

#### ISO

#### International Organization for Standardization

**ISO 15189** - for Laboratory Accreditation using criteria and procedures specifically developed to determine *technical competence*.

**ISO 9001-** standards to evaluate how management and service organizations manage the quality of their *product or service* 



#### **ILAC**

International Laboratory Accreditation Cooperation

This is the International authority on laboratory accreditation, with membership consisting of accrediting bodies and affiliated bodies throughout the world. American Association for Laboratory Accreditation (A2LA) is the accrediting organization member that accredited our laboratory. ILAC's goal is to provide recognition of competent testing facilities around the globe.

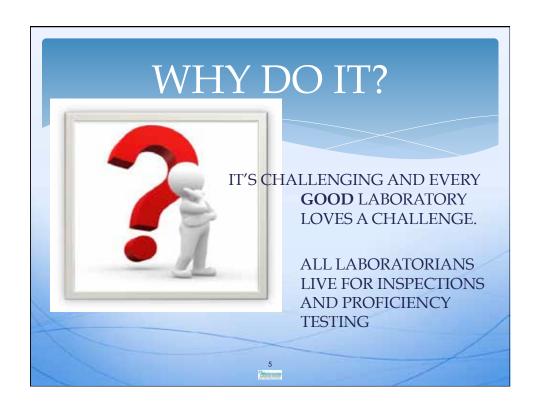


#### ISO 15189

#### ASSESSED FACTORS

- \* Technical competence of staff
- \* Validity and appropriateness of test methods
- \* Traceability of measurements
- \* Calibrations to national standards
- \* Suitability, calibration, & maintenance of equipment
- \* Testing environment
- \* Sampling, handling & transport of test items
- Quality assurance of test & calibration data







#### The REAL REASONS

- \* A COMPETITOR BECAME ISO ACCREDITED
- \* OUR LABORATORY HAD THE OPPORTUNITY TO BEGIN PERFORMING CLINICAL TRIALS
- \* ADVANCEMENT OF OUR QUALITY RECOGNITION NATIONALLY AND INTERNATIONALLY
- \* PRESTIGE



## WHO DID WE LOOK TO FOR ACCREDITATION?

- \* A2LA MET THE CRITERIA THAT WE WERE LOOKING FOR, BUT WE FOUND VERY FEW CLINICAL LABS WERE ACCREDITATED.
- \* ENVIRONMENTAL LABS MORE COMMONLY SOUGHT ISO ACCREDITATION-ISO/IEC 17125 (International Electrotechnical Commission)



## "IS THE JUICE WORTH THE SOUEEZE"

- \* MANY ASSOCIATES SAID "NO"
- \* NOT WORTH THE COST, TIME, EFFORT AND CHANGES

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#### "THE JUICE"

BUT THEN, GROWTH AND IMPROVEMENT REQUIRE WORK, SWEAT and TEARS.



### WHAT DID WE HOPE TO ACHIEVE?

- \* BETTER ORGANIZATIONAL CONTROL THRU:
  - Unification of Procedures, Policies, and Processes
  - 2. Enhanced Document Control
  - 3. Improved "Quality"
  - 4. Comprehensive Communication



## IMPLEMENTATION OF CHANGES

- \* AS A CLINICAL PATHOLOGIST I WANTED TO TWEAK SOME OF THE PRE-ANALYTICAL, ANALYTICAL AND POST ANALYTICAL PROCESSES AND PROCEDURES WITHIN THE LABORATORY
- \* WE EXCELLED IN OUR FLORIDA, NY, CLIA, CALIFORNIA AND COLA INSPECTIONS
- \* YET THERE ARE ALWAYS AREAS THAT COULD BE IMPROVED



#### WHAT WERE THE CHANGES?

- \* DOCUMENT CONTROL NEEDED TIGHTENING UP
  - 1. EACH DEPT. HAD ITS OWN FORMATS
  - 2. NO UNIFORM REFERENCING PROCESS
  - 3. REVIEW PROCESS VARIED IN EACH DEPT.
  - 4. VERSION CONTROL ???
  - 5. DUPLICATION OF SAME PROCEDURE IN DIFFERENT DEPARTMENTS
  - 6. OUT OF DATE PROCEDURES IN MANUALS

