#### Minutes of 10<sup>th</sup> Lab committee meeting held on 31<sup>st</sup> March, 2007 at Nirman Bhawan

The Tenth Laboratory Committee of RNTCP was held in the resource centre, IV Floor, A wing, Nirman Bhawan, New Delhi on 31<sup>st</sup> March, 2007. List of participants who attended the meeting is annexed at Annexure-I.

DDG welcomed all the members and briefly highlighted the objectives and agenda for the meeting. The objectives of the meeting were:

- Quarterly review of the progress on EQA activities.
- To communicate to the States about the activities required to be undertaken to implement RNTCP laboratory related activities, namely sputum microscopy EQA, capacity building of state level laboratories
- To review IRL accreditation progress
- To review DRS activities
- To review DOTS-Plus activities

DDG remarked that the most important activity at present is the accreditation process for the IRLs of 13 states, viz. Gujarat, Maharashtra, Andhra Pradesh, Kerala, Orissa, Rajasthan, West Bengal, Tamil Nadu, Jharkhand, Uttaranchal, Chhattisgarh, Haryana and Delhi. Appointment of microbiologist and lab technicians in the IRLs of Uttaranchal and Chhattisgarh is still pending and this issue has already been taken up with the concerned authority.

DOTS Plus activities were initiated in Gujarat and Maharashtra in the month of January 2007 and from March 2007, they have started sending sputum samples of MDR-TB suspects to their respective NRLs. Once the respective IRLs get accredited, the culture and drug sensitivity testing (DST) will be done by the IRLs themselves. Every effort needs to be made to accredit these labs as per the annexed schedule.

The process of accrediting and designating JALMA Institute as the 4<sup>th</sup> NRL is currently under way with TRC, Chennai

#### **EQA** implementation status

The NRLs submitted the status of their activities on the EQA reporting format. During the quarter, NTI, Bangalore and LRS Institute, Delhi visited 3 states each, and TRC, Chennai made 2 visits. The status of EQA implementation by states allotted to NTI, TRC and LRS Institute are appended at Annexures-III, IV and V respectively. Presentations were also made by the respective NRLs on their field visits and activities undertaken by them in the previous quarter.

- NTI conducted EQA training for STOs/STDC Directors, Microbiologists and LTs, culture and DST training for the IRL staff from Orissa and Haryana, and also training on 'Preventive maintenance and minor repair of Binocular Microscopes' for STLS/LTs from the north eastern states and Karnataka.
- RBRC procedure is not as per guidelines in some of the districts visited by the team in Orissa, Bihar and Jharkhand.
- The lab technicians for the IRL are still not in place in Jharkhand.

Officials from TRC visited Kerala and Tamil Nadu and made the following observations:

• Defective microscopes, shortage of lab consumables, single sputum collection in Kerala.

- AMC not effective, cedar wood oil still in use, blinding for RBRC not observed in Tamil Nadu.
- Biomedical waste disposal not as per guidelines in Kerala and Tamil Nadu.

Officials from LRS Institute visited Delhi, Haryana and Tripura in this quarter.

#### The lab committee recommended that

- The Directors of TRC, Chennai and NTI, Bangalore may meet the health secretaries of Tamil Nadu and Karnataka once in a quarter to discuss the lab related issues of these two states on behalf of CTD so that the programme in these two states can be improved.
- NTI may collect the feedback on the STLS training conducted by the Institute on preventive maintenance and minor repair of Binocular Microscopes from the states and submit the report to CTD.
- TRC needs to regularly monitor the lab related activities of Kerala and Tamil Nadu to ensure that the deficiencies noted in their visits are rectified.
- Use of ready made reagents should be discontinued in all the states.

#### Other issues & recommendations

- Microbiologist from Haryana informed that there is no budget allocation for IRL Haryana and the STCS is not providing TA/DA for IRL staff for their OSE visits and for attending trainings. The committee recommended that necessary funds for the IRLs should be provided from the state Societies as per guidelines.
- Initiatives to be taken to post the microbiologist (trained in C&DST at NRL) at IRL, Karnal so that culture and DST activities can be initiated at the earliest.
- As the old computer in IRL Karnal is not functioning, a new computer may be provided to the lab as per guidelines.
- Appointment of full time microbiologist is required at IRL, Kolkata and this issue to be discussed with the Health Secretary.
- Microbiologists and LTs from the IRLs of Delhi and Rajasthan should be trained in culture and DST at the NRL.
- Appointment of LTs in the IRL of Jharkhand to be done at the earliest.
- Appointment of IRL staff should be a priority issue for Uttaranchal and Chhattisgarh, and necessary steps should be taken by these states immediately to expedite the process.

