
Operational guidelines for **NATIONAL TOBACCO TESTING LABORATORIES**



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Acknowledgement

Establishment of National Tobacco Testing Laboratories (NTTLs) is a milestone for the Tobacco Control Programme in India. Over the years, the process of establishment of these laboratories has evolved through several facets of work that started with the identification of existing laboratories which could be upgraded for tobacco product analysis. Procurement of sophisticated equipment, recruitment of qualified scientific staff, implementation of capacity building measures through advanced training programmes and collaboration with other world-class WHO-recognised laboratories have been part of this long journey of NTTLs.

The drafting and finalization of the Operational Guidelines for National Tobacco Testing Laboratories has been a result of dedicated efforts and commitment, development of tobacco related expertise and the collective hard work of various contributors and we are extremely thankful to all of them. We would be failing in our endeavour, if we forget to thank Ms Preeti Sudan, Secretary (H&FW) and Dr. S. Venkatesh, Director General of Health Services for their encouragement and advice. Continuous support of Dr. A.K. Gadpayle, Addl DGHS; Dr. Mohd. Shaukat Usta, Advisor (NCD) and Mr Vikas Sheel (Joint Secretary, NTCP) provided the impetus for establishing and finally commissioning of the National Tobacco Testing Laboratories (NTTLs). We also acknowledge the guidance provided by Dr. Jagdish Prasad, who during his DGHS tenure was the constant force behind the establishment of India's first Tobacco Testing laboratories. We also thank Dr. N.S. Dharmshaktu [Principal Adviser] and Dr B.D. Athani [Principal Consultant] who provided directions to us in all the technical meetings.

Special thanks to Ms Vineet Munish Gill, former National Professional Officer (TFI) and Mr Praveen Sinha, National Professional Officer (Tobacco Control) of WHO-India Office for their support throughout our work.

The Directors of the three NTTLs [Dr. Ravi Mehrotra, NICPR, Noida; Dr. P.J. Gogoi, RDTL, Guwahati and Dr. Raman Mohan Singh, CDTL, Mumbai] deserve a special mention for their technical inputs.

I would amiss to not mention Professor H.M. Chawla, National Advisor (NTTL) who provided the basic framework for Operational Guidelines which was further updated with inputs from all our partners in Tobacco Control, State Nodal Officers, Staff in NTCP Division, MoHFW and the Technical Support Unit (NTTL) in Dte GHS.

Without naming individuals, we express our gratitude to all those who have directly or indirectly contributed towards bringing these guidelines to the fore.

(Dr. L. Swasticharan)
Chief Medical Officer
Dte GHS, MoHFW



प्रीति सूदन
सचिव
PREETI SUDAN
Secretary



सत्यमेव जयते



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

Dated : 27th May, 2019

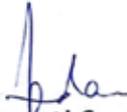
Message

In 2004, India ratified the WHO Framework Convention on Tobacco Control (FCTC) committing itself to comprehensive tobacco control. India also acceded to the FCTC's Illicit Trade Protocol in 2018, again augmenting its utmost intention for control of illicit trade of tobacco products.

The Ministry of Health & Family Welfare (MoHFW), Government of India, launched the National Tobacco Control Programme (NTCP) in the 11th Five Year Plan with the objective to facilitate the implementation of the Tobacco Control Laws, bring greater awareness about the harmful effects of tobacco, and to fulfil obligations under the WHO-FCTC. Over the years the programme has grown and is being implemented in all the districts of the country.

India is now taking steps towards implementing Article 9 of the treaty which calls for Parties to regulate contents of tobacco products and establishment of labs.

I am happy that India is commissioning three National Tobacco Testing Laboratories (NTTLs) which possess world class facilities to analyze various kinds of tobacco products. This step will facilitate scaling up the tobacco control measures not just in the country but also across the entire South East Asia Region.


(Preeti Sudan)

डॉ. एस वेंकटेश
Dr S. VENKATESH

DNB, MD, DPH, MPH (Harv) FAMS, FIPHA
Director General of Health Services



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली -110 108

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAWAN, NEW DELHI- 110 108
TEL.: 23061063, 23061438 (O), 23061924 (F)
E-mail : dghs@nic.in

दिनांक/Dated.....

