	SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the MRM Review Meeting - 17
	ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -17	

Management Review meeting of SNSC performance based on internal audit


Audit cycle – II, Jul to Dec 2014; Dated 03.03.2015

Attendance: By list (list enclosed). The representations were from the SN main lab for Hematology and Clinical Pathology, Clinical Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics and the Support Services, CSFU, HRD, Commercial, Housekeeping, Biomedical, Electrical, Training Dept, IT and all Internal auditors.

The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.

- a) The periodic review of requests, and suitability of procedures and sample requirements.
- b) Assessment of user feedback.
- c) Staff suggestions.
- d) Internal audits.
- e) Risk management.
- f) Use of quality indicators.
- g) Reviews by external organizations.
- h) Results of participation in inter laboratory comparison programmes (PT/EQA).
- i) Monitoring and resolution of complaints.
- j) Performance of suppliers.
- k) Identification and control of nonconformities.
- l) Results of continual improvement including current status of corrective actions and preventive actions.
- m) Follow-up actions from previous management reviews.
- n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system.
- o) Recommendations for improvement, including technical requirements.

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Quality Manager		Management Representative	

	SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the MRM Review Meeting - 17
	ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -17	

Audit Team Members and Audited labs/support services : Internal audit conducted based on new standard ISO 15189 : 2012 for the following departments

- Quality System : Ms.Y.Faritha Banu
- Blood Collection area, Lab enquiry and Reporting : Dr.N.Angayarkanni & Dr.J.Malathi
- Clinical Pathology and Hematology : Dr.N.Angayarkanni & Dr.J.Malathi
- Clinical and Special Biochemistry : Ms.K.Vanitha
- Clinical Microbiology and Serology : Ms.R.Punitham & Ms.Rajalakshmi
- Histopathology and Cytopathology : Ms.U.Jayanthi & Ms.R.Praveena
- Human Resource Department : Dr.B.Mahalakshmi
- Commercial : Ms.R.Punitham & Ms.R.Praveena
- Central Sterilization Facility Unit : Ms.Saumya.T.S
- Biomedical Department : Ms.R.Punitham & Ms.R.Praveena
- IT Dept : Dr.B.Mahalakshmi
- SNSC Cl.Lab, Pycrofts garden Road (Collection Centre) : Ms.R.Punitham & Dr.R.Gayathri

Non NABL :

- NSN Lab : Dr.K.Coral
- Cytogenetics : Ms.Saumya.T.S


a. The periodic review of requests, and suitability of procedures and sample requirements :

- This has been reviewed for the two quarters in the last 6 months, dept wise.

Corrective actions were taken wherever applicable.

1. Antibodies to Aquaporin 4 (AQP4) (NMO – IgG) – (IF/ELISA) is being done from Oct 2010 by Immunofluorescence or ELISA method planing to include in the next NABL Scope

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2. In the Surgery confirmation screen, the MRD number is coloured in pink whenever the results of tests L220 Abs to HIV 1 & HIV 2, L222 HBS Ag, 223 Abs to HCV is Positive . W.e.f September 17, 2014
3. Review of sample : Heparin sample collection: revised as 1.0 ml instead of two 0.5 ml for pediatric collections since 1st April 2014
4. B.SC MLT Students will join as “Interns” after their final exams and once they obtain their certificates, they will be brought under the rolls of the organization.

b. Assessment of user feedback :

Feedback analysis : This analysis is done in SN-Main lab (Cl.Haematology, Cl.Pathology & Cl.Biochemistry & SNSC Collection Centre – Pycrofts Road), Microbiology and Histopathology labs.

- Internal customer feedback : The observed measures (Jul - Dec 2014) were above the objective in all the laboratories.
 - Histopathology & Cytopathology (Jul – Dec’ 14) – 88.2% (Objective – 81%)
 - Microbiology & Serology (Jul – Dec’ 14) – 93% (Objective – 80%)
 - Main lab (Cl.Pathology, Hematology and Cl.Biochemistry) and SNSC Collection Centre , Pycrofts Road (Jul – Dec’ 14) - 82.4% (Objective – 80%)
- External customer feedback :
 - Main lab: Collection, Cl.Haematology,Cl.Pathology,Cl.Biochemistry (Jul-Dec’ 14)- 88% (Objective-80%)
 - SNSC Collection Centre – Pycrofts Road (Jul - Dec’ 14) – 89.3% (Objective - 85%)

