road/land belonging to villagers for more than four years. Besides, the Division also incurred an expenditure of ₹ 46.31 lakh[70] on the project.

On this being pointed, the Division stated (May 2017) that the process for invitation of tenders had started after the allotment of fund in September 2013 and agreements were executed accordingly. The Division also stated that the work would be completed after obtaining the approval of the revised estimate. However, the SE, ID, Rudraprayag, in its latest reply (November 2018), stated that (i) due to the objection raised by the villagers, the work on the original alignment cannot be executed and the work on the new alignment also cannot be undertaken due to non-approval of forest land and inappropriate benefit cost ratio; (ii) when steps were initiated for lifting the pipes, the villagers stopped the ID from lifting the pipes and demanded rent for dumping the pipes in their land. An estimate for lifting the pipes and payment of rent was being prepared and after its approval and sanction, the pipes would be lifted and kept in the store for use in any other project.

The Division, therefore, incurred an idle expenditure of ₹ 2.42 crore on procurement of pipes which were lying unattended in the open leaving it prone to the vagaries of nature, besides incurring an unfruitful expenditure of ₹ 46.31 lakh on other components of the project. Moreover, the intended objectives of the project had not been achieved even after a lapse of four years.

The matter was reported to the Government (May 2018); Reply was awaited (August 2019).

MEDICAL, HEALTH & FAMILY WELFARE DEPARTMENT

1.7 Functioning of blood banks in Uttarakhand

The blood banks could not make significant progress in phasing out replacement donors to achieve target of 100 per cent voluntary blood donation (VBD) as envisaged in the National Blood Policy. Information, Education and Communication activities carried out by State Blood Transfusion Council (SBTC) for promotion of voluntary blood donation was inadequate. There was significant difference in the percentage of VBD as per Annual Report of SBTC and figures obtained from the selected blood banks. Out of 35 blood banks in the State, 13 were operating with expired licence from five months to twenty years. Only 22 regular inspections could be carried out against 96 inspections required to be conducted during the period 2015-18. None of the blood banks selected by audit were inspected during 2015-18. Out of eight selected blood banks, five were not calibrating equipment in prescribed time. The Donor and the Master Registers were not being maintained in complete form as prescribed in the Act.

[70] Survey: ₹ 7.44 lakh, Compensation for forest land: ₹ 24.83 lakh, Approach road ₹ 7.95 lakh and Miscellaneous expenditure: ₹ 6.09 lakh.

1.7.1 Introduction

Blood transfusion is a life-saving intervention that has an essential role in patient management within health care systems. The Government of India (GoI) formulated (April 2002, amended in 2007 and 2016) National Blood Policy (NBP) for elimination of transfusion transmitted infection and for provision of safe and adequate blood transfusion services to the people through an integrated strategy[71]. Human blood being covered under the definition of 'drugs[72]' under the Drugs & Cosmetics (D&C) Act 1940, 'blood banks[73]' are regulated under the said Act and Rules framed there under, through issue of licence by the State Drug Controllers (SDC) after conducting inspection along with the Central Drug Standards Control Organisation (CDSCO), the licence approving authority.

The National Blood Transfusion Council (NBTC) is a policy formulating apex body in relation to all matters pertaining to the operation of blood centres while the State Blood Transfusion Council (SBTC) has the responsibility of implementing the blood programme in the State. National AIDS Control Organisation (NACO) allocates budget to NBTC for strengthening Blood Transfusion Services. As of March 2018, 35 blood banks were functioning in the State of which 20 were managed by the State Government as detailed in ***Appendix-1.7.1***, four by the Central Government, seven[74] by private parties and four by different charitable institutions. During the period 2015-16 to 2017-18, collection of blood units[75] in the State Government blood banks accounted for 48 to 53 *per cent* of the total collection in the State.

The theme based compliance audit on "Functioning of Blood Banks in Uttarakhand" during the period 2015-16 to 2017-18 was carried out between March and May 2018, through test-check of the records of SDC, State Blood Transfusion Council (SBTC),

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71 Includes collection of blood only from voluntary, non-remunerated blood donors, screening for all transfusion transmitted infections and reduction of unnecessary transfusion.

72 All medicines for internal or external use of human beings and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings.

73 "Blood Bank" means a place or organisation or unit or institution or other arrangements made by such organisation, unit or institution for carrying out all or any of the operations for collection, apheresis (It is the process by which blood drawn from a donor, after separating plasma or platelets, is re-transfused simultaneously into the said donor), storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components.

74 Out of seven blood banks managed by private parties, six are associated with hospitals and one is a standalone blood bank (not associated with any hospital).

75 One unit=350 ml.

Year	Blood collection (in unit) at various level					
	State Government	Central Government	Private	Charitable institutions	Stand alone blood bank	Total
2015-16	58,080(*53*)	832(1)	14,444(13)	5,860 (5)	30,872(28)	***1,10,088***
2016-17	59,068(*48*)	1,569(1)	23,175(19)	10,267(8)	29,793(24)	***1,23,872***
2017-18	60,836(*48*)	3,783(3)	21,177(17)	15,845(13)	24,696(19)	***1,26,337***

office of the Director General Health and eight[76] State Government blood banks selected on the basis of collection of maximum blood units during the period 2015-18.

1.7.2 Role of SBTC

As per NBP, SBTC would be responsible for implementation of the Blood Programme at State level. In Uttarakhand, SBTC was established[77] (August 2004) with the Secretary, Health & Family Welfare (H&FW) Department as its President. Scrutiny of records showed the following shortcomings:

1.7.2.1 Non-preparation of action plan

As per provision of the NBP, the SBTC was required to prepare an action plan for gradually phasing out replacement blood donors[78] and achieve 100 *per cent* target of collection of safe and quality blood from voluntary blood donors (VBD)[79]. However, it was observed that no such action plan was being prepared by the SBTC.