#### **DRS** activities

The intake of cases under DRS, Maharashtra was completed in the month of November 2006 and the results are being analyzed by NTI. The interim report (based on 70% test results) shows the level of MDR-TB isolates amongst new cases is 2.5% and retreatment cases is 10.9%.

TRC, Chennai presented the almost final report of the DRS survey in Gujarat. The level of MDR-TB isolates amongst new cases is 2.4% and retreatment cases 17.2%.

Based on the issues raised during the analyses of the interim results from the Gujarat DRS survey, the committee agreed that there needs to be modifications/revision of the Clinical Information Forms (CIF) which will provide information more relevant for the programme. Also for the surveys in Gujarat and Maharashtra, there is a need for validation of the data of the

Category II patients enrolled in the DRS with the data held in the RNTCP TB register and the individual patient treatment card. However **no** tracking and/or re-interviewing of patients is to be conducted to validate this data.

TRC informed that the pilot study on 100 MDR-TB suspects (200 samples) is underway in Andhra Pradesh. The exchange of cultures with the NRL and proficiency testing will be starting by April 2007.

Second line DST also been initiated by TRC on the isolates found to be MDR-TB from the DRS survey in Gujarat. NTI also will be sending the MDR-TB isolates of the Maharashtra DRS survey to TRC for second line DST.

In Orissa, the microbiologist of the IRL has received training in EQA, Culture and DST at national Institute. The proposed DRS survey of Orissa should be started at the earliest under the supervision of NTI.

The state of Uttar Pradesh has started collecting DMC-wise data for the purpose of the DRS survey of western UP, which will be supported by the JALMA Institute.

#### Accreditation of state designated IRLs

The timelines for accreditation of IRLs of the 13 states viz. Gujarat, Maharashtra, AP, Kerala, Orissa, Haryana, Delhi, West Bengal, Rajasthan, Tamil Nadu, Jharkhand, Uttaranchal, Chhattisgarh, were formulated and are appended at Annexure II. These states and their respective NRLs should ensure adherence to the timelines given so that the accreditation can be achieved as planned. All states should ensure that the required staff as per the programme guidelines are in place and trained.

Procurement of culture and DST equipments for another 5 states (MP, HP, UP (Lucknow), Karnataka and Punjab) is currently under process. All these states also should ensure that the necessary civil work is completed and required staff is appointed and trained in RNTCP, EQA and Culture & DST by their respective NRLs.

Close coordination between the state, suppliers and NRLs is needed to facilitate the installation of equipments in IRLs. The NRLs may visit their respective IRLs (especially Uttaranchal and Chhattisgarh where there is no microbiologist in the IRL) during the installation of equipments for facilitating the process. The states need to communicate regularly with their NRLs regarding the lab related activities.

Miscellaneous funds available with the state society should be utilized for the minor incidental expenses of the IRLs during installation of equipments.

The states should enter into AMC with the suppliers of the equipments for the maintenance utilizing the maintenance funds available with the state TB Society.

A certificate to the effect that all the equipments are biologically safe to use should be obtained after the initial installation and thereafter on an annual basis and the copy of this should be sent to Central TB Division and the respective NRLs.

The IRLs of Gujarat, Maharashtra and Haryana need to enter into AMC with one of the certified agencies available locally or nationally. A list of few agencies which can be contacted for this purpose is attached as Annex.VI.

The Central TB Division is supplying culture and DST consumables for one year's requirement of the IRLs. Subsequently, lab consumables and glass-ware for culture and DST may be procured at state level using World Bank procurement guidelines. The norms for this are at the rate of Rs 0.15 lakh per million population per year. The technical specifications of the required consumables and glass ware are available on the RNTCP website at <a href="http://www.tbcindia.org/Procurementnotices.asp">http://www.tbcindia.org/Procurementnotices.asp</a>. These specifications should be strictly adhered to.

