



**CARE TO MAKE
A DIFFERENCE**

**4th Annual Lab Quality Confab and Process Improvement Institute
November 2 – 3, 2010**

Spectra Labs Turns to ISO 15189's QMS
to Advance Performance
and Gain International Recognition

Presented by:
Chinu M. Jani
General Manager and Vice President
Spectra Laboratories



**CARE TO MAKE
A DIFFERENCE**

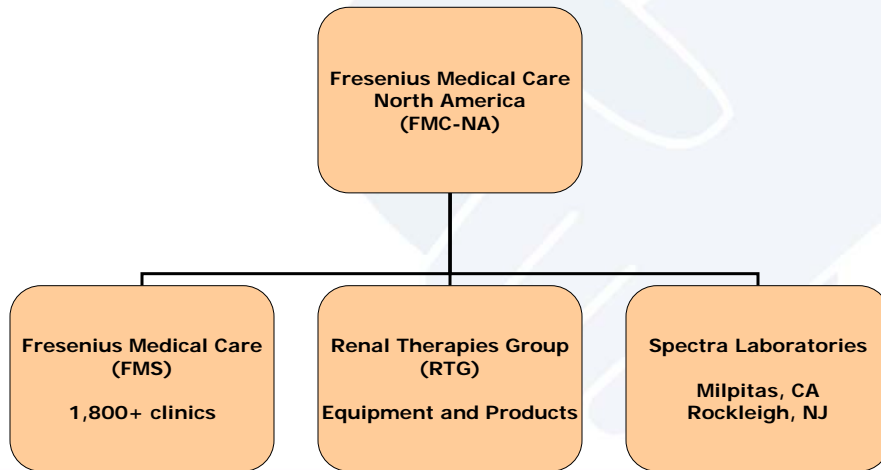
The world's largest
kidney care company . . .

**Fresenius Medical Care North
America (FMCNA)**





Fresenius Medical Care – North America (FMC-NA)



Spectra Laboratories

- Located in beautiful Rockleigh, NJ
- Specialty labs performing renal lab testing
- High-volume laboratory
 - Serving >120,000 patients and 1,800 clinics
 - Performing >40M tests
- Clinical trial testing





Spectra Laboratories

- Full service lab testing for
 - Atomic Absorption
 - Chemistry (automated and special)
 - Diagnostic Immunology
 - Environmental
 - Hematology
 - Microbiology



Scorecarding Clinic (Example)

Indicators (3-month patient avg.)	Individual Patient Target	Highest 10 th Percentile	Your % of Patients
eKdrt/V	≥ 1.20	>97% of pts with eKdrt/V ≥ 1.20	96
Hemoglobin	11.0 - 12.0 g/dL	>66% of pts with Hgb 11.0 - 12.0 g/dL	50
Albumin	≥ 4.0 g/dL	>44% of pts with Albumin ≥ 4.0 g/dL	30
Phosphorus	3.5 - 5.5 mg/dL	>65% of pts with Phosphorus 3.5 - 5.5 mg/dL	51





In Pursuit of Excellence

- Spectra made commitment in January 2005
- Full management support
- Committed quality system
- Guidance from consultant, Lucia Berte
- Transition from old to new QMS
- Restructured Quality Manual
- Electronic document management software



Our ISO Journey begins in 2005

February 28	Introduction to ISO workshop
March 23	Draft Quality Policy and QSE Policies
April 14	Inscribe Path of Workflow (POW), Processes and Procedures workshop
June 22	Write "non-lab" Processes and Procedures workshop
Sept. 15 & 21	Document Control Software selected and QSE Policies signed off
October 21	Build Training and Competencies workshop
November 29	Install Paradigm II Document Control Software





The journey continues: ISO milestones -- 2006

- Validate Processes workshop
- Quality Management System workshop
- Quality Manual signed and distributed
- “Town Hall” review of 15189 progress and future plans
- Develop and prepare process/procedure documents in new ISO format
- Configure and set up Paradigm II
- Develop Occurrence management or NCE (Nonconformance Event Management) program
- Slight setback due to resource diversion for company growth



The journey continues: ISO milestones -- 2007

- Launch NCE Program
- ISO 15189 Status Review and Project Planning workshop
- Refresher classes in Procedure Writing and Process Mapping
- In-services on NCE reporting and Corrective Action Plan
- Keep everyone on the ISO track and sustain momentum of the project
- Upgrade/update QMS and Quality Manual
- Develop Paradigm II web-based access
- Staff education in adherence to Document Management and NCE Management programs





The journey continues: ISO milestones -- 2008

- Launch updated Training/Competency program
- Updated Quality Manual signed off and ready for distribution
- Paradigm II launch and roll-out
- Internal Auditing workshop
- Prepare for ISO 15189 Accreditation



Final Tipping Point in Our ISO Journey

- **When A2LA presented the opportunity, ISO was about to “come of age”**
- **January 2010: consensus reached and rest is the history.**





Why A2LA?

