

The Blood Bankers' Legal Handbook The Blood Bankers' Legal Handbook

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Legal Handbook

By

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The Indian Society of Blood Transfusion and Immunohaematology
And
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Assisted by

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March 2003

Dedicated to
Mrs. Kanta Saroop Krishen

A pioneer in the field of
Voluntary Blood Donation in India

Who gave me her daughter, Niti,
to love and to cherish

And who has motivated millions
including my whole family
to share the joy of living
by donating blood

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Preface

My first attempt to compile a booklet on the legal aspects of blood donation was made in 1996 soon after the Supreme Court judgment was delivered. Since then, my involvement has increased many fold especially as Honorary Legal Adviser to the Blood Bank Society, Chandigarh as well as the ISBTI. The number of my donations has also reached 79.

Due to my professional preoccupations, I have not been able to devote as much time as I would have liked to the present work. But the motivation was very strong to release this book before the inauguration of the Rotary and Blood Bank Society Resource Centre at Chandigarh scheduled for mid 2003.

My thanks are due to Mr. Harpreet Singh Giani, Advocate, who has assisted me in compiling the entire manuscript and revising the final proofs for the present handbook.

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February 1, 2003

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A Brief Background

Chapter 1

A Brief Background

Today when medical practitioners talk of conserving blood, of collecting each individual unit of blood and even of splitting up every single drop of blood into its most basic usable components, it is almost unbelievable that just a few centuries ago, bad blood was blamed for virtually each and every ailment that afflicted a patient and that bleeding patients was an acceptable form of treating disease. Though this practice, called Phlebotomy, is no longer prevalent, still it only highlights the importance that the ancient Egyptian, Grecian and European cultures attached to blood.

It took the genius of the English physician William Harvey for the first modern

scientific study of the human anatomy to be undertaken and for the discovery of the circulation of blood. And that one crucial discovery way back in 1628, was followed up by a series of equally brilliant medical scientists who contributed to the science of haematology.

The early success of Richard Lower in 1665 in transfusing blood successfully from one dog to another fuelled a new interest in this promising new field, and at the same time other attempts to transfuse blood from lambs to humans ended in fatal disasters leading to the first blood transfusion related laws in 1677 banning animal to human blood transfusions. By 1818 however, the science of blood transfusion had started gaining ground and doctors like James Blundell had gone on not only to pioneer new instruments, but also to successfully demonstrate the life saving effects of blood transfusions.

After these landmark events, hematology has never looked back and today millions of lives are saved in hospitals and emergency rooms each year thanks to the untiring efforts of scientists, doctors, technicians and voluntary workers all over the world.

The Indian Context

India has never lagged behind in medical advances. Sushruta, acclaimed as the father of surgery in India lived many hundreds of years ago and had already undertaken a scientific study of the human anatomy. Historians have found credible evidence of the doctors of that age practicing advanced surgery, including plastic reconstructive surgery. Even today, Indian researchers and scientists are on the cutting edge of technology and research.

However, given the sheer size of our population, it is understandable, though unfortunate, that the benefits of these modern techniques and practices have not

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The National Aids Control Organization¹ (NACO), in the preface to its National Guidelines for the Appropriate Uses of Blood has underlined the many deficiencies in the Blood Transfusion Service (BTS) across the country. The guidelines highlight the seriousness of the situation and enumerate the many ills that exist in the current blood bank infrastructure.

The problem areas identified include an acute shortage of trained personnel and medical resources, the lack of adequate screening mechanisms, the high number of professional blood donors who sell their blood for money, the improper and inefficient use of blood etc.

The guidelines² issued by NACO are however a welcome step towards improving the BTS. But as always, active participation from each and every segment of society is needed to translate good intentions into positive action.

Non Governmental Organizations in India have always played a major role in this arena. A number of organizations have in the past stepped in to fill the gaps in the BTS and to provide assistance and guidance. Indeed, the impetus for the framing of a National Blood Policy came from the initiative taken by an NGO, Common Cause, which knocked at the Supreme Court's door and brought the sorry state of affairs to the attention of the apex court.

The Supreme Court had in the now famous Common Cause³ case directed the Indian government to come up with a comprehensive action plan to fortify the BTS in the country.

The National Blood Policy⁴ is therefore the direct consequence of that case and also of the efforts of numerous individuals and organizations. The draft policy had been circulated soon after the Supreme Court judgement inviting suggestions from different quarters. Many suggestions were received but the policy was not being finalised. Through the efforts of Mr. Apurba Ghosh, Secretary General of ISBTI, a powerful delegation of five members of parliament from West Bengal alongwith Dr P.L. Dhand, President Mrs. Kanta Saroop Krishen, Mr M.L. Sarin Honorary Legal Adviser & Dr V.P. Gupta, all of ISBTI met Mr Atal Behari Vajpayee, the Prime Minister of India in August 2001 and requested him to take a decision on the National Blood Policy. It goes to the Prime Minister's credit that soon thereafter the National Blood Policy was finalised and published.

There are so many instances of NGOs taking up the cause and performing

1. The National Aids Control Organization of the Ministry of Health and Family Welfare, Government of India
(<http://naco.nic.in>)
2. The NACO Guidelines for Appropriate Use of Blood (See <http://naco.nic.in/vsnaco/nacp/blood.htm>) :
See appendix.
3. See AIR 1996 Supreme Court 929 (See appendix)
4. The National Blood Policy (See <http://naco.nic.in/vsnaco/nacp/bidprog.htm>) ; See Appendix.
sterling work in this field. In some cases, NGOs like the Chandigarh Blood Bank Society have gone so far as to virtually adopt the entire city and the surrounding region and ensuring that the blood services available to the people are amongst the finest in the world.

The will already existed, the direction was provided by the Supreme Court of India and as a consequence, the National Blood Policy has been framed. The rest is all up to us.

Filing of the Writ Petition

The Voluntary Blood Donation Movement in India was growing very slowly. Most of the blood was collected from professional blood sellers who would indulge in unethical practices in order to make a few rupees. In fact there was a thriving trade in human blood. Blood purchased from undesirable sources, who may be diseased or drug addicts, would be sold for profit and in some cases even diluted to make one unit into two or more. Such sub-standard blood, when transfused proved more harmful than helpful for the recipients.

The Blood Bank Society in the Post Graduate Institute of Medical Sciences and Research (PGI) Chandigarh had been set-up in the year 1963 with the joint efforts of Dr.J.G.Jolly, the Head of the Blood Transfusion Department and Mrs.Kanta Saroop Krishen. The Blood Bank Society, run by a handful of voluntary workers succeeded in providing safe blood to one of the largest medical hospitals in the country Post Graduate Institute for Medical Education and Research (PGI) Chandigarh - through voluntary sources. However, at every stage the voluntary blood donation movement was threatened by professional blood banks. The supporters of the voluntary blood donation movement soon realized that there were serious deficiencies and shortcomings in the matter of collection, storage and supply of blood in India which in turn lead to malpractices and mal-functioning of blood banks in various parts of the country. Though organizations like the Blood Bank Society Chandigarh were functioning very smoothly, the voluntary blood donation movement in the rest of the country was growing extremely slowly and every effort to get Governmental support by approaching successive Union Health Ministers for enacting suitable legislation to ban the trade in human blood proved futile.

In the year 1992 Mrs.Kanta Saroop Krishen the Honorary Secretary of the Blood Bank Society and Dr. Manmohan Kaur, its member, both of Chandigarh, approached Mr. H.D.Shourie, a public spirited person for filing a public interest litigation under Article 32 of the Constitution in the Supreme Court of India. All the necessary data was provided to Mr.Shourie. The writ petition was filed in the name of Common Cause versus the Union of India and all the States and Union Territories with a prayer that directions be issued to ensure that positive and concrete steps are immediately initiated for eliminating the mal-practices and inadequacies in the functioning of blood

banks in India. The writ petition was filed and the judicial process was set in motion.

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The Common Cause Case and its Aftermath

Proceedings Before the Supreme Court

On the asking of the Supreme Court draft schemes were prepared and submitted to the Court for its consideration. After perusing all the recommendations made, detailed arguments were addressed and the Supreme Court by an exhaustive judgment¹ dated January 4, 1996 allowed the writ petition and issued a number of directions. The judgment of the Supreme Court is reported as AIR 1996 SC 929. The Apex Court kept in mind the short term objectives and the long term plan while issuing 18 directions. The most crucial being that all professional blood banks should be closed within a period not more than two years from the date of the judgment i.e. by January, 1998.

With the help of the Apex Court and through the kind services of Mr.H.D.Shourie of Common Cause, the Blood Bank Society Chandigarh and the Indian Society of Blood Transfusion and Immunohaematology (ISBTI) had achieved in three years what had not been possible in the previous three decades. All professional and unlicensed blood banks were to be discontinued and ultimately closed and buying and selling of blood was to be totally discontinued. Under the directions of the Supreme Court, a National Blood Transfusion Council, which was to be registered as a Society, was to be set-up at Delhi and similar State Blood Transfusion Councils were to be set-up in every State and Union Territory. Their objective was to strengthen the voluntary blood banking system and their programmes and activities were "to cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilization of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour industry and trade establishments and organization of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilization, separation of blood groups, proper labelling, proper storage and transport, quality control and achieving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking."²

At the 21st National Conference of the ISBTI held in Delhi some shortcomings in the enforcement of the directions of the Supreme Court were highlighted during a session in which Mr. H.D.Shourie was present in person. Consequently, a Contempt Petition was filed which shook the Central and the State Governments

out of their slumber. After being satisfied that the State Councils for Blood Transfusion had been set-up in accordance with the directions of the Supreme Court, the Contempt notices issued were discharged vide an order dated July 25, 1997 by passing the following order :

1. See appendix for complete judgement
2. AIR 1996 Supreme Court 929 Direction No. 7 : See appendix

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"After passing of the order dated May 9, 1997 further affidavits have been filed on behalf of the Union of India as well as on behalf of the various State Governments and Union Territories. We have perused the same. We find that State Councils for Blood Transfusion have been set up in all the States and Union Territories in accordance with the directions given by this Court. We also find that steps have been taken for licensing of the existing blood banks and steps have also been taken for discontinuing the operation of blood banks which have not been granted licences. Thus, the directions given by this Court in the judgment dated January 4, 1996 in that regard have been complied with. As regards further steps to be taken in pursuance of the directions contained in the said judgment we direct that the National Council for Blood Transfusion, in co-ordination with the State Councils, shall take necessary steps to ensure proper functioning of the blood banks (duly licensed) so that the need for blood in the various parts of the country can be met at short notice. The National Council shall also take steps to augment the availability of blood in the blood banks by organizing voluntary donation camps and by creating social awareness among the people about the need for voluntary donation of blood so that the prevailing practice of securing blood from professional blood donors is eliminated. With these observations we close this matter. While doing so we place on record our appreciation for the initiative taken by Shri H.D.Shourie, appearing in person on behalf of the petitioner-Society, in taking up this matter and for the assistance rendered by him to the Court. The writ petition is disposed of accordingly. The contempt notices which have been issued are discharged.

Sd/- S.C.AGRAWAL, J.

Sd/- J."

Follow up Action by the Government

In accordance with the directions issued, the National Blood Transfusion Council and State Blood Transfusion Councils were established throughout the country with the objective of taking all necessary steps to ensure proper functioning of licensed blood banks so that the need for blood in the various parts of the country could be met at short notice.

Amendments in the Income Tax Act, 1961

In compliance of the mandate of the Supreme Court, Section 80G of the Income Tax Act, 1961 was amended so as to make all donations to the National Blood Transfusion Council or the State Blood Transfusion Councils eligible for deduction from the taxable income of an Assessee. The relevant extract of

Section 80G after amendment is reproduced below :

Relevant Extract of section 80G of the Income Tax Act, 1961
80 G. "Deduction in respect of donations to certain funds, charitable institutions, etc.:"

(1)

In computing the total income of an assessee, there shall be deducted, in accordance with and subject to the provisions of this section :

- (i) in a case where the aggregate of the sums specified in sub-section (2) includes any sum or sums of the nature specified in subclause (iiia) or in sub-clause (iiiaa) or in sub-clause (iiiab) or in subclause (iiie) or in sub-clause (iiif) or in sub-clause (iiig) or sub-clause (iiih) or sub-clause (iiiha) or sub-clause (iiihb) or sub-clause (iiihc) or sub-clause (iiihd) or sub-clause (iiihe) or in subclause (vii) of clause (a) thereof, an amount equal to the whole of the sum or, as the case may be, sums of such nature plus fifty per cent of the balance of such aggregate; and
- (ii) in any other case, an amount equal to fifty per cent, of the aggregate of the sums specified in sub-section (2),

(2)

The sums referred to in sub-section (1) shall be the following, namely :(

a) any sums paid by the assessee in the previous year as donations to

-

- (i) the National Defence Fund set up by the Central Government; or
- (ii) the Jawaharlal Nehru Memorial Fund referred to in the Deed of Declaration of Trust adopted by the National Committee at its meeting held on the 17th day of August, 1964; or
- (iii) the Prime Minister's Drought Relief Fund; or
- (iiia) the Prime Minister's National Relief Fund; or

(iiiaa) . . .

(iiiab) . . .

(iiib) . . .

(iiic) . . .

(iiid) . . .

(iiie) . . .

(iiif) . . .

(iiig) . . .

(iiih) . . .

(iiiha)3 the National Blood Transfusion Council or to any State Blood

Transfusion Council which has its sole object the control, supervision, regulation or encouragement in India of the services related

3. Added by Finance Act, 1996, w.e.f. 1.4.1997

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(a)

"National Blood Transfusion Council" means a society registered under the Societies Registration Act, 1860 (21 of 1860), and has an officer not below the rank of an Additional Secretary to the Government of India dealing with the AIDS Control Project as its Chairman, by whatever name called;

(b)

"State Blood Transfusion Council" means a society registered, in consultation with the National Blood Transfusion Council, under the Societies Registration Act, 1860 (21 of 1860), or under any law corresponding to that Act in force in any part of India and has Secretary to the Government of that State dealing with the Department of Health, as its Chairman, by whatever name called; or

(iiihb) . . .

(iiihc) . . ."

Amendment in the Drugs and Cosmetics Rules, 1948

At the same time the spread of the HIV Virus in India and the need to check it added a greater degree of urgency to the regulation and control of blood banking in the largest democracy of the world. The need for having adequately trained staff manning blood banks; the need to have adequate equipment and storage facilities; the need to ensure hygiene and high level of cleanliness; the need to eliminate the trade in human blood led the Government to amending The Drugs and Cosmetics Rules 1945, framed under the Drugs and Cosmetics Act, 1940 extensively. While Chapter X-B4 prescribing the requirements for the collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products were incorporated in the 1945 Rules in the year 1993, at a time when the Common Cause writ petition was pending in the Apex Court, the said Rules were further extensively amended in the years 1996, 1999 and 2001.

In April 1999 Part XII-B5 was added to Schedule-F appended to the 1945 Rules which prescribes the requirements to be fulfilled for the functioning and operation of a blood bank and/or for preparation of blood components. Detailed provisions have been made for the accommodation, personnel, maintenance, equipment, supplies etc. required for establishing and running a blood bank. General conditions were also prescribed providing for a person qualified for blood

4. Inserted by GSR 28(E) Dt. 22.1.1993 (w.e.f. 22.1.1993)

5. Substituted by GSR 245 Dt. 5.4.1999 (w.e.f. 5.4.1999)

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donation.

Part XII-C6 of Schedule-F to the 1945 Rules prescribes in detail the requirements before blood products can be manufactured.

Short-comings and Steps still to be taken

Though many steps have been taken to eliminate trade in human blood, many shortcomings still remain. In some parts of the country blood banks continue to clandestinely function professionally by buying and selling blood while in other parts some blood banks, even though allegedly established and run by nonprofit organizations, continue to make profit by charging huge sums of money under the garb of "testing fees". At the same time the law is totally silent regarding the punishment to be meted out to an individual caught while attempting to sell his blood. In fact frequently professional blood sellers are caught posing to be relatives of patients while in fact they have offered to part with their pint of blood for a handful of rupees. What does a law abiding blood bank do faced with such a situation ? The answer to such a problem can only be provided by legislation. It is so stated in the National Blood Policy. Paragraphs 8.7 of the National Blood Policy⁷ prescribes that the "existing provisions of the Drugs and Cosmetics Rules will be periodically reviewed to introduce stringent penalties for unauthorised/irregular practices in blood banking system."

Requests have been made in the past to the Union Law Minister and the Union Health Minister to suitably amend either the Drugs and Cosmetics Act 1940 or any other appropriate law to provide for punishment for anyone attempting to sell blood or succeeding in doing so. In fact the legal provision should provide a heavy punishment so as to operate as a deterrent in future.

Another legal issue of vital importance, which needs to be addressed is whether a voluntary blood donor should be informed about any abnormal results disclosed while testing his blood. For example if a blood donor is found to be HIV positive, under the current instructions of the Ministry of Health he is not to be informed and instead his donated blood is to be destroyed.

I strongly feel that such a policy has to be changed immediately to ensure better healthcare for the voluntary blood donors.

6. Substituted by GSR 245 (E) Dt. 5.4.1999 (w.e.f. 5.4.1999)

7. See Appendix.

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Setting-up A Blood Bank

Blood Banking in India is governed by the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1951, framed thereunder. This basic statute lays down the various conditions that a blood bank must meet and the benchmarks that it must conform to.

Part X-B1 of the Rules deals with the requirements for the collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products.

The Red Tape

In order to set up a blood bank, an application has to be made to the Licensing Authority. The licence application has to be in Form 27-C or 27-E as prescribed in Schedule 'A' to the Rules and has to be accompanied by an application fee of Rs. 6000 and an inspection fee of Rs. 1500.

The Licensing Authority has been mandated under the Rules to verify the statements made in the application, to have the manufacturing and testing establishments inspected and in cases where the application is for the renewal of an existing licence, to call for and inspect past performance records of the blood bank.

Upon its satisfaction, the Licensing Authority prepares its report which it forwards to the Central Licence Approving Authority. The Central Authority may, if it so decides, cause another inspection of the premises to be conducted and upon its satisfaction, grant the licence for the operation of the blood bank. The licence is granted for an initial period of 5 years and is renewable for similar periods subsequently.

Extensive conditions which have to be fulfilled by a licensee are also spelt out in Rule 122-P1 of the Rules.

The Personnel

Rule 122-G of the 1945 Rules and Schedule F, Parts XII-B and XII-C1 appended thereto lay down the manpower requirements for a licensed blood bank. These include at least :

1. one full time Medical Officer who possesses an MD in Pathology or Transfusion medicine, or an MBBS degree with a diploma in Pathology or

1. See appendix
Setting-up A Blood Bank

Transfusion Medicine, or an MBBS degree and a years experience in a regular blood bank

2. Blood bank technicians possessing a Degree in Medical Laboratory Technology and six months experience in blood and blood components testing or a Diploma in Medical Laboratory Technology with a years' relevant experience

3. Registered nurses

4. Technical Supervisor (same qualifications as for Blood Bank Technicians)
The number of whole time technical personnel is also subject to the requirements laid down in the Director General of Health Services' Manual

The Physical Premises

The blood bank ought to be located in a hygienic place and should be well ventilated. For the purposes of the blood bank, an area of 100 square metres has been prescribed in the Rules. Additionally, an area of 50 square metres is required for the preparation of blood components²

Equipment

The Rules also lay down the minimum requirements for equipment in a blood bank. These include ³

1. Temperature recorders
2. Refrigerated centrifuge
3. Hematocrit centrifuge
4. General Laboratory centrifuge
5. Automated blood typing
6. Haemoglobinmeter
7. Refractometer or Urinometer
8. Blood container weighing device
9. Water bath
10. Rh view box
11. Autoclave
12. Serologic rotators
13. Laboratory thermometers
14. Electronic thermometers and

2. Drugs and Cosmetic Rules 1945, Schedule F, Part XII-B-I(B)

3. Drugs and Cosmetics Rules 1945, Schedule F, Part XII-B-I(E)

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Blood agitators

Similarly, the supplies and reagents⁴ are also prescribed in the rules as well as the Good Manufacturing Practices⁵

The Rules also require that all bio-medical waste generated in a Blood Bank shall be treated, disposed off or destroyed as per the provisions of the Bio-Medical Wastes (Management and Handling) Rules, 1996.⁶

There is an acute shortage of licensed blood banks in India that conform to these regulations and which provide good quality voluntarily donated blood to the public. Various estimates, including those of the NACO, put the figure of blood collected from volunteer donors even in the larger metro cities at a mere 50% of the demand. In smaller cities and in the heartlands of the country, the figures are even more dismal.

The Blood Bank Society Chandigarh

Chapter 4

The Blood Bank Society Chandigarh

The Blood Bank Society Chandigarh was established in the year 1963 at the behest of Dr. J.G.Jolly, the then Head of the Blood Transfusion Department at PGI, Chandigarh and Mrs. Kanta Saroop Krishen, who has served as its Honorary Secretary for the last 38 years. The Members of the Society consist of voluntary workers, united by their zeal to serve the community and provide safe blood to patients.

The Society has been run on purely voluntary, non-remunerative basis by its members for nearly four decades and has rendered yeoman service in the field of voluntary blood donation. Not only has it ensured that no professional blood bank comes up in Chandigarh or its vicinity but it has motivated hundreds of thousands of individuals to donate blood to further spread the message of safe blood. So much so that it has encouraged individuals and organizations to set-up voluntary blood banks all over the country.

The Blood Bank Society Chandigarh, especially its two members Mrs. Kanta Saroop Krishen and Dr. Manmohan Kaur, had provided all the inputs to Mr. H.D. Shourie, Director, Common Cause for filing a writ petition¹ in public interest in the Supreme Court which in turn led to extensive directions being issued by the Apex Court which has totally changed the future of the voluntary blood donation movement in the country.