The Committee approved the accreditation documents developed by the NRLs and CTD for the accreditation of the IRLs and Medical College Laboratories for performing mycobacterial culture and DST under RNTCP.

The Committee also approved the Fluorescent Microscopy Manual developed by the NRLs. This manual will be used as a reference material in IRLs and other laboratories where fluorescent microscopes are supplied by the programme.

The committee also agreed that the LRS Institute should get the renewal of accreditation of its culture laboratory by TRC, Chennai at the earliest. LRS Institute may follow up the letter sent by CTD in the month of January 2007 regarding this and take necessary steps to undertake the process of accreditation.

#### Laboratory related recommendations of the 2006 JMM

The committee considered the JMM recommendations and suggested that a workshop be held to review the programme's experience of implementing EQA, especially the experiences of implementing RBRC in such a large programme.

#### Laboratory network for field evaluation studies

The committee also agreed to create a network of laboratories for the undertaking of field evaluation studies utilizing the existing medical college labs, IRLs and NRLs.

#### FIND/MGIT field evaluation study

With reference to the proposal from FIND/BD regarding the use of MGIT liquid culture method as discussed in the 9<sup>th</sup> lab committee meeting, it was conveyed that FIND is in the process of finalizing the proposal in consultation with Dept. of Bio-Technology (DBT). Following the approval by DBT, the same will be submitted to Central TB Division for it's consideration.

# List of Participants of the 10<sup>th</sup> Lab Committee meeting of the RNTCP held in New Delhi on 31<sup>st</sup> March 2007

- 1. Dr. L. S. Chauhan, DDG (TB)
- 2. Dr. Prahlad Kumar, Director, NTI, Bangalore
- 3. Dr. Vanaja kumar, Dy.Director, Dept of Bacteriology, TRC Chennai
- 4. Dr .V.P.Mynedu, HOD, Dept. of Bacteriology, LRS Institute, Delhi
- 5. Dr. Ranjini Ramachandran, Asst. Director, TRC Chennai
- 6. Dr T. Ajay Kumar, Consultant Microbiologist, NTI, Bangalore
- 7. Dr.D.S Chauhan, JALMA Institute, Agra
- 8. Dr. Saxena, CMO, Central TB Division
- 9. Dr S. Sahu, NPO (TB), WHO India
- 10. Dr Fraser Wares, MO(TB), WHO India
- 11. Dr.Puneet Dewan, MO(TB), WHO-SEARO
- 12. Dr.T.V.Bhalodia, Director, STDC, Ahmedabad
- 13. Dr. Praveen Shanker, Microiologist, STDC, Trivandrum
- 14. Dr.N.Joshi, Microbiologist, STDC, Ahmedabad
- 15. Dr. Vijava Lalitha, Microbiologist, STDC, Hyderabad
- 16. Dr.(Mrs).S.N. Dongare, Microbiologist, STDC, Nagpur
- 17. Dr. Sant Lal Verma, Microbiologist, IRL, Karnal
- 18. Dr. Yamuna Mundade, RNTCP Medical Consultant, Central TB Division
- 19. Dr. Sarabjit Chadha, RNTCP Medical Consultant, Central TB Division
- 20. Dr.Sai Kumar, RNTCP Medical Consultant, Central TB Division
- 21. Dr.Mala Srikanth, RNTCP Medical Consultant, Central TB Division
- 22. Dr. Shruti Seghal, RNTCP Medical Consultant, Central TB Division
- 23. Dr Sheena Susan George, RNTCP Medical Consultant, Central TB Division