21/05/2019

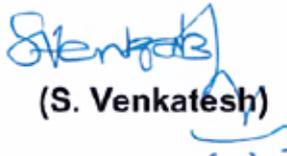


MESSAGE

Consumption of tobacco in any form causes premature deaths and diseases. According to WHO, tobacco is the single largest preventable cause for non-communicable diseases (NCDs). The leading cause of deaths from NCDs in 2015 were classified as cardiovascular diseases (17.7 million deaths) followed by cancers (8.8 million), respiratory diseases (3.9 million) and diabetes (1.6 million), the course of each of which has a correlation with tobacco consumption. The disease burden of NCDs can be considerably brought down by controlling the consumption of tobacco products.

India is a party to World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) and is committed to discourage the use of tobacco in any form. India is a pioneer in the implementation of the well funded National Tobacco Control Programme with support for dedicated manpower to carry out various activities as envisaged.

In its pursuit to discourage tobacco use, the Government of India has established three World class tobacco testing laboratories (two Regional and one Apex lab) to collect scientific information about the contents, constituents, ingredients, and emissions of the plethora of tobacco products consumed in the country. I am sure, that these laboratories will provide valuable scientific input to facilitate tobacco product regulation in the country and would simultaneously participate in international endeavours targeted towards tobacco control measures.


(S. Venkatesh)

CHAPTER 1

Tobacco Control in India

1.1 Tobacco Products in India

Tobacco use is the leading single preventable cause of deaths worldwide. Each year globally an estimated seven million deaths are attributed to the use of tobacco¹. On an average, tobacco users lose 15 years of life. Up to half of all tobacco users will die prematurely due to tobacco related causes. Most of these deaths will be in the middle and low-income nations, which would account for almost 80 percent of all tobacco related deaths².

India is the second largest tobacco producing nation and second largest consumer (27 crore) of tobacco world-wide. Mortality due to tobacco products in India is estimated at upwards of 13 lakh³. Out of these, 10 lakh are attributed to tobacco smoking and the rest to smokeless tobacco use. One feature of tobacco related mortality in India is the high incidence of oral cancer, exceeding even that of lung cancer and accounting for almost half of all oral cancers in the world⁴.

In most countries across the world tobacco use is synonymous to cigarette smoking. In contrast, tobacco use in India is in multiple forms. There are two types of tobacco products that are commonly used: smoking tobacco and smokeless tobacco. Smoking tobacco products include *bidis*, manufactured cigarettes, hand-rolled cigarettes, pipes, cigars, hookah, water-pipes and some other smoking tobacco products like *chuttas*, *dhumti* and *chillum*. Smokeless tobacco is used by either chewing or applying to the teeth and gums, or inhaling. Smokeless tobacco products used in India include chewing tobacco items such as betel quid with tobacco, *khaini*, *gutka*, *paan masala with tobacco*. Smokeless tobacco products such as *mishri*, *gul*, *bajjar*, *gudakhu*, etc. are applied to the teeth and gums, and the snuff is inhaled.³

1.2 COTPA, 2003

The Government of India has enacted “The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003” (COTPA) to regulate tobacco products in the interest of public health. The Act has following the main provisions:-

- (a) Section-4: Ban on smoking in public places- to protect the health of non-smokers from harmful effects of tobacco smoke (second hand smoke).

¹ WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies. Geneva: World Health Organization; 2017.

² WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER package. Geneva, World Health Organization, 2008

³ Tata Institute of Social Sciences (TISS), Mumbai and Ministry of Health and Family Welfare, Government of India. Global Adult Tobacco Survey GATS 2 India 2016-17.

⁴ Gupta PC 1999, 'Mouth cancer in India: A new epidemic?', Journal of the Indian Medical Association, vol.97, no.9., pp. 370-373. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/10638084>

- (b) Section-5: Ban on direct/indirect advertisement of tobacco products including sponsorship and promotion.
- (c) Section-6a: Ban on sale of tobacco products to and by minors (less than 18 years of age).
- (d) Section-6b: Ban on sale of tobacco products within 100 yards of educational institutions.
- (e) Section -7: Display of pictorial warnings on tobacco products' packages.

