad’s action plans through an objective to deliver high-impact training programs to meet the company’s business needs. Through employee surveys, Baldrige feedback, and information from the sources described above, L&D has identified and launched training in many areas.

5.2.a.2

Medrad’s organizational training needs are identified during the strategic planning process, either as part of functional planning or through the iterative execution process. Human Resources maps its plans to corporate goals, as shown in Figure 5.2-1, and to the strategies and actions that support those objectives. Human Resources and L&D also base their strategic plans and annual objectives on the plans of the busi-

![Figure 5.2-1. Medrad Learning & Development Process](image-url)
ness to ensure that resources and programs are aligned with business needs. This process addresses technological change, management and leadership development, new hire orientation, safety, performance measurement and improvement, and diversity. The approaches to new hire orientation and management and leadership development are highlighted in this section.

New hire orientation includes training on Medrad’s Qual- ity Philosophy, performance management process, employee handbook, and other essential information. Medrad’s president and CEO makes it a priority to attend and kick-off each monthly new employee orientation with a presentation about the company’s business and culture. (In November 2002, Training magazine recognized CEO John Friel as one of 11 CEOs “whose commitment to workforce development remains in stellar and lackluster economic times.”) New employees receive an introduction to Medrad’s philosophy and products, Performance Excellence, the Code of Conduct, basic safety, promoting respect in the workplace, training and development opportunities, and other business topics.

Each department has an orientation checklist of key points to be covered with each new employee. HR conducts new employee focus groups on a regular basis.

Management and leadership training includes PETL training, coursework through a partnership with Carnegie Mellon University, selected participation at Schering University in Germany, job rotations, project assignments, and volunteer work external to Medrad.

PETL is a leadership program designed to teach elementary leadership skills. L&D determined the need for such a program through surveys, focus groups, and individual contact. It benchmarked similar programs and partnered with outside vendors of training materials. The program was rolled out in three phases: (1) the design of seven classes; (2) determination of additional classes based on needs assessment and (3) an international roll-out of the program. L&D integrated PETL with the performance management process to motivate managers to take the course. L&D measures the effectiveness of PETL through the employee satisfaction survey and focus groups and through surveys of employees whose managers went through the training. The same survey given to a control group helps validate the survey results.

Medrad has formed training partnerships with several area colleges including Carnegie Mellon, one of the top five business schools in the country. Medrad and Carnegie Mellon jointly customized an Executive Leadership Development Program and a Middle Managers Leadership program.

Courses include managing innovation, culture and change, creating star performers, corporate strategy development, corporate finance, global strategy, marketing, renewal advantage, and a business simulation “game.” The program allows everyone in Medrad’s leadership group to learn common principles and strategies. This past year Medrad and Carnegie Mellon extended the leadership program to Carnegie Mellon’s sister school in Germany for Medrad’s European executives and managers.

In selecting leaders to take the courses, Medrad strives for a well-rounded and diverse cross-section of employees. Medrad also partners with Point Park College and the University of Pittsburgh, which offers an Executive MBA program.

Sales Training partners with L&D to determine sales training needs through the needs assessments and valid requirements processes. The identified needs are validated, discussed, and approved at the Quarterly Zone Meeting. The training includes a five-day orientation to the Sales Process (see 3.2a) for new sales, service, and application representatives, a course so successful existing representatives asked to take it. The course is now being refined for this audience. New sales, service, and applications representatives also take four weeks of product training during their first few months in the job. All representatives receive electronic and interactive training on new products as they are launched. Sales Training, sales representatives, and sales managers deliver training, with a “train the trainer” approach used outside the U.S. to transfer content and materials to international groups.

L&D develops safety training to address: (1) internal safety at Medrad facilities, which is provided through an e-learning approach; and (2) field safety, which is delivered through e-learning, video, and classroom training.

5.2.a.3 Medrad seeks training input from employees, supervisors, and managers primarily through the performance management process. Employees complete individual Development Plans that list education, training, and development needs that support the company’s goals and objectives and the employee’s career development. The L&D performance partners and the HR business group partners work with managers and employees in each group to solicit training needs on a regular basis. This information helps the L&D Leadership Team, Learning & Development, and HRAB assess the needs of employees and evaluate the best delivery options.

These groups also rely on other listening posts to solicit input from employees, managers, and supervisors, including meeting with different cross-functional teams, seeking informal conversations with employees and their supervisors, and analyzing the relevant results from the employee satisfaction.

L&D incorporates organizational learning and knowledge assets into training through the needs assessments and customer front-end analysis steps in the learning and development process (Figure 5.2-1). In addition, the L&D Leadership Team brings cross-functional knowledge to the advisory role it provides throughout the learning and development process.

5.2.a.4 Medrad delivers education and training through in-house courses taught by the training department, a training pool of employees (including the CEO and a majority of senior staff) or outside experts; partnerships with area colleges; sales representative and sales managers in the field, CD-ROM and video; computer-based training; and a toolkit used with the PM process to help employees develop the competencies identified in their development plans.
L&D seeks input from employees and their supervisors and managers during the customer front-end analysis phase of the learning and development process (Figure 5.2-1). The L&D Leadership Team also provides input on supervisor and manager needs. The instructional design phase includes steps to conduct an instructional analysis and develop instructional strategies.

Delivery approaches range from formal classroom teaching to electronic learning. For example, training on Medrad’s new products launched this year for sales representatives begins with e-learning. Employees must pass an online quiz to be eligible for interactive classes that use role-playing to reinforce new skills.

5.2.a.5
As part of the performance management process, managers and supervisors provide coaching and mentoring to reinforce the use of knowledge and skills acquired through training. The annual and six-month reviews of individual Development Plans provide a forum for discussing an employee’s expectations for training, to test those expectations after completion, and to reinforce training received.

As part of the instructional design phase, L&D designs measures of the application of new knowledge and skills.

To help institutionalize the application of training to daily work, Performance Excellence through Leadership (PETL) includes a course on “Making Training Pay Off.” The course helps participants get the most from their training experiences.

5.2.a.6
L&D uses the Kirkpatrick 4 Levels to measure training effectiveness:

- Reaction: Measures how participants react to the training through tools such as end-of-class surveys
- Content Mastery or Learning: Measures how people learn the material
- Application: L&D is currently developing measures of the application of new knowledge and skills
- Results: L&D works with its customers to define expectations and costs before training and to evaluate performance when training is completed to assess its value.