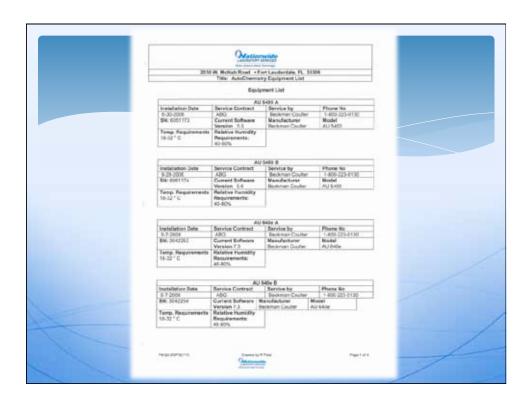


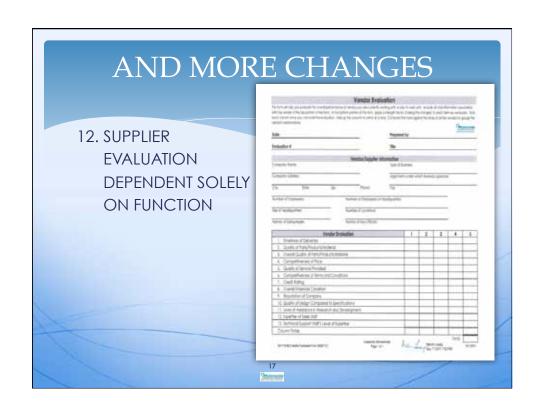
#### MORE CHANGES NEEDED

- 7. WHIMSICAL CHANGES-HAND WRITTEN CHANGES FOR SOME PROCEDURES
- 8. INCOMPLETE CHANGE CONTROL PROCESS
- 9. NO FORMAL LIBRARY DOCUMENTATION
- 10. OLD SOPS NOT WELL CATALOGUED









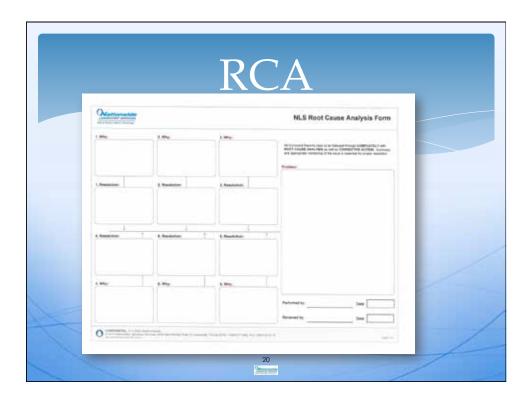


#### SOME CHANGES

- \* True team resolution of issues
- \* Good exposure of line staff to issues and resolution-became more operational savvy
- \* Developed a calibration department

  Provided very detailed traceability

  Detailed labeling of small instruments
- Significant training/understanding of root cause by all



## QUALITY PROGRAM

- \* PROGRAM IN PLACE BUT NEEDED HELP
- \* AUDITS-NEEDED TO BE MORE DIVERSE, IN DEPTH, WITH FOLLOW UP SUCH AS INTEGRATING COMPLAINTS AND ERRORS AND INCLUDE FOLLOW UP AUDIT FOR CORRECTIVE ACTION OUTCOME TO COMPLETE THE LOOP

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| 4   | Pre-examination procedures                | January  | 1/27/2012                              | Performed by<br>Mathy |  |
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|     | Organization                              |          | 1/27/0012<br>5/27/0012<br>5/25/2012    | Lucentes              | Control Department that were a first special limit is consider part  |
|     | Management system                         |          | 3/29/2012                              | ristrationstee        | SAME SAME MANUAL STATES AND EXCEPTION CONTRACT CONTRACT OF   |
|     | Accomplished and Engineers                | May      | 1/27/26/2:<br>05/39/2012<br>61/27/3013 | Kathy                 | *  |
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| 3   | Discurrent control                        | 300      | 6/22/2012                              | Louries               | Transmission and the second  |
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|     | Exertmeters by referral laboratories      |          | 6060012                                | Loundes               |  |
|     | Advancy services                          |          | 6/29/2012                              | Louistea              | in .   |

#### MORE QUALITY

- \* DOCUMENTED INFORMATION FLOW- UP AND DOWN TO ALL LEVELS- INVOLVE ALL STAFF
- \* ROOT CAUSE ANALYSIS
- \* FOLLOW THE SOP AS WRITTEN-TRACEABILITY AND UNCERTAINTY

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# ## Commence | Commence

### HOW DID WE ACCOMPLISH THIS?

- \* TOTALLY SUPPORTIVE AND ACTIVELY INVOLVED MANAGEMENT
- \* LEAD BY SMALL, VERY EXPERIENCED GROUP
- \* PROCESS SUPERVISOR DRIVEN:
  - 1. TASKS DELINEATED
  - 2. LINE STAFF INVOLVED
  - 3. CHECK FOR FUNCTIONALITY
  - 4. REPORT RESULT BACK
- \* REREVIEWED AGAINST THE STANDARD
- \* GREAT LINE STAFF SUPPORT FOR DAILY WORK



#### **NEGATIVES??**

- \* INVOLVES GREAT AMOUNT OF TIME
- \* SOME VERY PICKY ISSUES

A2LA directions for corrective action not always clear or consistent

causing more work for

the team

\* INCREASED "PAPER" WORK







#### POSITIVES!!

- \* IMPROVED-MORE ORGANIZED AND SMOOTHER FUNCTIONING OF ALL PROCESSES
- \* CONSISTENCY CLARITY OF TASKS
- \* COMPLETENESS OF FUNCTION
- \* GOOD LEARNING EXPERIENCE FOR ALL

#### CONCLUSION

\*We did achieve better organizational control which is paying dividends as we take on new challenges.