Milestones and Achievements

The Blood Bank Society Chandigarh has succeeded in meeting the blood requirements of the hospitals in Chandigarh and around exclusively from voluntary blood sources.

It has produced extensive publishable material in the field of motivation for encouraging persons to donate blood voluntarily. The programme devised especially to educate school and college children about the harmlessness and usefulness of donating blood has proved to be exceptionally successful.

The voluntary work done by Mrs.Kanta Saroop Krishen in the field of voluntary blood donation led to the Government of India conferring on her the prestigious Padam Shree Award.

4. Drugs and Cosmetics Rules 1945, Schedule F, Part XII-B—I(F)

5 . Drugs and Cosmetic Rules 1945, Schedule F, Part XII-B—I(G)

6. See Appendix 1. AIR 1996 Supreme Court 929 : See Appendix

The Blood Bankers' Legal Handbook The Rotary Blood Bank Society Resource Centre at Chandigarh

The Blood Bankers' Legal Handbook The Rotary Blood Bank Society Resource Centre at Chandigarh

The Blood Bank Society at the moment is busy in setting-up a Blood Resource Centre at Chandigarh jointly with the Rotary Foundation of Rotary International at an outlay of about Rs. 5 crores. (Rs 50 million). The idea of the proposed centre came from Mr.Sudhir Bhagwan, a Non-Resident Indian (NRI) and brother of Mrs. Kanta Saroop Krishen who has donated Rs.50 lakhs towards (US \$ 100,000/-) the project. The Rotary Club of Chandigarh joined hands with the Blood Bank Society to provide machinery and equipment worth nearly Rs.2 crores. The Resource Centre is at an advanced stage of completion and should be functional by the mid of 2003.

The Rotary and Blood Bank Society Resource Centre shall provide not only blood and its various components throughout North India but shall also train personnel in the field of blood banking and produce motivational material to educate the masses and spread the message of safe blood. Its objective is to provide State of the Art Blood Banking facilities of International standard in India. The Centre shall also educate the people to prevent the spread of AIDS throughout the country.

Donations to the Blood Bank Society, P.G.I., Chandigarh

All donations to the Blood Bank Society are eligible for Income Tax relief under section 80G of the Income Tax Act, 1961. Donations can also be made by Electronic Funds Transfer. The relevant bank details are as under....

Name and address of Bank State Bank of India, Medical Institute
Branch Sector 12, Chandigarh
Branch Number 1524
Account Name Blood Bank Society, PGI Chandigarh
SWIFT Details: SBI NIN BBA 141
Blood Bank Society Account
No. 01100065017 with State Bank of India
Medical Institute Branch No. 1524
Sector 12, Chandigarh, India

Donation to the Blood Bank Society can also be made in foreign currencies as it is registered under the Foreign Contribution (Regulations) Act, 1976 Vide FCRA No. 291420026

Resource Centre at Chandigarh

Saying Yes comes naturally to some, whether it is to new ideas or to a better way of doing something. That is how it began.

An NRI, Mr. Sudhir Bhagwan, inspired by the desire to do something for the city he grew up in, offered Rs. 50 Lakhs to the Blood Bank Society, Chandigarh to perpetuate the memory of his father, Mr. Vishan Bhagwan.

The Blood Bank Society, Chandigarh pondered whether to accept the challenge, to explore uncharted territory. The decision to create something better than what existed did not take long and thus was sown the idea of starting a Blood Center that would operate blood service oriented to the convenience and need of the public.

A daunting challenge faced the Society. A project as large as this had never been undertaken by a group of volunteer housewives. At the same time, a history of 38 years had been an eye opener in the matter of realizing the hardships the people faced in obtaining or even donating blood.

Data indicates that most of the blood donors are male who are generally working people. Their preference is to donate either before or after working hours or during lunch break. And that is precisely what they cannot do because the blood banks are not open.

Under the table deals prevail too and so does the indifferent, sometimes even callous attitude of the staff.

Half a crore was a magnificent gift indeed, but not adequate enough to set up an institution the Society had envisaged.

Efforts thus got underway to arrange for land, building, transfusion related equipment etc. The highest UT authorities at that time offered whole hearted support saying that "The Blood Bank Society was taking upon itself a service which government should be extending to the public."

A prime location plot of land was earmarked and given at a concessional rate. Construction cost would be met by the NRI's gift. A gold medal winning architect drew the plans and Fortis hospital authorities recommended their building contractor who would construct at a special rate under the supervision of the Fortis team.

Luck was with us when the Rotary Club Chandigarh agreed to be a partner and Mr. RK Saboo, former president, Rotary International took up the matter with

the Rotary Foundation and got their sanction to provide equipment worth Rs. 1.90

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The Blood Bankers' Legal Handbook Appendix 1—Glossary

The Blood Bankers' Legal Handbook Appendix 1—Glossary

Blood Bank Society members and blood donors set off on a campaign to tap their sources for donations in cash or kind. Credibility of the society and the Rotary built over decades brought forth a generous response. The result: a 12,000 square feet building was up in nine months; the medical director identified and the formal inauguration fixed for mid 2003.

What we aim at now is to have adequate resources available to meet the blood needs of those who cannot afford the testing and service charges. Friends and well wishers could contribute to build a Blood For All fund for the thousands who could be saved.

Appendix 1

Glossary

Act, The The Drugs and Cosmetics Act 1940 (as amended)
AIR All India Reporter (A legal journal)
Apex Court The Supreme Court of India
BTS Blood Transfusion Service
Common Cause An NGO headed by Mr. HD Shourie
Constitution The Constitution of India
Crore Ten millions (1,00,00,000)
Guidelines, The The National Guidelines for the Appropriate Uses of Blood,
published by the National Aids Control Organization
FORTIS The Ranbaxy Group's Speciality hospital located in Mohali,
Near Chandigarh.
HIV Human Immunodeficiency Virus
ISBTI Indian Society of Blood Transfusion and
Immunohaematology
Lakh One hundred thousand (1,00,000)
NACO National Aids Control Organization, Ministry of Health
and Family Welfare, India
NBTC National Blood Transfusion Council
NRI Non Resident Indian
NGO Non Governmental Organization
PIL A Public Interest Litigation filed under the provisions of the
constitution of India
PGI The Postgraduate Institute of Medical Education and
Research, Chandigarh
Phlebotomy The practice (now deprecated) of bleeding a patient in the
belief that it would drain him of bad humors and cure him
Rotary The Rotary Club; also Rotary International; also Rotary

Foundation

Rules, The The Drugs and Cosmetics Rules 1945 framed under the
Drugs and Cosmetics Act, 1940
SBTC State Blood Transfusion Council
Supreme Court The Supreme Court of India

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NACO Guidelines For Blood Storage Centres¹

Background

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To achieve the objective of providing safe & quality blood to all in need wherever and whenever required, it was felt necessary to establish storage centres which can receive tested and processed blood and blood components from authorised centres. This facility can be used for patients in the hospitals in the area where storage centre is located. The need for establishing such centres were:

I

Many doctors working in the first referral units and other hospitals in the rural areas, especially those working in the vicinity of highways, constantly complained of unavailability of blood.

I

In large cities and towns the number of blood banks have been increasing, as all hospitals small and big were required to establish their own blood banks. This has resulted in unnecessary proliferation of blood banks.

I For supplying blood to many private nursing homes, small private blood banks have mushroomed.

I For proper regulation of the system and to maintain quality, it is necessary to reduce the number of blood banks.

Location

I The storage centre can be established at any hospital, government or private. It may be in a rural or urban area.

I

Any blood bank presently collecting up to 2000 units of blood annually can be converted into a storage centre provided it can get affiliated to a larger blood bank for regular supply of blood.

I

The storage centre can get affiliated to any government or regional blood bank, which is approved by State Blood Transfusion Council (SBTC) and

licensed for the purpose. Private or commercial blood banks should not be given permission to supply blood to storage centres by the SBTC.

Requirements

I

The area required is only 10 sq.mts. well lighted, clean and preferably air-conditioned and should have equipments for storage as prescribed by Drugs & Cosmetics Rules.

1. See <http://naco.nic.in/vsnaco/nacp/bs.htm>

Appendix 2—NACO Guidelines For Blood Storage Centres

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The storage centre should have following equipment:

1. Blood bank refrigerator
2. Insulated boxes for transport of blood.
3. Microscope
4. Centrifuge
5. Incubator
6. Pipettes
7. Glassware

I The storage centre should have adequate provision for blood grouping reagents.

I The centre will have to maintain records for procurement, cross-matching and issue of blood and blood components and archive these for at least 5 years.

I The licence issued to the storage centre will require renewal every 2 years. In case if the licence of the affiliated parent centre is cancelled the licence of the storage centre will also be automatically cancelled.

I The storage centre can procure blood or components from more than one blood bank to ensure availability but an approval will be required for each case from SBTC and Drug Controller.

I The storage centre will adhere to biosafety guidelines.

Staff

I The staff i.e. M.O and technician are not required to be full time employees for the storage centre. They may have other duties in the hospital.

I The staff should preferably undergo an orientation training of approximately 1 week at the regional centre to which the storage centre is affiliated.

I The storage centre should work round the clock.

Storage

I

It is necessary to maintain the cold chain at all times during transport, storage and issue. Proper insulated carry boxes should be used during transportation of blood.

I The ice in use should be clean and should not come in direct contact with blood bags.

I Whole Blood and Packed Cells should be kept in blood bank refrigerator at $4 - 6^{\circ}\text{C} \pm 2$ up to 35 days. Red cells in additive solutions can be stored up

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Issue of Blood/Blood Component:

- | Blood may be issued to any hospital in the area against the prescription of a registered medical practitioner.
- | Patient's blood grouping and cross-matching should be carried out before issue

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First in first out (FIFO) policy where by older blood closer to expiry date is used first, should be followed. Unused blood should be sent back to the regional centre after its expiry date.

Blood Grouping

- | ABO/Rh grouping should be done by tube technique
- | Cell and serum grouping should be done and crosschecked.
- | Blood grouping reagents in use should be approved by regional centre and should undergo Quality Control test on receipt and daily.

Cell Grouping

- | Add 1 drop of Anti-A, Anti-B, Anti AB and Anti - D in 4 different tubes.
- | Add 1 drop of 2-5% cell suspension of patient's blood in each tube.

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- | Mix the contents and incubate at room temperature for 15 minutes
- | Centrifuge at 1000 rpm for 1 minute
- | Look for agglutination and record. All the negative results should be con

firmed under microscope.

Serum Grouping:

- | Add 2 drops of patient's serum in each of the 4 different tubes.
 - | Add 1 drop of 2% pooled A cells in first tube.
 - | Add 1 drop of 2% pooled B cells in second tube.
 - | Add 1 drop of 2% pooled O cells in third tube.
 - | Add 1 drop of 22% albumin and O cells in fourth tube.
- | Incubate first 3 tubes at room temperature for 15 minutes.
 - | Incubate fourth tube at 37°C for 30 minutes.
 - | Centrifuge at 1000 rpm for 1 minute
 - | Look for agglutination and record.

- | Proceed by washing cells in the 4th tube 3 times with saline and add 2 drops of AHG
- | Incubate for 15 minutes at room temperature.
- | Centrifuge, read and record.
- | While carrying out grouping always record results before documenting interpretations.
- | If there is discrepancy between cell and serum grouping, repeat the test.

Cross-Matching

- | For cross-matching routinely use saline and albumin or enzyme method.
- When a patient requires regular or massive transfusion use IAT method.

Saline Method

- | Add 2 drops patient's serum in a test tube.
- |
- Add 1 drop 5% donor's cells in the same tube.
- |
- Mix, incubate at room temperature for 15 minutes.
- |
- Centrifuge, read and record.

Albumin/Enzyme method

- |
- Add 2 drops patient's serum.
- |
- Add 2 drops 22% bovine albumin or 1 drop papain crysteine.
- |
- Add 1 drop 5% donor's red cells.

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Incubate at 37°C for 15 minutes.

|

Centrifuge, read and record.

IAT method

| Add 2 drops patient's serum.

| Add 1 drop 5% donor's red cells.

| Add 2 drops 22% bovine albumin.

| Incubate at 37°C for 15 minutes.

| Wash cells with isotonic saline three times.

| Decant after last wash

| Add 2 drops AHG

| Mix well, centrifuge

| Read and record.

Points to Remember:

| All tests performed should be recorded and signed by technician.

| Medical officer should supervise the technician's work of grouping, cross-matching and storage.

|

Samples of patients and donors should be stored for 7 days after issue but when transfusion is required 48 hours after one transfusion, fresh sample should be asked for cross-matching.

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Standard Operating Procedures (SOP) for storage, transport, issue, equipment maintenance, grouping and cross-matching should be written and made available for use.

|

The storage centres should maintain adequate stocks of colloids and crystalloids for initial volume replacement in emergency.

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Medical officer will be responsible for the overall working of the storage centre and hence he/she should ensure that the work is carried out systematically to avoid any errors leading to adverse transfusion reactions.

Appendix 3
National Guidelines
For Appropriate Use Of Blood¹

The guidelines are adapted from the following WHO documents on
Global Blood Safety Initiative:

- A. Guidelines
for appropriate use of blood WHO/GPNINF/89.8
WHO/LAB/89.10 Geneva 2-5 May, 1989
- B. Use of plasma substitutes and plasma in developing countries
WHO/GPA/INF/89.17 WHO/LAB/89.9 Geneva 20-22 March, 1989
- C. Autologous transfusion in developing countries WHO/GPNINF/91.1
WHO/LBS/91.2 Geneva December, 1990
- D. Guidelines for treatment of acute blood loss WHO/GPN INF/88.5 ,
Recommendations emerging out of the following National
W o r k s h o p s /
Meetings/Symposia have also been incorporated:

- A. Workshop on "Optimising the use of blood" held at Madras, 6th December,
1994
- B. Regional workshop under IND/CLR 001/ on preparing guidelines for rational
use of blood held at Bhopal 4th April, 1995.
- C. Meeting organised by the Government of India, Ministry of Health and
Family Welfare, held at the NACO Office, Delhi ,19th February,1996.
Glossary of terms and abbreviations used in this document
 - | Blood: Whole blood or red cell concentrate
 - | Packed red cell: Red cell concentrate
 - | Platelet transfusion: Platelet concentrate or platelet rich plasma (PRP)
 - | Leukocyte concentrate: Granulocyte concentrate
 - | Blood components: Packed red cells, Fresh plasma, Fresh frozen plasma,
LiquidPlasma, Cryoprecipitate, Cryo-poor plasma.

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Fresh frozen plasma: Plasma derived from whole blood within 6 hours of
collection from the donor and frozen immediately at -30°C or lower temperatures.

|
Liquid plasma: Plasma recovered from whole blood stored at 2-6°C for

1. See <http://www.naco.nic.in/nacp/blood.htm>

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been removed and plasma has been re-frozen.

I PRP: Platelet rich plasma

I FFP: Fresh frozen plasma

I DDAVP: Desmopressin (1,8-desamino-D-arginine vasopressin)

I ABT: Autologous blood transfusion

I PABD: Preoperative autologous blood donation

I AIVH: Acute isovolaemic haemodilution

I Hb/Hct: Haemoglobin concentration/Haematocrit

I DIC: Disseminated intravascular coagulation

I PPF: Purified protein fraction

I HES: Hydroxy ethyl starch

CHAPTER - 1

INTRODUCTION

1.

Blood transfusion has undoubted benefits. But it also carries serious risks including the possibility of transmission of infectious agents such as human immunodeficiency virus (HIV) and hepatitis viruses (HBV, HCV and others), Immune related problems (e.g. Intravascular haemolysis) and circulatory overload. Moreover, it is expensive and uses a scarce human resource.

2 Existing Situation and Remedial Measures

2.1 Several deficiencies exist in the blood transfusion centres across the country.

Consequently , the practice of transfusion medicine remains generally unsatisfactory.

2.2 There is marked shortage of space, equipment, reagents and trained manpower in majority of the transfusion centres.

2.3 There is a considerable shortage of blood even in the large metropolises: the supply is 50% or less of its requirement. The situation is worse with regard to the availability of blood components and plasma products. With increasing sophistication in practice of medicine and with introduction of tis-

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sue/organ transplantation, the need of blood and its products has increased still further.

2.4 There is a marked inadequacy of trained medical officers and technicians.

Most transfusion centres are under the charge of general medical officers or physicians from other specialties. They generally have little interest in the discipline of transfusion medicine and often lack knowledge of modern blood bank practices. Postgraduate courses in Transfusion Medicine should be started to reduce shortages of transfusion specialists. Introduction of cadre for the specialists will make the discipline attractive.

2.5 Except for a few large cities the blood donors are either professional donors or replacement donors. The voluntary donor base is small and even in metropolitan cities only about 30% units of blood are obtained from voluntary donations . Professional donors generally practice high-risk behaviour and have a greater likelihood of carrying transfusion - transmitted infections. Replacement donors are under social pressure from their friends and relatives and may hide their high-risk behaviour if any. There is an urgent need to increase voluntary donations. It would significantly improve the quality of blood.

2.6

There is lack of quality assurance in the techniques used for screening of blood for infectious agents, basic serology and component preparation. Blood is routinely screened for HIV and antibodies and HBs Ag. Some studies from India suggest relatively high prevalence of hepatitis C infection. It seems appropriate that whenever possible blood should be screened for this also.

3. Blood Transfusion Practices

3.1 Blood used for transfusion should be obtained from appropriately selected donors and appropriately screened for infectious agents.

3.2 The involvement of officer incharge of transfusion service is generally restricted to procurement and supply of blood. The attending physicians rarely , if at all, consult them to decide on the use of blood/components/products. The motivation and interest of the transfusion specialist will improve if they are involved in patient care. It is accepted that the primary responsibility for the decision to transfuse blood/component/product is that of the treating physician. It is highly desirable that the decision is made in consultation with the transfusion specialist.

3.3. The treating physician should seek advice of the transfusion specialist in choice of blood /components for patients with non-haemolytic febrile transfusion reactions (NHFT), autoimmune haemolytic anaemia, cold agglu24

3.4

Many transfusion officers and the treating physicians are not sensitized to the risks of blood Transfusion. Often the indications of transfusing whole blood , blood components, blood products or the plasma substitutes are not appreciated. Not infrequently whole blood is transfused instead of a more effective component.

Blood is also used despite the availability of safer alternative therapy such as administration of specific "haematinic" to correct nutritional anaemia. Most requests are for a single unit of blood which rarely, if at all , is of any benefit to the recipient and carries all the risks associated with blood transfusion. The use of single unit of blood should be strongly discouraged.

Use of whole blood should be discouraged. Facilities to prepare blood components should be made available in larger number of hospitals (see Chapter 4) Administration of components is safer, more effective and is a better utilization of a scarce human resource.

3.5 During undergraduate teaching there should be greater emphasis on risks and indications for transfusions and on alternative therapeutic approaches.

3.6 Compatibility testing must be carried out on all whole blood and red cell transfusions. In life-threatening emergencies ABO-compatible uncross-matched blood may be issued. Crossmatching, however, should proceed simultaneously and , if incompatibility is detected further transfusion of that unit of blood should be stopped immediately.

4. Hospital Transfusion Committee

4.1 It is almost imperative for each Hospital to formulate Hospital Transfusion Committee (HTC) consisting of blood users (such as representatives from surgical disciplines, internists, haematologists and anaesthesiologists), representatives from administration and nursing staff and blood transfusion specialist. The Committee may be headed by a senior doctor, preferably a clinician, with the transfusion specialist as the Member Secretary.

4.2 The Committee should meet once a month . The main functions of the Committee are as follows:

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4.2.1 Formulating policies with regard to use of blood, blood products and components,

4.2.2 Developing guidelines for use of blood substitutes,

4.2.3 Establishing Maximum Blood Ordering Schedules (MBOS) for surgical procedures. These should be written precisely giving definite

guidelines for most of the situations,

4.2.4 Monitoring source and supply of blood components,

4.2.5 Monitoring adverse effects of blood transfusion,

4.2.6 Auditing blood transfusion practices, reaction, quantity of blood/blood products used, quantity ordered and not used.

5. The level to which a transfusion centre should develop depends upon the nature and need of the the medical facility it is expected to serve. In general, however, the centres should try to attain the following level of development:

5.1

The service collecting 2,000 to 5,000 units of blood per year or a General Hospital up to 500 beds should have facilities for making packed red cells and plasma in a closed system.

5.2 Transfusion centre collecting 5,000 to 10,000 units of blood per year or a teaching hospital or a hospital with over 500 beds should have facilities to make packed red cells, plasma, FTP, cryoprecipitates and platelets..

5.3 The service collecting over 10,000 units per year or a superspeciality hospital should in addition to above have facilities for apheresis

5.4 The transfusion centres should aim at making components from above 80% of units collected.

CHAPTER 2

RED CELL TRANSFUSION

1 Introduction

In this chapter the clinical situation in which the primary objective is to improve oxygen delivery are discussed. Acute blood loss is discussed in chapter 3 and blood component therapy including haemostasis in chapter 4.

2. Surgery

2.1 Anaemic Patients: It is generally believed that patients should not undergo anaesthesia or surgery with Hb concentrations of less than 10 g/dl. There is evidence to indicate that this transfusion trigger value is too high and most patients without evidence of cardiac decompensation can withstand

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anaesthesia and surgery with Hb value of as low as 7.0 g/dl. The decision to transfuse prior to anaesthesia on surgery, however, depends on the rate of development of anaemia and patient's general condition, type of surgery and not solely on an arbitrarily defined Hb concentration or haematocrit value.

2.2 Amount of blood reserved: The amount of blood reserved for patients undergoing surgical operations varies with the type and complexity of the procedure. It should be determined by a careful audit of local surgical practice and maximum surgical blood ordering schedule (MSBOS).