Course participants evaluate training after every course. The feedback is used to modify and make improvements in the training. L&D collects and integrates feedback on individual training courses and on the overall design of training and uses it to improve current and future training.

Sales management and the Sales Training Department partner with L&D to evaluate and improve sales training using information from quarterly reviews of the sales training plan, customer satisfaction results, participant course evaluation sheets, follow-up interviews with participants and their managers, and assessments of the linkage to results and strategies.

As part of the strategic planning process, L&D reviews the training process by analyzing information from similar sources and by benchmarking other training programs. National training conferences sponsored by the American Society for Training and Development, Conference Board, and American Quality and Productivity Center provide additional information on how high-performing companies handle training and development.

5.2.b
Figure 5.2-2 identifies the range of mechanisms Medrad deploys to develop employees, from training to support (mentoring, management development) to empowerment (project involvement, PM/PAD, horizontal growth) to opportunities (job rotation, temporary assignments, IPO, technical career opportunities). In addition to PM and PAD, the IPO process and technical career opportunities model also promote employee development.

The third piece of the PM and PAD processes is the individual Development Plan (also referenced in 5.1b). Each employee’s plan states goals for developing skills needed in current and future positions and development goals for personal improvement. Six months after the goals are set the employee and his or her manager meet to review progress on the goals and make midpoint corrections.

At the end of every performance management year, managers provide an annual review to their employees using skills taught at the PETL “How to Conduct a Collaborative Performance Review” course, and discuss performance against objectives and performance plan goals. To verify completion of the review, every manager submits to Human Resources a signed review indicating that the process was complete.

![Figure 5.2-2. Employee Growth and Development Components](image-url)
Over and above the PM and PAD process, Medrad managers are encouraged to serve as career coaches for their employees. Guidelines for the IPO process, the tuition reimbursement process, special assignments and rotations, and key actions taught through PETL, reinforce the need for all managers to support employees in their development and the achievement of their career goals. Additionally, Medrad employees are encouraged to pursue outside education and coursework at accredited universities by using the Medrad Tuition Reimbursement program.

In support of employees who serve as military reservists, Medrad took an important step in 2003 to update the Military Leave Policy. Through benchmarking and business case development, the HRAB and MESA approved an enhancement to the policy that extended military leave benefits to superior levels.

To support employees who seek career enrichment by building a strong Medrad culture, employees may participate in several employee volunteer committees (see 5.3).

5.3 EMPLOYEE WELL-BEING AND SATISFACTION

5.3.a.1 Medrad improves workplace health, safety, and ergonomics through the Employee Safety Committee, Medical Response Team, and the corporate environmental, health, and safety function (EHS).

The EHS policy defines Medrad’s commitment to responsible environmental, health, and safety management through compliance with all laws, regulations and standards; the identification and mitigation of health, safety, and environmental risks; continual improvement of Medrad’s EHS performance; and proactive communication of Medrad’s EHS performance to all stakeholders.

The EHS function improves health and safety by identifying significant issues, hazards, and incidents through several key sources of information:

- EHA aspect assessment process modeled after ISO 14001;
- Third-party auditing;
- Accident/incident data review;
- Departmental leader identification;
- Employee Safety Committee observations
- Employee concerns expressed through communication vehicles such as the Rack.

Areas for improvement are categorized as a quick-hitter, departmental issue, or corporate-wide issue. Depending on the nature of the improvement, an owner is determined and objectives and targets set.

The Employee Safety Committee is a cross-functional group of employees responsible for periodic auditing of Medrad’s accident and illness prevention program, managing the Medical Response Team, and making recommendations to improve overall safety.

The Medical Response Team is comprised of employee volunteers trained and certified to administer first aid. Team members include emergency medical technicians and general response personnel. Medrad pays all expenses for training and certification.

Employees participate in improving health, safety, and ergonomics as members of the committee and team, through involvement in the EHS asset assessment process, by contributing suggestions for improvement through the VIP and Rack programs, and by serving on Safe Workplace Action Teams (S.W.A.T.) formed to tackle a specific area for improvement.

Medrad has conducted employee Health Fairs in Pittsburgh since 1985. In 2001, Medrad received the Healthy Workplace Award, a statewide award presented by the Pennsylvania Psychological Association.

5.3.a.2 A cross-functional team with members from IT, corporate communications, facilities, HR, customer support, shipping, and other areas developed plans covering how to assess situations, when to declare disasters, how to recover and verify systems, and how to handle logistics and communication. Simulations of the disaster recovery plans ensure that they work. In addition, the safety group conducts emergency evacuation tests.

The disaster recovery plans identify customer support, shipping, and front desk capabilities as critical areas to ensure continuity. The plans include business continuity activities such as how these groups will receive calls, where they will relocate, and how they will verify the system.

5.3.b.1 Human Resources worked with the Hay Group to identify employee survey questions that reflect key factors affecting well-being, satisfaction, and motivation. Medrad also routinely participates in and learns from surveys done for Fortune magazine’s “Best Places to Work.” Human Resources seeks input from the Medrad Employee Satisfaction Association (MESA) on the key factors affecting employee well-being, satisfaction, and motivation, and on the questions that would measure the company’s performance on those factors.

MESA’s mission is to represent employees by acting as a liaison between employees and management and to provide an avenue of communication on significant management/employee issues. Employees from different parts of the company are nominated by their fellow employees to serve on MESA.

MESA was created as a result of a cycle of improvement. Before MESA, Medrad’s Internal Activity Council handled its responsibilities and coordinated company activities. The time-consuming work made it difficult to find employees willing to participate. Focus groups and a Hoshin planning session that included representatives from all levels of the company proposed breaking up the council into MESA and MEGA, the Medrad Events and Group Activity Organization.

Human Resources and MESA rely upon several internal listening posts to determine the key factors affecting well-
being, satisfaction, and motivation including employee satisfaction surveys, feedback from employee interviews and performance management meetings, employee focus groups, MEGA, retention statistics, exit interviews, and productivity growth.

The MESA holds Senior Staff and EC accountable for action on issues raised by employee survey results. HR business group partners work with senior leaders to identify key issues and prioritize them based on survey results, focus groups, and other data. Senior leaders report progress monthly to the HRAB and MESA. The MESA meets quarterly with the CEO to ensure an open communication loop and to address questions and concerns.