In the absence of an action plan, the SBTC could not make significant progress as regards VBD in the State as elaborated in ***paragraph 1.7.3.1.***

In order to achieve 100 *per cent* Voluntary Blood Donation, the SBTC should ensure preparation of an action plan for gradually phasing out replacement blood donors.

1.7.2.2 Insufficient meetings of Governing Body of SBTC

As per SBTC Council Rules, 2004, the meetings of Governing Body of SBTC were to be held at least twice a year to review its functioning. However, it was noticed that out of six meetings required to be held, only two meetings[80] of the Governing body were conducted during the period 2015-18. As a result, matters like accounts for the past year, annual report of the state council, proposals for enquires and research work for the next year and demand of funds for the next year could not be reviewed and discussed on a regular basis.

1.7.2.3 Inadequate Information, Education and Communication (IEC) Activities conducted by the SBTC

The SBTC is a Society which is being financed by NACO and State Government through grants. The SBTC receives grants from Uttarakhand State AIDS Control Society (USACS) as provided by NACO and State grants are being received from the annual

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[76] (i) Sushila Tiwari Memorial (STM) Hospital, Haldwani, (ii) S.S. Jeena Base Hospital, Haldwani, (iii) L.D Bhatt Government Hospital, Kashipur, (iv) H.M.G. District Hospital, Haridwar, (v) SJNSM Government Joint Hospital, Roorkee, (vi) Doon Hospital, Dehradun, (vii) B.D. Pandey District Hospital Pithoragarh and (viii) Base Hospital Srinagar, Pauri.

[77] Under the Society Act, 1860.

[78] Family/replacement donor: A donor who gives blood to a member of the patient's family/community which may involve a hidden payment to the donor by the patient's family (ii) One who gives blood when it is required by a member of his /her family/community; this may involve coercion or payment and (iii) A member of the family or friend of the patient who donates blood in replacement of blood needed to a particular patient without involvement of benefits from any source.

[79] A voluntary blood donor is a person who gives blood, plasma or other blood components at his/her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money.

[80] 03 August 2015 and 18 May 2017.

budget of department of Health and Family Welfare. As per NBP, SBTC was to develop and launch IEC campaign using all channels of communication including mass media for promotion of voluntary blood donation and generation of awareness regarding dangers of procuring blood from paid donors as well as from unauthorised blood banks.

The budget allocated and expenditure incurred on IEC activities during the years 2013-14 to 2017-18 was as given in **Table-1.7.1** below:

Table-1.7.1: Detail of Budget Allocation and Expenditure on IEC activities

(*₹in lakh*)

Year	2013-14		2014-15		2015-16		2016-17		2017-18	
	Central	State	Central	State	Central	State	Central	State	Central	State
Grant received	25.40	11.50	8.96	Nil	Nil	Nil	1.00	2.20	1.41	Nil
Expenditure	16.47	3.89	6.99	0.16	3.29[81]	0.35	2.04[82]	2.07	1.41	Nil

Source: SBTC.

It is evident from the above table that there has been steep decline in grants allocated to SBTC by the GoI and the State Government for IEC activities. Audit scrutiny revealed that during the above period the SBTC did not request the GoI and the State Government to increase the amount of grants for IEC activities. It was also observed that in the year 2013-14, 27 IEC activities were conducted while during the year 2014-15, 2015-16, 2016-17 and 2017-18 nine, six, eight and only two activities respectively were conducted for promotion of voluntary blood donation.

On this being pointed out, SBTC stated that the IEC activities were being carried out by the National Aids Control Organisation (NACO). The reply was not tenable as it was mandatory on the part of SBTC to carry out IEC activities to raise the awareness of the need for regular blood donations to ensure quality, safety and availability of blood and blood components and to achieve the target of 100 *per cent* voluntary donations as per the guidelines of NBP. The shortfall in IEC activities has to be seen in the backdrop of poor achievement of the blood banks as regards VBD as discussed in ***paragraph 1.7.3.1***.

For promotion of voluntary blood donation, the SBTC should make efforts to launch IEC campaign using all channels of communication for generation of awareness in public.

1.7.2.4 Non-adherence with the provisions of National Blood Policy

The SBTC Uttarakhand did not adhere with the following provisions of the NBP.

Objective	Provision	Remarks
To strengthen manpower through human resource development	A separate department of transfusion medicine to be established in all medical colleges.	Presently, there are three medical colleges[83] in the State. Department of transfusion medicine was not established in any of the three medical colleges.

[81] From previous years' grants.

[82] Excess expenditure of ₹ 1.04 lakh was met from previous years' balances.

[83] Doon Medical College Dehradun, STM Medical College Haldwani and Government Medical College Srinagar.

	Separate cadre of doctors to be created for providing effective transfusion services in all blood banks.	No such cadre has been created by the State Government.
To encourage research and development in the field of transfusion medicine and related technology	Corpus of funds to be created by SBTC for facilitating research in transfusion medicine and technology related to blood banking.	No corpus of funds was created by SBTC for facilitating research.
	Computer based information and management system to be developed for use by all blood banks regularly to facilitate networking, in order to share information with other blood banks.	One blood bank at district hospital Pauri, in the State was yet to be connected with the network facility. As regards sharing of donor's information, SBTC stated that each blood bank was maintaining a donor's directory which also included rare blood group donors and they could be contacted in case of any emergency. However this data regarding information about donors is not maintained electronically in the blood banks.
To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in blood banks.	The State/SBTC was to enact rules for registration of private hospitals/nursing homes wherein a provision for affiliation with a licenced blood bank for procurement of blood for their patients was to be incorporated.	The State Government/SBTC did not formulate any such rules.