3 Anaemia

3.1

Measures to prevent nutritional anaemia have been introduced by the Government of India under National Nutritional Anaemia Control Programme. Iron and folic acid are administered prophylactically to certain population groups including pregnant women and children. Patients with chronic haemolytic anaemia require prophylactic administration of folic acid. Nutritional anaemias respond readily to appropriate haematinics. It is always important, in addition, to treat or correct the underlying cause of the anaemia. Most patients with anaemia of chronic renal failure respond to erythropoietin administration.

3.2 Red cell transfusion is necessary only if anaemia is associated with incipient or established cardiac failure. Transfusion of whole blood may cause circulatory overload in these patients. The risk is reduced with transfusion of red cell concentrates (administered at a rate not more than 1 ml/kg/hr) and concomitant diuretic therapy. Most patients with chronic anaemia without cardiac decompensation and Hb value of more than 6 g/dl do not need blood/red cell transfusion and should be managed with alternative specific therapy.

3.3

Anaemia due to infections (e.g. malaria, hookworm, tuberculosis) usually responds to treatment of the underlying infection and by supplementing the haematinic, where appropriate. Red cell transfusion is not usually required.

4 Hereditary Haemolytic Anaemias

4.1 Blood Transfusion is not required for the management of patients with hereditary haemolytic anaemias in a steady state.

4.1.1 Red cell transfusion is indicated in patients:

1. With severe anaemia and incipient or established cardiac failure;

2. With sickle cell anaemia in sequestration crisis with rapidly falling haemoglobin concentration;

3. Whom delivery is imminent and whose Hb is less than 8 g/dl;

4. Who have acute haemorrhage, but whose blood pressure and oxygenation are not maintained by plasma substitutes.

4.2 Thalassaemic Syndromes

4.2.1 Patients with beta- thalassaemia major are transfusion dependent.

The type of red cell preparation, the frequency of transfusion and the method used to prevent iron overload should be decided, taking into account the available resources. Packed red cells are preferred to whole blood. Pre-transfusion haemoglobin level should be maintained at 10 g/dl or higher.

4.2.2 Splenic artery embolisation or splenectomy may be necessary for patients with hypersplenism

4.2.3 Some thalassaemia intermedia patients who develop splenomegaly and hypersplenism need splenic artery embolisation or splenectomy.

They do not need regular transfusions to sustain life. The indication for red cell transfusion in them are the same as outlined in section 4.1.

5. Neonatal Period

5.1 Blood transfusion requirements for neonates can be reduced by:

1. Providing adequate antenatal care;

2. Training health care personnel in the techniques of safe delivery;

3. Encouraging breast-feeding ;

4. Providing vitamin K prophylaxis for all new borns;

5. Providing phototherapy facilities at maternity units for the treatment of neonatal hyperbilirubinaemia;

6. Introducing laboratory microtechniques to reduce the amount of blood lost through frequent sampling.

5.2

The main indication for cell transfusion are severe neonatal anaemia and/or jaundice due to :

1. Acute haemorrhage;

2. Alloimmunisation (e.g ABO or Rh (D) haemolytic disease of the new born);

3. Septicaemia;

4. Prematurity;

5. G6PD Deficiency.

Preparation of several paediatric bags from single blood units should be encouraged . These can be produced in a closed system by collecting blood in multiple bags and transferring the portions of blood into satellite bags. Sometimes blood is collected in a single bag and transferred to smaller bags by sterile connection devices. Alternatively blood may be directly collected into 100 ml paediatric collection bags. The use of blood from a single donation for repeated transfusion to the same patient increases safety by reducing multiple donor exposure. This also improves the efficient use of blood donations.

6. Pregnancy

Red cell transfusion is indicated for management of severe anaemia associated with incipient or established cardiac failure. It may be necessary in the management of obstetric haemorrhage or for a patient approaching delivery with Hb less than 7 g/dl.

CHAPTER 3

APPROPRIATE USE OF PLASMA SUBSTITUTES, PLASMA AND WHOLE BLOOD IN MANAGEMENT OF ACUTE BLOOD LOSS

1. Introduction

The risks of transfusion and shortages of blood components have been dealt with in chapter 1. The same apply to their use in management of acute blood loss (haemorrhage) as well. In patients with haemorrhage the physicians often transfuse blood, where it may not be required or where it is given in excess of requirement . Physicians, must ensure that the transfusion is clearly indicated and that the benefits outweigh its risks. They should try to reduce blood transfusion and use alternative methods wherever possible.

Blood transfusion should not be the first consideration for patients with acute haemorrhage. Blood volume replacement is initially more urgent than red cell replacement.

Accurate diagnosis, adequate oxygenation and volume replacement with plasma substitutes (crystalloids and colloids), and prompt and meticulous surgical care, may obviate the need for blood transfusion.

2. General Principles of Management of Acute Blood Loss

2.1 Effects of blood loss are determined not only by its amount as a proportion of the patient's blood volume but also by the patient's clinical state i.e. age, Appendix 3—National Guidelines For Appropriate use of Blood

extent of trauma, pre-existing disease, blood pressure, pulse rate, central venous pressure and urine flow . The administration of plasma substitutes is often preferred to transfusion of blood or plasma as these are readily available and do not carry the risks associated with use of whole blood and plasma. In addition , blood is rarely necessary in the initial stages of treatment of hypovolaemia.

2.2

Generally, a previously healthy adult can tolerate a loss upto 20% of the circulating blood volume without transfusion. Volume replacement with plasma substitutes will be necessary for a loss between 20% to 30%.

Blood transfusion is required , in addition , when the loss exceeds 30% , particularly in patients with massive haemorrhage (more than 50% of blood lost in less than three hours). As indicated before, the determinant of treatment however, is the clinical state of the patient.

3. Transfusion Options

3.1 Plasma

Plasma, if at all, should rarely be used to correct hypovolaemia. Despite its physiologic property of maintaining oncotic pressure, it is not the first choice for correction of hypovolaemia, due to the risk of transmitting infections. Crystalloids, synthetic colloids, or albumin or PPF are safer and preferable.

The major therapeutic value of plasma is in its haemostatic properties. When albumin or PPF are not available cryosupernatant or FFP may be used in the management of hypovolaemia.

3.2 Crystalloids

Crystalloids (e.g. physiological saline, Ringer's lactate) can effectively correct hypovolaemia even in massive injuries. The crystalloids rapidly diffuse into the interstitial fluid space. Therefore, the volume administered is about three times the estimated blood loss. As part of the administered load is excreted in urine, the duration of their effect depends on the rate of urinary output. Additional crystalloid solutions may be required within a few hours.

3.2.1 Side effects

A fraction of the infused crystalloids passes into the interstitial space and may cause tissue oedema. Transient tissue oedema is acceptable except possibly in high-risk patients, e.g. , with severe anaemia or cardiopulmonary dysfunction. Even large volumes of crystalloids used for resuscitation seldom produce pulmonary oedema in the absence of heart

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failure.

3.3 Synthetic Colloids

3.3.1 General

Colloid solutions exert an oncotic pressure because of the macromolecules they contain; this retains water and thus volume in the circulation.

The oncotic pressure increases with the number of molecules and with the concentration of colloid. The size of molecules is also important, because larger molecules leave the circulation more slowly.

Dextran 70, hydroxyethyl colloids and gelatine solutions (e.g. succinylat

ed gelatine and urealinked gelatine) are commonly used synthetic colloids.

Dextran and HES (6% and 10%) are true plasma expanders, i.e. the intravascular volume effect exceeds the infused volume by withdrawing fluid from the extravascular space, which becomes dehydrated.

The gelatins have no expanding effect because of their relatively low concentration, and because some of their smaller molecules escape rapidly from the circulation. The initial intravascular volume effect is roughly equal to the infused volume.

The volume effect of dextran 70 and HES is more prolonged than that of the gelatins. Gelatins act as osmotic diuretics because they pass rapidly into the extravascular space and through the kidneys into the urine. Therefore, when they are administered, one or two litres of supplementary crystalloid solutions should be given in addition to the daily metabolic requirement. Alternatively, the urine output should be measured and the excess replaced, preferably by fluids given orally.

The colloids (hydroxyl-ethyl-starch, dextran or gelation) are retained within the circulation for longer periods (4-8 hours). They are potentially life-saving, the user must therefore be familiar with their use in patients with acute protein depletion (e.g. burns).

3.3.3

Side effects

Synthetic colloids may cause circulatory overload but this risk is smallest with the gelatins. Anaphylactoid reactions have been described in association with all synthetic colloids, varying from cutaneous rashes to lethal shock. The total incidence varies between 0.07% and 0.25%, depending upon the colloid used but the incidence of severe reactions is

less than 0.02%. Severe reactions usually occur shortly after the start of the infusion. Close observation of the patient and meticulous monitoring of the vital signs are therefore particularly important during this period. Facilities must be readily available for prompt resuscitation of patients with anaphylactic shock.

Synthetic colloids may cause red cell aggregation but this is not a significant problem with the products currently available, particularly if a blood sample for cross-matching is obtained before these are transfused.

Dextran 70 interferes with platelet and factor VIII function. This may cause abnormal bleeding if more than 1000-1500 ml are given to an adult within 24 hours. It is contraindicated in patients with pre-existing haemostatic abnormalities.

HES also interferes with haemostatic mechanism though less so than dextran. There is concern about prolonged tissue storage of the high molecular weight fractions and its possible longterm effect. After a single infusion of 450ml of HES in man, small quantities of the material are still demonstrable in the circulation after one and a half months and repeated administration has a cumulative effect.

The gelatins do not show clinically relevant interference with haemostasis and even severe thrombocytopenia is not a contraindication to their use.

4. Albumin and Plasma Protein Fraction (PPF)

4.1

Albumin Versus Synthetic Colloids

There is a fundamental difference between albumin and synthetic colloids. Molecular weight of albumin is 6600 daltons. It accounts for two-thirds of the normal oncotic pressure of 26-28 mm Hg. It is a "monodisperse" colloid: i.e. all albumin molecules have the same size and weight. By contrast, the synthetic colloids are "polydisperse", that is, mixtures of various molecular fractions with substantially different sizes and weights. They are therefore characterised by average molecular weight.

4.2 The concentration of albumin in albumin solutions and PPF preparations varies between 50 and 250 g/l. Depending on the clinical state, the albumin infused has a physiological half-life of approximately 18 days. These preparations do not contain any coagulation factors. They are pasteurized to inactivate human immunodeficiency virus (HIV), and the hepatitis and other viruses. Albumin preparations are more stable and produce fewer adverse reactions than PPF but are more expensive. Production of albumin

and PPF requires complex manufacturing techniques with rigid quality control.

4.2.1 Side effects

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Hypotension due to vasoactive kinin and knininogen may occur during rapid infusions of PPF. Anaphylactoid reactions occur with both types of preparation but are less frequent than with the synthetic colloids.

5. Practical Guidelines for Management of Haemorrhage

- 5.1 Prompt control of external haemorrhage and urgent restoration of blood volume are the most important steps to be taken.
- 5.2 Oral rehydration with salt solution (sodium chloride 3.5g, sodium bicarbonate 2.5g, potassium chloride 1.5g and glucose 20g dissolved in one litre of potable water) may be started immediately provided there is no suspicion of a gastrointestinal lesion and surgery is not imminent.
- 5.3 An intravenous infusion should be started if the pulse rate exceeds 100 per minute in an adult (modified according to age for paediatric patients) and/or the systolic blood pressure is less than 90 mm Hg.
- 5.4 Depending on the amount of blood loss, initial pulse and blood pressure and the patient's response, treatment should begin with 1000-2000 ml of crystalloids e.g., physiological (0.156 mol/l) saline or Ringers's lactate. This is infused intravenously within 15-30 minutes, or until the pulse is less than 100 per minute. The urinary output should reach at least 30ml per hour. The rate of the infusion is adjusted to maintain these levels.

5.5

If circulatory stability is not achieved by 2000 ml of crystalloids (or proportionately less in children), the patient should be transferred as soon as possible to a treatment centre where blood is available and haemorrhage can be controlled. If this is not immediately possible it is preferable to continue with 500-1000 ml of synthetic colloid. If colloids are not available, proceed with crystalloids up to 7000 to 8000 ml within 24 hours provided that the renal output remains satisfactory.

- 5.6 The adequacy of treatment is assessed by serially monitoring skin temperature, urinary output, venous filling, blood pressure and pulse.
- 5.7 If internal haemorrhage is suspected, and in order to minimize reactivation of bleeding, the systolic blood pressure should not be raised above 90 mm Hg. Such patients are rapidly transferred to an institution with appropriate treatment facilities.

5.8

It is important that records of the clinical condition and all treatment given
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be kept and that they accompany the patient on transfer to another treatment facility.

5.9

Notes

(i)

The volumes given above are suitable for adults. Children less than two years old should not receive more than 30 ml /kg physiological saline within six hours because of the danger of precipitating congestive cardiac failure.

(ii)

Ringer's lactate and some gelatins contain calcium ions and may therefore induce clotting in the administration set when blood is administered subsequently through the same set. Intravenous infusion sets and lines must first be flushed out with physiological saline or, preferably, blood or plasma should be transfused through a different set.

(iii)

Gelatin is usually given in doses of up to 50 ml/kg within 24 hours but up to 5 litres may be given in 24 hours if urinary output is satisfactory. Doses of dextran 70 Or HES should not exceed 20 ml/kg per 24 hours.

(iv)

The rate of infusion of albumin (50g/l) and of PPF varies with the clinical situation. Fast rates may be necessary to maintain adequate tissue perfusion. Occasionally PPF may cause hypotension. The patient must be monitored closely and another plasma substitute should be used if this occurs.

(v)

Solutions containing dextrose should not be mixed with blood in the same administration set as they cause haemolysis.

7. Training of Personnel

Personnel who will use plasma substitutes in the absence of a physician should be trained in at least the following areas:

1. Prompt control of external bleeding.
2. Assessing skin temperature and measuring the pulse rate and systolic blood pressure.
3. Recognition of the clinical signs of hypovolaemia and of the features of impending and manifest shock,
4. Record-keeping including charting input (type, quality and time of infused fluids) and urinary output (volume and time of voiding),
5. Preparing and starting an intravenous infusion,
6. Ability to administer recommended doses,
7. Recognition of signs of circulatory overload and of other reactions attributable to the infusion(s),

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of signs of contamination of intravenous fluids and ability to commence
corrective action immediately,
9. Recognition of the need for a patient to be transferred to specialized treatment
facility and organization of transport for this purpose.
Ideally, this training should be included in the general curriculum of paramedical
health personnel.

8. Supply of Plasma Substitutes

8.1 Crystalloids

Physiological saline is stable at ambient temperature for more than one year
and is cheaper than the synthetic colloids. There are few risks associated
with its administration (see section 3.2.1). Physiological saline should
therefore be available at all levels of the health services. Treatment can be
started at this level and the patient may be transferred for further management
(e.g. to a district hospital) if necessary. Other crystalloids (e.g.
Ringer's lactate) may be used instead of physiological saline.

8.2 Synthetic Colloids

Apart from HES which is apparently stable at ambient temperature above
35° C,
They are sensitive to temperature above 30°C. Degradation into smaller
molecules begins after one month's storage above 40°C and is very marked
after five or six months . They should preferably be stored below 20°C.
Treatment with synthetic colloids costs two or three times that of treatment
with equivalent amounts of crystalloids. Moreover, a higher level of training
is required for people who will administer them because of the risks associated
with their use (see Section 3.3.3)

Since synthetic colloids are useful for managing some patients with haemorrhage
(see Section 5.5), they should be available at district hospitals
where a doctor will supervise their use and treat complications if necessary.
Larger stocks would be required in intermediate and tertiary referral hospitals.
Despite their cost, synthetic colloids are useful and safe alternatives to
blood transfusion.

8.3 Albumin and PPF

These can be produced only in fractionation plants. They are stable for several
years at refrigeration temperature and for three years at temperature
below 30°C Apart from the hypotensive episodes which may occur when

PPF is infused at more than 10 ml/minute, they are relatively safe. If afford-

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able, they are the colloids of choice for management of patients with burns and they may also be useful in the management of major haemorrhage.

8.3 Plasma

Plasma is obtained from blood by centrifugation (preferably), for which a refrigerated centrifuge is required, or by sedimentation. Storage of fresh frozen plasma and cryosupernatant requires a freezer (at least 20° C). Cryoprecipitate can be lyophilized, simplifying its storage and transport, but this technology is not widely available and in most centres it must therefore be stored in freezer. In addition to these disadvantages and the others already outlined (see Section 3.1), plasma is expensive. The synthetic colloids are therefore preferable for the correction of hypovolaemia in patients with haemorrhage. It is reasonable for stocks of cryoprecipitate, cryosupernatant or frozen fresh plasma to be available for management of disorders of haemostasis (see Chapter 3) and of burns.

9. Approaches to Minimize use of Blood and Blood Products in the Management of Blood Loss

The loss of blood is not an indication for its replacement. Only when blood loss is life-threatening, it should be replaced . The main aim of restoring the blood volume is to maintain the adequate supply of oxygen. In addition to replacement of blood other measures such as oxygen therapy, pain relief, careful monitoring of signs of hypoxia and assurance should be done. The blood, plasma and plasma substitutes should be given in the right amount to restore tissue perfusion as assessed by clinical signs i.e. pulse rate, skin temperature, blood pressure, central venous pressure (whenever possible) and half hourly urinary output

9.1 Transfusion of large volumes of blood (such as equivalent to one or more of the patient's volume) may occasionally lead to metabolic disturbances or dilutional effects especially in patient with shock, acidosis or haemolysis and in neonates receiving exchange transfusion.

9.1.1 Hyperkalaemia from elevated potassium level of stored blood is a rare complication.

9.1.2 Metabolic problems from high level of acid and ammonia are sometimes seen in patients with circulatory shock.

9.1.3 Rapid infusion of citrated blood or plasma through a central vein catheter may cause hypocalcaemia and consequent arrhythmias.

Hypocalcaemia can be corrected by intravenous administration of calcium.

9.1.4 Transfusion of large volumes of cold blood may significantly lower the body temperature. Cold blood can be warmed by blood-warming

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9.1.5 Large volume transfusion of stored blood (deficient in labile coagulation factors and viable platelets) may cause clinically significant fall in coagulation factors and platelets. These deficiencies can be corrected by administration of FFP, fresh blood or platelets. The decision to transfuse these is made on the basis of laboratory and clinical features.

9.1.6 Microaggregates form in the stored blood. These can cause pulmonary microvascular obstruction with pulmonary dysfunction and hypoxaemia. In bypass surgery the pulmonary vascular bed is excluded, therefore, microembolisation of the cerebral, retinal and renal circulation may occur from the microaggregates. These are effectively removed by microfilters with pore size of 40 µm.

10. Fresh Blood

The term "Fresh blood" is not used in any definite connotation. Several surgeons insist on its use to control acute haemorrhage. It is not established that it has a definite benefit. It is mandatory that blood has to be screened for HIV and hepatitis viruses. It, therefore, is often not possible to arrange fresh blood during emergencies. If, however, deficiencies of coagulation factors or platelets are suspected, specific components can be administered along with the red cell concentrate. "It is doubtful whether there are any circumstances in which fresh whole blood is essential" (Mollison et al. Blood transfusion in Clinical Medicine, Ninth edition, 1993). In the neonates exchange transfusion is given with blood which is less than 5 days old to avoid hyperkalaemia and to provide red cells with 100% oxygen-carrying capacity.

CHAPTER 4

APPROPRIATE USE OF BLOOD COMPONENTS

1. Introduction

Blood components include: Red cell concentrates, plasma (fresh plasma, FFP, cryo-poor plasma, liquid plasma), platelet concentrates and granulocyte concentrates.

Other plasma products such as albumin, plasma protein fraction (PPF), immunoglobulins and factor VIII concentrates are made commercially or at the national fractionation plants and are discussed briefly. Red cell concentrates are dealt in chapter 2. Other components are discussed under disease conditions in chapters 3 and 4.

Appendix 3—National Guidelines For Appropriate use of Blood

2. Disorders of Haemostasis

Haemostatic disorders are generally caused by deficiency of coagulation factors, thrombocytopenias and presence of circulating anticoagulants. Various therapeutic options available to control or prevent bleeding in these diseases include specific factor concentrates cryoprecipitate, fresh frozen plasma (FFP), cryo-poor plasma, platelet concentrate, platelet rich plasma (PRP) and pharmacological agents e.g. vitamin K, des-amino arginine vasopressin (Desmotressin/DDAVP) and protamine sulphate.

In each patient with bleeding disorders the cause should be established with adequate history, clinical examination and laboratory investigations.

2.1 Coagulation factor concentrates

Concentrates of coagulation factors are the most effective and safe form of therapy for specific coagulation factor deficiencies. These, however, are mainly obtained from the fractionation of plasma and are not readily available to patients at affordable cost.

2.2 Cryoprecipitate

Cryoprecipitate is rich in factor VIII, von Willebrand's factor, fibrinogen, fibronectin and factor XIII. It contains about 70% of factor VIII and is the most concentrated form other than the factor VIII concentrates. In addition, it is useful for treatment of von Willebrand's disease, factor XIII deficiency, fibrinogen deficiencies and DIC.

2.3 Plasma

2.3.1 Fresh Frozen Plasma (FFP)

FFP contains the coagulation factors present in the original unit of blood. On an average 1 ml of plasma, contains one unit of each of the coagulation factors other than the fibrinogen. FFP is the treatment of choice for replacement of coagulation factor deficiencies where the specific factor concentrate is not available, immediate reversal of warfarin effect, DIC and TTP (thrombotic thrombocytopenic purpura). FFP is also indicated in patients with bleeding tendencies due to multiple coagulation factors deficiencies such as liver disease, DIC, massive blood transfusion and cardiovascular bypass surgery.

2.3.2 Cryo-poor plasma

Cryo-poor plasma is poor in factor VIII, fibrinogen, von Willebrand's factor XIII but contains other coagulation factors. It may therefore, be used for the management of factor IX deficiency and for haemostatic disorders complicating liver disease.