The following tobacco products mentioned in the schedule are regulated under COTPA:

- (a) Cigarettes
- (b) Cigars
- (c) Cheroots
- (d) Beedis
- (e) Cigarette tobacco, pipe tobacco and hookah tobacco
- (f) Chewing tobacco
- (g) Snuff
- (h) Pan Masala or any chewing material having tobacco as one of its ingredients (by whatever name it is called)
- (i) Gutka
- (j) Tooth powder containing tobacco.

Further, Section 7 (5) of COTPA 2003 states that 'No person shall, directly or indirectly, produce, supply or distribute cigarettes or any other tobacco products unless every package of cigarettes or any other tobacco products produced, supplied or distributed by him indicates thereon, or on its label, the nicotine and tar contents, on each cigarette or as the case may be on other tobacco products along with the maximum permissible limits thereof.' Section 11 also states that 'For purposes of testing the nicotine and tar contents in cigarettes and any other tobacco products the Central Government shall by notification in the Official Gazette grant recognition to such testing laboratory as that Government may deem necessary.

1.3 National Tobacco Control Programme

Government of India launched the National Tobacco Control Programme (NTCP) in the year 2007-08, with the aim to (i) create awareness about the harmful effects of tobacco consumption, (ii) reduce the production and supply of tobacco products, (iii) ensure effective implementation of the provisions under COTPA (iv) help the people quit tobacco use, and (v) facilitate implementation of strategies for prevention and control of tobacco advocated by WHO Framework Convention of Tobacco Control .

Establishment of National Tobacco Testing laboratories (NTTLs) is one of the key deliverables of the NTCP. In pursuance of this objective, the following three existing laboratories of the Government of India have been identified whose capacity has

been augmented to undertake testing of tobacco products, as enshrined in the COTPA:

1. National Tobacco Testing Laboratories (Apex) at National Institute of Cancer Prevention and Research (NICPR)-Noida Campus, Plot No. 1-7, Sector-39, Noida- 201301, Uttar Pradesh, India.
2. National Tobacco Testing Laboratories at Central Drug Testing Laboratory (CDTL), Mumbai Campus, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai-400008.
3. National Tobacco Testing Laboratories at Regional Drug Testing Laboratory (RDTL), Guwahati Campus, Six Mile, Guwahati-781022, Assam.

As stated above, the NTTL at NICPR, Noida has been envisioned as the Apex Laboratory with certain additional mandates.

CHAPTER 2

National Tobacco Testing Laboratories

2.1 Vision of NTTLs

The NTTLs are envisioned as accredited world class laboratories engaged in providing analytical facilities for tobacco and tobacco products to generate scientific information for public health.

2.2 Mission of NTTLs

The NTTLs shall:

- Undertake analysis of all tobacco products through specialized equipment and experimental facilities using scientific methods.
- Participate in the generation of global tobacco testing protocols, round robin tests, method validation and development of analytical methods for testing of tobacco products.
- Undertake relevant research on developing new technologies for tobacco analysis and on safe disposal of tobacco related wastes.
- Provide scientific analytical information to NTCP.
- Share information, knowledge and technical expertise with others: WHO or bilaterally with any other interested country as approved by competent authority.

2.3 Administrative and Technical Control of NTTLs

The NTTLs will be under the administrative control of the Additional Secretary, Ministry of Health and Family Welfare, in charge of NTCP.

A **National Technical Advisory Committee (NTAC)** consisting of the following members has been constituted to guide the NTTLs on all technical issues as required:

1. DGHS: Chairman
2. Members:
 - a. Adviser (NCD)/DDG (NCD)
 - b. Director (NTCP), MoHFW
 - c. National Advisor (NTTLs)
 - d. Director of the three National Tobacco Testing Laboratories
 - e. Head, Centre for Environmental and Occupation Health, National Centre for Disease Control (NCDC), Delhi

- f. Any other expert may be co-opted by the Chairman as per requirement of expertise
- g. CMO (NTCP), Dte. GHS : Member Secretary

The NTAC will meet at least thrice a year to oversee/monitor the progress of work and to advise on mid-term corrections to be implemented by the NTTLs. A small functional working group under a suitable officer may also be carved out of the NTAC to meet as per requirement.