Appropriate action should be taken by the SBTC for implementation of provisions of the National Blood Policy in the State

1.7.2.5 Inadequate staff

To carry out the smooth functioning of the SBTC, the NACO sanctioned (May 2009) one post of director[84], two posts of Deputy Assistant Director[85], one post of Section Officer and eight posts of subordinate staff. The State Government created (June 2016) one post of Director, two posts of Deputy Assistant Directors and 06 posts of subordinate staff (through outsourcing) for SBTC. The post of Section Officer and two subordinate staff were not created by the State Government. Further, the created posts of Deputy Assistant Directors have been not filled up in SBTC. The SBTC did not make any effort to augment its manpower by bringing the matter to the notice of the State Government as well as to NACO.

On this being pointed out, the SBTC replied that there was no need to fill the vacant posts in the SBTC.

[84] Ex-officio post and charge was being looked after by the Director, Uttarakhand State Aids Control Society (USACS).

[85] Medical-01 and IEC-01.

For effective monitoring of implementation of the National Blood Policy in the State, the State Government may augment the staff of the SBTC as proposed by NACO.

1.7.3 Voluntary Blood Donation

1.7.3.1 Collection of blood from voluntary donors

Voluntary blood donation programme is the foundation for safe and quality blood transfusion service as the blood collection from voluntary non-remunerated blood donors is considered to be the safest. In this context, the NBP provides that the practice of replacement donors shall be gradually phased out in a time-bound programme in order to achieve 100 *per cent* voluntary non-remunerated blood donations.

(a) Position of Voluntary blood donation in selected blood banks

Scrutiny of records of the selected blood banks revealed that the blood banks, except HMG District Hospital Haridwar, could not make significant progress in phasing out replacement donors to achieve the 100 *per cent* target as envisaged in NBP. In five out of eight test-checked blood banks[86], the percentage of VBD decreased in 2017-18 as compared to 2015-16 against the total blood units collected (TBC). Moreover, in absence of an action plan by the SBTC for gradually phasing out the replacement donor, seven out of eight test-checked blood banks[87] could not even achieve 40 *per cent* of the target as detailed in ***Appendix-1.7.2*** and these blood banks mainly depended on replacement donations.

In reply, the concerned blood blanks, while accepting the facts, assured that compliance with the policy would be made in future.

The SBTC should ensure preparation of an action plan for achieving 100 *per cent* Voluntary Blood Donation and also ensure its compliance by all the blood banks in the State.

(b) Mismatch of data

There was a significant difference in the percentage of VBD as per the Annual Report of SBTC and as obtained from the selected blood banks as detailed in ***Appendix-1.7.2***.

The SBTC stated that the figures shown in the annual report were sum of voluntary blood donors and family donors. However, as per NACO's definition, family donor falls under the category of replacement donors. The data of SBTC regarding VBD was, therefore, inflated and did not depict the correct position of VBD in the State.

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[86] (i) STM Hospital Haldwani (ii) SS Jeena Base Hospital Haldwani (iii) LD Bhatt Hospital Kashipur (iv) HMG District Hospital Haridwar and (v) SJNSM Hospital Roorkee.

[87] (i) STM Hospital Haldwani (ii) SS Jeena Base Hospital Haldwani (iii) LD Bhatt Hospital Kashipur (iv) SJNSM Hospital Roorkee (v) Doon Hospital Dehradun (vi) BD Pandey Hospital Pithoragarh and (vii) Base Hospital Srinagar.

(c) Position of Voluntary blood donation in private, central government, charitable and standalone blood banks

The Annual Report in respect of VBD prepared by the SBTC for Private, Central Government, Charitable and Standalone blood banks revealed that during the period 2015-18, the percentage of VBD was very low in seven blood banks[88]. Moreover, it was zero *per cent* in case of blood bank at BHEL, Haridwar as given in **Table-1.7.2** below. These blood banks largely collected blood from replacement donors.

However, the percentage of VBD in eight blood banks was satisfactory and 100 *per cent* VBD was also achieved by the IMA blood bank during the above period.

Table-1.7.2: Detail of percentage of VBDs in private/Central Government/charitable/standalone blood banks

Sl. No.	Blood bank	Percentage of VBD[89]			
		Name of Blood Bank	2015-16	2016-17	2017-18
1.	**Private**	Max Hospital,Dehradun	*7*	*5*	*18*
2.		HIHT Jollygrant, Dehradun	*89*	*63*	*67*
3.		Subharti, Dehradun	-	*22*	*19*
4.		Srikrishna, U.S. Nagar	-	*11*	*20*
5.		Kailash, Dehradun	-	-	*13*
6.		Jeevan Rekha Hospital, Kashipur	*100*	*100*	*94*
7.	**Central**	MH, Dehradun	*100*	*97*	*100*
8.		MH, Roorkee	*71*	*91*	*100*
9.		BHEL, Haridwar	*0*	*0*	*0*
10.		AIIMS, Rishikesh	-	*61*	*43*
11.	**Charitable**	Sewa Charitable blood bank, Bajpur	--	--	*20*
12.		Mahant Indresh Hospital, Dehradun	*84*	*96*	*98*
13.		RKMS, Haridwar	*4*	*9*	*37*
14.		Kashipur Charitable blood bank, Kashipur	--	--	*81*
15	**Stand alone**	IMA blood bank, Dehradun	*100*	*100*	*100*

Source: Progress Report of SBTC.

Note: *Sl. No. 3, 4, and 10 commenced from 2016-17 and Sl. No. 5, 11 and 14 commenced from 2017-18.*

The SBTC stated that 100 *per cent* voluntary donation was not possible and private blood banks had certain limitations regarding appointment of sufficient staff, *etc.* for the purpose. The reply of the SBTC was not acceptable as the NBP provides that at the State level, the SBTC is fully responsible to implement the provisions of the policy to phase out the replacement donor and 100 *per cent* collection through VBD was envisaged. Further, IMA blood bank (a Standalone blood bank) operated by the private party has achieved 100 *per cent* VBD in three consecutive years during the period 2015-18 and this blood bank has contributed highest number of blood units in the State during the above period.