## Annexure-II

## Revised Action Plan for Accreditation of culture labs (31<sup>st</sup> March, 2007)

State	NRL	Activities/ Remarks	Timeline
Gujarat	TRC	Training of Microbiologist & LTs in C&DST	April 2007
		2.Bio-safety certification of equipments	April 2007
		3.Fill up the application form & send to NRL& CTD	April 2007
		4.NRL pre assessment visit to IRL	May 2007
		5.Starting of cultures( Pilot study)	May 2007
		6. Send cultures / Exchange of strains with NRL( NRL ↔ IRL )	July-August 2007
		7. Results of proficiency testing	October 2007
		Accreditation visit by NRL	November 2007
		9. Time for corrective actions	December 2007
		10. Accreditation	Dec 07/Jan08
		11. Intake of first MDR suspect	March 2007 (at NRL)
		12. First MDR-TB patient registered for Cat IV treatment	May/June 2007
Maharashtra	NTI	Bio safety Certification of the equipments	April-May 2007
		2.Fill up the application form & send to NRL& CTD	May 2007
		3.NRL pre assessment visit to IRL	June 2007
		4.Pilot study started	Feb 2007
		5. Send existing cultures / Exchange of strains with NRL( NRL ↔ IRL )	February 2007
		6. Results of proficiency testing	May 2007
		7. Accreditation visit	June 2007
		8. Time for corrective actions	June 2007
		9. Accreditation	July 2007
		10. Intake of first MDR suspect	March 2007 (at NRL)
		11. First MDR-TB patient registered for Cat IV treatment	May/June 2007
Andhra	TRC	1. Installation of equipments	April 2007
Pradesh		2.Biosafety certification of equipments	April 2007
		3.Fill up the application form & send to NRL& CTD	April 2007
		4.NRL pre assessment visit to IRL	May 2007
		5. Pilot study started ( on existing BS Cabinet)	Jan 2007

		6. Send existing cultures / Exchange of strains with NRL( NRL ↔ IRL )	April 2007
		7. Results of proficiency testing	July 2007
		8. Accreditation visit	August 2007
		9. Time for corrective actions	September 2007
		10. Accreditation	October 2007
		11. Intake of first MDR suspect	November 2007
		12. First MDR-TB patient registered	January 2008
		for Cat IV treatment	,
Kerala	TRC	1. Training for the untrained LTs in C& DST	April/May 2007
		2. Installation of equipments	April 2007
		3. Bio safety certification of	May 2007
		equipments	
		4. Fill up the application form & send to NRL& CTD	May 2007
		5.NRL pre assessment visit to IRL	June 2007
		6.Starting of cultures( Pilot study)	June 2007
		7. Send cultures / Exchange of	September 2007
		strains with NRL( NRL↔IRL)	
		Results of proficiency testing	November 2007
		Accreditation visit	December 2007
		10. Time for corrective actions	January 2008
		11. Accreditation	February 2008
		12. Intake of first MDR suspect	March 2008
		13. First MDR-TB patient registered	June 2008
		for Cat IV treatment	
Haryana	LRS	Training of untrained LTs in C&DST	May 2007
		2. Installation of equipments	April 2007
		3.Bio safety certification of equipments	April 2007
		4. Fill up the application form & send to NRL& CTD	May 2007
		5.NRL pre assessment visit to IRL	June 2007
		6.starting of cultures( Pilot study)	June 2007
		7. Send cultures / Exchange of strains with NRL( NRL↔IRL)	September 2007
		8. Results of proficiency testing	November 2007
		9. Accreditation visit	December 2007
		10. Time for corrective actions	January 2008
		11.Accreditation	February 2008
		12. Intake of first MDR suspect	March 2008
		13. First MDR-TB patient registered	June 2008
		for Cat IV treatment	