In Japan, employees and managers have the option to participate on a similar team called MJEC. This group also serves as a communication vehicle, meeting bimonthly with the NMKK president to surface employee concerns and address employee special events needs.

5.3.b.2

To support employees, HR established the Employee Satisfaction Center (ESC), which is the first point of contact for employee questions. The ESC also services job applicants, retirees, and former employees. HR designed the ESC in 2002 after benchmarking best practices and consulting with companies about current thinking on the process. The ESC tracks calls and intranet “hits” and uses the data to prioritize issues to address. ESC members and HR business group partners attend the monthly MESA meetings to ensure consistent communication and issue management.

Medrad supports its employees in a variety of other ways as well. MEGA, an organization comprised of employees from throughout the company, promotes a strong corporate culture by planning, coordinating, and executing corporate events. Company-sponsored and MEGA-organized events include a Christmas party and summer picnic.

Medrad supports its employees with health plans, 401k plans, career counseling, tuition reimbursement, and sponsorship of participation in the Executive MBA program. Medrad pays approximately 10% more of each employee’s health plan costs than comparable companies. The company also manages a scholarship program—the Wilson Scholarship.

Medrad provides an Employee Assistance Program offering free, confidential help to employees with job stress, emotional difficulty, legal concerns or other family problems. It offers a variety of flexible work arrangements including flexible time, reduced work hours, and job sharing. It promotes membership in a local health club by paying part of the monthly fee, allowing payroll deduction for the employee’s part of the fee, and arranging special discounts on most extra-cost services. Employee representatives manage this relationship with the health club. Medrad also sponsors employee sports leagues including golf, volleyball, rowing, bowling, and softball.

5.3.b.3

Medrad’s primary method of measuring employee well-being, satisfaction, and motivation is the semiannual employee mini-survey. The company conducted its first employee satisfaction survey in 1989 and has continually improved the process since then. The addition of several questions provided by MESA last year is one example.

In 1999 HR modified the survey to enable direct comparisons with Hay best-in-class survey benchmarks. HR uses the results of the surveys to gauge progress over time and to help assess overall HR direction. Managers and HR review the results with groups of employees to understand the attitudes behind the responses and to gain insight into issues and potential solutions. The results are aggregated with other measures including turnover, absenteeism, internal hiring, safety indicators, and productivity measures, and analyzed to evaluate and improve employee well-being, satisfaction, and motivation.

HR pays special attention to the comparative survey scores of different departments and different employee groups and initiates corrective action as needed. It also addresses low scores corporate-wide by designing and implementing processes that will improve those areas. IPO and the performance management process are just two examples of significant improvements that came out of this analysis.

On a monthly basis, Executive Committee members report initiatives against selected survey gaps using a department scorecard. As described above, the survey reflects input from a cross-section of employees through MESA, focus groups, and informal discussions, and includes questions that address key issues for employees at all levels and locations worldwide.

5.3.b.4

The Senior Staff relates the results of the employee survey and other well-being, satisfaction, and motivation measures to corporate scorecard and other business results to identify, prioritize, and act upon areas to improve. At Senior Staff meetings, senior leaders receive input from the HR Advisory Board and review information and data related to organizational health. In addition, as noted in (1), the Executive Director of HR works with MESA to prioritize employee issues that support employee survey results and corporate scorecard goals. Compensation for managers is tied to performance on the employee growth and satisfaction scorecard goal.

One of the five goals tracked on the corporate scorecard is to “improve employee growth and satisfaction,” which also supports achievement of the other four goals. By placing employee growth and satisfaction alongside other key business results on the highly visible corporate scorecard, Medrad effectively communicates the relationship between an improving work environment and an improving business. By involving senior leaders in regular reviews of these scorecard measures, Medrad promotes a systems perspective that recognizes the link between improving employee growth and satisfaction and improving performance on all corporate goals.
6 Process Management

6.1 VALUE CREATION PROCESSES

6.1.a.1

Medrad conducts business through the key processes shown in Figure 6.1-1. It defines value creation processes as those processes that help produce value—products and services—for its customers. The value creation processes listed in Figure 6.1-2 generate the design, production, and delivery of Medrad’s products and services. Revenue produced by these products and services contribute to the company’s profitability and business success. Portfolio planning and business development are described in 2.1, and the sales and service processes are explained in 3.1 and 3.2.

6.1.a.2 & 6.1.a.3

Medrad designs its products, services, and production/delivery processes within the framework of either the Integrated Product Development Process (iPDP) or the Portfolio Planning process (see 2.1a). As part of the strategic planning process, the Portfolio Planning process identifies product development initiatives, prioritizes them, and promotes alignment within the company [see 2.1a(1) and Figure 2.1-2]. Resources are allocated in the action budgeting phase of strategic planning, based on project priority. Medrad uses the iPDP to translate these initiatives into new or improved products and services. The iPDP employs concurrent activities to simultaneously develop new products and the processes to build and service them (Figure 6.1-3). A cross-functional Product Development Team (PDT) carries out the iPDP from concept to design transfer with responsibilities extending beyond development to life cycle support. As part of the project charter, the PDT establishes team boundaries and develops project objectives. Under the leadership of a program manager, each PDT tailors the iPDP to its development project. The cross-functional nature of the team involves representatives from all critical internal departments, customers, and suppliers in product and service development.

The iPDP is a stage/gate process with criteria for moving from one stage to the next. The product design process incorporates knowledge gained from benchmarking the APQC-IBC model and complies with Quality System Regulations (QSRs) and Medrad’s ISO-based quality system standards. The design process and sub processes link directly to design control elements in Medrad’s quality system. Detailed procedures dictate the processes and tools to be used through the iPDP to ensure that quality, cost, and cycle time objectives are met.

The voice of the customer and changing market requirements feed the Portfolio Planning process described in 2.1a(1) through the listening posts shown in Figure 3.1-1.

Product definition during the first stage of the iPDP requires the collection of market and technical information before the PDT is formed. It requires more market information upon approval of the PDT’s business proposal, which is then used with technical design feasibility to verify that the entire proposed system meets customer and market requirements.