[88] Serial Numbers 1, 3, 4, 5, 9, 11 and 13 of **Table-1.7.2**.

[89] Percentage of VBD calculated against the total blood units collected by the blood bank concerned.

1.7.4 Regulatory issues

1.7.4.1 Issue/ renewal of the license for blood banks

Blood being identified as 'drug', blood banks are regulated under the Drug and Cosmetic Act and Rules made there under. The SDC is the regulatory authority, responsible for issue of licences to blood banks with the approval of CDSCO. Before issue and renewal of licences, joint inspection along with the Drug Inspector, CDSCO is to be conducted. The process of issue/renewal of licence is detailed in ***Appendix-1.7.3.*** The licences are valid upto five years after which the same are to be renewed after conducting fresh joint inspection as regards the availability of required manpower and infrastructure. During the period 2015-18, there were 17 blood banks in the State whose licences were due for renewal. Out of these, licences of only four blood banks were renewed as detailed in ***Appendix-1.7.4***.

Scrutiny of records of the SDC revealed that out of 35 blood banks in the State, 13 (12 Government and one Private) blood banks were running with expired licence (as on June 2018). Out of these 13 blood banks, the case of Doon blood bank has been referred to CDSCO for approval and six blood banks were running without licence for a period ranging from six months to two years due to inspection not being carried out by the licensing authorities. In six cases, the inspection authorities had conducted the inspection and highlighted various shortcomings like insufficient space for storage of blood and laboratory; unsatisfactory cleanliness of the blood bank; non-calibration of equipment, inadequate maintenance of records and non-working of thermographs as detailed in ***Appendix-1.7.4***. However, the deficiencies were not addressed by the blood banks and these were running without licence for period from eight months to twenty years[90] as detailed in ***Appendix-1.7.5.*** As per Rule 122-O of the Drug and Cosmetic Act, the licensing authority or approving authority may cancel or suspend the licence of a blood bank after giving the licencee an opportunity to show cause, why such an order should not be passed. However, no action had been taken by the licensing authority or approving authority against the blood banks that failed to rectify the deficiencies pointed out in the joint inspection of the blood banks.

Operation of blood banks without licence implied dilution in the standards required for quality control and is fraught with the risk of supply of unsafe blood.

The State Drug Controller should ensure taking appropriate action against the defaulter blood banks as per provision of the Drugs and Cosmetics Act.

[90] District Hospital, Pithoragarh and District Hospital, Uttarkashi were running without licence for 20 years and more than 10 years respectively.

1.7.4.2 Irregularities in the process of issue/renewal of licences to blood banks

During scrutiny of records of SDC of Uttarakhand, the following irregularities were noticed in renewing licences of blood banks:

Name of the blood bank	Criteria	Observations
Subharti Hospital, Dehradun	As per the condition of the Licence, any change in the technical staff, as mentioned in the licence, would be forthwith reported to the Licensing Authority. Where any change in the constitution of the blood bank takes place, the current licence would be deemed to be valid for maximum period of three months from the date on which the change has taken place.	The licence of blood bank for the period (May 2015 to May 2020) was renewed (May 2015) by the licensing authority by mentioning the name of working technical staff. At the time of joint inspection (May 2017) by the licensing authorities, it was noticed that technical staff which were mentioned in licence had already left the blood bank one year before the date of joint inspection. As per the condition of the licence, the licence was valid for maximum three months. The blood bank was, therefore, running without valid licence.
Sushila Tiwari Memorial (STM) Hospital, Haldwani	The licence was to be provided in continuity.	The licence was due for renewal from February 2010 to February 2015 but it was renewed for the period from March 2012 to March 2017. Thus the gross negligence on the part of the licensing authority let the blood bank operate without any valid licence for more than two years.
All blood banks	The National Blood Policy (NBP) provides that issuing/renewal of licences to blood banks are subject to condition that the licencee has to seek 'No objection certificate' (NOC) from the SBTC by submitting photo copy of previous licence, blood collection report, proof and detail of Medical Officer and counsellor, annual report indicating blood component of separation facilities *etc.*	Scrutiny of records revealed that licences were being issued/renewed to all blood banks without the necessary NOC from the SBTC.

1.7.4.3 Lack of regular inspections of blood banks

As per terms and conditions of the licence, for ascertaining the standard of the blood and blood products, a blood bank should be re-inspected periodically at least once in a year from the date of licensing, by a team comprising of Drug Inspectors of CDSCO and State licensing authority and if required with an expert.

As per Annual Report of the SBTC, 96 inspections[91] were to be carried out by the licensing authority during 2015-18. However, information collected from the SDC revealed that only 22 inspections[92] could be carried out during the above period. Moreover, audit noticed that none of the test-checked blood banks were inspected during 2015-18.

[91] 2015-16=30; 2016-17=33 and 2017-18=33 (Total-96).
[92] 2015-16=03; 2016-17=08 and 2017-18=11 (Total-22).

On being pointed by audit, the SDC stated that regular inspections could not be carried out due to shortage of staff. In absence of inspections of the blood banks, the quality of the blood and blood components could not be ensured.

To ensure the functioning of the blood banks as per provision of the Drugs and Cosmetics Act, the license approving (CDSCO) and issuing (State Drug Controller) authorities should conduct regular inspection of the blood banks.

