

ISO 15189

Understanding the
obvious and subtle
Benefits

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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.

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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

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WHY DO IT?



IT'S CHALLENGING AND EVERY **GOOD** LABORATORY LOVES A CHALLENGE.

ALL LABORATORIANS LIVE FOR INSPECTIONS AND PROFICIENCY TESTING

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We did it because

- * LABORATORIANS LOVE
- * TO WORK,
- * WORK,
- * WORK.



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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

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WHO DID WE LOOK TO FOR ACCREDITATION ?

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

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“IS THE JUICE WORTH THE SQUEEZE”

- * 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:
 1. Unification of Procedures, Policies, and Processes
 2. Enhanced Document Control
 3. Improved "Quality"
 4. Comprehensive Communication

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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

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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

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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


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MORE CHANGES

11. DETAILED INSTRUMENT INFORMATION NOT IN ONE PLACE

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 2010 W. Bellish Road • Fort Lauderdale, FL 33308 Title: AutoChemistry Equipment List			
Equipment List			
AU 5400 A			
Installation Date	Service Contract	Service by	Phone No.
6-30-2008	ABC	Beckman Coulter	1-800-223-8130
SN: 6051173	Current Software Version 5.5	Manufacturer	Model
		Beckman Coulter	AU 5400
Temp. Requirements	Relative Humidity Requirements:		
18-32 ° C	40-90%		
AU 5400 B			
Installation Date	Service Contract	Service by	Phone No.
9-29-2008	ABC	Beckman Coulter	1-800-223-8130
SN: 6061174	Current Software Version 5.5	Manufacturer	Model
		Beckman Coulter	AU 5400
Temp. Requirements	Relative Humidity Requirements:		
18-32 ° C	40-90%		
AU 5400 A			
Installation Date	Service Contract	Service by	Phone No.
5-7-2009	ABC	Beckman Coulter	1-800-223-8130
SN: 3042251	Current Software Version 7.3	Manufacturer	Model
		Beckman Coulter	AU 5400
Temp. Requirements	Relative Humidity Requirements:		
18-32 ° C	40-90%		
AU 5400 B			
Installation Date	Service Contract	Service by	Phone No.
5-7-2009	ABC	Beckman Coulter	1-800-223-8130
SN: 3042254	Current Software Version 7.3	Manufacturer	Model
		Beckman Coulter	AU 5400
Temp. Requirements	Relative Humidity Requirements:		
18-32 ° C	40-90%		

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AND MORE CHANGES

12. SUPPLIER EVALUATION DEPENDENT SOLELY ON FUNCTION

Vendor Evaluation

The form will be used to evaluate the overall performance of vendors and currently existing with it. It is to be used only for vendors who are currently active in the evaluation process. All the information on this form, plus a rating from 1 to 5, will be used to determine the overall performance of vendors. The overall performance of vendors will be used to determine the overall performance of vendors.

Title _____ **Requested by** _____

Production # _____ **Title** _____

Vendor/Supplier Information

Company Name _____ **Type of Supplier** _____

Company Address _____ **Approximate year when business started** _____

City _____ **State** _____ **Zip** _____ **Phone** _____ **Fax** _____

Number of employees _____ **Number of locations or installations** _____

Year of establishment _____ **Number of contracts** _____

Name of Company _____ **Name of Key Officer** _____

Vendor Evaluation	1	2	3	4	5
1. Accuracy of Deliveries					
2. Quality of Products/Services					
3. Overall Quality of Products/Services					
4. Competitiveness of Price					
5. Quality of Service Provided					
6. Competitiveness of Service/Contract Conditions					
7. Credit Rating					
8. Overall Impact of Vendor					
9. Reliability of Company					
10. Quality of Vendor's Compliance to Specifications					
11. Level of Attention to Research and Development					
12. Superiority of Labor Cost					
13. Technical Support Staff Level of Expertise					
Column Total					

11/11/12 Vendor Evaluation Form 11/11/12

Created by: _____ Page 1 of 1

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SECURITY CHANGES

* 13. SECURITY OF OLD RECORDS



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

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RCA

The image shows a 'NLS Root Cause Analysis Form' from the National Institute of Standards and Technology. The form is designed for a 5 Whys analysis, with columns labeled '1 Why', '2 Why', and '3 Why' repeated in four rows. To the right of the 5 Whys grid is a large box for 'Problem'. At the bottom right, there are fields for 'Performed by' and 'Reviewed by', each with a date field. The form includes a logo for the National Institute of Standards and Technology and a footer with contact information.