Listening posts provide information about customer and market requirements to the PDT, as shown in Figure 3.1-1.
The PDT uses this information to identify essential requirements that are incorporated into the product/service specifications. Ongoing involvement in the iPDP by marketing and involvement by field representatives and customers enables the PDT to integrate customer and market changes throughout the design process. The Systems Engineering group leads the translation of customer requirements into engineering specifications, validates the translation, and ensures adherence to concurrent engineering practices.

Meditron has identified three Vectors of Differentiation that provide direction for differentiating products and services from competitors while adding value for customers. As Figure 6.1-4 shows, new and growing markets seek new capabilities, growing and mature markets value productivity, and all markets demand total customer support. Key requirements for Medrad’s value creation processes are listed in Figure 6.1-2.

As with customer requirements, new technology is first incorporated into product and service design during the Portfolio Planning part of the strategic planning process. As described in 2.1a(1), product line planning teams identify product and manufacturing technologies that support increased margins. Product Innovation and Advanced Development (PIAD) and Manufacturing Engineering develop these technologies so that they are ready for insertion into current or future product development initiatives, thereby reducing schedule and technology risk. As noted above, technical information throughout the project is used to determine if the proposed system meets requirements.
Medrad also establishes partnerships with external design resources to further identify and explore application of new technologies. Design processes address design quality, cycle time, and cost control through concurrent engineering, rapid prototyping, design for manufacture and assembly (DFMA), visual work instructions, and initiatives that target cycle time improvement. Production and delivery processes are designed concurrently with new products through the ipDP.

DFMA ensures that new product designs are producible in a manner that supports Medrad’s goals of lower production cycle time, high first run yield, on-time delivery, and cost-efficient production. The PDT defines cost and operations performance in the product specifications. As designs evolve, manufacturing engineering works with design engineering to estimate costs and to model and analyze the design to identify opportunities for component cost reduction, ease of assembly, and overall production feasibility. DFMA modeling helps design engineers make quantitative trade-offs for producibility with other design parameters such as functionality, maintainability, and reliability. The DFMA model output generates assembly instructions that are used in production.

Medrad uses visual work instructions on moderate and high volume electromechanical production lines to communicate product specifications to electro-mechanical production operators. As part of the Medflow project, a Visual Work Instruction Team developed these instructions. The team is part of a larger Medflow team that tailored lean manufacturing concepts to Medrad’s electro-mechanical production line to improve cycle time, inventory control, on-time delivery, and consistent daily output. This approach proved successful and the Sterile Disposables Enterprise is now adopting it.

Medrad’s software processes are developed using guidelines from the Software Engineering Institute, an internationally recognized center of expertise on software quality and reliability. Medrad’s software process is detailed in the Software Development and Maintenance Procedure, providing a methodology for achieving software design quality and high first run design yield through systematic defect prevention and isolation. Medrad automated the mechanical design process through design automation, analysis, rapid prototyping, and simulation software.

Transfer of learning takes place through project trackers, project histories, and the ipDP intranet site’s repository of best practices from individual projects. Product Development Teams create project histories throughout the ipDP, as shown in Figure 6.1-3. The histories include an analysis of events that occurred during development, a timeline, and an analysis of opportunities for improvement. This information is communicated through semiannual new product all-hands communication meetings, management meetings, and new product transfer reviews. Formal project histories are presented to new PDTs when they can benefit from relevant past experiences. The ipDP intranet site includes one-page descriptions of Darn Good Examples (Medrad’s term for best practices) for each development activity, stored for use by future project teams.

Manufacturing engineering follows the manufacturing process flow model (Figure 6.1-5) to concurrently design product and delivery processes in the ipDP. Representatives from manufacturing, quality assurance, service, marketing, and procurement participate in the PDT and ensure alignment of production and delivery processes with key operational performance requirements. They design production and delivery processes to meet QSR requirements and industry standards, which also produce key operational requirements.

When elements of production and 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 as a result of the Supplier Integration Transformation (SIT) process (see 6.1-5). SIT began as a way to focus on core competencies and leverage supplier capabilities by outsourcing select product components to superior suppliers. It evolved into supplier participation on PDTs because of the impact design suppliers could...
have on corporate goal achievement.

The design of production and delivery processes also incorporates learning from production operators, industrial and manufacturing engineering, and benchmarking.

Operators offer suggestions and ideas through the Rack system (see 5.1a) and regular communication meetings. The involvement of representatives from manufacturing and quality assurance on the PDTs provides a conduit from current operator experience to new manufacturing design processes.

Groups of manufacturing engineers meet semiannually to update strategic operations plans to align them with the five corporate goals and Medrad’s strategic plan. The engineers provide a link between the company’s strategic direction and work of the PDTs.

Medrad benchmarks its production and delivery processes to adopt best industry practices. For example, the Medflow production process reflects lean manufacturing approaches learned by benchmarking one of Industry Week’s “Best Plants.”

Verification & Validation (V&V) is a close-loop approach to validating customer requirements and verifying that design specifications meet those requirements. V&V activities integral to the system design and development process are continuous throughout product development.

The final step in Stage III of the manufacturing process flow model (Figure 6.1-5) is design qualification, a documented assessment of process capability or system design capability prior to plant installation. Three critical process validation steps are accomplished in Stage IV:

- **Installation qualification**: A documented assessment of equipment or system installation in manufacturing, including assurance that appropriate calibration and maintenance are performed;
- **Operation qualification**: A documented assessment of equipment or system providing assurance that the equipment is capable of consistently producing results at and within process limits.
- **Performance qualification**: A documented assessment that the outputs are effective and repeatable.

Design analysis also includes product specification reviews; design reviews; UL, CSA, and ETL reviews; and FDA, TUV, and Japan Ministry of Health reviews.

All results of customer reviews, design analysis, prototyping and pilot manufacturing, and field trials are incorporated into the stage transfer criteria for product launch.

Process and test equipment are designed concurrently to facilitate the timely introduction of products and services. The design of automated manufacturing process and test equipment adheres to the same design control process as product design and include thorough requirements, verification and validation activities, and design reviews to verify that sound design practices are being followed.

Reliability screening accelerates the detection of latent defects and helps ensure that trouble-free products will be delivered to customers.

New production processes are tested in the new process prototype lab before moving online to make sure process issues are debugged and fixed and documentation is ready.