The execution of technical work will be assigned to the NTTLs by the National Advisor (NTCP) on behalf of the NTAC. The Directors of the parent institutions wherein the laboratories are established will serve as the ex-officio Director of the respective NTTLs.

The approved scientifically defined work will be undertaken at the identified NTTL under the overall directions of Directors of NTTL.

2.4 Terms of Reference (ToRs) of NTAC

The following are the ToRs of the NTAC:

1. To draw up a plan of work, capacity building, training programs, round robin tests and validation protocols for NTTLs.
2. To consider and make recommendations on matters of policy relating to research including matters referred to it by NTCP division.
3. To oversee quality assurance and improvement in respect of activities allocated to NTTLs including their annual reports on work done internally and externally and to ensure that identified plans are executed efficiently within allocated time scale.
4. To provide inputs on technical issues in the light of global findings, knowledge and expertise.
5. To suggest ways to resolve conflicting/out of range of results reported on analyte concentration by any laboratory, and reassign the work (if required).
6. To recommend/develop protocols (either externally or internally) and measures for data generation, handling, confidentiality, data retrieval and final diagnosis and disposal.
7. To analyze the documents on the results of research activities and opine its usefulness to the country objectives. NTAC may constitute subgroups for help with identification of subject experts.
8. NTAC shall be empowered to identify most appropriate institutions and experts for generation/outsourcing of relevant data/study/expertise.
9. Constitution of grievance committees for technical and administrative staff in dealing with technical methods/equipment use etc.
10. Any other issue with the approval of the Chair.

2.5 Technical Support Unit

A Technical Support Unit (TSU) is set up in the Directorate General of Health Services with the following objectives:

- To assist in setting up and upgradation of the NTTLs.
- To coordinate development of protocols, operational guidelines, and Standard Operating Procedures (SOPs) for testing various chemicals in tobacco products.
- To guide implementation of selected SOPs, Round Robin Tests or other measures.
- To provide scientific laboratory data to the NTCP division, MoHFW to facilitate tobacco product regulation.
- To design and deliver training programs for capacity building of human resources deployed at NTTLs.

The TSU comprises of the following members:

1. Chief Medical Officer (NTCP), Dte. GHS
2. National Advisor (NTTLs), MoHFW
3. Senior Project Associate (NTTLs), MoHFW
4. Junior Project Associate (NTTLs), MoHFW

2.6 Human Resource for the National Tobacco Testing Laboratories

During the initial phase, the following scientific and administrative staff [on contractual basis] to support the Director of the National Tobacco Testing Laboratories (NTTLs) in carrying out various activities of the labs. Augmentation of staff will be considered as per requirement:

S. No.	Designation	Numbers (Total 10)
1.	Senior Scientific Officer-I	1
2.	Senior Scientific Officer-II	1
3.	Technical Officer Grade-II	1
4.	Technical Assistant	3
5.	Administrative Assistant	1
6.	Accounts Assistant	1
7.	Instrument Attendant	2

2.7 Accreditation, Quality Assurance and Control

NTTLs have commitment to produce valid, reproducible, and accurate scientific data for analysis of tobacco and tobacco products. The quality control process ensures that our laboratory results are precise and accurate. Any observed inadvertent errors would be addressed and resolved as per standard laboratory practices.

Internal quality audits with respect to specific protocols, schedules and standard operating procedures would be put in place on a regular basis. The review of procedures, personnel and machines would be determined to adapt post audit corrective measures in right earnest. Significant deviations from expected results will be investigated and dealt with appropriately.

2.8 Publication of results, copyright and intellectual property

The copyright of all reports, results, documents, training modules etc. developed in these labs shall exclusively rest with MoHFW. All the staff working at the NTTLs will sign a confidentiality agreement and would abide by the maintenance of secrecy regarding the activities of NTTLs and will not disclose to anybody except when it is authorized explicitly by the NTAC. Specific permission of the Chair of the NTAC will be required for publication of results in research journals.