2.3.3 Liquid or recovered plasma

2.3.4 Side effects

FFP may cause circulatory overload particularly in children, and when it is infused rapidly for the correction of haemostatic disorders. FFP, cryoprecipitate and cryosupernatant may transmit infectious agents such as HIV and the hepatitis viruses. Methods for treating cryoprecipitate to inactivate viruses have been described but the technology is not yet widely available. The risk of contamination with microorganisms is increased if the closed system (e.g., double or multiple plastic bags) has not been used for collection of the blood and harvesting of plasma. Incompatible transfusion reactions may occur if ABO-specific or compatible plasma is not transfused. Allergic reactions range from cutaneous rashes to severe anaphylaxis, hypotension and shock.

2.4 Platelets

Platelet transfusion (platelet concentrate and platelet-rich plasma) are indicated in patients who have haemorrhagic manifestations either from thrombocytopenia (due to deficient platelet production) or from functional disorders of platelets. They generally have little role in the management of bleeding in patients with immune thrombocytopenia. There is lack of agreement on the cut off values for platelets below which platelet transfusion should be given. The decision is made on the basis of severity of bleeding and the cause of thrombocytopenia. In general, however, platelet transfusions are not required with platelet counts above 10,000 per ul unless the patient has serious bleeding such as intracranial haemorrhage. The platelet requirement increases in presence of active bleeding, splenomegaly and septicemia.

Thrombocytopenic patients who have to undergo surgery that is likely to cause significant blood loss, or those who are at risk of developing further fall in platelet count from therapy may need prophylactic platelet transfusions. Repeated platelet transfusions often lead to alloimmunisation and refractoriness to subsequent platelet transfusions. To limit the number of donor exposures apheresis platelets are recommended.

2.5 Pharmacological agents

Wherever possible, use of pharmacological agents is preferred to administration of blood products.

2.5.1 In patients with deficiency of vitamin K-dependent factors, vitamin K administration is the treatment of choice except in patients in whom immediate reversal of effects of warfarin is required.

2.5.2 DDAVP is treatment of choice for most patients with von willebrand's disease and mild haemophilia.,

2.5.3 Intravenous immunoglobulin (IVIG) and oral or parenteral glucocorticoids are useful therapeutic agents in patients with immune thrombocytopaenia especially ITP.

2.5.4 Protamine sulphate is used to reverse the effect of heparin therapy

2.5.5 Vitamin K is the treatment of choice for haemorrhagic disease of the newborn. Blood and blood components are rarely required.

2.5.6 Parenteral vitamin K administration is the treatment of choice for bleeding episodes due to coagulation abnormalities complicating obstructive jaundice or liver disease. If this is not effective, cryosupernate or plasma(FFP) or factor concentrate may be necessary.

2.5.7 Identification and treatment of underlying cause and correction of fluid and electrolyte balance are fundamentally important in the management of patients with disseminated intravascular coagulation.

Cryoprecipitate, FFP or platelets may be required for management of these patients. Red cells may also have to be given if severe symptomatic anaemia develops.

3. Infections

3.1

Granulocyte transfusions

Granulocyte transfusion (granulocyte concentrate) Prepared by leucapheresis are useful in patients with neonatal septicaemia and agranulocytosis with infections not controlled by use of appropriate antibiotic therapy for 48 hours. Leucocyte concentrates prepared from buffy coat are of little therapeutic value.

3.2 In several neutropenic conditions especially following cancer chemotherapy or pretransplant myeloablative therapy, growth factors (GM-CSF- & G-CSF) are useful in raising the neutrophil count in a shorter period.

4. Burns

4.1 Volume replacement is usually necessary only when the burn exceeds 20% of the body surface area. Crystalloids and colloids may suffice during the first 24 hours.

4.2 Albumin or plasma protein fraction are the preparations of choice for correcting acute protein depletion in patients with burns, but they are expensive. When they are not available cryosupernate or fresh frozen plasma (FFP) may be used.

AUTOLOGOUS TRANSFUSION

1 Introduction

1.1 Autologous transfusion is the collection and subsequent reinfusion of the patient's own blood or blood components. Recently interest in autologous transfusion has increased because of concerns of transfusion-transmitted disease from homologous blood-blood collected from donors other than the patient. Autologous transfusion has special relevance for situations where the (hepatitis Band C) may be high in blood donor populations, and where appropriate screening techniques may not be generally available.

1.2 Autologous transfusion not only prevents transmission of disease but also avoids immunological complications of homologous transfusion such as alloimmunisation and transfusion reactions. Autologous transfusion permits greater flexibility in the use of the homologous blood supply.

1.3 These guidelines address only the collection and storage of liquid autologous whole blood or red blood cells.

1.4 Blood transfusion, whether autologous or homologous, should be used only when clearly indicated. Many patient can tolerate low level of haemoglobin without transfusion. Whenever possible, techniques to reduce the need for transfusion should be employed. These include meticulous attention to surgical haemostasis and increased use of crystalloid and/ or colloid solutions.

1.5 Autologous blood transfusion is most useful in elective or planned surgical procedures. However, most planned surgical procedures do not result in sufficient blood loss to require transfusion. In general, autologous transfusion should be considered if it is anticipated that the surgical procedure will result in sufficient blood loss to require homologous transfusion.

1.6 The principal options for autologous transfusion are:

Preoperative autologous blood donation -acute isovolaemic haemodilution Intraoperative blood salvage -Postoperative blood salvage These techniques can be used alone or in combination to reduce or eliminate the need for homologous blood;

1.7 A Programme for autologous transfusion should be incorporated into a comprehensive plan for blood transfusion services. autologous blood transfusion should complement and extend efforts to recruit safe voluntray donors of homologous blood.

- 1.7.1 Responsibility for the development and implementation of an autologous blood programme should be with a physician who is familiar with these techniques. The physician responsible for blood transfusion services would normally manage a preoperative donation programme. A surgeon or anaesthesiologist would normally manage intraoperative and postoperative blood salvage and acute isovolaemic haemodilution.
- 1.7.2 Health professional involved in autologous blood donation and salvage programmes should be properly trained in these procedures.
- 1.7.3 Regional training workshops, audiovisual learning aids and relevant technical literature are all useful training techniques.
- 1.8 A well organized blood transfusion service will facilitate the introduction of an autologous transfusion programme. These programmes should be designed with appropriate and realistic targets and basic quality assurance indicators. The Programmes should be periodically reviewed to determine the degree to which these targets are being achieved.

2. Preoperative Autologous Blood Donation

- 2.1 Preoperative autologous blood donation (PABD) is an effective procedure for patients undergoing elective surgery. The patient's blood is collected prior to elective surgery so that at time of operation there are one or more units of either whole blood or red cells available for blood replacement if operative blood loss necessitates transfusion. Patients should not be encouraged to donate autologous blood if transfusion is unlikely during surgery.
- 2.2 A programme for PABD requires precise record-keeping and labelling and adequate facilities for the collection and storage of blood. A well organized blood transfusion service is, therefore essential.
- 2.3 The benefits to the patient include reduction of the need for homologous blood transfusion with its attendant risks of transmissible diseases and transfusion reactions. In addition bone marrow erythropoiesis is stimulated, resulting in a more rapid recovery of pre-transfusion haemoglobin levels following surgery. The benefits to the blood transfusion service include the ability to provide blood for surgical procedures in areas where the homologous blood supply may be unpredictable. In addition unused autologous units may be transferred or "crossed-over" to the homologous blood supply provided the autologous donor has met all the criteria for homologous blood donation including screening for infectious agents.

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A well organised Blood Transfusion Service (BTS) is a vital component of any health care delivery system. An integrated strategy for Blood Safety is required for elimination of transfusion transmitted infections and for provision of safe and adequate blood transfusion services to the people. The main component of an integrated strategy include collection of blood only from voluntary, non-remunerated blood donors, screening for all transfusion transmitted infections and reduction of unnecessary transfusion.

The Blood Transfusion Service in the country is highly decentralised and lacks many vital resources like manpower, adequate infrastructure and financial base. The main issue, which plagues blood banking system in the country, is fragmented management. The standards vary from State to State, cities to cities and centre to centre in the same city. In spite of hospital based system, many large hospitals and nursing homes do not have their own blood banks and this has led to proliferation of stand-alone private blood banks.

The blood component production/availability and utilisation is extremely limited. There is shortage of trained health-care professionals in the field of transfusion medicine.

For quality, safety and efficacy of blood and blood products, well-equipped blood centres with adequate infrastructure and trained manpower is an essential requirement. For effective clinical use of blood, it is necessary to train clinical staff. To attain maximum safety, the requirements of good manufacturing practices and implementation of quality system moving towards total quality management, have posed a challenge to the organisation and management of blood transfusion service.

Thus, a need for modification and change in the blood transfusion service has necessitated formulation of a National Blood Policy and development of a National Blood Programme which will also ensure implementation of the directives of Supreme Court of India—1996.

Mission Statement:

The policy aims to ensure easily accessible and adequate supply of safe and quality blood and blood components collected / procured from a voluntary non-remunerated regular blood donor in well equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions. Transfusion under supervision of trained personnel for all who need it

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irrespective of their economic or social status through comprehensive, efficient and a total quality management approach will be ensured under the policy.

11. Objectives of the Policy

To achieve the above aim, the following objectives are drawn:

1. To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.
2. To make available adequate resources to develop and re-organise the blood transfusion services in the entire country.
3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.
4. To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.
5. To encourage appropriate clinical use of blood and blood products.
6. To strengthen the manpower through human resource development.
7. To encourage Research & Development in the field of Transfusion Medicine and related technology.
8. 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.

Objective - 1:

To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.

Strategy:

- 1.1. A national blood transfusion Programme shall be developed to ensure establishment of non-profit integrated National and State Blood Transfusion Services in the country.
 - 1.1.1 National Blood Transfusion Council (NBTC) shall be the policy formulating apex body in relation to all matters pertaining to operation of blood centres. National AIDS Control Organisation (NACO) shall allocate a budget to NBTC for strengthening Blood Transfusion Service.
 - 1.1.2 State/UT Blood Transfusion Councils shall be responsible for implementation of the Blood Programme at State/UT level, as per the recommendations of the National Blood Transfusion Council.
 - 1.1.3 Mechanisms for better co-ordination between NBTC and SBTCs

shall be developed by the NBTC.

1.1.4 Mechanisms shall be developed to monitor and periodically evaluate the implementation of the National Blood Programme in the country.

1.1.5 The enforcement of the blood and blood products standards shall be the responsibility of Drugs Controller General India) as per Drugs and Cosmetics Act/Rules, with assistance from identified experts.

1.1.6 NBTC shall ensure involvement of other Ministries and other health programmes for various activities related to Blood transfusion services.

1.2. Trading in blood i.e. Sale & purchase of blood shall be prohibited.

1.2.1 The practice of replacement donors shall be gradually phased out in a time bound programme to achieve 100% voluntary non-remunerated blood donation programme.

1.2.1.1 State/UT Blood Transfusion Councils shall develop an action plan to ensure phasing out of replacement donors.

1.3

The following chain of Transfusion Services shall be promoted for making available of safe blood to the people.

1.3.1

State Blood Transfusion Councils shall organise the blood transfusion service through the network of Regional Blood Centres and Satellite Centres and other Government, Indian Red Cross Society & NGO run blood centres and monitor their functioning. All Regional Centres shall be assigned an area around in which the other blood banks and hospitals which are linked to the regional centre will be assisted for any requirement and shall be audited by the Regional Centre. It will also help the State Blood Transfusion Council in collecting the data from this region.

1.3.2 The Regional Centres shall be autonomous for their day to day functioning and shall be guided by recommendations of the State/UT Blood Transfusion Councils. The Regional Centre shall act as a referral centre for the region assigned to it.

1.3.3 NBTC shall develop the guidelines to define NGO run blood centres so as to avoid profiteering in blood banking.

1.4

Due to the special requirement of Armed Forces in remote border areas, necessary amendments shall be made in the Drugs & Cosmetics Act/Rules to provide special licences to small garrison units. These units

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shall also be responsible for the civilian blood needs of the region.

Objective- 2:

To make available adequate resources to develop and re-organise the blood transfusion service in the entire country.

Strategy:

2.1 National & State/UT Blood Transfusion Councils shall be supported/
strengthened financially by pooling resources from various existing programmes
and if possible by raising funds from international / bilateral
agencies.

2.2 Efforts shall be directed to make the blood transfusion service viable
through non-profit recovery system.

2.2.1. National Blood Transfusion Council shall provide guidelines for
ensuring non-profit cost recovery as well as subsidised system.

2.2.2. Efforts shall be made to raise funds for the blood transfusion service
for making it self-sufficient.

2.2.3. The mechanism shall be introduced in government sector to route
the amounts received through cost recovery of blood/blood components
to the blood banks for improving their services.

Objective - 3:

To make latest technology available for operating the blood transfusion services
and ensure its functioning in an updated manner.

Strategy:

3.1 Minimum standards for testing, processing and storage shall be set and
ensured.

3.1.1 Standards,

Drugs & Cosmetics Act/Rules and Indian

Pharmacopoeia shall be updated as and when necessary.

3.1.2. All mandatory tests as laid down under provisions of Drugs &
Cosmetics Act/Rules shall be enforced.

3.1.3. Inspectorate of Drugs Controller of India and State FDA shall be
strengthened to ensure effective monitoring.

3.1.4.

A vigilance cell shall be created under Central/State Licensing

Authorities.

3.2. A Quality System Scheme shall be introduced in all blood centres.

3.2.1. Quality Assurance Manager shall be designated at each Regional Blood Centre/any blood centre collecting more than 15,000 units per year to ensure quality control of Blood & its components in the region assigned. He shall be exclusively responsible for quality assurance only.

3.2.2 Every blood centre shall introduce an internal audit system to be followed by corrective actions to reduce variations in Standard Operating Procedures(SOPs) as a part of continuous improvement programme.

3.2.3. Regular workshops on the subject of quality assurance shall be conducted to update the personnel working in blood centres.

3.2.4.

Regular proficiency testing of personnel shall be introduced in all the blood centres.

3.3. An External Quality Assessment Scheme (EQAS) through the referral laboratories approved by the National Blood Transfusion Council shall be introduced to assist participating centres in achieving higher standards and uniformity.

3.3.1. Reference centres shall be identified in each State/UT for implementation of EQAS. All blood centres shall be linked to these reference centres for EQAS.

3.3.2. NBTC shall identify a centre of national repute for quality control of indigenous as well as imported consumables, reagents and plasma products.

3.4.

Efforts shall be made towards indigenisation of kits, equipment and consumables used in blood banks.

3.5. Use of automation shall be encouraged to manage higher workload with increased efficiency.

3.6. A mechanism for transfer of technology shall be developed to ensure the availability of state-of-the-art technology from outside India .

3.7.

Each blood centre shall develop its own Standard Operating Procedures on various aspects of Blood Banking.

3.7.1. Generic Standard Operating Procedures shall be developed by the National Blood Transfusion Council as guidelines for the blood centres.

3.8. All blood centres shall adhere to bio-safety guidelines as provided in the Ministry of Health & Family Welfare manual "Hospital-acquired Infections : Guidelines for Control" and disposal of bio-hazardous waste as per the provisions of the existing Biomedical Wastes(Management & Handling)

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Rules - 1996 under the Environmental Protection Act - 1986.

Objective - 4:

To launch extensive awareness programmes for blood banking services including donor motivation, so as to ensure adequate availability of safe blood.

Strategy:

4.1 Efforts shall be directed towards recruitment and retention of voluntary, non-remunerated blood donors through education and awareness programmes.

4.1.1 There shall not be any coercion in enrolling replacement blood donors.

4.1.2 The replacement donors shall be encouraged to become regular voluntary blood donors.

4.1.3

Activities of NGOs shall be encouraged to increase awareness about blood donation amongst masses.

4.1.4. All blood banks shall have donor recruitment officer/donor organiser.

4.1.5. Each blood centre shall create and update a blood donor's directory which shall be kept confidential.

4.1.6. In order to increase the donor base specific IEC campaigns shall be launched to involve youth in blood donation activities.

4.2. Enrolment of safe donors shall be ensured.

4.2.1 Rigid adherence to donor screening guidelines shall be enforced.

4.2.2 At blood donation camps, appropriate attention shall be paid on donor enrolment and screening in accordance with national standards instead of number of units collected.

4.2.3 A

Counselor in each blood centre shall be appointed for pre and post donation counseling.

4.2.4 Result seeking donors shall be referred to a Blood Testing Centre (BTC) for post donation information and counseling.

4.3

State/UT Blood Transfusion Councils shall recognise the services of regular voluntary non-remunerated blood donors and donor organisers appropriately.

4.4 National/State/UT Blood Transfusion Councils shall develop and launch an IEC campaign using all channels of communication including mass-media for promotion of voluntary blood donation and generation of awareness regarding dangers of blood from paid donors and procurement of blood from unauthorised blood banks/laboratories.

4.5 National / State / UT blood transfusion councils shall involve other departments / sectors for promoting voluntary blood donations.

Objective: 5:

To encourage appropriate clinical use of blood and blood products.

Strategy:

5.1 Blood shall be used only when necessary. Blood and blood products shall be transfused only to treat conditions leading to significant morbidity and mortality that cannot be prevented or treated effectively by other means.

5.2 National Guidelines on "Clinical use of Blood" shall be made available and updated as required from time to time.

5.3

Effective and efficient clinical use of blood shall be promoted in accordance with guidelines.

5.3.1 State/UT Governments shall ensure that the Hospital Transfusion Committees are established in all hospitals to guide, monitor and audit clinical use of blood.

5.3.2 Wherever appropriate, use of plasma expanders shall be promoted to minimise the use of blood.

5.3.3

Alternative strategies to minimise the need for transfusion shall be promoted.

5.4 Education and training in effective clinical use of blood shall be organised.

5.4.1 Medical Council of India shall be requested to take following initiatives:

5.4.1.1 To introduce Transfusion Medicine as a subject at undergraduate and all post graduate medical courses.

5.4.1.2 To introduce posting for at least 15 days in the department of transfusion medicine during internship.

5.4.1.3 To include Transfusion Medicine as one of the subjects in calculating credit hours for the renewal of medical registration by Medical Council of India, if it is introduced.

5.4.2

CME and workshops shall be organised by State Blood Transfusion Councils in collaboration with professional bodies at regular intervals for all clinicians working in private as well public sector in their States.

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5.5

Blood and its components shall be prescribed only by a medical practitioner registered as per the provisions of Medical Council Act - 1956.

5.6

Availability of blood components shall be ensured through the network of regional centres, satellite centres and other blood centres by creating adequate number of blood component separation units.

5.7

Appropriate steps shall be taken to increase the availability of plasma fractions as per the need of the country through expanding the capacity of existing centre and establishing new centres in the country.

5.8

Adequate facilities for transporting blood and blood products including proper cold-chain maintenance shall be made available to ensure appropriate management of blood supply.

5.9

Guidelines for management of blood supply during natural and man made disasters shall be made available.

Objective: 6:

To strengthen the manpower through Human Resource Development.

Strategy:

6.1 Transfusion Medicine shall be treated as a speciality.

6.1.1 A separate Department of Transfusion Medicine shall be established in Medical Colleges.

6.1.2 Medical Colleges/Universities in all States shall be encouraged to start PG degree (MD in transfusion medicine) and diploma courses in Transfusion Medicine.

6.1.3 PG courses for

technical training in transfusion medicine (PhD / MSc) shall also be encouraged.

6.2 In all the existing courses for nurses, technicians and pharmacists, Transfusion Medicine shall be incorporated as one of the subjects.

6.3

In-service training programmes shall be organised for all categories of personnel working in blood centres as well as drug inspectors and other officers from regulatory agencies.

6.4 Appropriate modules for training of Donor Organisers/Donor Recruitment Officers shall be developed to facilitate regular and uniform training programmes

to be conducted in all States

6.4.1 Persons appointed as Donor Organisers/Donor Recruitment Officers shall undergo training for Donor Motivation and Recruitment organised by State Blood Transfusion Councils.

6.5

Short orientation training cum advocacy programmes on donor motivation and recruitment shall be organised for Community Based Organisations(CBOs)/NGOs who wish to participate in Voluntary Blood Donor Recruitment Programme.

6.6

Inter-country and intra-country exchange for training and experience of personnel associated with blood centres shall be encouraged to improve quality of Blood Transfusion Service.

6.7 States/UTs shall create a separate cadre and opportunities for promotions for suitably trained medical and para medical personnel working in blood transfusion services.

Objective: 7:

To encourage Research & Development in the field of Transfusion Medicine and related technology.

Strategy:

7.1

A corpus of funds shall be made available to NBTC/SBTCs to facilitate research in transfusion medicine and technology related to blood banking.

7.2

A technical resource core group at national level shall be created to coordinate research and development in the country. This group shall be responsible for recommending implementation of new technologies and procedures in coordination with DC(I).

7.3 Multi-centric research initiatives on issues related to Blood Transfusion shall be encouraged.

7.4 To take appropriate decisions and/or introduction of policy initiatives on the basis of factual information, operational research on various aspects such as various aspects of Transfusion Transmissible Diseases, Knowledge, Attitude and Practices (KAP) among donors, clinical use of blood, need assessment etc shall be promoted.

7.5

Computer based information and management systems shall be developed which can be used by all the centres regularly to facilitate networking.

Objective: 8:

To take adequate legislative and educational steps to eliminate profiteering in blood banks.

Strategy:

8.1 For grant/renewal of blood bank licenses including plan of a blood bank, a

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8.2

Fresh licenses to stand-alone blood banks in private sector shall not be granted. Renewal of such blood banks shall be subjected to thorough scrutiny and shall not be renewed in case of non-compliance of any condition of licence.