A cross-functional team selects suppliers based on Medrad’s Supplier Selection and Certification Policy. The team uses self-assessment checklists and Medrad audits to choose suppliers based on key requirements of quality, delivery, cost, and service. It also considers overall production capabilities, customer service, management, geographic location, and their status as a disadvantaged or small business. If the initial evaluation uncovers process problems, the problems must be corrected before Medrad will certify the supplier. Before a supplier can provide a new part or material, its process capabilities for providing the part or material are examined.

The Procurement and Supplier Quality Management group is responsible for ensuring that supplier performance requirements are met. The group measures key supplier performance monthly using a supplier scorecard that awards points for quality, delivery, cost, and service. The group communicates the requirements through part descriptions on purchase orders, detailed drawings, specification/data sheets, material specifications that include packaging and/or special handling requirements, and incoming inspection plans.

Medrad has moved to a scheduling agreement with many key suppliers. Suppliers have a specified delivery date and have gained manufacturing flexibility to improve service and scheduling. Suppliers who achieve superior performance levels are eligible for long-term contracts, single sourcing, or exclusive supply agreements.

### 6.1.a.4

Key performance indicators used to control and improve Medrad’s value creation processes are listed in Figure 6.1-2.

Medrad manages these processes through in-process monitoring, field and complaint failure analysis, and process trend analysis. In many departments, scorecards are used to measure performance against goals that are directly waterfalled from the corporate scorecard goals. Operations, for example, has an Operations tracker that waterfalls to departments and, ultimately, to production line trackers. All steps are controlled by documented procedures. In the case of the electro-mechanical enterprise (the current integration of injectors and MR products), the Medflow project has established visual work instructions to help maintain consistency in day-to-day operations. All team members in production and delivery receive training on processes and procedures. Traceability is maintained and all products and materials are checked for accuracy by comparing them to a tracker document.

FRACAS (Failure Reporting Analysis and Corrective Action System) is a best practice endorsed by the Reliability Analysis Center for improving the reliability of products after launch. Medrad’s FRACAS system, the latest cycle of improvement in Medrad’s reliability approaches, encompasses all product lines. It has driven 100% reliability improvements in several Medrad products, improving warranty failure rates and service repair trends as shown in Figures 7.2-1 and 7.2-2.
Operators collect process information at each significant point in the production process. Quality Improvement Teams (QIT) may be formed to incrementally improve processes. Monthly departmental Product Quality Reports display data on all in-process measures and final inspections across all product lines. Quality control, quality assurance production management, and manufacturing engineering analyze the reports for trends, process changes, and corrective actions.

In the supply chain management process, all suppliers receive feedback through first run yield measurements and corrective action forms. The cross-functional Material Review Board (MRB) analyzes defective or questionable materials detected during production and the field return process. The MRB and the assigned supplier quality management group representative deliver feedback to the supplier. The MRB determines resolution or final disposition and documents its decision using Material Disposition forms (MDFs). If appropriate, supplier quality assurance manages supplier performance. Where warranted, teams will formally use the Supplier Corrective Action Request (SCAR) based on the MDF. The supplier is required to determine and put into writing the root cause of the problem and the immediate and long-term actions that will be taken to prevent recurrence.

The design engineers, supplier quality engineers, and buyers closest to suppliers provide performance feedback and specification requirements.

6.1.a.5
Operators follow controlled procedures for testing critical performance characteristics throughout the production process. The test procedures are based on the product design specifications and functional requirements developed by PDTs during the iPDP, ensuring that customer requirements are met and production and delivery processes are prevention-based. Design of experiments is used to develop process specifications.

In the electro-mechanical enterprise, test results are gathered in a shared database, analyzed, and are used to help determine corrective actions. Where warranted, teams will formally use the Supplier Corrective Action Request (SCAR) based on the MDF. The supplier is required to determine and put into writing the root cause of the problem and the immediate and long-term actions that will be taken to prevent recurrence.

The design engineers, supplier quality engineers, and buyers closest to suppliers provide performance feedback and specification requirements.

6.1.a.6
A number of teams work to improve value creation processes using the strategic planning process, Hoshin planning tools, simulation methods, and process mapping.

• Senior Staff, in Performance Excellence Team meetings (PET), uses overall business results, project histories, comparative studies, and inputs from customers, partners, the management team, and employees to drive broad cross-functional improvement through the strategic planning process.

• The operations management and enterprise teams review operating results and process capability to identify and prioritize improvements. QITs and process teams implement the improvements.

• QITs are chartered to make specific process improvements.

• Business and process teams, product development teams, advisory boards, QITs, and other teams use process mapping and reengineering tools to investigate and eliminate the root causes of process failures.

The New Product Strategic Team (NPST) Advisory Board has overall responsibility for improvements in the iPDP. The NPST meets every other week to review strategic and tactical information about ongoing products and to give direction to the PDTs based on their findings.

The cross-functional Configuration Control Board (CCB) manages the introduction of changes to production processes and product and service documentation. It ensures that all
proposed changes are carefully evaluated, relevant documentation is revised, and changes are implemented.

The supply chain management function, working with several QITs and process teams including supplier selection, supplier performance measurement, and supplier quality assurance, works to improve supply chain processes. Inputs to the improvement process include interviews with key suppliers, supplier performance data and trends, stakeholder input, and benchmark information.

Supply chain improvements are shared with others in the company through the Operations Quality Council, new product reviews, Quarterly Business Reviews, Quality Forums, and Performance Excellence Conference. Improvements are also discussed directly with new product teams, the new product strategic team, and the PET, and through the internal information network.

Examples of recent improvement in supply chain management include the Supplier Integration Transformation process (SIT; see 6.1a), improvements in the supplier scorecard. Cross-functional screening criteria are used to narrow the list of suppliers invited to participate.

At the highest level, advisory boards and function leaders review the key processes shown in Figure 6.1-2 to determine if process improvements are needed. They make recommendations for broad cross-functional or very large scope process improvement initiatives for the Senior Staff’s May PET meeting. Senior Staff and PETAB select initiatives for inclusion in the coming year’s Top 12 objectives based on cost-benefit analysis, the degree of alignment with corporate objectives, the availability of key resources, contribution to Baldrige OFI gap closure, the ability to manage the changes that will result, and other criteria. The PETAB analyzes the suggested initiatives and makes a prioritized recommendation to the PET, which makes the final decision on key process improvement initiatives for the coming and subsequent years. Improvements that can be accomplished within the resources of a single function are prioritized, planned, and resourced as part of the function planning and action budgeting phases of strategic planning (see 2.1, 2.2).