1.7.5 Quality control of blood and blood components

As per provisions of the Act, the blood banks are required to conduct various test (screening) of collected blood against Syphilis, Malaria, HIV I and II, Hepatitis B and C by using various methods *viz.* Nucleic Acid Amplification Test (NAT), Enzyme Linked Immune Sorbent Assay (ELISA) III and IV and Rapid test kits. All these tests have varying sensitivity to detect infections; some can detect infections within a shorter period of the donor getting infected (window period). The following shortcomings were noticed during the audit scrutiny:

1.7.5.1 Inadequate screening of blood for HIV

As per directions of NACO, screening of blood for HIV should necessary be carried out by utilising three different antigens *viz.* two rapid and one Elisa antigens or two Elisa and one rapid antigen. It was further directed that ELISA reader and necessary ELISA test kits and various Rapid test kits for screening the blood against AIDS, Hepatitis B&C, Syphilis and Malaria have to be made available to all blood banks by the USACS. It was observed that all the selected blood banks except blood bank at HMG District Hospital, Haridwar were not utilising the ELISA reader for screening the blood against HIV thereby putting recipients of blood susceptible to infection. However, all collected blood units (except in blood bank at Pithoragarh as described in ***paragraph 1.7.6 b***), were being screened/tested for Hepatitis B, Hepatitis C, Syphilis and Malaria by the various Rapid test kits as provided / specified by the NACO.

When the matter regarding non utilisation of ELISA antigen for testing of blood units against HIV was pointed out by the audit, the blood banks, while accepting the fact, stated that the ELISA HIV test kits were not provided by USACS.

The SBTC and the State Drug Controller should monitor the compliance of NACOs' guidelines regarding screening of blood against HIV.

1.7.5.2 Ineffective Calibration of equipment by the blood banks

The Act, *inter alia,* required that equipment used in blood banks for collection, processing, testing, storage of blood and blood components are to be observed, standardised and calibrated on a regular and scheduled basis. Laboratory thermometers are required to be calibrated before initial use; Hematocrit centrifuge has to be calibrated annually and four other equipment[93] have to be calibrated on six monthly basis. Audit

[93] General lab centrifuge, automated blood typing, hemoglobinometer and refractometer or urinometer.

observed that the equipment of three blood banks[94] were not calibrated since 2016; in District hospital Pithoragarh, equipment were not calibrated since 2015 and in STM College Haldwani from 2017 as detailed in ***Appendix-1.7.6.***

On this being pointed out, the Department, while accepting the fact, stated that the calibrations would be carried out in future.

Non-calibration of equipment at prescribed interval is fraught with the risk of inaccurate and unreliable reading which might result in an unreliable quality of blood collected and issued thereby putting the patients at risk.

1.7.5.3 Donor register

The Act provides that each blood bank is required to maintain donor register indicating serial number, date of donation, name, address and signature of donor with the particulars of age, weight, haemoglobin, blood group, blood pressure, medical examination, bag number and patient's detail, category of donation, deferral records[95] and signature of the Medical Officer in-charge. Further, general conditions for donation of blood provide that the donor should be in the age of 18 to 65 years; weight should not be less than 45 kilograms; haemoglobin should not be less than 12.5 grams; and blood pressure should be in normal condition without medicine.

Audit observed that in all the selected blood banks except SS Jeena Hospital Haldwani, this register was not being maintained in complete form as prescribed in the Act. The age, weight, haemoglobin, blood group, blood pressure, signature of donor and signature of medical officer were not being recorded in the register. As a result, compliance with the above mentioned general conditions for blood donation could not be ascertained.

1.7.5.4 Master Register

The Act prescribes a master register for blood and blood components which should be maintained by each blood bank. This register should indicate bag serial number, date of collection, date of expiry, quantity in ml., RH group, results for testing of HIV, Malaria, Hepatitis, Syphilis, name and address of the donor with particulars, utilisation issue number, component prepared or discarded and signature of the Medical Officer-in-charge.

Scrutiny of records of selected blood banks revealed that three[96] blood banks were not maintaining master register and the other five[97] were not maintaining this register in complete form. The quantity of blood, RH group, utilisation issue number and signature of Medical Officer were not being recorded in the register. These blood banks, therefore,

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94 (i) L D Bhatt Hospital, Kashipur (ii) S S Jeena Hospital, Haldwani and (iii) S J N M Hospital, Roorkee.

95 Deferral records are the part of blood donor records. It is the record of donors who have been excluded from blood donation as found suspected of having an infectious disease.

96 (i) S T M College, Haldwani (ii) B D Pandey District Hospital, Pithoragarh and (iii) L D Bhatt Hospital, Kashipur.

97 (i) S S Jeena Base Hospital, Haldwani (ii) H M G District Hospital, Haridwar (iii) S J N S M Govt. Joint Hospital, Roorkee (iv) Doon Hospital, Dehradun and (v) Base Hospital Srinagar, Pauri.

did not have master records as prescribed for blood and its components and this was against the provision of the Act.

On this being pointed out, the blood banks while accepting the fact, assured that compliance with the Act would be made in future.

For compliance of all provisions of the Drugs and Cosmetics Act, the SBTC and the State Drug Controller should ensure monitoring the functioning of the blood banks and also ensure that all provisions of the Act are being complied with by blood banks in the State.

1.7.6 Gross Violation of Act by the blood bank at District Hospital Pithoragarh

Apart from the above mentioned shortcomings relating to quality control of blood and blood components by the selected blood banks, scrutiny of records and physical inspection of blood bank of B D Pandey District Hospital, Pithoragarh revealed the following shortcomings:

(a) This blood bank has been operating without a valid licence since 1998. It failed to remove all the shortcomings[98] pointed out by the joint inspection team in 2002, 2007, and 2018. In-spite of its poor functioning, no stringent action had been taken by the licensing authority endangering the life of both the donor and recipient.

(b) The Act provides that the collected blood may be properly screened for detecting HIV, Hepatitis B&C, Malaria and Syphilis in order to provide quality blood which is free from any transmissible disease. However, it was observed that during 02 February 2017 to 31 March 2018 (14 months), 1,194 blood units[99] were screened without screening for Malaria and during 21 July 2016 to 31 March 2018 (20 months), 707 blood units[100] were screened without screening for Syphilis and blood units issued to patients.