8.3 All State/UT Blood Transfusion Councils shall develop a State Action Plan for the State/UT Blood Transfusion Service where in Regional Blood Transfusion Centres shall be identified. These centres shall be from Government, Indian Red Cross Society or other NGO run blood banks of repute. Approved regional blood centres/government blood centres/Indian red cross blood centres shall be permitted to supply blood and blood products to satellite centres which are approved by the committee as described in para 8.1. The Regional Centre shall be responsible for transportation, storage, cross-matching and distribution of blood and blood products through satellite centres.

8.4

A separate blood bank cell shall be created under a senior officer not below the rank of DDC(I) in the office of the DC(I) at the headquarter. State/UT Drugs Control Department shall create such similar cells with the trained officers including inspectors for proper inspection and enforcement.

8.5

As a deterrent to paid blood donors who operate in the disguise of replacement donors, institutions who prescribe blood for transfusion shall be made responsible for procurement of blood for their patients through their affiliation with licensed blood centres.

8.6 States/UTs shall enact rules for registration of nursing homes wherein provisions for affiliation with a licensed blood bank for procurement of blood for their patients shall be incorporated.

8.7 The existing provisions of Drugs & Cosmetics Rules will be periodically reviewed to introduce stringent penalties for unauthorised/irregular practices in blood banking system.

Appendix 5—AIR 1996 Supreme Court 929

Appendix 5

AIR 1996 Supreme Court 929

S.C. AGRAWAL, AND

G.B. PATTANAIK, JJ.

Writ Petn. (Civil) No. 91 of 1992. D/-4-1-1996.

Common Cause, Petitioner
versus
Union of India and others, Respondents.

Drugs and Cosmetics Act (23 of 1940), Ss.16, 33—Drugs and Cosmetics Rules (1945), R.124—Blood banks—Malpractices and Malfunctioning Committee of experts set up by Supreme Court and Indian Red Cross Society—Recommendations/suggestions for revamping system of blood banks in country in the form of plans for implementation on immediate basis and for long term implementation - In view of the potentialities of harm in prevailing state of affairs and need for speedy action in that regard, Supreme Court issued directions to Union Govt, and State Govts.

(Paras 13, 14)

S.C. AGRAWAL, J.—Blood is an essential component of the body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human-being. At the same time blood, instead of saving life, can also lead to death of the person to whom the blood is given if the blood is contaminated. As a result of developments in medical science it is possible to preserve and store blood after it has been collected so that it can be available in the case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its components and make the same available when needed. In view of the dangers inherent in supply of contaminated blood it must be ensured that the blood that is available with the blood banks for use is healthy and free from infection.

2. In this petition filed by way of Public Interest Litigation under Article 32 of the Constitution the petitioners has high-lighted the serious deficiencies and shortcomings in the matter of collection, storage and supply of blood through the various blood centres operating in the country and has prayed that an appropriate writ order or direction be issued directing the Union of India and the States and the Union Territories, who have all been impleaded as respondents in this petition, to

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ensure that proper positive and concrete steps in a time bound programme are immediately initiated for obviating the malpractices, malfunctioning and inadequacies of the blood banks all over the country and to place before this Court a specific programme of action aimed at overcoming the deficiencies in the operation of blood banks.

3. For the purpose of regulating its collection, storage and supply, blood is treated as a "drug" under the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'the Act'). In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as 'the Rules') made under the Act, provisions regarding equipment and supplies required for a blood bank were contained in Part XII-B, which was inserted vide Notification dated June 24, 1967. In the said part, requirements regarding Equipment, Blood collection supplies, Canter equipment and Emergency equipment for the Blood Donor Room were prescribed. Similarly provisions were made for the Laboratory, General Suppliers, Technical staff, Accommodation for Blood Bank, Label for whole blood and Colour scheme for Label etc.

4. In 1990, M/s. A.F. Ferguson & Co., a Management Consultancy Firm, was entrusted by the Government of India, Ministry of Health with the study of blood banking system in the country. The scope of the said study was to :

- i) assess the status of Government, Private, Commercial and Voluntary blood banks;
- ii) recommended policy and procedural changes; and
- iii) prepare a scheme for modernisation;

5. The report submitted by the said consultancy firm to the Government in July, 1990, high-lights the deficiencies with regard to the facilities of testing blood, licensing of blood banks and professional donors and storage of blood. In the said report it was stated :

i)

Out of the total number of 1018 blood banks as many as 616 are reported to be unlicensed. There are only 201 licensed commercial blood banks; the supply of blood by licensed commercial blood banks is only about 1/4th of the blood used in the hospitals of the Country.

ii)

No medical check up is done on the blood sellers; their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling their blood. Such blood sellers suffer from various infections and their haemoglobin is lower than the prescribed level. It has been reported that there are many

persons who donate blood 5-6 times in a month; poverty makes them to do so at first but later it is reported to become like an addiction, the blood seller enjoying the dizziness due to reduced supply.

iii)

It is a mandatory requirement to conduct tests on blood which is to be administered to a patient or to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, viral hepatitis, malaria, venereal diseases etc. It is reported that mandatory tests which are required to be done are rarely conducted. Most of the AIDS surveillance centres are not functioning efficiently and up to 85 per cent of blood collected in the country is not screened for AIDS. Under an action plan to screen blood for AIDS 37 blood testing centres were to be set up in 29 cities, but only 11 testing centres were functioning by July, 1990, and training of technicians for these centres was lagging.

iv)

The blood banks presently thrive on bleeding 4000 to 5000 regular professional donors in 18-20 cities. The professional blood donors, which include many, are reported to be victims of ill-health, low haemoglobin levels and many infections, and are bled at frequent intervals by the commercial blood banks.

v)

Storage facilities in the blood banks are far from satisfactory. The blood banks have necessarily to possess facilities like refrigerators exclusively for storage of blood with a specified range of temperature for ensuring safety of blood. In the existing blood banks many items of equipment remain unattended for years, electricity failures are frequent, generators are a rarity. This applies not only to commercial blood banks but even to some of the government hospitals. Many times of the basic equipment needed for blood banks are not available and a good part of them do not have even adequate storage facilities.

vi)

Many of the blood banks are located in unhygienic environment and they collect and store blood in very dirty conditions.

vii)

In some places strong middle men operate for the blood banks by arranging for donors. The middle men dictate the charges to be paid and take a heavy commission; the selection of donors disregards the level of health etc.

viii) A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high risk group for Hepatitis and AIDS and are unfit to donate blood.

ix)

Trained personnel are generally not available in the blood banks. Most of the blood banks lack trained post-graduates at the helm; they have no donor organisers to bring voluntary donors; and many of them are manned by technical staff who do not have requisite qualification of a diploma in Medical Laboratory Technology. At present there is not even a course to provide post-graduate specialisation in the field of blood

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x)

In the storage of blood the basic and essential requirements of clean environment, shelf life of blood etc. are ignored. Nexus is reported to be existing between the attending doctor of the patient and the commercial blood bank, with the former directing the patients to the latter, and the latter giving a percentage of the sale to the former.

6. According to the report of M/s. A.F. Ferguson & Co. out of the total number of 1018 blood banks in the country, 203 are commercial blood banks and the rest are controlled by the Central Government, State Governments, Private Hospitals and voluntary organisations. The volume of the blood collected by the commercial blood banks is 4.7 lakhs units out of the total of 19.5 lakhs units by all blood banks and that commercial blood banks are collecting blood mostly from professional donors while the other blood banks under the control of the State Governments, Central Governments, Private organisations and voluntary organisations are collecting blood mostly from the relatives of the patients or from the voluntary donors.

7. In the counter affidavit filed by Dr. Lalgudi Vaidyanathan Kannan, Deputy Drugs Controller, on behalf of the Union of India it is stated that after the receipt of the report of M/s.Ferguson & Co., the Drugs Controller, India, by his letter dated August 23, 1990 asked all the State Drug Controllers (who are the licensing and enforcing authorities under the Act) to ensure that inspections are carried out of all commercial blood banks and unlicensed Government blood banks keeping in view the standards prescribed in the Act and Rules and phased programme of inspection covering first the commercial/private blood banks and thereafter the Government blood banks was suggested. It was also suggested that the private/commercial blood banks should not be allowed to operate unless they fulfil all the requirements prescribed in the Rules and each unit of blood is tested for blood transmissible diseases (Hepatitis, HIV, Syphilis etc.) and that unlicensed blood banks are to be licensed only after ascertaining that they conform to the standard laid down under the Rules. It was also suggested to the State Governments that the licences of blood banks who do not comply with the provisions of the Rules should be cancelled and the State Drug Controller were asked to send the status reports of blood banks in their respective States. As per the information forwarded by 23 State Governments/Union Territories, about 341 blood banks are unlicensed and most of them are run by Red Cross Societies and Charitable institutions. In the said counter affidavit mention is also made of the steps that have been taken in the matter of testing of blood for AIDS, storage facilities in blood banks, for upgradation and modernisation of Government managed blood banks, and training of drugs inspectors and blood banks technical person-

nel.

8. During the pendency of this writ petition, action has also been taken to revise the Rules governing the licencing and operation of the blood banks and by the Drugs and Cosmetics (First Amendment) Rules 1982 published in the Gazette of India vide Notification dated January 22, 1993, Part X-B has been inserted in the Rules and Part XII-B has been substituted. In part X-B (Rules 122-F to 122-P) provisions have been made prescribing the requirements for collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products and for grant and for renewal of licence for the operation of a blood bank/processing of human blood for components/ manufacture blood products. Under the said provisions licence can only be granted/renewed with the approval of the Central Licence Approving Authority viz. the Drugs Controller of India. Part XII-B contains provisions relating to space, equipment and supplies required for a Blood Bank.

9. During the course of the hearing of this petition, the petitioner submitted a draft scheme and a scheme was also submitted by the Union of India. In the affidavit filed by Dr. Shiv Lal, Addl. Director, National Aids Control Organisation, along with the scheme, it was stated that the Central Council of Health, in which the State Health Ministers are members, is the highest Forum for Policy framework and that the said Council has given guidelines in respect of Blood Banks and Transfusion Service and its recommendations are as under :—
“Blood being a vital input in the present day medicare services the acute shortage of which is hampering the effectiveness of our services the joint Conference recommends that urgent steps should be taken by the States/Union Territories Governments and the Central Government.

1.

To build up adequate blood banking services at State/District level including provision of trained/qualified man power.
Necessary action should be initiated in right earnest for achieving the objective in view.

2.

To educate and motivate people about blood donation on a voluntary basis.

3.

To provide adequate encouragement to voluntary donors.

4.

To enforce quality control of blood in all its facets of collection, distribution and storage.”

In the said affidavit it was also state that although the World Health Organisation has prescribed that nearly 40 lakhs units of blood is required for the country, the collection is only 19.5 lakhs units at present and, therefore, it is not possible to ban professional donors at this stage unless the donations of blood by

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way of voluntary donation are increased. In the said affidavit it was further stated that most of the Government Blood Banks are lacking in man powers, training and laboratory facilities to test blood for blood transmissible diseases and to augment this, the Central Government has provided funds to various State Governments during 1990-91 and 1991-92 to modernise the Government Blood Banks. According to the said affidavit, the main objective for the modernisation of the Blood Banks have been provided into long term objectives and medium term objectives as under :

"I. Long term objectives:

(a)

Make available high quality blood and blood components in adequate quantity to all users.

(b)

Ensure wide usage of blood components.

(c)

Expand voluntary and replacement donor base, so as to phase out professional blood donors.

II. Medium term objectives :

(a)

To provide minimum possible facilities for blood collection, storage and testing in all Government Blood Banks.

(b)

To make available the trained man-power in all Government Blood Banks.

(c)

To ensure the awareness of clinicians and Blood Banks staff on the advantages of blood components.

(d)

To ensure the effective geographical coverage keeping in mind the different volumes of blood requirement in different cities.

(e)

To increase public awareness about the risks in using blood from commercial Blood Banks and professional donors and the harmlessness of blood donation."

10. On a perusal of the draft scheme that was submitted by the petitioner and the draft scheme submitted by the Union of India, it was felt that it would facilitate matters if the question of necessary steps which may be required for further strengthening the existing frame-work about licensing of blood banks and obtaining

blood donations is examined by a Committee which would place its suggestions before the Court for consideration. By order dated 11th February, 1994 a committee of the following persons was constituted to examine the matter and submit its report :

1.

Additional Secretary, Ministry of Health holding the charge of Director,
National Aids Control Organisation as Chairman.

2.

Drugs Controller of India.

3. Mr. H.D. Shourie.

The said committee felt that since Indian Red Cross Society is presently involved to a considerable extent in blood banking operations and it has branches spread all over the country and it has capacity to further strengthen itself for looking after the various aspects of functioning of blood banks, it may be recognised as nodal agency in the field of blood banking and blood transfusion technology in the country. The Committee suggested that detailed discussions to finalise assessments in this regard may be held with the Indian Red Cross Society. Having regard to the said suggestions by the committee constituted by the Court, the Indian Red Cross Society constituted a committee of experts to examine the matter and to prepare a draft blue print. The said committee of experts in its report dated April 15, 1995 has indicated the following fields in which measures are required to be taken :

1.

Building a powerful voluntary blood donation movement to augment supplies of safe quality blood and blood components.

2.

Exercising economy by processing whole blood for blood components.

3.

Introducing screening procedure to minimize the danger of transmissible diseases like AIDS, Hepatitis etc.

4.

Standardize technological procedures for rigid enforcement of quality control, and good manufacturing practices.

5.

Providing technical services for raising the standard of blood centre operations and assistance for administrative, motivational and technical problems encountered.”

It has proposed an action plan in three parts : Immediate Plan, Short Term Plan and Long Term Plan, which are as follows :

“Immediate Plan.

1.

To establish an administrative unit at the national headquarter under the charge of a project director.

2.

To identify and strengthen a minimum of 2 Red Cross blood centres for each state for augmenting the existing blood programme. Necessary inputs towards staff, equipment and consumables for the development should be made available at once. Basic requirements to procure accreditation from DC(I) should be ensured.

3.

Donor recruitment and intensification of donor motivation drive may be taken up on priority basis. Involvement of media may be ensured through Information and Broadcasting Ministry.

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A crash programme for short term training of medical officers, technicians and medical social workers, nurses of concerned centres may be undertaken. This distance learning programme prepared by the WHO may be helpful in updating the knowledge of technologists at the centres being strengthened.

5.

In addition to the blood centre, strengthening programme, steps may be taken for planning and initiating action for the establishment of regional blood centres at the following 16 metropolitan cities with 2 million population having many large medical super speciality institutions.

1. Delhi
9. Bhopal
2. Lucknow
10. Ahmedabad
3. Patna
11. Bombay
4. Calcutta
12. Hyderabad
5. Gauhati
13. Bangalore
6. Cuttack
14. Trivandrum
7. Nagpur
15. Madras
8. Jaipur 16. Chandigarh

Each centre will be expected to collect 150,000 to 200,000 units annually.

These will be screened, processed and distributed as blood components to local hospital based centres against service charges. As the regional centres will supplement the blood supplies through the existing system it would help in weeding out the blood supply from paid blood sellers. Therefore it is of paramount importance that top priority is given for the establishment of these centres.

Short Term Plan :

1.

Coordination of the blood programme of large medical colleges having more than 1000 beds and/or collecting over 10,000 units.

2.

Establishment of post graduate training centres at places where facilities

for fulfilling the norms of the Medical Council of India exist. In the initial stages Faculty support can be obtained from departments of pathology. At the following cities post graduate training can be started:

1. Chandigarh
6. Bombay
2. Delhi
7. Hyderabad
3. Lucknow
8. Bangalore
4. Calcutta
9. Trivandrum

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5. Jaipur
10. Madras

Training of paramedical workers can also be undertaken at these centres.

3.

Coordination of all other voluntary organisations working for the promotion of the blood programme by the Red Cross Society would further help in achieving the target of donor recruitment with greater vigour and better evaluation.

4.

A national workshop at the Red Cross headquarters may be organised for officers of all centres being strengthened and the representatives of regional centres to provide necessary guidance for uniform and standardised policies and practices.

Long Term Plan :

1.

To upgrade all other blood centres.

2.

Establishment and upgradation of blood centres in areas where it does not exist.

3.

Planning of more regional centres.

4.

Establishing fractionation centres.

5.

Establishment of therapeutic centres for blood related disorders.

6.

Programmes for indigenisation of equipped software and reagents.

7.

Establishment of tissue typing facilities for Bone Marrow and organ transplant.”

After considering the said report of the committee of experts set up by the Indian Red Cross Society, the committee constituted by the Court submitted its final report which was filed along with the affidavit of Shri Ashwini Kumar, Deputy Drugs Controller of India in the Directorate General of Health Services dated October 26, 1995. The committee has made the following recommendations and has suggested steps for revamping the system of blood banks in the country in the form of plans of implementation on immediate basis and for long term implementation.

For Immediate Implementation:

(i)

A National Council on Blood Transfusion should be established. It should consist of Director General of Health Services, Drug Controller of India, representative of Ministry of Finance, high level representatives of Indian Red Cross Society and selected five major medical and health institutions of the country, and three eminent citizens, presided over by the Additional Secretary of the Ministry of Health who is in charge of

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operations of the programme of National Aids Control Organisation.

The Council should be provided the basic secretariat under charge of a Director by the Ministry of Health and be located in suitable premises at Delhi for effective functioning.

It would be desirable to register the Council as a Society under the Societies Registration Act for enabling it to have its own identity and funds and also for enabling it to raise funds from various sources including contributions from trade, industry and individuals. The basic requirements of its functioning should be provided by the Ministry of Health. The Council will be policy formulating body in relation to all matters pertaining to operation of blood banks.

(ii)

The Ministry of Health, with the assistance of National Council, will ensure the establishment of State Level Councils, at suitable centres, preferably headquartered at the premises of some outstanding medical institutions or hospitals. The State Councils should have on them representatives of important medical institutions of the State, selected representatives of blood banks of repute, a representative of Red

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ross,

and should include the State Director of Health Services as well as State Drug Controller operating under a designated Director and presided over preferably by the State Government Secretary in charge of health.

A representative of the State Ministry of Finance should also preferably be on the Council. The size of State Council should preferably be restricted to the maximum of about 11 members. The Director of Health Services should provide the Committee the basic essentials of secretariat and funds for its functioning. The State Councils, as in the case of National Council, should be registered as Society under the Societies Registration Act for maintaining their identity and for purposes of collection of funds in the shape of contributions from individuals and corporate bodies. The State Councils should endeavour to operate on the basis of policies formulated by the National Council, effectively implementing the policies and programmes formulated by them.

(iii)

Programmes and activities of the National Council and State Councils should cover the entire range of services related to operation and

requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

Long Term Objectives :

i) The programme formulation at the national level and State levels should take into account the requirements of laying down targets for achievement, including the establishment of appropriately designed and equipped blood banks, ensuring that all blood banks are licensed, making satisfactory arrangements for collection and storage of collected blood, fractionalisation of blood into the components. Special emphasis will need to be laid in the programme on the attainment of prescribed targets of organising camps for voluntary collection of blood through motivational campaigns and utilisation of the media. The State Councils shall submit their programmes and targets to the National Council and thereafter continue to submit quarterly reports to the Central Council about the fulfilment of the targets relating to the programmes.

ii)

The National Council and State Councils should launch effective programmes and organise campaigns for collecting funds for implementation of their programmes, supplementing the funds allotted to them respectively by the Government of India and the State Governments. For the purpose of facilitating the collection of funds for blood banking purposes the Government of India in the Ministry of Finance should, at the earliest, be approached by the Ministry of Health to secure special dispensation under Section 35 of the Income-tax Act, making it possible to grant exemption of 100 per cent basis to the donations given to regis-

tered and authorised National Council and State Councils. The fulfilment of this objective should be specifically reported by the Ministry of Health to the Hon'ble Supreme Court. The National Council and State Councils should also utilise opportunities which may be available for securing financial sanction and other support to their blood banking programmes from International sources and other donor agencies.

iii)

The Ministry of Health should follow up the recommendations made by the Expert Committee set up by the Indian Red Cross Society to start

M.D. Course in blood transfusion technology, and to also undertake the preparation of comprehensive programme for training of personnel operating in relation to various aspects of functioning of blood banks, storage of blood, fractionalisation of blood, and transfusion of blood.

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iv)

The system of licensing of blood banks will be strengthened to ensure that all quality banks operating in the country are equipped with licenses within a period of not more than one year. Where any blood banks remain ill-equipped for being licensed, and remain unlicensed after the expiry of the period of one year, their operations should be rendered impossible through suitable action under appropriate legislation. It shall be a policy objective of the Ministry of Health as well as the National Council and the State Councils established on the basis of these recommendations that the prevalent system of professional donors is discouraged through utilisation of all appropriate media, through withdrawal of licences where any such blood bank has been licensed, and by launching prosecutions under the appropriate provisions of law. The objective of total elimination of professional donors should be achieved in a period of not more than two years through utilisation of all requisite measures. For attainment of objectives and programmes of the local organisation, the State Govt. will be approached for providing the requisite inspectorate for continuing inspection of blood banks.

11. The Committee has taken note of the programme for preventing infection and strengthening of Blood Banking system in the country that is being implemented by the National Aids Control Organisation, which is annexed as Annexure-I to the report of the Committee.

12. The Indian Association of Blood Banks has been impleaded as a party in these proceedings and an affidavit of Dr. V.B. Lal, President of the said association has been filed.

13. We have heard Shri H.D. Shourie, the petitioner in person, Shri A.S. Nambiar, the learned Senior Counsel for the Union of India, Shri P.P. Rao, learned Senior Counsel for the Indian Association of Blood Banks, Dr. V. Gauri Shankar, learned Senior Counsel for the Indian Red Cross Society and the learned Counsel appearing for the States. Keeping in view the report of the committee that has been constituted by this Court and the report of the committee of experts set up by the Indian Red Cross Society and the programme that is being implemented by the National Aids Control Organisation as well as the submissions of the learned counsel, we are of the view that suitable action should be taken by the Union Government as well as the Governments of the States and the Union Territories Administration in accordance with the plan for immediate implementation as well as the plan for long term implementation suggested by the committee constituted by this Court.