CHAPTER 3

Tobacco Product Analysis

3.1 Tobacco Product Analysis

One of the important roles of NTTLs concerns with scientific analysis of smoking and non- smoking (smokeless) tobacco products by utilizing standard operating procedures worked out by World Health Organization (WHO) or their globally validated modifications.

Requests for analysis of tobacco products may be received from different quarters by the NTCP Division for varied purposes.

The samples of tobacco products may have their origin in the follow up of procedures required for up-holding provisions of law of the land or for generation of scientific data by NTTLs themselves for specific purposes of research and development or for validation experiments in association with different collaborating National and International organizations for public health. Analysis of tobacco products can also be requested by state governments to fulfil mandatory requirement for implementation of relevant COTPA 2003 laws and directions or Food Safety and Standards Act or any other provisions of law as directed by any court of law etc.

The NTTLs may also conduct routine analysis of tobacco products to generate scientific data on the constituents, contents, emissions, additives etc in commercial tobacco products as stipulated in Article 9 and 10 of Framework Convention of Tobacco Control (FCTC) of WHO.

All requests for analysis of tobacco products may be sent through designated officials/government agency at the following address:

Technical Support Unit

National Tobacco Control Programme
Directorate General of Health Services
Room no. 743, A-wing
NirmanBhawan, Maulana Azad Road
New Delhi-110011

tsu.nttldghs@gmail.com, 011-23063537

Once the clearance is obtained from TSU, the unit will also guide the sender to send the samples in a proper manner, quantity and packaging to the NTTL at NICPR, Noida at the following addresses, from where it would be coded and processed in the three labs:

Technical Officer

National Tobacco Testing Laboratories (Apex)
at National Institute of Cancer Prevention and Research (NICPR) - Noida
Campus,
Plot No. 1-7, Sector-39,
Noida- 201301, Uttar Pradesh, India

3.2 Type of Tobacco Product samples and Procedure for their collection

Though it is not exhaustive, the following are situations in which some type of tobacco product samples may arrive at the NTTLs:

- a. Products that are suspected to contain tobacco or its variants in violation of identified COTPA- 2003 and food safety laws. Such products may often have been seized by Government authorities for violation of provisions of various laws of the country or for analysis ordered by any court of law
- b. Tobacco products procured for scientific data collection and repository for designing regulatory provisions. Such samples will be sourced through State Nodal Officers or as directed by NTCP or at request by WHO-FCTC Global Hub of Smokeless Tobacco set up at ICMR-National Institute of Cancer Prevention and Research (NICPR), Noida.
- c. Tobacco products for studies on validation of WHO standard operating procedures and collaborative work with National and International agencies will be undertaken when approved by NTAC.

3.3 Receipt and coding of samples in the labs

The samples received in undamaged and good condition will be coded at the apex NTTL, Noida (UP) with the help of TSU, NTCP, New Delhi. No uncoded sample will be analyzed by the NTTLs. A receipt of the samples from Government Agencies or State Nodal Officers in good condition will be conveyed by the apex NTTL at Noida which will keep a record of all samples received and coded.

Decoding of results of the tobacco product samples will again be done under the guidance of the TSU.

Analytical results are to be kept confidential with the Technical Support Unit. Information gathered will be shared only with designated officials approved by NTAC for NTTLs.

Research and development work on tobacco products has to have the administrative and financial approval from NTAC. Publication of research and commercial analysis will be possible with approval of NTAC. Over time, automation to ensure data storage and security will be worked out by the TSU under the directions of the NTAC.

3.5 Analysis of Tobacco Products and Reporting

The coded samples would be sent to the identified NTTL for analysis for specific parameters. The data generated in the lab will remain confidential and will be revealed only to the designated officials identified by NTCP/NTAC in writing. No attempt will be made to decode the sample, declaration of equipment used or the protocols utilized unless permitted by NTAC explicitly.

Report on analysis or data collection will be generated by the scientific officers or technical officers at the concerned lab and would be required to be signed by the NTTL Director or his nominee in a prescribed form and will remain recorded for internal consumption and appropriate directives of NTAC. Consolidated technical report signed by the designated official in the Ministry of Health will be sent to the requisitioning official or agency for their use. Data generated will be preserved in data repository for designing regulatory mechanisms.