- A2LA, founded in 1978, is based in Frederick, MD
- 29 programs of accreditation
- A2LA accreditation is recognized by:
 - Asia-Pacific Laboratory Cooperation (APLAC)
 - Inter-Americas Accreditation Cooperation (IACC)
 - 65 signatories to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition agreement
 - 32 signatories to the Asia-Pacific Laboratory Accreditation Cooperation mutual recognition agreement



A2LA: 29 Programs of Accreditation

- Acoustics and vibrations
- Animal drug testing
- Automotive EMC
- Biological
- Calibration
- Chemical
- Construction Materials
- Electrical
- Environmental
- Environmental Lead (Pb)
- Food Chemistry
- Food Microbiology
- Geotechnical Engineering
- Horse Racing
- Information Technology
- Kentucky UST
- Mechanical
- Non-Destructive
- Putting Green Materials
- Thermal
- Site Testing/Calibration
- Wyoming LAUST
- Medical (ISO 15189)
- Forensic Sciences
- Proficiency Testing Providers
- Reference Material Providers
- Product Certification Bodies
- Gaming Industry





CARE TO MAKE
A DIFFERENCE

Tactics for momentum

Spectra at its Best

Proud to go ISO 15189

Let's go ISO!

 **spectra**
laboratories



CARE TO MAKE
A DIFFERENCE

Let's go ISO!

**ISO at last, no more delay
ISO Captains, lead the way
ISO PROUD, that's what I say
'Cause ISO is here to stay!**

 **spectra**
laboratories



CARE TO MAKE
A DIFFERENCE

Staff HLAB Go-Live Preparedness Tracking

Assess employee preparedness for HLAB go-live in each of their assigned areas/functions, using a scale from 1 - 5 (1= Poor, 5 = Proficient) or NA

Position	Last Name	First Name	Order Entry	Patient Inquiry	Work-listing	Quality Control	Result Monitor	Result Entry	Auto-release ON/OFF	Adding Comment	Corrected Report	Cancellation	Order Monitor	Pending	Other	Other	Other



CARE TO MAKE
A DIFFERENCE

Our gains at Spectra

- Employee-centric program
 - 5-year journey has been transformational
 - Instilled unwavering confidence
 - True employee engagement
 - Lucid training tools for verifiable competency
 - Higher morale – employees feel good about themselves and “their Spectra”





Reduction in Base Salary and Overtime

- 4.7% ↓ in base salary
- 38% ↓ in overtime

Total Favorable = \$800K/year



A Tale of Two Journeys



Achieving ISO Accreditation...



is like Building a Home.....





CARE TO MAKE
A DIFFERENCE

A Tale of Two Journeys

- Grading & Building Permit
- Commitment – Form Team & Management Support
- Foundation
- OSE policies
- Rough Carpentry
- QMS & Quality Manual
- Concrete Slabs
- Train in procedure writing & process mapping
- HVAC
- Install document control software
- Plumbing & Electric
- Develop Occurrence Management



CARE TO MAKE
A DIFFERENCE

A Tale of Two Journeys

- Roofing
- Training and Competencies
- Exterior Finish
- Strong Internal Auditing
- Insulation, Drywall, Floor Finishes and Paint
- Comprehensive Management Review
- Final Inspection and Permits
- Mock audit and ISO Inspection





Things we think we did right

- Put the right people in leadership roles – vision, commitment, dedication
- Engaged the right consultant to start us off on the right track
- Leadership team persevered to keep momentum going despite delays and obstacles
- Reorganized QS Department with the right staffing to execute critical QMS components such as NCE, management review, internal audit, training/competency, quality manual, etc.



Management things we could have done better

- Enhance employee engagement down to the lowest level – which we are doing now
- We are never “done” . . . it’s kind of like my golf game!





Spectra Laboratories

- We are the laboratory of choice, *passionate* about advancing the quality of life.



Acknowledgment of contribution

- Susan Dodd
- Betty Lim
- Ray Minnick
- Maria Sarcona