14. It is no doubt true that after the report of M/s. A.F. Ferguson & Co. the Union Government has taken certain steps towards improving the state of affairs

regarding the blood banks in the country and the National Aids Control Organisation is also working in this field. But a lot more is required to be done as would be evident from the reports of the Committee constituted by this Court and the Committee of Experts appointed by the Indian Red Cross Society. The Committee constituted by this Court has made concrete suggestions in this regard. We are in agreement with the recommendations of the said committee that the entire range of schemes related to operation and requirements of blood donations, launching programmes of blood banks including the launching of effective motivation campaigns for stimulating voluntary blood donations, training of personnel in relation to all operations of blood banking should be entrusted to an autonomous representative body at the national level which may be called the National Council on Blood Transfusion, as suggested by the Committee. The National Council would exercise the functions entrusted to it in coordination with similar bodies established at State Level which may be called State Councils. In order that they may have their own individuality and funds and are able to raise funds from various sources including of contributions from trade, industry and individuals the National Council and the State Councils should be constituted as societies registered under the Societies Registration Act. The National Council and the State Councils should undertake the measures suggested by the Committee constituted by the Court as well as the Committee of experts appointed by the Indian Red Cross Society and while doing so they should coordinate their activities with those of the National Aids Control Organisation and other agencies in this field. Keeping in view the potentialities of the harm in the prevailing state of affairs and the need for speedy action in this regard, we consider it appropriate to give the following directions :

1. The Union Government shall take steps to establish forthwith

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National Council of Blood Transfusion as a society registered under the Societies Registration Act. It would be a representative body having in it representation from the Directorate General of Health Services of the Government of India, the Drug Controller of India, Ministry of Finance in the Government of India, Indian Red Cross Society, private blood banks including the Indian Association of the Blood Banks, major medical and health institutions of the country and non-government organisation active in the field of securing voluntary blood donations.

In order to ensure coordination with the activities of the National Aids Control Organisation, the Additional Secretary in the Ministry of Health, who is in charge of the operations of the programme of National Aids Control Organisation for strengthening the blood banking system could be the President of the National Council

2. The National Council shall have a secretariat at Delhi under the charge of a Director.

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The basic requirements of the funds for the functioning of the National Council shall be provided by the Government of India but the National Council shall be empowered to raise funds from various other sources including contributions from trade, industry and individuals.

4. In consultation with the National Council, the State Governments/ Union Territory Administration shall establish a State Council in each State/Union Territory which shall be registered as a society under the Societies Registration Act. The State Council should be a representative body having in it representation from Directorate of Health Services in the State, State Drug Controller, Department of Finance of the State Government/Union Territory Administration, important medical institutions in the State/Union Territory, Indian Red Cross Society, private blood banks, Non-Governmental Organisations active in the field of securing voluntary blood donations. The Secretary to the Government in charge of the Department of Health could be the President of the State Council.
5. The State Council should have its headquarters at the premises of the premier medical institution or hospital in the State/Union Territory and should function under the charge of a Director.
6. The funds for the State Council shall be provided by the Union of India as well as the State Government/Union Territory Administration. The State Council shall also be empowered to collect funds in shape of contributions from trade, industry and individuals.
7. The programmes and activities of the National Council and the State Councils shall cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation, separation of blood groups, proper labelling, proper storage and transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.
8. The National Council shall undertake training programmes for training of technical personnel in various fields connected with the operation of blood banks.
9. The National Council shall establish an institution for conducting research in collection, processing, storage, distribution and transfusion

of whole human blood and human blood components, manufacture of blood products and other allied fields.

10. The National Council shall take steps for starting special post-graduate courses in blood collection, processing, storage and transfusion and allied fields in various medical colleges and institutions in the country.

11. In order to facilitate the collection of funds for the National Council and the State Councils, the Government of India (Ministry of Health and Ministry of Finance) should find out ways and means to secure grant of 100% exemption from income-tax to the donor in respect of donations made to the National Council and the State Councils.

12. The Union Government and the Governments of the States and Union Territories should ensure that within a period of not more than one year all blood banks operating in the country are duly licensed and if a blood bank is found ill equipped for being licensed, and remains unlicensed after the expiry of the period of one year, its operations should be rendered impossible through suitable legal action.

13. The Union Government and the Governments of the States and Union Territories shall take steps to discourage the prevalent system of professional donors so that the system of professional donors is completely eliminated within a period of not more than two years.

14. The existing machinery for the enforcement of the provisions of the Act and the Rules should be strengthened and suitable action be taken in that regard on the basis of the Scheme submitted by the Drugs Controller (I) to the Union Government for upgradation of the Drugs Control Organisation in the Centre and the States (Annexure II to the affidavit of Shri R. Narayanaswami, Assistant Drug Controller, dated September 16, 1994).

15. Necessary steps be taken to ensure that Drugs Inspectors duly trained in blood banking operations are posted in adequate numbers so as to ensure periodical checking of the operations of the blood banks throughout the country.

16. The Union Government should consider the advisability of enacting a separate legislation for regulating the collection, processing, storage, distribution and transportation of blood and the operation of the blood banks in the country.

17. The Director General of Health Services in the Government of India,

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18. It will be open to the Director General of Health Services, Government of India as well as the National Council to seek clarification/modification of these directions or further directions in this matter.

15. The writ petition is disposed with these directions. No order as to costs.

Order accordingly.

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
WRIT PETITION [CIVIL] NO. 91 OF 1992

Common Cause, A Regd. Society, New DelhiAppellant

versus

Union of India & Ors.Respondents

ORDER

After passing of the order dated May 9, 1997 further affidavits have been filed on behalf of the Union of India as well as on behalf of the various State Governments and Union Territories. We have perused the same. We find that State Councils for Blood Transfusion have been set up in all the States and Union Territories in accordance with the directions given by this Court. We also find that steps have been taken for licensing of the existing blood banks and steps have also been taken for discontinuing the operation of blood banks which have not been granted licences. Thus, the directions given by this Court in the judgment dated January 4, 1996 in that regard have been complied with. As regards further steps to be taken in pursuance of the directions contained in the said judgment we direct that the National Council for Blood Transfusion, in co-ordination with the State Councils, shall take necessary steps to ensure proper functioning of the blood banks which have been licensed and establishment of new blood banks (duly licensed) so that the need for blood in the various parts of the country can be met at short notice. The National Council shall also take steps to augment the availability of blood in the blood banks by organising voluntary donation camps and by creating social awareness among the people about the need for voluntary donation of blood so that the prevailing practice of securing blood from professional blood donors is eliminated. With these observations we close this matter. While doing so we place on record our appreciation for the initiative taken by Shri

H.D. Shourie, appearing in person on behalf of the petitioner-Society, in taking up this matter and for the assistance rendered by him to the Court. The writ petition is disposed of accordingly. The contempt notices which have been issued are discharged.

NEW DELHI Sd/- S/C/ AGRAWAL, J.

July 25, 1997 Sd/- J.

1. See <http://www.isbt-web.org/ethics.pdf>

The Blood Bankers' Legal Handbook

The Blood Bankers' Legal Handbook

6

The ISBT Ethical Code For Blood Donation
and Transfusion¹

A code of ethics for blood donation and transfusion as adopted by the
General Assembly of the International Society of Blood Transfusion (ISBT),
12 July 2000

The objective of this code is to define the ethical principles and rules to be
observed in the field of transfusion medicine

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.

2. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.

3. In the event that the patient is unable to give prior informed consent, the basis for treatment must be in the best interests of the patient.

4. A profit motive should not be the basis for the establishment and running of a blood service.

5. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.

6. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.

7. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the patient.

8. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.

9. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.

Appendix 7—Drugs & Cosmetics Rules, 1945—Part 1—Preliminary

10. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.

11. Donors and recipients should be informed if they have been harmed.

12. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.

13. Genuine clinical need should be the only basis for transfusion therapy.

14. There should be no financial incentive to prescribe a blood transfusion.

15. Blood is a public resource and access should not be restricted.

16. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.

17. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorized to do so should be in compliance with this code of ethics.

1. Subs. By GSR 370(E), dt 7-4-1994 (w.e.f. 7-4-1994)

2. The words "except the State of J & K" omitted by GSR 358, dt 5-3-1975 (w.e.f. 15-3-1975)

3. Ins. By GSR 923(E), dt 14-12-1992 (w.e.f. 14-12-1992 (w.e.f. 14-12-1992)). Earlier entry on "British Pharmacopoeia" omitted by GSR 19, dt 15-12-1977.

4. Subs. By S.O. 4816, dt 19-11-1969 (w.e.f. 6-12-1969).

5. Ins. by GSR 680(E), dt 5-12-1980 (w.e.f. 5-12-1980).

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Relevant extracts from the Drugs & Cosmetics

Rules, 1945

No. F. 28—10/45—H(1), the 21st of December 1945—In exercise of the powers conferred by Sections 16(2), 12, 33 and 33-N1 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government is pleased to make the following rules.

Part 1

Preliminary

1. Short title, extent and commencement.—(1) These Rules may be called the Drugs and Cosmetics Rules, 1945.
(2) They extend to the whole of India 2[* * *]
2. Definitions. —In these Rules, unless there is anything repugnant in the subject or context —
 - (a) "the Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940), as amended from time to time;
 - 3[(b) "Central Licence Approving Authority" means the Drugs Controller, India, appointed by the Central Government
 - (c) "Director" means the Director of the Central Drugs Laboratory;
 - (d) "Form" means a Form set forth in Schedule A;
 - 4[(dd) Homoeopathic medicines include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route;
 - (e) "Laboratory" means the Central Drugs Laboratory;
6. Ins by S.O. 1196, dt 9-4-1960 (w.e.f. 14-5-1960).
7. Ins. by S.O. 2139, dt 5-6-1972 (w.e.f. 12-8-1972).
8. Ins. by S.O. 2139, dt 5-6-1972 (w.e.f. 12-8-1972).
9. Amended under Government of India Noti. No. F. 1-3/51-DS, dt 15-10-1954.
10. Ins. by GSR 681(E), dt 6-6-1988 (w.e.f. 6-6-1988).
11. Amended by Government of India Noti. No. F.1-16/57-D, dt 15-6-1957.

12. Amended by Government of India Noti. No. F. 28-10/45-H(1), dt 31-3-1957.

13. Amended by Government of India Noti. No. F, 1-16/57-D. dt 15-6-1957

Appendix 7—Drugs & Cosmetics Rules, 1945—PartX-B

5[(ea) "registered Homoeopathic medical practitioner" means a person who is registered in the Central Register or a State Register of Homoeopathy;]

6[(ee) Registered medical practitioner means a person

(i) holding a qualification granted by an authority specified or notified under Section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine 7(excluding the Homoeopathic system of medicine); or

(iii) registered in a medical register 8(other than a register for the registration of Homoeopathic practitioners) of a State, who although not falling within sub-clause (i) or sub-clause (ii) is declared by a general or special order made by the State Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this Act; or

(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or

(v) who is engaged in the practice of veterinary medicine and who possesses qualifications approved by the State Government;]

9[(f) 'retail sale' means a sale 10(whether to a hospital, or a dispensary, or a medical, educational or research institute or to any other person) other than a sale by way of wholesale dealing;

11(g) 'sale by way of wholesale dealing' means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical, educational or research institution;

12(h) "Schedule" means a Schedule to these Rules;

13(i) State Government in relation to a Union Territory means the Administrator thereof;

(j) "Poisonous substance" means a substance specified in Schedule E.

14[PART X-B

REQUIREMENTS FOR THE COLLECTION, STORAGE,

14. Ins. by GSR 28(E), dt 22-1-1993 (w.e.f. 22-1-1993).

15. Ins. by GSR 245(E), dt 5-4-1999 (w.e.f. 5-4-1999)

N

BLOOD, HUMAN BLOOD COMPONENTS BY BLOOD
BANKS AND MANUFACTURE OF BLOOD PRODUCTS

15[122-EA. Definitions. —(1) In this Part and in the Forms contained in Schedule A and in Part XII-B and Part XII-C of Schedule F, unless there is anything repugnant in the subject or context,—

- (a) "apheresis" means the process by which blood drawn from a donor, after separating plasma or platelets or leucocytes, is re-transfused simultaneously into the said donor;
- (b) "autologous blood" means the blood drawn from the patient for re-transfusion into himself later on;
- (c) "blood" means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant;
- (d) "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, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components;
- (e) "blood component" means a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor;
- (f) "blood product" means a drug manufactured or obtained from pooled plasma of blood by fractionation, drawn from donors;
- (g) "donor" means a person who voluntarily donates blood after he has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or kind from any source, but does not include a professional or a paid donor;

Explanation—For the purposes of this clause, benefits or incentives like pins, plaques, badges, medals, commendation certificates, time-off from work, membership of blood assurance programme, gifts of little or intrinsic monetary value shall not be construed as consideration.

- (h) "leucapheresis" means the process by which the blood drawn from a donor,
 - 16. Ins. by GSR 245(E), dt 5-4-1999 (w.e.f. 5-4-1999).
 - 17. Su bs. By GSR 601(E), dt 24-8-2001 (w.e.f. 24-8-2001)
 - 18.. Subs, by GSR 601(E), dt 24-8-2001 (w.e.f. 24-8-2001).
 - 19.. Ins. by GSR 245(E), dt 5-4-1999 (w.e.f. 5-4-1999).
 - 20. Ins. by GSR 245(E), dt 5-4-1999 (w.e.f. 5-4-1999).

after leucocyte concentrates have been separated is re-transfused simultaneously into the said donor;

(i) "plasmapheresis" means the process by which the blood drawn from a donor, after plasma has been separated, is re-transfused during the same sitting into the said donor;

(j) "plateletpheresis" means the process by which the blood drawn from a donor, after platelet concentrates have been separated, is re-transfused simultaneously into the said donor;

(k) "professional donor" means a person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient-patient and includes a paid donor or a commercial donor;

(l) "replacement donor" means a donor who is a family friend or a relative of the patient-recipient.

122-F. Form of application for licence for operation of Blood Bank/processing of whole human blood for components/manufacture of blood products for sale or distribution. —(1) Application for the grant and/or renewal of licence for the operation of a Blood Bank/processing of human blood for components/manufacture of blood products shall be made to the Licensing Authority appointed under Part VII in Form 27-C 16(or Form 27-E), and shall be accompanied by (licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every inspection thereof or for the purpose of renewal of licence)17;

Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry the fee payable for the renewal of the licence18(shall be rupees six thousand and inspection fee of rupees one thousand and five hundred plus an additional fee at rate of rupees one thousand per month or a part thereof in addition to the inspection fee):

Provided further that a licensee holding a licence in Form 28-C 19(or Form 28-E, as the case may be,) for operation of Blood Bank/processing of whole human blood for components/manufacture of blood products shall apply for grant of licence under sub-rule (1) before the expiry of the said licence on Form 27-C20(or Form 28-E, as the case may be) and he shall continue to operate the same till the orders on his application are communicated to him.

21(Explanation—For the purpose of this rule, "Blood Bank" means a place or

21. Subs. By GSR 89(E), dt 14-2-1996 (w.e.f. 14-2-1996).

22. Subs. By GSR 601(E), dt 24-8-2001 (w.e.f. 24-8-2001).

23. Subs. By GSR 601(E), dt 24-8-2001 (w.e.f. 24-8-2001).

24. ins. by GSR 89(E), dt 14-2-1996 (w.e.f. 14-2-1996).

25. Subs. As per Corrigendum vide GSR 447(E), dt 10-6-1993 to GSR 28(E), dt. 22-1-1993.

(2) A fee of rupees one 22(thousand) shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

(3) Application by a licensee to manufacture additional drugs listed in the application shall be accompanied by a fee of rupees 23(three hundred) for each drug listed in the application.

(4) On receipt of the application for the grant or renewal of such licence, the Licensing Authority shall. —

(i) verify the statements made in the application form;

(ii) cause the manufacturing and testing establishment to be inspected in accordance with the provision of Rule 122-I; and

(iii) in case the application is for renewal of licence, call for informations of past performance of the licensee.

(5) If the Licensing Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in the rules, he shall prepare a report to that effect and forward it along with the application 24(and the licence (in triplicate) to be granted or renewed, duly completed) to the Central Licence Approving Authority;

Provided that if the Licensing Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules, he may, by order, for reasons to be recorded in writing, refuse to grant or renew the licence, as the case may be.

(6) If, on receipt of the application and the report of the Licensing Authority referred to in sub-rule (5)25 and after taking such measures including inspection of the premises, by the Inspector, appointed by the Central Government under Section 21 of the Act, and or along with the Expert in the field concerned if deemed necessary, the Central Licence Approving Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in these rules, he may grant or renew the licence, as the case may be;

Provided that if the Central Licence Approving Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules he may, notwithstanding the report of the Licensing Authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of licence, as

26. Ins. by GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999).

27. Ins. by GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999).

28. Subs. By GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999.)

29. April 5, 1999

the case may be, and shall supply the applicant with a copy of the inspection report.

122-G. Form of licence for the operation of a Blood Bank/processing of whole human blood for components and manufacture of blood products and the conditions for the grant or renewal of such licence.—A licence for the operation of a Blood Bank or for processing whole human blood for components and manufacture of blood products shall be issued in Form 28-C 26(or Form 28E on Form 26-G or Form 26-I, as the case may be). Before a licence in Form 28C 27(or Form 28-E or Form 26-G or Form 26-I, as the case may be,) is granted or renewed the following conditions shall be complied with by the applicant:

28(i) The operation of Blood Bank and/or processing of whole human blood for components shall be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person who is whole time employee and who is Medical Officer, and possessing -

(a) Postgraduate degree in Medicine M.D. (Pathology/Transfusion Medicines); or

(b) Degree in Medicine (M.B.B.S.) with Diploma in Pathology or Transfusion Medicines having adequate knowledge in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components; or

(c) Degree in Medicine (M.B.B.S.) having experience in Blood Bank for one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components.

the degree or diploma being from a University recognised by the Central Government.

Explanation—For the purposes of this condition, the experience in Blood Bank for one year shall not apply in the case of persons who are approved by the Licensing Authority and/or Central Licence Approving Authority prior to the commencement of the Drugs and Cosmetics (Second Amendment) Rules, 199929).

(ii) The applicant shall provide adequate space, plant and equipment for any or all the operations of blood collection or blood processing. The space,

30. Ins. by GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999).

31. Ins. by GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999).

32. Subs. By GSR 601(E), dt. 24-8-2001 (w.e.f. 24-8-2001).

33. Subs. By GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999).

34. Subs. As per Corrigendum vide GSR 447(E), dt. 10-6-1993 to GSR 28(E), dt. 22-1-1993

35. Subs. As per Corrigendum vide GSR 447(E), dt. 10-6-1993 to GSR 28(E), dt. 22-1-1993.

(iv)The applicant shall provide adequate arrangements for storage of whole human blood, human blood components and blood products.

(v) The applicant shall furnish to the Licensing Authority, if required to do so, data on the stability of whole human blood, its components or blood products which are likely to deteriorate, for fixing the date of expiry which shall be printed on the labels of such products on the basis of the data so furnished.

122-H. Duration of licence. —An original licence in Form 28-C 30(or Form 28-E) or a renewed licence in Form 26-G 31(or Form 26-I) unless sooner suspended or cancelled shall be 32(valid for a period of five years on and from the date on which) it is granted or renewed.

122-I. Inspection before grant or renewal of licence for operation of Blood Bank, processing of whole human blood for components and manufacture of blood products. —Before a licence in 33(Form 28-C or Form 28-E is granted or a renewal of licence in Form 26-G or Form 26-I is made, as the case may be,) the Licensing Authority or the Central Licence Approving Authority, as the case may be, shall cause the establishment in which Blood Bank is proposed to be operated/whole human blood for components is processed 34(I) blood products are manufactured to be inspected by one or more Inspectors, appointed under the Act and/or along with the Expert in the field concerned. The Inspector or Inspectors shall examine all portions of the premises and appliances/equipments and inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for operation of blood bank/processing of whole human blood for components/manufacture of blood products together with their (testing)35 facilities and also enquire into the professional qualification of the expert staff and other technical staff to be employed.

122-J. Report by Inspector—The Inspector or Inspectors shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendation in accordance with the provisions of Rule 122-I to the Licensing Authority or to the Central Licence Approving Authority.

122-K Further application after rejection - If within a period of six months

36. Ins. by GSR 601(E), dt. 24-8-2001 (w.e.f. 24-8-2001).

37. Subs. By GSR 245(E), dt. 5-4-1999 (w.e.f. 5-4-1999).

38. Subs. As per Corrigendum vide GSR 447(E), dt. 10-6-1993 to GSR 28(E), dt. 22-1-1993.

from the rejection of application for a licence the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees 36(two hundred and) fifty the Licensing Authority may, if after causing further inspection to be made is satisfied that the conditions for the³⁷(grant or renewal of a licence have been complied with, shall grant or renew the licence in Form 28-C or Form 28-E

Provided that in the case of a drug notified by the Central Government under Rule 68-A, the application, together with the inspection report and the Form of licence (in triplicate to be granted or renewed), duly completed shall be sent, to the Central Licence Approving Authority, who may approve the same and return it to the Licensing Authority for issue of the licence.)

122-L. Delegation of powers by the Central Licence Approving Authority.—The Central Licence Approving Authority may, with the approval of the Central Government, by notification delegate his powers of signing licences and any other power under rules to persons under his control having same qualifications as prescribed for Controlling Authority under Rule 50-A, for such areas and for such periods as may be specified.

122-M. Provision for appeal to the State Government by a party whose licence has not been granted or renewed.—Any person who is aggrieved by the order passed by the Licensing Authority or Central Licence Approving Authority, as the case may be, may within thirty days from the date of receipt of such order, appeal to the State Government or Central Government, as the case may be, after such enquiry into the matter as it considers necessary and after giving the said person an opportunity for representing his view in the matter may pass such order in relation thereto as it thinks fit.