6.2 SUPPORT PROCESSES

6.2.a.1
Medrad identifies key support processes as those processes that support the value creation processes and key stakeholder requirements. Key support processes are listed in Figure 6.2-1. Human Resource management processes are described in Category 5. Information management processes are covered primarily in Category 4. Strategic alignment and deployment is the subject of Category 2.

6.2.a.2
Key requirements for Medrad’s key support processes are shown in Figure 6.2-1. Functions and process owners determine these requirements during the strategic planning process. As described in 2.2a(1), each function analyzes its performance based on factors which may include in-process and end-of-process measures, customer and supplier listening posts, employee listening posts, benchmark and comparative studies, FDA and ISO findings, and Baldrige feedback. From this analysis, and in alignment with corporate goals and objectives, functions identify and prioritize improvement opportunities that include changes in performance requirements.

6.2.a.3
Functional units and process teams design business processes through the process shown in Figure 6.2-2. The process extends the functional strategic planning process that is part of strategic planning (see Figure 2.1-2).

The design of business processes begins with alignment with Medrad’s corporate goals and financial plans. Inputs to the design process may include information about competitors, customers, market conditions, global growth requirements, new business opportunities, current critical improvement initiatives, business development needs, product performance in the field, and a self-assessment of the business process.

Functional and process teams manage support processes through the monitoring of process indicators, process capacity or failure analysis, complaints, and the analysis of process trends. Process teams and QITs use process mapping and re-engineering tools to develop processes that meet customer, quality, and operational performance requirements. They gather information at each key point in their processes.
6.2.a.4
Key performance indicators for all business processes are listed in Figure 6.2-1. As indicated in Figure 6.2-2, these measures support corporate scorecard goals and Top 12 objectives as well as performance improvement initiatives.

6.2.a.5
Functional units, process teams, and QITs minimize costs through the process design/redesign approach described above.

6.2.a.6
Medrad drives improvement of support processes through the strategic planning process, which also provides a forum for sharing improvements throughout the company. Functions, process teams, and QITs improve performance using the approaches described throughout this section. In addition to strategic planning, improvements are discussed and shared through the advisory boards, Quarterly Business Reviews, executive committee meetings, CEO’s monthly report, Quality Forums, the corporate scorecard, Medrad’s intranet home page, and other intranet sites.

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**Figure 6.2-1. Key Support Processes**

<table>
<thead>
<tr>
<th>Process</th>
<th>Description</th>
<th>Performance Requirements</th>
<th>Indicators</th>
</tr>
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<tbody>
<tr>
<td>Human Resource Management</td>
<td>5.1, 5.2, 5.3</td>
<td>• Increase employee growth and satisfaction</td>
<td>• Employee satisfaction survey results</td>
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<td></td>
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<td>• Employer turnover rate</td>
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<td>• Women &amp; minorities in high level position</td>
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<td>• IPO jobs filled internally</td>
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<td>• Gainsharing payout</td>
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<td>• OSHA reportable incident rate</td>
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<td>• Market based compensation percentile</td>
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<tr>
<td>Information Management</td>
<td>6.2</td>
<td>• Timely information and analytic tools for decision-making</td>
<td>• Intranet page views</td>
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<td></td>
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<td>• Technology to support process improvements</td>
<td>• Server up-time</td>
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<td>• Help Desk response</td>
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<td>• Time allocation to strategic projects</td>
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<td>• Project tracker</td>
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<tr>
<td>Financial Management</td>
<td>2.1, 4.1</td>
<td>• Efficient use of resources</td>
<td>• CMB/employee</td>
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<td></td>
<td>• Expense as % of revenues</td>
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<td>• North American Days Sales Outstanding</td>
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<td>• Capital investment</td>
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<td>Legal and Regulatory Compliance</td>
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<td>• Compliance with applicable laws and regulations</td>
<td>• Audit Results</td>
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<td>• FDA Audit Findings</td>
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<td>• Ethics hotline activity</td>
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<tr>
<td>Strategic Alignment and Deployment</td>
<td>2.1, 2.2</td>
<td>• Achieve corporate scorecard goals</td>
<td>• CMB grows faster than sales</td>
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<td>• Sales grow 15%/year</td>
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<td>• CMB/EE grows &gt;110%</td>
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<td>• Improve Top Box scores</td>
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<td>• Beat Hay best-in-class</td>
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<td>• Sales Revenue Projection</td>
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**Figure 6.2-2. Business and Support Process Design**
7.1 CUSTOMER-FOCUSED RESULTS

7.1.a. CUSTOMER-FOCUSED RESULT:

Medrad’s key measures of customer satisfaction are a fully independent external customer satisfaction survey and third-party surveys commissioned by Medrad.

The industry magazine Medical Imaging (MIM) annually surveys readers on the performance of 57 medical imaging companies in ten areas: (1) quality of products introduced; (2) price performance of products; (3) upgradeability of technology; (4) product training; (5) ease of integration with facility; (6) product/technology positioning for the future; (7) business management of P&L, acquisitions, mergers, and divestitures; (8) ability to capitalize on new and niche markets; (9) internal company leadership; and (10) product service and support. The survey compares Medrad to best-in-class and key competitors.

Respondents rate companies based on a high score of 5 (excellent) and a low of 1 (poor). Only the top 20 companies are ranked for each question; a rating of 21 on a figure indicates that the company did not score in the top 20. The rankings in Figures 7.1-1, 7.1-2, and 7.1-3 compare Medrad with a major competitor, and a Baldrige Award recipient. Medrad moved from top 20 status in 1996 to top five in 2000 to third in 2002 and second in 2003. A former Baldrige recipient ranked sixth overall in 2002 and the major competitor was not in the top 20. In the ten performance areas, Medrad ranked first in two, second in two, third in four, and fourth in two. Medrad’s major competitor did not finish higher than 13th in any area.

Medrad differentiates itself through its customer focus and quality, and the 2002 Medical Imaging survey validated its effective differentiation in these areas.
7.1a.2
Medrad’s monthly North American survey measures customer-perceived value by comparing Medrad to its competitors. As Figure 7.1-8 shows, Medrad consistently scores the same or better than its competitors with the majority rating Medrad better than competitors.

The regional customer satisfaction surveys also ask about customers’ willingness to recommend Medrad. North America has been at or near 100% for the past three years (Figure 7.1-9).