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c. Staff suggestions : 1 Suggestion

- Clinical Haematology & Clinical Pathology : Cell phone usage has been restricted inside the laboratory. This announcement is made symbolically has been placed in Main lab entrance

d. Internal audits :

- Internal audit - II conducted by Internal Assessors based on New Standard ISO 15189 : 2012, all the NCs have been closed on stipulated time interval.
- (Minor NC-51, Major NC-26) : All are closed.


e. Risk management : 1

- Clinical Haematology & Clinical Pathology : Discussion held in inter departmental meeting about emergency exit. If any untoward accident occur with in the lab how to handle
Decision taken : In case of any emergency Training room / Haematology lab open window has to be used if needed.

f. Use of quality indicators : Quarterly reports submitted by all the labs / collection centre, monitored by QM.

- Pre Analytical : Sample collection, Transport time, Repeat & Rework : All are within the objective From Jul – Dec 2014.
- Analytical : (Internal & External QC, Equipment down time) All are within the objective From Jul – Dec 2014 except: Clinical & Special Biochemistry, Histopathology & Cytopathology – Equipment down time and QC in the same and in microbiology/serology and Histopathology/cytopathology: CAPA documented
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From Jul – Dec 2014, except Haematology & Cl.Pathology, Histopathology & Cytopathology - CAPA documented.

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- All the Dy Technical managers are requested to submit the quantitative measures, through quarterly reporting in the form of graph which also needs to be displayed in the lab.(Quarterly/half-yearly and one year data with a comparison of the previous corresponding set)
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 6 months From Jul – Dec 2014, dept wise. Corrective actions were taken wherever applicable Henceforth a yearly comparison will be made on the statistics as part of QI.

g. Reviews by external organizations :

- Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012 (Validity till February 2016) for SN Main Hospital & SNSC Centre at pycrofts road
- Absolute Alcohol Renewal of license done on April' 14. Valid upto Mar-2015
- Biomedical Department : Renewal of Calibration Certificate done for 2014 - 2015
 - Temperature Indicator with Sensor - Valid upto April 2015
 - Digital Multimeter - Valid upto May 2015
 - Digital Tachometer - Valid upto September 2015
 - Weight box - Valid upto December 2015
 - Digital stopwatch - Valid upto December 2015
 - BP Apparatus - Valid upto December 2015
 - Glass Thermometer - Valid upto December 2015
- Maintenance Department : Renewal of Calibration Certificate done for 2014 - 2015
 - Temperature Indicator with Sensor - Valid upto November 2015
 - Hygrometer - Valid upto December 2015

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h. Results of participation in inter laboratory comparison programmes (PT/EQA) :

- This has been reviewed for the two quarters in the last 6 months, From Jul – Dec 2014 dept wise Satisfactory Results except Haematology & Clinical Pathology, Microbiology, Clinical & Special Biochemistry – CAPA documented.
- MOU with Lister lab for Outsource : renewal has been made and valid till October 2016.

i. Monitoring and resolution of complaints :

- Based on Internal & External feedback forms (Jul - Dec' 14) actions were taken and the issues settled (as in point b)


j. Performance of suppliers :

- Vendor evaluation completed for the period of (Jul – Dec' 14) is given by commercial.
- Vendor Complaint for the period of (Jul – Dec' 14) : 1 Complaint : Action taken
- Material Specification Sheet & Approved vendor list for the year 2015 was updated.
- As announced by QM , hence forth no deviation of MSS is allowed without justifications as per formats followed by amendments.

k. Identification and control of nonconformities :

- Daily non conformances are documented in all the laboratories and discussed in the respective Departmental lab meetings for corrective action. CAPA are documented for detailed ones.
- As requested by QM, all technical and non-technical staff including secretaries are encouraged to independently mention the daily NC in the records followed by supervisors attestation.