122-N. Additional information to be furnished by an (applicant)³⁸ for licence or by a licensee to the Licensing Authority.—The applicant for the grant of licence or any person granted a licence under the Part shall, on demand furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation, rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matter, which may be required for the purpose of verifying the correctness of the statement made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

39. Ins. by GSR 20(E), dt. 11-1-1996 (w.e.f. 11-1-1996).

40. As inserted by Corrigendum vide GSR 514(E), dt. 6-11-1996.

41. Subs. By GSR 245(E), dt. 5-4-1999).

42. As corrected by Corrigendum vide GSR 447(E), dt. 10-6-1993.

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Appendix 7—Drugs & Cosmetics Rules, 1945—Part X-B

122-O. Cancellation and suspension of licences.—(1) The Licensing Authority or Central Licence Approving Authority may for such licences granted or renewed by him after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reason thereof, cancel a licence issued under this part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates 39(or direct the licensee to stop collection, storage, processing, manufacture and distribution of the said substances and 40(thereupon order the destruction of substances and) stocks thereof in the presence of an Inspector), if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or Rules thereunder.

(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1) prefer an appeal against that order to the State Government or Central Government, which shall decide the same.

122-P. Conditions of Licence.—41(A licence in Form 28-C, Form 28-E, Form 26-G or Form 26-I shall be subject to the special conditions set out in Schedule F, Part XII-B and Part XII-C, as the case may be, which relate to the substance in respect of which the licence is granted or renewed and to the following general conditions, namely:

(i)

- (a) The licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a Blood Bank for processing whole human blood, its components and/or manufacture of blood products.
- (b) The licensee shall maintain staff, premises and equipment as specified in Rule 122-G. The licensee shall maintain necessary records and registers as specified in Schedule F, Parts XII-B and XII-C.
- (c) The licensee shall test in his own laboratory whole human blood, its components and blood products and (maintain records and) 42 registers in respect of such tests as specified in Schedule F, Parts XII-B and XII-C. The records and register shall be maintained for a period of five years from the date of manufacture.
- (d) The licensee shall maintain/preserve reference 43(sample and) supply to the Inspector the reference sample of the whole human blood collected by him in an adequate quantity to conduct all the prescribed tests. The licensee shall supply to the Inspector the reference sample for the purpose of testing.

43. As corrected by Corrigendum vide GSR 447(E), dt. 10-6-1993.

44. As corrected by Corrigendum vide GSR 447(E), dt. 10-6-1993.

(ii)

The licensee shall allow an Inspector appointed under the Act to enter, with or (without)⁴⁴ prior notice, any premises where the activities of the Blood Bank are being carried out for the processing of Whole Human Blood and/or Blood Products, to inspect the premises and plant and the process of manufacture and the means employed for standardising and testing the substance.

(iii)

The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and rules thereunder have been observed.

(iv)

The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the operation of a Blood Bank/processing of whole human blood for components and/or manufacture of blood products and any material alterations in the premises or plant used for that purpose which have been made since the date of last inspection made on behalf of the Licensing Authority before the grant of the licence.

(v)

The licensee shall on request furnish to the Licensing Authority, or Central Licence Approving Authority or to such Authority as the Licensing Authority, or the Central Licence Approving Authority may direct, from any batch unit of drugs as the Licensing Authority or Central Licence Approving Authority may from time to time specify, sample of such quantity as may be considered adequate by such Authority for any examination and, if so required, also furnish full protocols of the test which have been applied.

(vi)

If the Licensing Authority or the Central Licence Approving Authority so directs, the licensee shall not sell or offer for sale any batch/unit in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorising the sales of batch/unit has been issued to him by or on behalf of the Licensing Authority or the Central Licence Approving Authority.

(vii) The licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch/unit of the substance has been found by the Licensing Authority or the Central Licence Approving Authority not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do, withdraw, from sales and so far as may in the particular circumstances of the case be

45. Ins by GSR 245(E), dt 5.4.99 (w.e.f. 5.4.99)

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(viii) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Further no batch/unit manufactured under this licence shall be supplied/distributed to any person without prescription of a Registered Medical Practitioner.

(ix)

The licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any Rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the Rules, these would come in force four months after publication in the Official Gazette.

(x)

The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and defects noticed.

(xi)

The licensee shall destroy the stocks of batch/unit which does not comply with standard tests in such a way that it would not spread any disease/infection by way of proper disinfection method.)

45(xii) All bio-medical waste shall be treated, disposed of or destroyed as per the provisions of the Bio-Medical Wastes (Management and Handling) Rules, 1996.

(xiii) The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components and/or manufacture blood products from the blood drawn from such a donor.

Appendix 7—Prescribed Forms under the Drugs & Cosmetics Rules, 1945

(FORM 26-G46

(See Rule 122-F)

Certificate of renewal of licence to operate a Blood Bank for processing of whole human blood and/or* for preparation for sale or distribution of its components

1. Certified that licence No.....granted
on.....to M/sfor the operation of a Blood
Bank for processing of whole human blood and/or for preparation of its components
at the premises situated at.....is hereby renewed
with effect from.....to.....

2.

Name(s) of Items:

1.

2.

3.

3.

Name(s) of competent Technical Staff:

1.

2.

3.

4.

5.

6.

Date.....

Signature.....

Name and Designation.....

Licensing Authority

.....

Central Licence Approving Authority

*Delete whichever is not applicable.)

46. Subs. by GSR 345(E), dt 5-4-1999 (w.e.f. 5-4-1999)

41. Ins. by GSR 245(E) dt. 5.4.1999 (w.e.f. 5.4.1999)

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(See Rule 122-I)

Certificate of renewal of licence for manufacture of blood products

Certified that licence number.....granted
on.....to M/s.....for
manufacture of blood products at the premises situated at
..... is hereby renewed with effect from
.....to.....

2. Name(s) of item(s):

- 1.
- 2.
- 3.

3. Names of competent Technical Staff

(a) responsible for manufacturing (b) responsible for testing

1. 1.
2. 2.
3. 3.
4. 4.

Signature.....

Name and Designation.....

Licensing Authority

.....

Central Licence Approving Authority.

48. Subs. by GSR 245(E) dt. 9.4.1999)

(FORM 27-C48

(See Rule 122-F)

Application for grant/renewal* of licence for the operation of a Blood Bank for processing of whole blood and/or* preparation of Blood Components

1. I/We.....of
M/s.....

hereby apply for the grant of licence/renewal of licence number.....

dated.....to operate a Blood

Bank, for processing of whole blood and/or* for preparation of its components on
the premises situated at.....

2. Name(s) of the item(s):

1.

2.

3.

3. The name(s), qualification and experience of competent Technical Staff
are as under:

(a) Name(s) of Medical Officer.

(b) Name(s) of Technical Supervisor.

(c) Name(s) of Registered Nurse.

(d) Name(s) of Blood Bank Technician.

4. The premises and plant are ready for inspection/will be ready for inspection
on

5. A licence fee of rupeesand an inspection fee
of rupees has been credited to the Government under
the Head of Account.....(receipt enclosed)

Dated.....

Signature.....

Name and

Designation.....

*Delete whichever is not applicable.

Note: 1. The application shall be accompanied by a plan of the premises, list
of machinery and equipment for collection, processing, storage and
testing of whole blood and its components, memorandum of associa

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2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the Zonal/Sub Zonal Officers concerned of the Central Drugs Standard Control Organisation.)

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(FORM 27-E)49

(See Rule 122-F)

Application for grant/renewal* of licence to manufacture blood products for sale or distribution

1. I/We.....of M/s..... hereby apply for the grant of licence/renewal of licence number dated..... To manufacture blood products on the premises situated at.....

2. Name(s) of Item(s):

- 1.
- 2.
- 3.
- 4.

3. The name(s), qualification and experience of competent Technical Staff as under:

(a) responsible for manufacturing (b) responsible for testing

1. 1.
2. 2.
3. 3.

4. The premises and plant are ready for inspection/will be ready for inspection on.....

5. A licence fee of rupees..... and an inspection fee of rupees has been credited to the Government under the Head of Account.....(receipt enclosed).

Dated..... Signature.....

Name & Designation.....

*Delete whichever is not applicable

Note: 1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/ constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents

relating to ownership or tenancy of the premises.

2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the

49. Ins. by GSR 245(E), dt. 5.4.1999 (w.e.f. 5.4.1999)

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Zonal/Sub Zonal Officers concerned of the Central Drugs Standard
Control Organisation.)

(FORM 28-C50
(See Rule 122-G)

Licence to operate a Blood Bank for collection, storage and processing of
whole human blood and/or* its components for sale or distribution

1.

Number of licence Date of issue
at the premises situated at.....

2.

M/s.....is hereby licensed to collect, store,
process and distribute whole blood and/or its components.

3.

Name(s) of the item(s):

1.

2.

3.

4.

Name(s) of competent Technical Staff:

1.

2.

3.

4.

5.

6.

5. The licence authorises licensee to collect, store, distribute, and processing
of whole blood and/or blood components subject to the conditions
applicable to this licence.

6. The

licence shall be in force from

.....to.....

7. The licence shall be subject to the conditions stated below and to such
other conditions as may be specified from time to time in the Rules made
under the Drugs and Cosmetics Act, 1940.

Dated..... Signature.....

Name and Designation.....

Licensing Authority

Central Licence Approving Authority

*Delete whichever is not applicable.

50. Subs. by GSR 245(E) dt. 5.4.1999 (w.e.f. 5.4.1999).

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1. The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components from the blood collected from such a donor.
2. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.
4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.)

51. Ins. by GSR 245(E) dt. 5.4.1999 (w.e.f. 5.4.1999)

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(FORM 28-E51

(See Rule 122-G)

Licence to manufacture and store blood products for sale or distribution

1. Number of licence.....Date of issue
.....at the premises situated at.....

2. M/s is hereby licensed to
manufacture, store, sell or distribute the following blood products:3.

Name(s) of the item(s):

- 1.
- 2.
- 3.
- 4.
- 5.

4. Name(s) of competent Technical Staff:

(a) responsible for manufacturing (b) responsible for testing

1. 1.
2. 2.

3. 3.

5. The licence authorises the licensee to manufacture, store, sell or distribute the blood products, subject to the conditions applicable to this licence.

6. The licence shall be in force from To

7. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the Rules made under the Drugs and Cosmetics Act, 1940.

Dated..... Signature.....

Name & Designation.....

Licensing Authority

Central Licence Approving Authority

*Delete whichever is not applicable

Conditions of Licence

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The licensee shall not manufacture blood products from the blood drawn from any professional donor or paid donor.

2. This licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

3. Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.

4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.)

52. PART XII-B & XII-C subs by GSR 245 (E), dated 5.4.199 (wef. 5.4. 1999)

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SCHEDULE F

PART XII—B52

REQUIREMENTS FOR THE FUNCTIONING AND
OPERATION OF A BLOOD BANK AND/OR FOR
PREPARATION OF BLOOD COMPONENTS.

1. BLOOD BANKS/BLOOD COMPONENTS

A. GENERAL

1. Location and Surroundings: The blood bank shall be located at a place which shall be away from open sewage, drain, public lavatory or similar unhygienic surrounding.

2. Building: The building(s) used for operation of a blood bank and/or preparation of blood components shall be constructed in such a manner so as to permit the operation of the blood bank and preparation of blood components under hygienic conditions and shall avoid the entry of insects, rodents and flies. It shall be well lighted, ventilated and screened (mesh), wherever necessary. The walls and floors of the rooms, where collection of blood or preparation of blood components or blood products is carried out shall be smooth, washable and capable of being kept clean. Drains shall be of adequate size and where connected directly to a sewer, shall be equipped with traps to prevent back siphonage.

3. Health, clothing and sanitation of staff: The employees shall be free from contagious or infectious diseases. They shall be provided with clean overalls, head-gears, foot-wears and gloves, wherever required. There shall be adequate, clean and convenient hand washing and toilet facilities.

B. ACCOMMODATION FOR A BLOOD BANK:

A blood bank shall have an area of 100 squares metres for its operations and an additional area of 50 square metres for preparation of blood components. It shall be consisting of a room each for

- (1)Registration and medical examination with adequate furniture and facilities for registration and selection of donors;
- (2)Blood collection (air-conditioned);
- (3)Blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degree centigrade to 25 degree centigrade);
- (4)Laboratory for blood group serology. (air-conditioned);
- (5)Laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV-antibodies (air-conditioned);

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(7) Refreshment-cum-rest room (air-conditioned)

(8) Store-cum-records

Notes: (1) The above requirements as to accommodation and area may be relaxed, in respect of testing laboratories and sterilization-cum-washing room, for reasons to be recorded in writing by the Licensing Authority and/or the Central Licence Approving Authority, in respect of blood banks operating in hospitals, provided the hospital concerned has a pathological laboratory and a sterilization-cum-washing room common with other departments in the said hospital.

(2) Refreshments to the donor after phlebotomy shall be served so that he is kept under observation in the Blood Bank.

C. PERSONNEL

Every blood bank shall have following categories of whole time competent technical staff:(

a) Medical Officer, possessing the qualifications specified in condition (I) of Rule 122-G.

(b) Blood Bank Technicians(s), possessing

(i) Degree in Medical Laboratory Technology (M.L.T.) with six months experience in the testing of blood and/or its components; or

(ii) Diploma in Medical Laboratory Technology (MLT) with one year's experience in the testing of blood and/or its components,

The degree or diploma being from a University/Institution recognised by the Central Government or State Government.

(c) Registered Nurse(s)

(d) Technical Supervisor (where blood components are manufactured), possessing

(i) Degree in Medical Laboratory Technology (M.L.T.) with six months' experience in the preparation of blood components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T.) with one year's experience in the preparation of blood components.

The degree or diploma being from a University/Institution recognised by the Central Government or State Government.

Notes:

(1) The requirements of qualification and experience in respect of Technical Supervisor and Blood Bank Technician shall apply in the cases of persons who are approved by the Licensing Authority

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and/or Central Licence Approving Authority after the commencement of the Drugs and Cosmetics (Amendment) Rules, 1999.

- (2) As regards the number of whole time competent technical personnel, the blood bank shall comply with the requirements laid down in the Directorate General of Health Services Manual.
- (3) It shall be the responsibility of the licensee to ensure through maintenance of records and other latest techniques used in blood banking system that the personnel involved in blood banking activities for collection, storage, testing and distribution are adequately trained in the current Good Manufacturing Practices/Standard Operating Procedures for the tasks undertaken by each personnel. The personnel shall be made aware of the principles of Good Manufacturing Practices/Standard Operating Procedures that affect them and receive initial and continuing training relevant to their needs.

D. MAINTENANCE

The premises shall be maintained in a clean and proper manner to ensure adequate cleaning and maintenance of proper operations. The facilities shall include:

- (1) Privacy and thorough examination of individuals to determine their suitability as donors.
- (2) Collection of blood from donors with minimal risk of contamination or exposure to activities and equipment unrelated to blood collection.
- (3) Storage of blood or blood components pending completion of tests.
- (4) Provision for quarantine, storage of blood and blood components in a designated location, pending repetition of those tests that initially give questionable serological results.
- (5) Provision for quarantine, storage, handling and disposal of products and reagents not suitable for use.
- (6) Storage of finished products prior to distribution or issue.
- (7) Proper collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.
- (8) Adequate and proper performance of all procedures relating to plasmapheresis, plateletpheresis and leucapheresis.
- (9) Proper conduct of all packaging, labeling and other finishing operations,
- (10) Provision for safe and sanitary disposal of (i) Blood and/or blood components not suitable for use, distribution or sale.

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Trash and items used during the collection, processing and compatibility testing of blood and/or blood components.

E. EQUIPMENT

Equipment used in the collection, processing, testing, storage and sale/distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance. The equipment shall be observed, standardised and calibrated on a regularly scheduled basis as described in the Standard Operating Procedures Manual and shall operate in the manner for which it was designed so as to ensure compliance with the official requirements (the equipments) as stated below for blood and its components.

Equipment that shall be observed, standardised and calibrated with at least the following frequencies:

EQUIPMENT PERFORMANCE FREQUENCY FREQUENCY OF CALIBRATION

1. Temperature

Compare against Daily As often as necessary recorder thermometer

2. Refrigerated

Observe speed and Each day of use As often as necessary centrifuge temperature

3. Hematocrit

— — Standardise before centrifuge initial centrifuge use, after repair or adjustments, and annually

4. General lab

— — Tachnometer, every Centrifuge 6 months.

5. Automated

Observe controls Each day of use — Blood typing for correct results

6. Haemoglo-

Standardize Each day of use — binometer

against
cyanamethemoglobin
standard

7. Refractometer
Standardize —ditto—
of Urinometer
against distilled
water

8. Blood container Standardize —ditto— As often as necessary.
weighing device against container
of known weight

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EQUIPMENT PERFORMANCE FREQUENCY FREQUENCY OF
CALIBRATION

9. Water Bath Observe Each day of use As often as necessary
temperature
10. Rh view box —ditto— —ditto— —ditto—
(wherever
necessary)
11. Autoclave —ditto— Each time of use —ditto—
12. Serologic Observe controls Each day of use Speed as often as
rotators for correct results necessary
13. Laboratory — — before initial use

thermometers

14. Electronic
— Monthly —
thermometers

15. Blood agitator
Observe weight of Each day of use Standardize with
the first container container of known
of blood filled for mass or volume before
correct results initial use, and after
repairs or adjustments.

F. SUPPLIES AND REAGENTS

All supplies and reagents used in the collection, processing, compatibility
testing, storage and distribution of blood and blood components shall be stored at

proper temperature in a safe and hygienic place, in a proper manner and in particular

(a)all supplies coming in contact with blood and blood components intended for tranfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product.

(b)Supplies and reagents that do not bear an expiry date shall be stored in a manner that the oldest is used first.

(c)Supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer.

(d)All final containers and closures for blood and blood components not intended for tranfusion shall be clean and free of surface solids and other contaminants.

(e)Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its

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- (f) Representative samples of each lot of the following reagents and/or solutions shall be tested regularly on a scheduled basis by methods described in the Standard Operating Procedures Manual to determine their capacity to perform as required:

Reagents and solutions Frequency of testing along
with controls

Anti-human serum Each day of use

Blood grouping serums Each day of use

Lectin Each day of use

Antibody screening and reverse Each day of use
Grouping cells

Hepatitis test reagents Each run

Syphilis serology reagents Each run

Enzymes Each day of use

HIV I and II reagents Each run

Normal saline (LISS and PBS) Each day of use

Bovine Albumin Each day of use

G. GOOD MANUFACTURING PRACTICES (GMPs)/STANDARD
OPERATING PROCEDURES (SOPs):

Written Standard Operating Procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage and sale or distribution of blood and/or preparation of blood components for homologous transfusion, autologous transfusion and further manufacturing purposes.

Such procedures shall be available to the personnel for use in the areas concerned. The Standard Operating Procedures shall inter alia include:

- (1) (a) criteria used to determine donor suitability.
(b) methods of performing donor qualifying tests and measurements including minimum and maximum values for a test or procedure, when a factor in determining acceptability;
(c) solutions and methods used to prepare the site of phlebotomy so

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as to give maximum assurance of a sterile container of blood.

- (d) method of accurately relating the product(s) to the donor;
(e) blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood drawn from the donor;
(f) methods

- of component preparation, including any time restrictions
for specific steps in processing;
- (g) all tests and repeat tests performed on blood and blood components
during processing;
 - (h) pre-transfusion testing, wherever applicable, including precautions
to be taken to identify accurately the recipient blood components
during processing;
 - (i) procedures of managing adverse reactions in donor and recipient
reactions;
 - (j) storage temperatures and methods of controlling storage temperatures
for blood and its components and reagents;
 - (k) length of expiry dates, if any, assigned for all final products;
 - (l) criteria for determining whether returned blood is suitable for reissue;
 - (m) procedures used for relating a unit of blood or blood component
from the donor to its final disposal;
 - (n) quality control procedures for supplies and reagents employed in
blood collection, processing and re-transfusion testing;
 - (o) schedules and procedures to safeguard its mix-ups, receipt, issue,
rejected and in-hand;
 - (p) labelling procedures to safeguard its mix-ups, receipt, issue, rejected
and in-hand; procedures for plasmapheresis, plateletpheresis
and leucapheresis if performed, including precautions to be taken
to ensure re-infusion
 - (q) procedures for plasmapheresis, plateletpheresis and leucapheresis
if performed, including precautions to be taken to ensure re-
infusion of donor's own cells.
 - (r) Procedures for preparing recovered (salvaged) plasma if performed,
including details of separation, pooling, labelling,, storage
and distribution.
 - (s) All records pertinent to the lot or unit maintained pursuant to these
regulations shall be reviewed before the release or distribution of a
lot or unit of final product. The review or portions of the review may

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(2) A licensee may utilise current Standard Operating Procedures, such as the Manuals of the following organisations, so long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this Part, namely:({

- i) Directorate General of Health Services Manual.
- (ii) Other Organisations' or individual blood bank's manuals, subject to the approval of State Licensing Authority and Central Licence Approving Authority.

H. CRITERIA FOR BLOOD DONATION:

Conditions for donation of blood:

(1) General.—No person shall donate blood and no blood bank shall draw blood from a person, more than once in three months. The donor shall be in good health, mentally alert and physically fit and shall not be inmate of jail, persons having multiple sex partners and drug-addicts. The donors shall fulfill the following requirements, namely:({

- a) the donor shall be in the age group of 18 to 60 years;
- (b) the donor shall not be less than 45 kilograms;

- (c) temperature and pulse of the donor shall be normal;
- (d) the systolic and diastolic blood pressures are within normal limits without medication;
- (e) haemoglobin which shall not be less than 12.5 grams;

- (f) the donor shall be free from acute respiratory diseases;
- (g) the donor shall be free from any skin diseases at the site of phlebotomy;
- (h) The donor shall be free from any disease transmissible by blood transfusion, insofar as can be determined by history and examination indicated above;

- (i) The arms and forearms of the donor shall be free from skin punctures or scars indicative of professional blood donors or addiction of self injected narcotics.