Delhi	LRS	1. Training of Microbiologist & LTs in	April 2007
		C&DST	

		Ta=	T
		2.Bio-safety certification of equipments	April 2007
		3.Fill up the application form & send to NRL& CTD	May 2007
		4.NRL pre assessment visit to IRL	June 2007
		5.Starting of cultures ( pilot study )	June 2007
		6. Send cultures / Exchange of strains with NRL( NRL ↔ IRL )	September 2007
		7. Results of proficiency testing	November 2007
		Accreditation visit by NRL	December 2007
		9. Time for corrective actions	January 2008
		10. Accreditation	February 2008
		11. Intake of first MDR suspect	March 2008
		12. First MDR-TB patient registered	June 2008
		for Cat IV treatment	
Rajasthan	NTI	Training of Microbiologists & LTs in C& DST	April 2007
		2.Installation of equipments	April 2007
		3.Bio safety Certification of the equipments	May 2007
		4.Fill up the application form & send to NRL& CTD	June 2007
		5.NRL pre assessment visit to IRL	July 2007
		6.Starting of cultures( pilot study)	July 2007
		7. Send cultures / Exchange of strains with NRL( NRL ↔ IRL )	October 2007
		8. Results of proficiency testing	January 2008
		9. Accreditation visit	February 2008
		10. Time for corrective actions	March 2008
		11. Accreditation	April 2008
		12. Intake of first MDR suspect	May 2008
		13. First MDR-TB patient registered	August 2008
		for Cat IV treatment	
Tamil Nadu	TRC	1. appointment of 3 LTs & their training	June 2007
		2.Installation of equipments	April 2007
		3.Biosafety certification of equipments	April 2007
		4.Fill up the application form & send to NRL& CTD	May 2007
		5.NRL pre assessment visit to IRL	June 2007
		6. Starting of cultures( Pilot study)	June 2007
		7. Send cultures / Exchange of strains with NRL( NRL ↔ IRL )	September 2007
		8. Results of proficiency testing	October 2007
		Accreditation visit	November 2007
		10. Time for corrective actions	Dec 2007
		11. Accreditation	Jan 2008
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		12. Intake of first MDR suspect	Feb 2008
		13. First MDR-TB patient registered for Cat IV treatment	May 2008
Orissa	NTI	Installation of equipments	April 2007
		Bio safety certification of equipments	May 2007
		3. Fill up the application form & send to NRL& CTD	May 2007
		4.NRL pre assessment visit to IRL	June 2007
		5.Starting of cultures( Pilot study)	June 2007
		6. Send cultures / Exchange of strains with NRL( NRL↔IRL)	September 2007
		7. Results of proficiency testing	November 2007
		8. Accreditation visit	December 2007
		9. Time for corrective actions	January 2008
		10. Accreditation	February 2008
		11. Intake of first MDR suspect	March 2008
		12. First MDR-TB patient registered	June 2008
		for Cat IV treatment	
West Bengal	NTI	1.Posting of Microbiologist	??May 2007
		2.Training of microbiologist & LTs	June 2007
		3. Installation of equipments	May 2007
		4.Bio safety certification of equipments	May 2007
		5. Fill up the application form & send to NRL& CTD	July 2007
		6.NRL pre assessment visit to IRL	August2007
		7.starting of cultures( Pilot study)	September 2007
		8. Send cultures / Exchange of strains with NRL( NRL↔IRL)	December 2007
		Results of proficiency testing	February 2008
		10. Accreditation visit	March 2008
		11.Time for corrective actions	April 2008
		12.Accreditation	May 2008
		13. Intake of first MDR suspect	June 2008
		14. First MDR-TB patient registered for Cat IV treatment	September 2008

Jharkhand (	NTI	1. Posting of LTs in IRL	??April/May 2007		
LTs must be posted in the		2.Training of Microbiologists& LTs in C& DST	May /June 2007		
IRL at the		3.Installation of equipments	May 2007		
earliest)		4.Bio-safety certification of equipments	May 2007		
		5.Fill up the application form & send to NRL& CTD	July 2007		

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13 Intake of first MDR suspect	August 2008
14. First MDR-TB patient registered for Cat IV treatment	November 2008

## (NTI)Annexure-III

								Sta	tus of	EQA ir	mplemen	ıtatior	1					
		H	RD stat	tus at IRL/ST	DCs		E	QA Trair	ning sta	atus	Panel		Re	porting-di	listrict to IRL	-		
!	STDC D	riector	Micro	obiologist	LTs at IRL	L/STDC	TD	DTOs		STLS	test slides	I	Anexure E	Anexure M		Annexure G		
States	In place	Traine d in EQA	In place	Trained in EQA	In place	Traine d in EQA	In place	Traine d in EQA	In place	Trained in EQA	preparati	recd	No expect	No recd last qtr	INO EXPECT	No recd this year (2006)	No. expecte d	Date
Bihar	Yes	NA	Yes	Yes	2	2	38	37	157	133	Yes	Started	l in July 06	<u>.</u>		0	1	1st March '0'
Jammu & Kashmir	yes	Yes	Yes	Yes	3	2	14	14	41	41	Yes	8	14	8	14	0	1	Not received
Jharkhand	Yes	Yes	Yes	Yes	Nil	NA	22	20	60	57	No	48		56*3(6 districts)	294*3	1	1	1st March '0'
Karnataka	Yes	No	Yes	Yes	3	3	28	17	116	107	Yes	84	84	84	84	1	1	1st March '0'
Madhya pradesh	Yes	Yes	Yes	Yes	4	4	45	40	142	133	No	31	45	31	714*3	0	1	1st March '0'
Maharastra	Yes	Yes	Yes	Yes	6	6	48	48	206	206	Yes	124	144 ( 48 * 3)	123	144 ( 48 * 3)	1	1	1st March '0'
Orissa	Yes	Yes	yes	Yes	2	2	31	30	41	41	Yes	8*3	8*3	31*3	31*3	0	1	1st March '0'
Pondicherry	Yes	Yes	Yes	Yes	3	3	1	1	4	4	Yes	1	1 1	13*3	13*3	1	1	1st March '0'
Rajasthan	Yes	Yes	Yes	Yes	3	3	28	28	139	132	Yes	28*3	28*3	713*3	713*3	1	1	1st March '0'
West Bengal	Yes	Yes	1	Yes	3	2	19	Yes	189	No	Yes	56	57	2571	2551	1	1	1st March '0'