7.2 PRODUCT AND SERVICE RESULTS

7.2.a
The key indicators of product and service performance that are important to customers are those indicators listed with “production and delivery” process in Figure 6.1-2. Medrad tracks warranty repair rates for all key products, with generally improving trends. Examples include the consistent improvement noted in figures 7.2-1 and 7.2-2.

7.2-1 EnVision Warranty Performance

7.2-2 9500 Monitor Warranty Performance
Service response time is important to customers. An initiative to reduce the number of calls with response times greater than 30 minutes was initiated in July 2002. To date, this effort has reduced the number of those calls by more than 75%.

Reducing defects is critical to improving product quality and reliability. Figure 7.2-3 shows the favorable defect reduction for syringes due to process improvements. The first run yield (FRY) for the injector process shows significant improvement since 2000 (Figure 7.2-4) because of continuing process improvements, parts certifications, supplier management, PCB process improvements, and testing coverage. The 2002 Medflow initiative (see 6.1a(4)) accelerated FRY improvements.

Figures 7.2-5 and 7.2-6 show Medrad’s on-time shipment performance for selected products with comparisons to average and best-in-class companies from PRTM’s database. MR on-time shipment performance improved even as inventory was being reduced.

Acceptance rates of products at Medrad’s European (MEBV) and Japanese (NMKK) offices are indicators of product performance (Figures 7.2-7 and 7.2-8). The Japanese office began acceptance tracking in 2000.
7.3. FINANCIAL & MARKET RESULTS

7.3.a.1
Three corporate scorecard goals are key indicators of financial performance: profit growth (CMB) greater than revenue growth (Figure 7.5-8), revenue growth of at least 15% annually (Figure 7.5-9), and CMB/employee growth of at least 10% (Figure 7.5-10). Medrad’s revenue has grown steadily from $35 million in 1988 to $251 million in 2002. The company’s average annual increase rate is 15.2% for the last four years (Figure 7.5-9). CMB is an economic value added indicator Schering uses to measure its operating groups’ performance.

The MDC, a benchmark of comparable companies, is one comparison Medrad uses to assess its management of expense reductions and efficiency improvements.

Medrad’s market share leadership is shown in Figures P.2-1 and P.2-2. Medrad has higher market share than market leaders in the scanner and contrast markets that Medrad benchmarks (“benchmark market leader”), which have similar numbers of competitors, indicating the success of its customer satisfaction approaches. Medrad tracks U.S. syringe market share quarterly. International syringe market share data is not available. Injector data has not been available long enough to establish trends. Medrad’s revenues from OEM channels have risen on average, faster than market growth.

Figure 7.3-5 shows the impact of the economic downturn on the Medrad DOW average and best in class in the last couple years, a trend Medrad did not share.

Figure 7.3-1 Revenue Growth

Figure 7.3-2 Revenue by Region

Figure 7.3-3 Operating SGA Exp as % of Revenue

Figure 7.3-4 R&D Expense as % of Revenue

Figure 7.3-5 Operating Income as a % of Revenue

Figure 7.3-6 Business Development Contributions to Sales (000s).
7.4 HUMAN RESOURCE RESULTS

7.4.a.1

Medrad tracks productivity as a primary measure of work system performance and effectiveness. As Figure 7.5-10 shows, the company has doubled CMB per employee since 1997 in support of one of the corporate scorecard goals. Figures 7.4-1 and 7.4-2 show significant productivity improvements for both syringes/disposables and injectors.

Medrad also measures work system performance and effectiveness through turnover (employee retention), internal hiring, and diversity in high-level positions. Turnover is a lagging indicator of employee satisfaction. Medrad’s total turnover remains well below the benchmark, which is turnover data from Fortune magazine’s Top 10 Places to Work (Figure 7.4-3). In addition, the benchmark includes only voluntary separations while Medrad includes all turnover to be conservative in benchmarking results. Medrad uses the IPO process and measures to communicate job opportunities and recruit employees to new positions. Figure 7.4-4 shows the percent of new postings filled internally and the percent filled by employee referrals.

To promote diversity, Medrad tracks the percentage of women and minorities in high-level positions (Figure 7.4-5). Medrad’s goal to achieve 24% is based on the benchmark of 28% established by Fortune magazine’s “Top 10 Best Places to Work.”

Medrad also evaluates the effectiveness of its work system through the recognition it receives. In 2001, the People Do Matter organization honored Medrad with the People Do Matter Award, which recognizes innovation in HR strategies. Medrad has won the Best Places to Work in Pennsylvania Award twice, most recently in 2001, and was recognized as one of Pennsylvania’s “Psychologically Healthy Places to Work” by the Pennsylvania Psychiatric Association.

7.4.a.2

Learning & Development uses the Kirkpatrick 4 levels to measure training effectiveness, which includes end-of-class surveys and the application of new knowledge and skills. Figure 7.4-6 shows employee satisfaction with their Performance Excellence through Leadership (PETL)
7.4.a.3

One of Medrad’s five corporate scorecard goals is to “improve employee growth and satisfaction.” The key indicator of performance on this goal is the employee satisfaction survey. As Figure 7.4-9 shows, Medrad continues to exceed the Hay Best-In-Class benchmark, which is the top 20 companies in the Hay survey (see 5.3b1).

Medrad’s employees participate in the company’s growth and productivity successes through annual gainsharing checks given when CMB and corporate scorecard goals are met. As Figure 7.4-10 shows, gainsharing payouts have exceeded the goals, helping Medrad achieve its goal of improving growth and satisfaction while supporting the Medrad Philosophy of creating “an enjoyable and rewarding place to work.”

Medrad promotes employee well-being by providing a safe work environment, excellent benefits, and recognition for outstanding performance. The key measure of safety is the OSHA reportable incident rate. Figure 7.4-11 shows a sustained low rate that has been well below that of the medical device industry for the past nine years. While the national trend is for employees to absorb more of their health benefits cost (Figure 7.4-12), Medrad covers more of its employees’ total medical benefits cost than the national average, reported by Towers Perrin. Figure 7.4-13 shows the number of employees who have submitted “Thank You’s” to recognize coworkers for exceptional performance that continually makes a difference (see 5.1b).
7.5 ORGANIZATIONAL EFFECTIVENESS RESULTS

7.5.a.1

Figures 7.4-1 and 7.4-2 display productivity improvements in units produced per person for syringes/disposables and injectors. Medrad improved productivity without laying off employees to achieve it, demonstrating the effectiveness of its process improvement and HR approaches.