On this being pointed out, the Medical Officer, Blood Bank, Pithoragarh replied that the screening of Malaria was being carried out through slide method. The reply is not acceptable as there is no provision in the Act for carrying out the Malaria test with slide method. During the above period, the blood bank did not have the required numbers of test kits for screening the collected blood units for Malaria and Syphilis as per the stock records of the Hospital.

Physical verification of the blood bank showed the following deficiencies:

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98 Sterilisation and wash room not provided; laboratory for transmissible disease is also used as storage of other consumable items; records and store rooms were not in proper way; blood screening for transmissible disease was done only by Rapid Kits method, Elisa was not being used, *etc*.

99 Only 291 test kits (91 opening balance+200 were received during the mentioned period) were available in the stock while 1,485 blood units were screened during the period *i.e.* (1,485-291= 1,194).

100 Only 3,318 VDRL test kits (1,318 opening balance+2,000 were received during the mentioned period) were available in the stock while 4,025 blood units were screened during the period. *i.e.* (4,025-3,318=707).

The Act provides that there should be separate laboratory for blood group serology and laboratory for blood transmissible diseases like hepatitis, Syphilis, Malaria and HIV.

It was observed that testing of blood group serology and blood transmissible diseases were being carried out together in a single laboratory by the blood bank as depicted in ***Photograph No. 1.7.1*** alongside.

Photograph No. 1.7.1: *Testing of blood group serology and blood transmissible diseases were being carried out in a single laboratory by the blood bank.*

The Act provides that operation of the blood bank and preparation of blood components should be under hygienic conditions. The wall and floors of the rooms, where collection of blood or preparation of blood components is carried out should be smooth, washable and capable of being kept clean. Drains should be of adequate size and connected directly to the sewer.

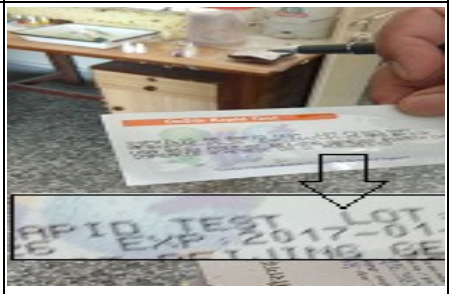
During the physical verification, it was noticed that in the absence of proper drainage system, water was overflowing from the drain and scattered on the floor. The disposable items were kept in the gallery of the blood bank. As a result, blood bank was operating in unhygienic conditions as depicted in ***Photograph No. 1.7.2*** alongside. Moreover, waste blood and blood tubes were thrown in the bin kept on the testing table as depicted in ***Photograph No. 1.7.1*** alongside.

Photograph No.1.7.2: *Functioning of Hospital in very unhygienic conditions.*

Candle flame was being utilised for locking the blood bags in place of tube sealer as depicted in ***Photograph No. 1.7.3*** alongside, though the tube sealers were available in the store of the blood bank. This unhygienic practice may affect the quality of the blood.

Photograph No.1.7.3: *Candle flame was being utilised in Hospital.*

Expired testing kits were being utilised for cross matching of the blood as depicted in ***Photograph No. 1.7.4*** alongside. A number of expired rapid test kits for testing Syphilis were found in the store.



Photograph No. 1.7.4: *Expired testing kits were being utilised for cross matching of the blood.*

For gross violation of the Drugs and Cosmetics Act, the SDC should ensure taking appropriate action against the blood bank as per Rule 122-O of the Act.

1.7.7 Non-establishment of blood bank at district Champawat

The NBP provides that in the State, every district should have at least one blood bank. It was observed that even after sixteen years of implementation (2002) of the NBP, no blood bank had been established in district Champawat till the date of audit (May 2018). It was also noticed that the Chief Medical Officer informed (June 2016) the DG, Health that due to non-establishment of the blood bank, patients could not get the blood on time and as a result, many patients died for want of blood. However, no action was taken by the DG, Health in this regard even after lapse of two years (June 2018).

On this being pointed out, the SBTC replied that the blood bank building was constructed in 2011 as per norms. However, the essential equipment could be procured only during 2016-17 as fund was not available during 2011-12 to 2015-16. Further, it was replied that the District Hospital had applied for licence in 2017-18 for establishment of the blood bank. The reply of SBTC is not acceptable as the demand of funds was made by the SBTC only in 2015-16.

Inordinate delay in establishment of the blood bank in Champawat, therefore, not only revealed the indifference of the Health Department but also endangered the lives of patients.

1.7.8 Conclusion

The blood banks could not make significant progress in phasing out replacement donors to achieve 100 *per cent* target of VBD as envisaged in the Blood Policy in absence of an action plan by the SBTC and insufficient IEC activities. There was a significant difference in percentage of VBD as per Annual Report of SBTC and figures obtained from selected blood banks. Out of 35 blood banks in the State, 13 were running with expired licences from five months to 20 years due to non-inspection by the licensing authorities or non-removal of shortcomings by the concerned blood banks. Only 22 inspections could be carried out against 96 inspections during the period 2015-18. None of the blood banks selected by the audit were inspected during the period 2015-18. Out of eight selected blood banks, five were not calibrating equipment in prescribed time. The donor and master registers were either not being maintained or maintained in incomplete form. Gross violation of Act was noticed in blood bank at district hospital Pithoragarh and there was inordinate delay in establishing blood bank in district Champawat.

The matter was reported to the Government (June 2018), Reply was awaited (August 2019).