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1. Results of continual improvement including current status of corrective actions and preventive actions :

Continual Improvement : (Jan to Dec 2014)


- All NABL Manuals have amended as per new standard ISO 15189:2012
- NABL Desktop audit completed on 25th August 2014 for the same NABL recommended the Continuation of the accreditation status
- Cobas C111 Table top fully automated biochemistry analyzer installed May 2014 QC with CMC Vellore initiated for the same communicated to NABL office on July 2014 in dest top audit and it was approved.
- New Automatic tissue processor Medimeas MTP-M111 Purchased July 2014 (Histopathology)
- New clinitek Advantus (Urine analyzer) has been installed on 15th Sep 2014 for clinical pathology and interfaces on 27th Sep 2014 for the same has been communicated to NABL office on 8th October 2014
- Lab investigations for the Fast track Cataract surgeries has been implemented in SNSC Collection Centre - Pycrofts road on 03.04.2014 onwards. The Lab technicians are sent to the respective floor for the collection to keep in line with the fast track.
- From May 26th onwards, tests for CRP is performed once in a day at 2.00 pm and reports will be typed and uploaded on the same day by 5.30 pm
- CSF Protein Method has been changed from Lowry method to Pyrogallol red Method from May 2014 onwards - (Non NABL)
- To ensure constant quality of kit and quality of reporting using the kit - Serum samples (Positive and Negative serum) tested with the previous kit will also be tested with the new

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- kit when it is opened for the first time for use from June 2014 onwards (Microbiology & Serology, Biochemistry)
- The Drop down menu for choosing the organisms name as being introduced in the HMS system for Microbiology reports from 23rd September 2014 onwards.
 - In order to streamline the verification of test reports duty roaster has been scheduled – To avoid delay in generation of reports from November 2014 onwards (Microbiology & Serology)
 - The SOP on External services and supplies and Stores has been verified by Bio-engineering and Commercial Heads based on which revision has been made. The SOP on Personnel has been verified by the HR based on which revision is made. The policy on Laboratory Information Management has been verified by the IT Head and the revisions completed.
 - Quality Policy & Quality Objectives has been revised as per ISO 15189:2012 Guidelines
 - NABL Tool kit (List of NABL Documents) has been implemented.
 - A format for documenting Staff suggestions, Risk management was given to all the Dy.Tech managers on October 2014 to be used in the respective laboratories and report through the quarterly report to QM
 - A format for documenting Computer calls log book (from March 2014 onwards) & Vendor complaint form has been introduced on October 2014
 - A meeting convened on 22nd Nov 2014 to discuss the feasibility of the “online version of requisition form” with IT, DPS and Main lab. The IT has requested 6 months time. Ms. Sumathy IT was reminded of the same.
 - Discussion held with Ms.Akila Ganesan (SGM) on December 2014 regarding NSN lab to be changed as NSN Collection Centre for the same NSN Lab converted to NSN Collection centre form 7th February 2015 onwards.

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- Internal assessors (10 members) attended the Internal Audit and Quality Management System Certificate course for ISO 15189:2012 for the year 2014.

Corrective action & Preventive action :

- Quality Control Programme : Internal and External QC, ILQC, PT programme in each of the lab has been verified. The labs have taken appropriate corrective actions as required
- Measure on QC is verified Quarterly by QM as part of Quality Indicator.

m. Follow-up actions from previous management reviews :

- Internal audit – 1 conducted by Mr.Surendran, ACME Consultancy (Out source) on September 2014 based on new standard ISO 15189 : 2012. The revision of manual was done with the assistance of this consultancy service.
- External Training : Dr.N.Angayarkanni, Dr.Doreen Gracias, Ms.R.Punitham, Dr.B.Mahalakshmi, Dr.J.Malathi, Ms.K.Vanitha, Ms.Saumya T.S, Ms.Faritha Banu, Ms.Praveena and Ms.Rajalakshmi attended the Internal Audit and Quality Management System Certificate course for ISO 15189:2012
- Ms. Manimegalai, Ms. Gayathri, Ms. Logeshwari, Ms.Parameshwari attended the “Talent Quest” A state Level Talent search for Life science Award 2014 conducted by TechMed Healthcare on 12th Oct. 2014 at New College, Chennai. Ms. Logeshwari was selected for the 2nd round of the “Talent Quest” on 18th Oct. 2014 at BalaMandhir, German Hall and T.Nagar Chennai.
- Ms.Punitham attended “Achieving Excellence in Leadership” training programme
- Internal training (Soft skill training) programme conducted through training department
- Internal and external training details are documented and verified by QM. However training department shall be audited henceforth separately

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n. Changes in the volume and scope of work, personnel, and premises that could affect the quality management system :

List of Accreditation tests at SNSC Clinical laboratory :

- Clinical Haematology : 17 and Clinical Pathology : 19
- Clinical and Special Biochemistry : 20
- Clinical Microbiology and Serology : 26
- Histopathology : 6 and Cytopathology - 4

Total: 92 Tests

- **Revision in scope in 2015 application proposed :** Antibodies to Aquaporin 4 (AQP4) (NMO – IgG) – (IF/ELISA)

Staff adequacy: Adequate. However, the turn over is very high in Microbiology as trained /specialized in microbiology personal and secretary for report typing was hard to get as expressed by the head of the Microbiology lab.