Medrad’s key measure of product development cycle time is slip rate, which is one element of the project trackers that program managers use to track cycle time. Figure 7.5-1 aggregates new product slip rate over the past seven-product introductions and shows dramatic improvement. Medrad’s new product development group is working toward best-in-class cycle times as defined by PRTM’s Medical Device and Equipment (MD&E) consortium (Figure 7.5-2).

Medrad has used a Supplier Scorecard since the mid-1990s to rate suppliers on quality, delivery, cost, and service [see 6.1a(3)]. To be considered an “outstanding supplier,” a supplier must score at least 95% on the scorecard. Figure 7.5-3 shows the jump in outstanding suppliers since the program began in 2000. The jump from 2001 to 2002 reflects Medrad’s efforts to increase awareness and the importance of the scorecard among its suppliers and the improvement programs Medrad initiated at supplier sites.

Patents are critical to Medrad’s ability to sustain market share in existing and newly created markets. Since 1993, Medrad has dramatically increased the number of patents generated by its R&D activities (Figure 7.5-4). In the last five years, Medrad has received nearly three times more patents worldwide than its closest competitor, helping it maintain its technological lead and market share.

7.5.a.2

Key measures of key support processes—most of which are presented throughout this Category (see list in Figure 6.2-1)—include key performance indicators for information management. As an internal service provider to the entire company, IT uses a scorecard to track its approach to serv-
ing internal customers’ information needs. Figure 7.5-5 shows one scorecard measure: the IT Help Desk’s performance closing Help Desk calls by priority deadline. IT uses the data to identify issues and take actions. Figure 7.5-6 shows a steady climb in the number of Medrad intranet visits, which IT and the intranet business owners use to assess the effectiveness of the intranet and its content.

Working capital is another area that Medrad manages in pursuit of its CMB per employee scorecard goal.

7.5.a.3 Medrad’s five corporate scorecard goals measure the accomplishment of the company’s organizational strategy and action plans [see P.1a(2)]. Results since the inception of the corporate goals are shown in Figures 7.5-8 through 7.5-12. In 2001 Medrad changed its customer satisfaction survey approach to a Top Box methodology, tracking only improvements in the highest or “Top Box” satisfaction category [see 3.2b(1)]. Execution of Medrad’s annual Top 12 objectives and supporting function objectives fuels consistent achievement of the corporate scorecard goals.

7.5-6 Intranet Visits Per Month

![Intranet Visits Per Month](image)

7.5-7 NA Days Sales Outstanding

7.5-8 Exceed the Financials

7.5-9 Grow the Company

7.5-10 Improve Quality & Productivity

7.5-11 Improve Customer Sat. (Satisfaction > Prior Year)

7.5-12 Improve Employee Growth & Satisfaction (Beat the Hay Best-in Class)
7.6 GOVERNANCE AND SOCIAL RESPONSIBILITY RESULTS

7.6.a.1
Medrad’s parent, Schering, hires an independent accounting firm to audit Medrad’s financial records annually, to assure fiscal accountability. The accounting firm does not have a consulting practice, which enhances the independence of the audit. Medrad has received no citations from these audits.

7.6.a.2
Medrad measures ethical behavior at its Business Ethics Committee meetings. These meetings review ethics reports, and assess the usage and effectiveness of ethics information and reporting channels. The employee survey also has a question on perception of ethics, with favorable trends.

Medrad’s three stakeholders are customers, employees, and its parent, Schering. Stakeholder trust in Medrad’s governance is measured for each stakeholder. The Medical Imaging survey is an indicator of customer confidence in Medrad’s governance. This survey rates the top 20 medical imaging companies on a number of factors [see 7.1a(1)], one of which is “internal company leadership”. The rankings in Figure 7.6-1 compare Medrad with a major competitor, and a Baldrige Award recipient. Medrad moved from a ranking of 15 in 1996 to 3 in 2002, indicating customers’ strong and increasing confidence in Medrad’s governance. Employee confidence in Medrad’s governance is measured through its employee survey. One of the questions on the Spring survey asks employees to rate the “job being done by senior management.” Figure 7.6-2 shows that employee confidence has increased each year since 2000, and beat the Hay companies’ best-in-class benchmark this year. The Hay benchmark is a group of 20 high-performing companies that Medrad uses to benchmark employee satisfaction (see 5.3b1).

Schering’s confidence in Medrad’s governance is assessed and discussed as appropriate at the semi-annual meetings of Medrad’s Board of Directors (see 1.1b).

7.6.a.3
Medrad measures regulatory compliance through FDA and ISO audits. Improvements in the company’s internal audit process reduced the number of non-compliance citations since 1994. None of the annual ISO audits conducted since 1996, including audits in Medrad’s European and Japanese offices, had any non-conformances. Since 1995, Medrad has had seven FDA inspections. For any issue noted during an inspection a “483 item” is issued and several such items can be issued during an inspection. Figure 7.6-3 shows Medrad’s generally favorable trend of FDA compliance. Six of the seven FDA inspections Medrad has received since 1995 had no 483 items; only one inspection had any 483 items and that had only one.

Medrad’s quarterly Management Review meeting (MMR) tracks quality system issues that surface anywhere within the company to assure prompt resolution.

Medrad’s parent, Schering, hires an independent firm to audit Medrad’s environmental, health, and safety (EHS) programs and practices every four years.

7.6.a.4
Medrad encourages employees to personally support the United Way, matching 70% of employee contributions. Figure 7.6-4 shows that contributions of Medrad and its employees have more than doubled since 1995. Medrad’s United Way Day of Caring continues to be the largest single-company participation in the history of the local United Way, a record set by Medrad in 1998 when 630 people participated. In 2002, 750 employees worldwide participated in the Day of Caring. The United Way presented Medrad with the United Way Gold Award in 2001 and the Balto Award in 2002 to honor the many ways Medrad contributes to the United Way.
Medrad is an environmentally conscious company with a good environmental compliance record. Medrad’s pollution prevention efforts earned recognition from Allegheny County, which awarded Medrad the Envirostar Award for the company’s sterilization gas recovery process.

Figure 7.6-4. United Way Contributions