Appendix-1.7.1
(Reference: Paragraph 1.7.1; Page 40)

Collection of blood units in decreasing order by 20 State blood banks

Sl. No.	Name of Blood Bank	Number of Blood Units Collected			Grand Total
		2015-16	2016-17	2017-18	
1.	Sushila Tiwari Memorial Hospital Trust	10,970	10,742	10,927	32,639
2.	SS Jeena Base Hospital Haldwani, Nainital	6,831	7,089	7,547	21,467
3.	LD Bhatt Govt. Hospital, Kashipur	6,625	6,770	7,211	20,606
4.	HMG District Hospital Blood Bank, Haridwar	6,273	6,809	8,440	21,522
5.	J LN District Hospital, Rudrapur*	6,070	6,338	6,014	18,422
6.	SJNSM Govt. Joint Hospital, Roorkee	6,220	6,074	6,165	18,459
7.	Doon Hospital, Dehradun	6,180	5,425	5,008	16,613
8.	B D Pandey District Hospital Blood Bank Pithoragarh	2,421	2,700	2,289	7,410
9.	Base Hospital Sri Nagar, Pauri	2,259	1,606	1,711	5,576
10.	Combined Hospital Kotdwar	1,396	1,867	1,757	5,020
11.	District Hospital Almora	1,015	953	1,016	2,984
12.	SPS Govt. Hospital Rishikesh, D.dun	290	850	633	1,773
13.	District Hospital Blood Bank, Uttarkashi	425	619	567	1,611
14.	B D Pandey D H Blood Bank, Nainital	484	462	549	1,495
15.	Govind Singh Mahar Govt. Hosp. Ranikhet, Almora	356	459	438	1,253
16.	District Hospital Gopeshwar, Chamoli	265	171	223	659
17.	District Hospital Bauradi, Tehri	Nil	102	283	385
18.	District Hospital Blood Bank, Pauri	Nil	32	58	90
19.	District Hospital, Blood Bank, Bageshwar	Nil	Nil	Nil	Nil
20.	District Hospital Blood Bank, Champawat	Nil	Nil	Nil	Nil

Source: Information collected from SBTC, Dehradun.
****It was taken for pilot study.***

Appendix-1.7.2
(Reference: Paragraph 1.7.3.1 a & b; Page 44)

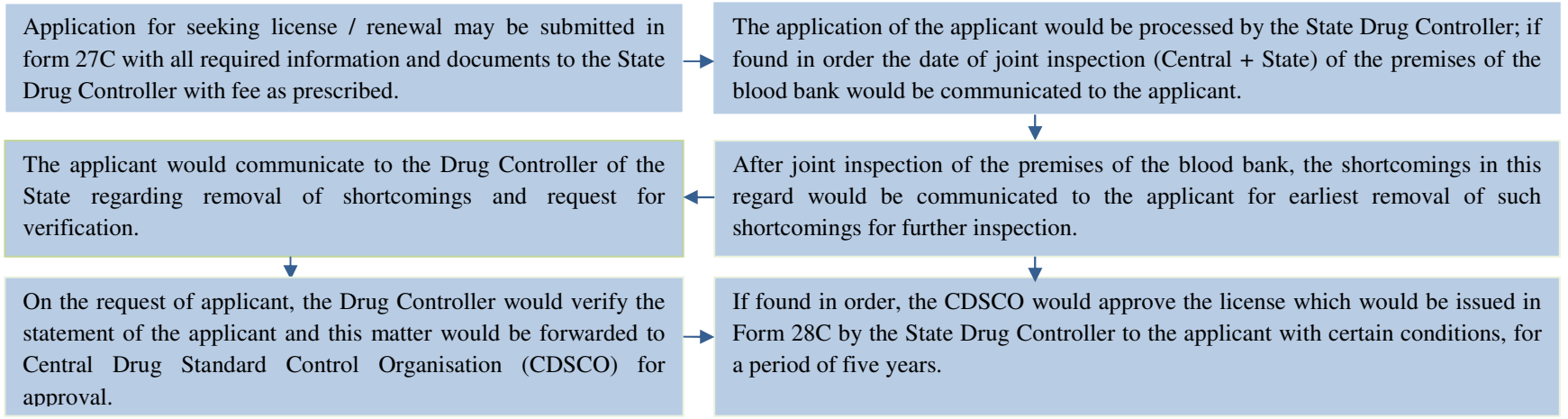
Position of VBD in selected eight blood banks and its percentage shown in the progress report by the SBTC

Sl. No.	Name of blood bank	2015-16			2016-17			2017-18		
		TBC	VBD	Percentage shown by the SBTC in progress report	TBC	VBD	Percentage shown by the SBTC in progress report	TBC	VBD	Percentage shown by the SBTC in progress report
1.	STM Hospital, Haldwani	10,970	3,216 (*29*)	*94*	10,742	2,098 (*20*)	*95*	10,927	2,646(*24*)	*94*
2.	SS Jeena Base, Hospital Haldwani	6,831	1,813 (*27*)	*92*	7,089	1,865 (*26*)	*74*	7,547	1,705(*23*)	*88*
3.	LD Bhatt, Hospital Kashipur	6,625	2,186 (*33*)	*83*	6,770	2,136 (*32*)	*81*	7,211	2,308(*32*)	*82*
4.	HMG Hospital Haridwar	6,273	4,493 (*72*)	*88*	6,809	5,400 (*79*)	*89*	8,440	5,902(*70*)	*77*
5.	SJNSM Hospital, Roorkee	6,220	2,488 (*40*)	*80*	6,074	3,166 (*52*)	*67*	6,165	2,281(*37*)	*68*
6.	Doon Hospital, Dehradun	6,180	1,112 (*18*)	*86*	5,425	1,356 (*25*)	*83*	5,008	1,102(*22*)	*82*
7.	BD Pandey Hospital, Pithoragarh	2,421	637 (*26*)	*84*	2,700	949 (*35*)	*79*	2,289	734 (*32*)	*81*
8.	Base Hospital, Srinagar	2,259	792 (*35*)	*79*	1,606	530 (*33*)	*89*	1,711	616 (*36*)	*83*

Source: Information provided by Selected Blood Banks and progress report of SBTC.
Note: figures in bracket depicted the percentage of VBD against the TBC.

Appendix-1.7.3
(Reference: Paragraph 1.7.4.1; Page 46)

Process of issue / renewal of license



Source: SDC, Dehradun.