Resignations :

- Microbiology: One Executive : Ms.Revathy Menon
One Lab Technician : Mr.Vinayagam
One Secretary : Ms.Gayathri
- Main lab: One Executive : Mr. Samvel,
Two Lab Assistants : Ms.Uma Maheshwari, Ms.Saraswathi One Secretary : Ms.Sathya
- Cytogenetics (Non NABL) : One Lab Technician : Ms.Karthiyayini

Refilling of the post:


- Microbiology : One Technical Assistant : Ms.Shafiya Begum
One Secretary : Ms.Sureka
One post is still unfilled

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- Main lab: Two Lab Technicians : Ms.Logeshwari & Ms.Suganya
 One Lab Assistant : Ms.Soumiya.E.R
 One Secretary : Ms.Asvini
- Histopathology : One Lab Technician : Ms.Thenmozhi
- Cytogenetics (Non NABL) : One Lab Technician : Ms.Porkodi
- Document control: Version numbers of documents revised in 2014 (Jan - Jun'14) :
 - Quality System
 1. Internal Audit Schedule : SNSC/IAS/2014/Version : 1.0
 2. Annual Audit Plan : SNSC/AAP/2014/Version : 1.1
 3. Internal Audit Check List 1 & 2 : SNSC/IACL-1/2/2014/Ver1.0
 4. Checklist for Medical Laboratories Collection Centre : SNSC/CC-CL/2014/Ver-1.0
 5. Material Specification Sheet : SNSC/MSS/2014/Ver-1.0
 6. Equipment Downtime : SNSC/EDT/2014/Ver-1.1
 7. PMT / Calibration Plan : SNSC/PM-CP/2014/Version 1.2
 8. SNSC Collection Centre Quarterly reporting to Quality Manager on Continual Improvement : SNSC/QR-CC/2014/Ver-1.1
 9. Quarterly reporting of the Dy Technical Managers to the Quality Manager on Continual Improvement :SNSC/QR/2014/Ver-1.7
 10. Staff Suggestions : SNSC/SSF/2014/Ver-1.0
 11. Lab Requisition Form : F/SNSC/ML/LRF/1.17
 12. Risk Management : SNSC/RM/2014/Ver-1.0
 13. Vendor Complaint Form : SNSC/VC/2014/Ver-1.0
 14. Amendment Request Form : SNSC/ARF/2014/ Version -1.4
 15. Recruitment of Laboratory Staff : SNSC/RLS/2014/Version -1.1

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o. Recommendations for improvement, including technical requirements :

- Risk Management, Staff Suggestions has been included in Quarterly reporting of each of the Lab to the QM on continual improvement.
- Preventive Maintenance & Calibration plan format made uniform in Laboratory and Biomedical Engineering
- Guideline for interns in Laboratory given to HR
- Material specification sheet to be strictly implemented
- Staff suggestion to be encouraged and acted upon
- All internal assessors except 4 more were trained in the revised guideline. They will be sent for training this year.
- The policy of IP billing Registration to be clarified and stated in QSM/QSP
- Requisition form to be made in HMS- shall be followed up.
- Quality Plan for the year 2015 prepared.
- All issues related to logo to be informed to QM office promptly.
- Daily NC and CAPA to be adequately addressed and documented by each lab.
- As recommended by MR, henceforth representative from NABH (Ms. Mahalakshmi and a consultant will be requested to attend the MRM meeting 2 every year)

Thank You

Dr. N. Angyarkanni,
 Quality Manager,
 Medical Research Foundation
 SNSC Laboratory
 Chennai – 600 006.

Forwarded by:

Dr.S.B.Vasanthi
 Management Representative
 Medical Research Foundation
 SNSC Clinical Laboratory
 Chennai – 600 006.

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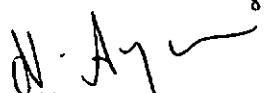
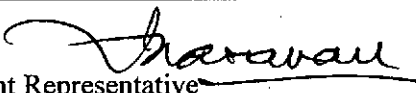
Management Review meeting of SNSC performance based on Re-Assessment audit

Jan to May 2015 : Dated 26.08.15

Attendance: By list (list enclosed). The representations were from the Hematology and Clinical Pathology, Clinical Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics.