## (TRC)Annexure-IV

						EC	QA Stat	us in	the Co	untrv	at the	end of	4th qua	arter 2		, ,	IIIGAU		
	ŀ	IRD s	status	at IRL	/STD				ing sta		Panel test	Reporting - district to IRL							
States	STDC Director		Microbiolo gist		LTs at		DTOs		STLS		slides prepar ation	Annex E		Annex M		Annex G		Date	Districts visited by
	In plac e	Trai ned in EQA	In plac e	Traine d in EQA	plac	Trai ned in EQA	No. in place	Trai ned in EQA	No. in place	Trai ned in EQA	Yes/N o	No. recd last qtr	No. expec ted	No. recd last qtr	No. expec ted	No. recd this year	expe		IRL
Andhra Pradesh	Yes	Yes	Yes	Yes	4	4	23/24	23	170	168	Yes	24	24	24	24	1	1	11& 12Dec06 13&14Dec 06	Prakasam Nellore
Chhattis garh	Yes	Yes	No	NA	No	NA	16	12	62	61	No	16	16	15	16				
Gujarat	Yes	No	Yes	Yes	4	2	27	27	125	122	Yes	81	81	81	81	1	1	09& 10Nov06 20&21Dec 06 22& 23Dec06 26& 27Dec06 29&30Dec 06	Vadodara-R VMC Surendranagar Bhavnagar
Goa	No	No	Yes	Yes	1	No	1	1	3	3	No	24	24	24	24	1	1	28-11- 2006 11-12- 2006	North Goa South Goa
Kerala	Yes	Yes	Yes	Yes	4	1	14	12	68	63	Yes	168	168	168	168	1	1	7-12-06 to	Kozhikode

Punjab	Yes	Yes	Yes	Yes	2	2	18	17	56	47	Yes	54	54	54	54	1	1	8-12-06 30& 31oct06 4&5dec06 11&12 dec06 16-12-06 19& 20dec 21& 22dec 23 -12-06 27- 28dec06	Bhatinda Rupnagar Kapurthala Mansa Ludhiana Sangrur Moga Ferozpur
Sikkim	Yes	Yes	Yes	Yes	1	No	4	4	5	5	Yes	60	60	60	60	1	1	15-11-06 22-11-06	West District East District
Tamil Nadu	No	No	Yes	Yes	1	No	24	24	160	160	No	8	30	8	30		-		
UP- Lucknow	No	No	Yes	Yes	2	2	35	31	180	176	No	9	9	30	35	1	1	Dec-06	Lucknow
UP-Agra	Yes	Yes	No	NA	2	2	35	26	154	148	No	28	63	58	105			28-12-06	Ferozabad

#### Annex.VI

### List of firms IRLs( Gujarat, Maharashtra& Haryana) can contact for AMC & Biosafety certification of Laboratory equipments

1. AEROMECH EQUIPMENTS PVT LTD

Plot NO: 1059, Munnusamy Salai

KK Nagar (West) Chennai 600 078. Phone: 044-42185562 Email: aeromech@vsnl.net

Website: www.aeromechindia.com

2. Clean Air Systems No 4, Senthil Nagar 100 ft Road Chennai 600 094

3. Klenzaids Group A 21, MIDC, Street 3 Andheri (E) Mumbai 400 093.

Email: <a href="mailto:klenzaids@vsnl.com">klenzaids@vsnl.com</a>