Appendix-1.7.4
(Reference: Paragraph 1.7.4.1; Page 46)

Position of Non-renewal of license as on March 2018

Sl. No.	Name of Blood Bank	Validity of License	Non removal of shortcomings by the blood banks so far	Ramifications of deficiencies
1.	Sushila Tiwari Medical College	26.03.2017	None of the equipment was found calibrated; cleanliness of the blood bank in serology laboratory and TTI lab. was not satisfactory; thermograph recorder out of order; non testing facility of Elisa Reader.	Blood and blood components are susceptible to contamination, not following the process may increase the risk of transfusion transmissible infection to recipient of the blood.
2.	District Hospital, Pithoragarh	29.06.1998	Cleanliness of the blood bank in TTI lab. not satisfactory; non-calibration of equipment; thermograph recorder found out of order; non testing facility of Elisa Reader.	
3.	LD. Bhatt Hospital, Kashipur	08.10.2017	Non-calibration of equipment; thermograph recorder found out of order.	Not following the process may increase the risk of transfusion transmissible infection to recipient of the blood.
4.	SPS Government Hospital, Rishikesh	23.04.2017	Non-calibration of equipment; no procedure in place to monitor the temperature of refrigerator used to store diagnostic kits and regents; stand by refrigerator for storage of screened blood found out of order.	
5.	SS Jeena Hospital Haldwani	09.10.2017	Non-calibration of equipment.	
6.	District Hospital, Uttarkashi	31.12.2006	Non-calibration of equipment; non testing facility of Elisa Reader; dielectric sealers out of order; blood storage refrigerator for storage of unscreened blood found out of order; Screened and unscreened blood units stored in same refrigerator.	

Appendix-1.7.5
(Reference: Paragraph 1.7.4.1; Page 46)

Position of Non-renewal of license as on June 2018

Sl. No.	Name of Blood Bank	Date of establishment of the blood bank	Validity of License up to	Action of licensing Authority	Reasons for non-renewal of license	Remarks
1.	Doon Hospital Dehradun	10.10.12	09.10.2017	Inspected on 26.01.18	Sent to CDSCO for approval	Running without licence from 10.10.2017 (eight months)
2.	SPS Government Hospital Rishikesh	24.04.2012	23.04.2017	Inspected on 26.01.18	Non removal of shortcomings by the blood banks so far	Running without licence from 24.04.2017 (one year three months)
3.	District Hospital, Uttarkashi	20.01.1998	31.12.2006	Inspected on 08.03.18	-do-	Running without licence from 01.01.2007 (eleven year six months)
4.	SS Jeena Hospital Haldwani	10.10.2002	09.10.2017	Inspected on 04.01.18	-do-	Running without licence from 10.10.2017 (eight months)
5.	Sushila Tiwari Medical College	27.03.2012	26.03.2017	Inspected on 05.07.17	-do-	Running without licence from 27.03.2017 (one year three months)
6.	LD. Bhatt Hospital, Kashipur	09.10.2012	08.10.2017	Inspected on 28.11.17	-do-	Running without licence from 09.10.2017 (eight months)
7.	District Hospital, Pithoragarh	30.06.1997	29.06.1998	Inspected on 27.03.18	-do-	Running without licence from 30.06.1998 (20 years). Since license not renewed from 1998
8.	Jeevan Rekha Hospital Kashipur	27.08.2012	26.08.2017	Not Inspected so far	Failure of licensing authority to conduct inspection	Running without licence from 27.08.2017 (ten months)
9.	District Hospital, Pauri	28.12.2012	27.12.2017	Not Inspected so far	-do-	Running without licence from 28.12.2017 (six months)
10.	District Hospital, Almora	01.01.2013	31.12.2017	Not Inspected so far	-do-	Running without licence from 01.01.2018 (six months)
11.	G S M District Hospital, Ranikhet	15.06.2011	14.06.2016	Not Inspected so far	-do-	Running without licence from 15.06.2016 (two years)
12.	District Hospital, Chamoli	11.04.1997	31.12.2017	Not Inspected so far	-do-	Running without licence from 01.012018 (six months)
13.	B.D. Pandey (M) Hospital, Nainital	01.01.2013	31.12.2017	Not Inspected so far	-do-	Running without licence from six months
14.	Himalayan Hospital Institute, Dehradun	30.12.2012	31.12.2017			Renewed
15.	Max Super Hospital, Dehradun	27.12.2012	28.12.2017			Renewed
16.	H.M.G. Dist. Hospital, Haridwar	26.01.2012	27.01.2017			Renewed
17.	JLN Dist. Hospital, Rudrapur, U S Nagar	30.12.2011	31.12.2016			Renewed

Source: Information collected from SDC, Dehradun.
Note 1- As per Drug and Cosmetics Act 1940 the inspection of blood bank has to be carried out jointly by the team of CDSCO and SDC.
Note 2- No punitive measures or provision of penalties has been described in the Act against the defaulter licencee.

Appendix-1.7.6
(Reference: Paragraph 1.7.5.2; Page 49)

Position of Non-Calibration of equipment during 2015 to March 2018

Name of Equipment	Periodicity of Calibration	Not calibrated since
Hematocrit centrifuge	Annually	LD Bhatt hospital Kashipur & SS Jeena hospital, Haldwani from 04/2016 to 03/2018
		SJNM hospital, Roorkee from 2016/09 to 03/2018
		District hospital Pithoragarh from 05/2015 to 03/2018
		Sushila Tiwari Medical College, Haldwani from 2017/02 to 03/2018
General lab centrifuge, Automated blood typing, Haemoglobino meter, Refractometer	In every six month	LD Bhatt hospital Kashipur & SS Jeena hospital, Haldwani from 04/2016 to 03/2018
		SJNM hospital, Roorkee from 2016/09 to 03/2018
		District hospital Pithoragarh from 05/2015 to 03/2018
		STM College, Haldwani from 2017/02 to 03/2018