The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.

- a) The periodic review of requests, and suitability of procedures and sample requirements.
- b) Assessment of user feedback.
- c) Staff suggestions.
- d) Internal audits.
- e) Risk management.
- f) Use of quality indicators.
- g) Reviews by external organizations.
- h) Results of participation in inter laboratory comparison programmes (PT/EQA).
- i) Monitoring and resolution of complaints.
- j) Performance of suppliers.
- k) Identification and control of nonconformities.
- l) Results of continual improvement including current status of corrective actions and preventive actions.
- m) Follow-up actions from previous management reviews.
- n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system.
- o) Recommendations for improvement, including technical requirements.

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Audit Team Members and Audited labs/Support services : External audit conducted based on new standard ISO 15189 : 2012 for the following departments

- Quality Manual : Dr.Srinivas Kancharla – Lead Assessor
- Clinical Pathology and Hematology : Dr.Tadury Madhukar Subbarao - Technical Assessor
- Clinical and Special Biochemistry : Dr.Jothi Malar - Technical Assessor
- Clinical Microbiology and Serology : Dr.Savitha Nagaraj - Technical Assessor
- Histopathology and Cytopathology : Dr.Veena R - Technical Assessor
- SNSC Cl.Lab, Pycrofts Road (Collection Centre) : Dr.Srinivas Kancharla- Lead Assessor

a. The periodic review of requests, and suitability of procedures and sample requirements :

This has been reviewed for the two quarters in the last 6 months, dept wise. Corrective actions were taken wherever applicable.

- Antibodies to Aquaporin 4 (AQP4) (NMO – IgG) – (IF/ELISA) is being done from Oct 2010 by Immunofluorescence or ELISA method for the same has been included in NABL scope of testing.
- Amino Acid Profile has been deleted in NABL scope of testing 2015 (due to poor sample numbers for the last two years)

b. Assessment of user feedback :

This analysis is done in SN-Main lab (Cl.Haematology, Cl.Pathology & Cl.Biochemistry & SNSC Collection Centre – Pycrofts Road), Microbiology and Histopathology labs.

Internal customer feedback : The observed measures (Jan – Jun'15) were above the objective in all the laboratories.

- Histopathology & Cytopathology (Jan - Jun'15) - 92% (Objective - 81%)
- Microbiology & Serology (Jan - Jun'15) - 91% (Objective - 80%)
- Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and SNSC Collection Centre - Pycrofts Road) (Jan - Jun'15) - 82% (Objective - 80%)

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External customer feedback :

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry
(Jan - Jun'15) - 89.5% (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road (Jan - Jun'15) - 89% (Objective - 80%)

c. Staff suggestions : 15 (Jan – Jun'15). Most of it was on salary improvement and has been forwarded to HR. The rest were on environmental issues

d. Internal audits :


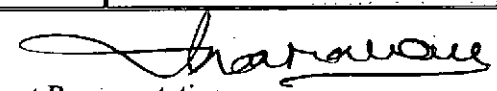
- Internal audit - II (2014) conducted by Internal Assessors based on New Standard ISO 15189 : 2012, all the NCs have been closed on stipulated time interval.
(Minor NC-51, Major NC-26) : All are closed.
- External audit (May 30th & May 31st) conducted by External Assessors based on New Standard ISO 15189:2012, all the NCs corrective action has been taken in stipulated time interval (Minor NC -11, Major NC – 3)
- NABL recommended for renewal of accreditation in accordance with ISO 15189:2012.
Certificate Validity period : 14.08.2015 - 13.08.2017

e. Risk management : 3

- Clinical Haematology : Wrong updation, High value reported without repeating the test
- Clinical Biochemistry : Wrong Updation

Decision taken : ITSR raised and report was amended – CAPA Documented

f. Use of quality indicators : Quarterly reports submitted by all the labs / collection centre, monitored by QM.