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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

AUDIT SCHEDULE


 2030 W. McNab Rd. Ft. Lauderdale, FL 33309
 Title: CQI BILLBOARD: ISSUES / INVESTIGATION / RESOLUTION
 Year: 2012

QC 1400 Elements to be audited	Due Month	Performed Date	Performed by	Comments
5.6 Pre-examination procedures	January	1/07/2012	Kathy	OK
5.9 Identification and control of nonconformities	February	2/26/2012	Louise	Review and investigate rework control gaps with SAJ Kelly
5.11 Corrective Action		2/26/2012	Louise	QA SOP12 DC being changed add rework control section 5/16/2012
5.7 Post-examination procedures (TAT)	March	3/26/2012	Louise	Update TAT procedure updated 10/1/2012
4.6 External services and supplies		3/26/2012	Kathy & Louise	QA SOP12 DC being reviewed (add rework control) updated 10/1/2012 New Standard Operating Control Sheets for reworkable June 2012/2012
4.1 Organization	March	3/27/2012	Louise	Update Organizational chart - waiting on final approval 10/22/12 update presentation slide 66 (10/21)
4.9 Management system		3/28/2012	Kathy & Louise	Update Safety Manual Update Job Descriptions updated 10/1/2012
5.3 Laboratory Equipment	May	1/27/2012	Kathy	OK
5.2 Accommodation and Environmental Conditions		5/22/2012	Kathy	Update IT Procedures & process on 10/22/2012 Update Manual Update 10/22/2012 (slide 22)
4.3 Document control	June	6/22/2012	Louise	OK
4.4 Review of request, tenders and contracts		6/26/2012	Louise	QC SOP12 needs revision and updated signature. QC SOP12 updated on 2/16/2012
4.5 Examination by referral laboratories	6/26/2012	Louise	OK	
4.7 Advisory services	6/26/2012	Louise	OK	

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



TRACEABILITY


Nationwide Calibration Services
www.nationwidecal.com

NLS Thermometer and Hygrometer List

NLS No. #	Model No	Description	S/N	Due Date	NLS Location	Instrument Site Location
Y01	Model 15-077-001	Traceable 100 Pressure Preamplifier Thermometer	111431100	3/26/2013	GCN	Site 2000-216-943-001
Y02	Model 14-648-52	Traceable Humidity Thermometer	111639000	8/27/2013	GCN	
Y03	Model 14-648-53	Traceable Humidity Thermometer	111639100	8/27/2013	GCN	
Y04	Model 14-648-54	Traceable Humidity Thermometer	111639200	8/27/2013	GCN	
Y05	Model 14-648-55	Traceable Humidity Thermometer	111639300	8/27/2013	GCN	
Y06	Model 14-648-56	Traceable Humidity Thermometer	111639400	8/27/2013	GCN	
Y07	Model 14-648-57	Traceable Humidity Thermometer	111639500	8/27/2013	GCN	
Y08	Model 14-648-58	Traceable Humidity Thermometer	111639600	8/27/2013	GCN	
Y09	Model 14-648-59	Traceable Humidity Thermometer	111639700	8/27/2013	GCN	
Y10	Model 14-648-60	Traceable Humidity Thermometer	111639800	8/27/2013	GCN	
Y11	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114411800	3/26/2013	GCN	Site #111800
Y12	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114411900	3/26/2013	GCN	Site #111900
Y13	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412000	3/26/2013	GCN	Site #112000
Y14	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412100	3/26/2013	GCN	Site #112100
Y15	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412200	3/26/2013	GCN	Site #112200
Y16	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412300	3/26/2013	GCN	Site #112300
Y17	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412400	3/26/2013	GCN	Site #112400
Y18	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412500	3/26/2013	GCN	Site #112500
Y19	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412600	3/26/2013	GCN	Site #112600
Y20	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412700	3/26/2013	GCN	Site #112700
Y21	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412800	3/26/2013	GCN	Site #112800
Y22	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114412900	3/26/2013	GCN	Site #112900
Y23	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413000	3/26/2013	GCN	Site #113000
Y24	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413100	3/26/2013	AUTO	Site #113100
Y25	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413200	3/26/2013	AUTO	Site #113200
Y26	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413300	3/26/2013	AUTO	Site #113300
Y27	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413400	3/26/2013	AUTO	Site #113400
Y28	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413500	3/26/2013	AUTO	Site #113500
Y29	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413600	3/26/2013	AUTO	Site #113600
Y30	Model 15-077-20	Traceable Solar Preamplifier Thermometer	114413700	3/26/2013	AUTO	Site #113700



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

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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



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MORE

* AND OF COURSE
THERE IS THE.....

*COST



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POSITIVES!!

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

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CONCLUSION

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

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Thanks to the staff



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And special thanks to

* Kathy And Marta