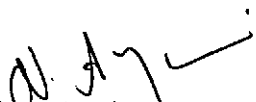
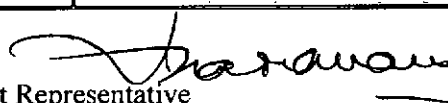
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- Pre Analytical : Sample collection, Transport time, Repeat & Rework : All are within the objective (Jan - Jun'15)
- Analytical : (Internal & External QC, Equipment down time) All are within the objective From Jan – Jun'15 except : Clinical Haematology – EQAS & IQC, Clinical Biochemistry – EQAS & IQC, Histopathology - IQC : CAPA documented
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From Jan – Jun'15 except : Clinical Biochemistry, Histopathology - Turn around time : CAPA documented.
- All the Dy Technical managers are requested to display the quantitative measures, in the form of graph. (Quarterly/half-yearly/one year data with a comparison of the previous corresponding set)
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 6 months From Jan – Jun'15, dept wise. Corrective actions were taken wherever applicable.

g. Reviews by external organizations :

- Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012 (Validity till February 2016) for SN Main Hospital & SNSC Centre at pycrofts road
- Absolute Alcohol Renewal of license done on April'15. Valid upto Mar-2016.
- GJ Multiclave (For Biomedical waste) renewal has been done on May 2015 for SN Main, SNSC Collection centre – Pycrofts road (Valid upto May 2018)
- Biomedical Department : Renewal of Calibration Certificate done for 2015 - 2016
 - Digital Multimeter (3 1/2 DGT) – Valid upto August 2015
 - Digital Tachometer - Valid upto September 2015
 - Temperature Sensor (PT-100) - Valid upto November 2015
 - Digital Multimeter (Agilent) - Valid upto November 2015

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- Temperature Indicator with Sensor (Ecoscan Temp6/Temp6 Temp 01R)- Valid upto April 2016
 - BP Apparatus (Deluxe) - Valid upto December 2015
 - BP Apparatus (Diamond) - Valid upto December 2015
 - Weight box - Valid upto December 2015
 - Digital stopwatch - Valid upto December 2015
 - Glass Thermometer (Foreign make) - Valid upto December 2015
 - Glass Thermometer (Jennc Research Make) - Valid upto December 2015
- Maintenance Department : Renewal of Calibration Certificate done for 2014 - 2015.
- Temperature Indicator with Sensor - Valid upto November 2015
 - Hygrometer - Valid upto December 2015

h. Results of participation in inter laboratory comparison programmes (PT/EQA) :

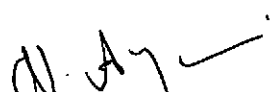
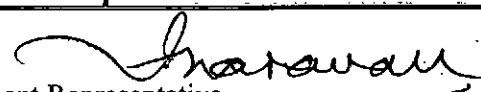
- This has been reviewed for the two quarters in the last 6 months, From Jan - Jun'15 dept wise : Satisfactory Results.
- MOU with Lister lab for Inter Lab Comparison : renewal has been made and valid till July 2017.

i. Monitoring and resolution of complaints :

- Based on Internal & External feedback forms (Jan - Jun'15) actions were taken and the issues settled (as in point b)

j. Performance of suppliers :

- Vendor evaluation completed for the period of (Jan - Jun'15) is given by commercial dept.
- Vendor Complaint for the period of (Jan - Jun'15) : 1 Complaint (Settled)

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k. Identification and control of nonconformities :

- Daily non conformances are documented in all the laboratories and discussed in the respective Departmental lab meetings for corrective action. CAPA are documented for detailed ones.
- As requested by QM, all technical and non-technical staff including secretaries are encouraged to independently state the daily NC in the records followed by supervisors attestation.

l. Results of continual improvement including current status of corrective actions and preventive actions :

Continual Improvement : (Jan to Jun 2015)

- NABL Re-Certification audit completed on 30th & 31st May 2015.
- Renewal of NABL Accreditation for SNSC Clinical Laboratory.
- Internal assessors (5 members- Dr.S.Krishnakumr, Dr.K.Lily Therese, Dr.K.Coral, Dr.R.Gayathri, Ms.U.Jayanthi) attended the Internal Audit and Quality Management System Certificate course for ISO 15189:2012 for the year 2015.
- Ms.Punitham & Ms.Saumya.T.S attended the CME programme (Total Quality Management in Laboratory Medicine) conducted by Madras Medical Mission on 31.01.15
- **Haematology & Clinical Pathology** : Indent has been raised for the purchase of fully automated coagulometer ACL ELITE PRO
- Sound proof room has been constructed for the paediatric collection area
- Beckman fully automated urine analyzer is being scrutinized for purchase
- Secretaries have been involved in Internal / External feedback forms statistical work. Suggestions and comments are being managed by technical manager
- Daily Quality control for blood grouping reagents has been started. Titre, Avidity and Specificity for each New Lot of Blood group kit has been implemented.

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- **Histopathology lab** : New camera attachment for Nikon Microscope (Eclipse) was Purchased in April 2015
- New hot air oven Purchased – July 2015
- **Biochemistry Lab** : Dr. Doreen Gracías has been given Inchargeship for Clinical Biochemistry from 15th June 2015 onwards. She will look into the daily QC.
- Dr.K.Coral & Ms.U.Jayanthi attended ISO 15189 : 2012 Internal Audit & Quality Management System Training
- Amino Acid Profile test has been removed from the NABL Scope of testing due to less number of collections for last one year.
- OGTT test Biological Reference Range introduced for patient care.
- New test code: 104 introduced for GDM (Gestational Diabetes Mellitus). (Non NABL)
- Plasma Homocysteine turn around time has been reduced from 10 days to 5 days. (Non NABL)
- HbA1C turn around time has been reduced from 24 hours to 5 hours. (From August 2015) (Non NABL)
- **Microbiology lab** : Schedule has been prepared distributing the work load equally to all technical staff
- Mycology EQAS is added which is being conducted by mycology division, department of medical microbiology, postgraduate institute of medical education and research Chandigarh.
- The Quality control for detection of HIV 1 & HIV 2 antibodies by western blot test is being carried out by split sampling method.
- E-strip for Benzyl penicillin are included for Antibiotic Susceptibility Test.

Corrective action & Preventive action :

- Quality Control Programme : Internal and External QC, ILQC, PT programme in each of the lab has been verified. The labs have taken appropriate corrective actions as required
- Measure on QC is verified Quarterly by QM as part of Quality Indicator.

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m. Follow-up actions from previous management reviews :

- External Training : Dr.K.Lily Therese, Dr.S.Krishna Kumar, Dr.K.Coral, Dr.Gayathri, Ms.Jayanthi attended the Internal Audit and Quality Management System Certificate course for ISO 15189:2012
- Internal training (Soft skill training) programme conducted through training department
- Internal and external training details are documented and verified by QM.

n. Changes in the volume and scope of work, personnel, and premises that could affect the quality management system :

List of NABL Accreditation tests at SNSC Clinical laboratory approved in the recertification audit (validity) :

- Clinical Haematology : 17 and Clinical Pathology : 19
- Clinical and Special Biochemistry : 19
- Clinical Microbiology and Serology : 27
- Histopathology : 7 and Cytopathology - 4

Total: 93 Tests

Staff adequacy: Adequate.

Resignations :

- Microbiology: One Junior Scientist : Ms.Dhanurekha
One Senior Lab Technician : Ms.Evangelin
- Main lab: Junior Executive : Ms. Praveena
Two Lab Technicians : Ms.Manimekalai, Mr.Syed Yamin

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**SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -18

Minutes of the
MRM Review
Meeting - 18

Refilling of the post:

- Microbiology : Nil
- Main lab: One Junior Executive : Ms.Priya
One Lab Technician : Ms.Suganya
Two Lab Assistants : Ms.Shanthi K.M, Ms.Jayashree
- Histopathology : One Lab Technician : Ms.Thenmozhi
One Junior Scientist : Ms.Saranya

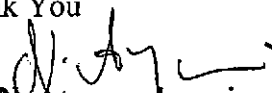
Promotions:

- Ms.Faritha Banu promoted to E2 Grade
- Document control: Version numbers of documents revised in 2015 (Jan - Jun'15):
 - Quality System : Staff Suggestion Form : SNSC/SSF/2015/Ver-1.1

o. Recommendations for improvement, including technical requirements :

- Material specification sheet to be strictly implemented
- Staff suggestion to be encouraged and acted upon
- Requisition form to be made in HMS- shall be followed up.
- All issues related to logo to be informed to QM office promptly.
- Daily NC and CAPA to be adequately addressed and documented by each lab.

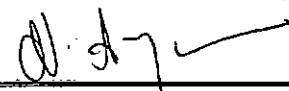
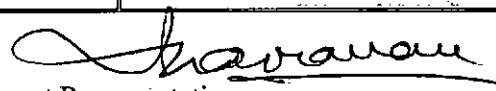
Thank You


Dr. N. Angayarkanni,
Quality Manager,
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SNSC Laboratory
Chennai – 600 006.

Forwarded by: 

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Deputy Management Representative
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