(2) Additional qualifications of a donor. —No person shall donate blood, and 53. Subs for "Hepatitis B infection" by GSR 40(E) dt 29.1.2001 (w.e.f. 1.6.2001)

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no blood bank shall draw blood from a donor, in the conditions mentioned in column (1) of the Table given below before the expiry of the period of deferment mentioned in the column (2) of the said Table.

Table: Deferment of blood donation

CONDITIONS PERIOD OF DEFERMENT

1 2

- (a) Abortions 6 months
- (b) History of Blood transfusion 6 months
- (c) Surgery 12 months
- (d) Typhoid 12 months after recovery
- (e) History of Malaria and duly treated 3 months (endemic) 3 years (non-endemic area)
- (f) Tattoo 6 months
- (g) Breast feeding 12 months
- (h) Immunization (Cholera, Typhoid, 15 days Diphtheria, Tetanus, Plague, Gammaglobulin
- (i) Rabies vaccination 1 year after vaccination
- (j) History of Hepatitis in family 12 months or close contact
- (k) Immunoglobulin 12 months

(3) No person shall donate blood and no blood bank shall draw blood from a person, suffering from any of the diseases mentioned below, namely:(

- a) Cancer
- (b) Heart disease
- (c) Abnormal bleeding tendencies
- (d) Unexplained weight loss
- (e) Diabetes controlled on insulin
- 53(f) Hepatitis infection
- (g) Chronic nephritis
- (h) Signs and symptoms suggestive of AIDS
- (i) Liver disease
- (j) Tuberculosis

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Polycythemia Vera

(l) Asthma

(m) Epilepsy

(n) Leprosy

(o) Schizophrenia

(p) Endocrine disorders

GENERAL EQUIPMENTS AND INSTRUMENTS:

1. For blood collection room:

(j) Donor beds, chairs and tables: These shall be suitably and comfortably cushioned and shall be of appropriate size

(ii) Bedside table

(iii) Sphygmomanometer and Stethoscope.

(iv) Recovery beds for donors.

(iv) Refrigerators, for storing separately tested and untested blood, maintaining temperature between 2 and 6 degree centigrade with digital dial thermometer, recording thermograph and alarm device, with provision for continuous power supply.

(v) Weighing devices for donor and blood containers.

2. For haemoglobin determination:

(i) Copper sulphate solution (specific gravity 1.053)

(ii) Sterile lancet and impregnated alcohol swabs.

(iii) Capillary tube (1.3 x 1.4 x 96 mm for Pasteur pipettes)

(iv) Rubber bulbs for capillary tubings.

(v) Sahli's haemoglobinometer/Colorimetric method.

3. For temperature and pulse determination:

(i) Clinical thermometers.

(ii) Watch (fitted with a seconds-hand) and a stop-watch.

4.

For blood containers:

(a) Only disposable PVC blood bags shall be used (closed system) as per the specifications of IP/USP/BP.

(b) Anti-coagulants: The anti-coagulant solution shall be sterile, pyrogen-free and of the following composition that will ensure satisfactory safety and efficacy of the whole blood and/or for all the separated blood components.

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(i)

Citrate Phosphate Dextrose Adenine solution (CPDA) or

Citrate Phosphate Dextrose Adenine-1(CPDA-1) - 14 ml. Solution shall be required for 100 ml of blood.

Note 1.

(i) In case of single/double/triple/quadruple blood collection bags used for blood component preparations, CPDA blood collection bags may be used.

(ii) Acid Citrate Dextrose solution (A.C.D. with Formula A). I.P. - 15 ml solution shall be required for 100 ml of blood.

(iii) Additive solutions such as SAGM, ADSOL, NUTRICEL may be used for storing and retaining Red Blood Corpuscles up to 42 days.

Note 2.

The licensee shall ensure that the anti-coagulant solutions are of a licensed manufacturer and the blood bags in which the said solutions are contained have a certificate of analysis of the said manufacturer.

5. Emergency equipments/items:

- (i) Oxygen cylinder with mask, gauge and pressure regulator.
- (ii) 5 per cent Glucose or Normal Saline.
- (iii) Disposable sterile syringes and needles of various sizes.
- (iv) Disposable sterile I.V. infusion sets.
- (v) Ampoules of Adrenaline, Noradrenaline, Mephentin, Betamethasone or Dexamethasone, Metoclopramide injections.
- (vi) Aspirin

6. Accessories:

- (i) Such as blankets, emesis basins, haemostats, set clamps, sponge forceps, gauze, dressing jars, solution jars, waste cans.
- (ii) Medium cotton balls, 1.25 cm adhesive tapes.
- (iii) Denatured spirit, Tincture Iodine, green soap or liquid soap.
- (iv) Paper napkins or towels.
- (v) Autoclave with temperature and pressure indicator.
- (vi) Incinerator
- (vii) Stand-by generator

7. Laboratory equipment:

- (i) Refrigerators, for storing diagnostic kits and reagents, maintaining a temperature between 4 to 6 degrees centigrade (plus/minus 2 degree centigrade) with digital dial thermometer having provision for continuous power supply.

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Compound Microscope with low and high power objectives.

(iii) Centrifuge Table Model

(iv) Water bath: having range between 37 degree centigrade to 56 degree centigrade

(v) Rh viewing box in case of slide technique.

(vi) Incubator with thermostatic control.

(vii) Mechanical shakers for serological tests for Syphilis.

(viii) Hand-lens for observing tests conducted in tubes.

(ix) Serological graduated pipettes of various sizes.

(x) Pipettes (Pasteur)

(xi) Glass slides

(xii) Test tubes of various sizes/micrometer plates (U or V type)

(xiii) Precipitating tubes 6 mm x 50 mm of different sizes and glass beakers of different sizes

(xiv) Test tube racks of different specifications.

(xv) Interval timer electric or spring wound.

(xvi) Equipment and materials for cleaning glass wares adequately.

(xvii) Insulated containers for transporting blood, between 2 degree centigrade to 10 degree centigrade temperatures, to wards and hospitals.

(xviii) Wash bottles

(xix) Filter papers

(xx) Dielectric tube sealer.

(xxi) Plain and EDTA vials

(xxii) Chemical balance (wherever necessary)

(xxiii) ELISA reader with printer, washer and micropipettes.

J. SPECIAL REAGENTS:

(1) Standard blood grouping sera Anti A, Anti B and Anti D with known controls.

Rh typing sera shall be in double quantity and each of different brand or if from the same supplier each supply shall be of different lot numbers.

(2) Reagents for serological tests for syphilis and positive sera for controls.

(3) Anti-Human Globulin Serum (Coomb's serum).

(4) Bovine Albumin 22 per cent Enzyme reagents for incomplete antibodies.

54. Ins by GSR(E) dt 29.1.2001 (w.e.f. 1.6.2001)

55. Ins by GSR (E) dt 29.1.2001 (w.e.f. 1.6.2001)

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(5) ELISA or RPHA test kits for Hepatitis and HIV I & II.

(6) Detergent and other agents for cleaning laboratory glass wares.

K. TESTING OF WHOLE BLOOD:

(1) It shall be responsibility of the licensee to ensure that the whole blood collected, processed and supplied conforms to the standards laid down in the

Indian Pharmacopoeia and other tests published, if any, by the Government.

(2) Freedom from HIV antibodies (AIDS) Tests. - Every licensee shall get samples of every blood unit tested, before use, for freedom from HIV I and HIV II antibodies either from laboratories specified for the purpose by the Central Government or in his own laboratory. The results of such testing shall be recorded on the label of the container.

(3) Each blood unit shall also be tested for freedom from Hepatitis B surface antigen 54 (and Hepatitis C Virus antibody), VDRL and malarial parasite and results of such testing shall be recorded on the label of the container.

Note: (a) Blood samples of donors in pilot tube and the blood samples of the recipient shall be preserved for 7 days after issue.

(c) The blood intended for transfusion shall not be frozen at any stage.

(d) Blood containers shall not come directly in contact with ice at any stage.

L. RECORDS:

The records which the licensee is required to maintain shall include inter alia the following particulars, namely:

(1) Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, haemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer Incharge.

*Extract from Schedule P

S. No. Name of Drug Expiry period in months Conditions of storage

1. Anti-Haemophilic Human Globulin 12 In a cool place.
2. Dried Plasma 60 At temperature not exceeding 25°C.
3. Dried Normal Human Serum Albumin 60 At temperature not exceeding 25°C.
 4. Frozen Plasma 60 In deep freeze.
 5. Liquid Plasma 24 In cold place.
6. Liquid Normal Human Serum Albumin 60 In cold place.
7. Whole Human Blood

(a) Collected in ACD solution 21 days At temperature between 4°C and 6°C.

(b) Collection in CPDA solution 35 days At temperature between 4°C and 6°C.

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records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml ABO/Rh Group, results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L. Hepatitis B surface antigen 55 (and Hepatitis C Virus antibody) and irregular antibodies (if any), name and address of the donor with particulars, utilisation issue number, components prepared or discarded and signature of the Medical Officer Incharge.

(3) Issue register: It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion.

(4) Records of components supplied: Quantity supplied; compatibility report, details of recipient and signature of issuing person.

(5) Records of A.C.D/C.P.D./CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply, and results of testing.

(6) Register for diagnostic kits and reagents used: Name of the kits/reagents, details of batch number, date of expiry and date of use.

(7) Blood Bank must issue the cross matching report of the blood to the patient together with the blood unit.

(8) Transfusion adverse reaction records.

(9) Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.

Note: The above said records shall be kept by the licensee for a period of five years.

M. LABELS:

The labels on every bag containing blood and/or component shall contain the following particulars, namely:

(1) The proper name of the product in a prominent place and in bold letters on the bag.

(2) Name and address of the blood bank.

(3) Licence number

(4) Serial number

(5) The date on which the blood is drawn and the date of expiry as prescribed under Schedule P* to these rules.

(6) A coloured label shall be put on every bag containing blood. The following

56. Ins by GSR 40(E) dt 21.01.2001 (w.e.f. 1.6.2001

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colour scheme for the said labels shall be used for different groups of

blood:

Blood Group Colour of the label

O Blue

A Yellow

B Pink

AB White

(7) The results of the tests for Hepatitis B surface antigen 56 (and Hepatitis C Virus antibody), syphilis, freedom from HIV I and HIV II antibodies and malarial parasite.

(8) The Rh group.

(9) Total volume of the blood, the preparation of blood, nature and percentage of anti-coagulant.

(10) Keep continuously temperature at 2 degree centigrade to 6 degree centigrade for whole human blood and/or components as contained under III of Part XII-B.

(11) Disposable transfusion sets with filter shall be used in administration equipment.

(12) Appropriate compatible cross matched blood without a typical antibody in recipient shall be used.

(13) The contents of the bag shall not be used if there is any visible evidence of deterioration like haemolysis, clotting or discoloration.

(14) The label shall indicate the appropriate donor classification like "Voluntary Donor" or "Replacement Donor" in no less prominence than the proper name.

Note:

1. In the case of blood components, particulars of the blood from which such components have been prepared shall be given against item numbers (5), (7), (8), (9) and (14).

2. The blood and/or its components shall be distributed on the prescription of a Registered Medical Practitioner.

II. BLOOD DONATION CAMPS

57. Ins by GSR 218 (E) dt 28.03.2001 (w.e.f. 28.03.2001)

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blood donation camp may be organised by (

- a) a licensed designated Regional Blood Transfusion Centre; or
- (b) a licensed Government blood bank; or;
- (c) the Indian Red Cross Society 57; or
- (d) a licensed blood bank run by registered voluntary or charitable organisations recognised by State or Union Territory Blood Transfusion Council.)

Note:

(i) "Designated Regional Blood Transfusion Centre" shall be a centre approved and designated by a Blood Transfusion Council constituted by a State Government to collect, process and distribute blood and its components to cater to the needs of the region and that centre has also been licensed and approved by the Licensing Authority and Central Licence Approving Authority for the purpose.

(ii) The designated Regional Blood Transfusion Centre, Government blood bank and Indian Red Cross Society shall intimate within a period of seven days, the venue where blood camp was held and details of groupwise blood units collected in the said camp to the Licensing Authority and Central Licence Approving Authority.

For holding a blood donation camp, the following requirements shall be fulfilled/ complied with, namely:

(A) Premises, personnel etc:

- (a) Premises under the blood donation camp shall have sufficient area and the location shall be hygienic so as to allow proper operation, maintenance and cleaning.
- (b) All information regarding the personnel working, equipment used and facilities available at such a Camp shall be well documented and made available for inspection, if required, and ensuring
 - (i) continuous and uninterrupted electrical supply for equipment used in the Camp.
 - (ii) Adequate lighting for all the required activities;
 - (iii) Hand-washing facilities for staff;
 - (iv) Reliable communication system to the central office of the Controller/Organiser of the Camp;
 - (v) Furniture and equipment arranged within the available place;
 - (vi) Refreshment facilities for donors and staff;

(vii) Facilities for medical examination of the donors;
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(viii) Proper disposal of waste.

(B)

Personnel for Out-door Blood Donation Camp:

To collect blood from 50 to 70 donors in about 3 hours or from 100 to 120 donors in 5 hours, the following requirements shall be fulfilled/complied with:

(i) One Medical Officer and two nurses or phlebotomists for managing 6-8 donor tables;

(ii) Two medico social workers;

(iii) Three blood bank technicians;

(iv) Two attendants;

(v) Vehicle having a capacity to seat 8-10 persons, with provision for carriage of donation goods including facilities to conduct a blood donation camp.

(C)

Equipments:

1. BP apparatus.

2. Stethoscope.

3. Blood bags (single, double, triple, quadruple).

4. Donor questionnaire.

5. Weighing device for donors.

6. Weighing device for blood bags.

7. Artery forceps, scissors.

8. Stripper for blood tubing.

9. Bed sheets, blankets/matress.

10.

Lancets, swab stick/tooth picks.

11.

Glass slides.

12.

Portable Hb meter/copper sulphate.

13.

Test tube (big) and 12 x 100 (small).

14.

Test tube stand.

15.

Anti-A, Anti-B and Anti-AB, Antisera and Anti-D

16.

Test tube sealer film

17.

Medicated adhesive tape.

18.

Plastic waste basket.

19.

Donor cards and refreshment for donors.

20.

Emergency medical kit.

21.

Insulated blood bag containers with provisions for storing between 2
degree centigrade to 10 degree centigrade.

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Dielectric sealer or portable tube sealer.

23. Needle destroyer (wherever necessary).

III. PROCESSING OF BLOOD COMPONENTS FROM
WHOLE BLOOD BY A BLOOD BANK

The Blood components shall be prepared by blood banks as a part of the Blood Bank services. The conditions for grant or renewal of licence to prepare blood components shall be as follows:

(A) ACCOMMODATION

- (1) Rooms with adequate area and other specifications, for preparing blood components depending on quantum of workload shall be as specified in item B under the heading "I . BLOOD BANKS/BLOOD COMPONENTS" of this Part.
- (2) Preparation of Blood components shall be carried out only under closed system using single, double, triple or quadruple plastic bags except for preparation of Red Blood Cells Concentrates, where single bags may be used with transfer bags.

(B) EQUIPMENT

- (i) Air conditioner;
- (ii) Laminar air flow bench;
- (iii) Suitable refrigerated centrifuge;
- (iv) Plasma expresser
- (v) Clipper and clips and or dielectric sealer;
- (vi) Weighing device;
- (vii) Dry rubber balancing material;
- (viii) Artery forceps, scissors;
- (ix) Refrigerator maintaining a temperature between 2 degree centigrade to 6 degree centigrade, a digital dial thermometer with recording thermograph and alarm device, with provision for continuous power supply;
- (x) Deep freezers maintaining a temperature between minus 30 degree centigrade to minus 40 degree centigrade and minus 75 degree centigrade to minus 80 degree centigrade;
- (xi) Refrigerated Water bath for Plasma Thawing;
- (xii) Insulated blood bag containers with provisions for storing at appropriate temperature for transport purposes;

58. Ins by GSR 40 (E) dt 29.1.2001 (w.e.f. 1.6.2001)

(C) PERSONNEL

The whole time competent technical staff meant for processing of Blood Components (that is Medical Officer, Technical Supervisor, Blood Bank Technician and Registered Nurse) shall be as specified in item C, under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part.

D. TESTING FACILITIES

General: Facilities for A, B, AB and O groups and Rh(D) grouping. Hepatitis: B surface antigen 58 (and Hepatitis C Virus antibody), VDRL, HIV 1 and HIV II antibodies and malarial parasites shall be mandatory for every blood unit before it is used for the preparation of blood components. The results of such testing shall be indicated on the label.

(E) CATEGORIES OF BLOOD COMPONENTS

(1) CONCENTRATED HUMAN RED BLOOD CORPUSCLES:

The product shall be known as "Packed Red Blood Cells" that is Packed Red Blood Cells remaining after separating plasma from human blood.

General Requirements:

- (a) Storage: Immediately after processing, the Packed Red Blood Cells shall be kept at a temperature maintained between 2 degree centigrade to 6 degree centigrade.
- (b) Inspection: The component shall be inspected immediately after separation of the plasma, during storage and again at the time of issue. The product shall not be issued if there is any abnormality in colour or physical appearance or any indication of microbial contamination.
- (c) Suitability of Donor: The source blood for Packed Red Blood Cells shall be obtained from a donor who meets the criteria for Blood Donation as specified in item H under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part.
- (d) Testing of Whole Blood from which Packed Red Blood Cells are prepared shall be tested as specified in item K relating to Testing of Whole Blood under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part.
- (e) Pilot samples: Pilot samples collected in integral tubing or in separate pilot tubes shall meet the following specifications:
 - (i) One or more pilot samples of either the original blood or of the Packed Red Blood Cells being processed shall be preserved with each unit of Packed Red Blood Cells which issued.
 - (ii) Before they are filled, all pilot sample tubes shall be marked or identified

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(iii) Before the final container is filled or at the time the final product is prepared, the pilot sample tubes accompanying a unit of Packed Red Blood Cells, shall be attached in a tamper-proof manner that shall conspicuously identify removal and re-attachment.

(iv) All pilot sample tubes, accompanying a unit of packed red blood cells, shall be filled immediately after the blood is collected or at the time the final product is prepared, in each case, by the person who performs the collection of preparation.

(F) PROCESSING

(i) Separation: Packed Red Blood Cells shall be separated from the whole blood, (
a) if the whole blood is stored in ACD solution within 21 days, and
b) if the whole blood is stored in CPDA-1 solution, within 35 days, from the date of collection. Packed Red Blood Cells may be prepared either by centrifugation done in a manner that shall not tend to increase the temperature of the blood or by normal undisturbed sedimentation method. A portion of the plasma, sufficient to ensure optimal cell preservation, shall be left with the Packed Red Blood Cells.

(ii) Packed Red Blood Cells Frozen: Cryoprotective substance may be added to the Packed Red Blood Cells for extended manufacturer's storage not warmer than minus 65 degree centigrade provided the manufacturer submits data to the satisfaction of the Licensing Authority and Central Licence Approving Authority, as adequately demonstrating through in-vivo cells survival and other appropriate tests that the addition of the substance, the material used and the processing methods result in a final product meets the required standards of safety, purity and potency for Packed Red Blood Cells, and that the frozen product shall maintain those properties for the specified expiry period.

(iii) Testing: Packed Red Blood Cells shall conform to the standards as laid down in the Indian Pharmacopoeia.

(2) PLATELETS CONCENTRATES:

The product shall be known as "Platelets Concentrates" that is platelets collected from one unit of blood and re-suspended in an appropriate volume of original plasma.

General Requirements:

(i) Source: The source material for platelets shall be platelet rich plasma or buffy coat which may be obtained from the whole blood or by plateletpheresis.

(ii) Processing:

(a) Separation of buffy-coat or platelet-rich plasma and platelets and re-suspension of the platelets shall be in a closed system by centrifugal method with appropriate speed, force and time.

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 degree centigrade to 24 degree centigrade. When it is to be transported from the venue of blood collection to the processing laboratory, during such transport action, the temperature as close as possible to a range between 20 degree centigrade to 24 degree centigrade shall be ensured. The platelet concentrates shall be separated within 6 hours after the time of collection of the unit of whole blood or plasma.

(c) The time and speed of centrifugation shall be demonstrated to produce an unclumped product, without visible haemolysis, that yields a count of not less than 3.5×10^{10} (3.5×10 raised to the power of 10) and 4.5×10^{10} (4.5×10 raised to the power ten) i.e. platelets per unit from a unit of 350 ml. And 450 ml blood respectively. One per cent of total platelets prepared shall be tested of which 75 per cent of the units shall conform to the above said platelet count.

(d) The volume of original plasma used for re-suspension of the platelets shall be determined by the maintenance of the pH of not less than 6 during the storage period. The pH shall be measured on a sample of platelets which has been stored for the permissible maximum expiry period at 20 degree centigrade to 24 degree centigrade.

(e) Final containers used for platelets shall be colourless and transparent to permit visual inspection of the contents. The caps selected shall maintain a hermetic seal to prevent contamination of the contents. The container material shall not interact with the contents, under the normal conditions of the storage and use, in such a manner as to have an adverse effect upon the safety, purity, potency, or efficacy of the product.

At the time of filling, the final container shall be marked or identified by number so as to relate it to the donor.

(iii) Storage: Immediately after re-suspension, platelets shall be placed in storage not exceeding a period of 5 days, between 20 degree centigrade to 24 degree centigrade, with continuous gentle agitation of the platelet concentrates maintained throughout such storage.

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Testing: The units prepared from different donors shall be tested at the end of the storage period for -

- (a) Platelet count;
- (b) PH of not less than 6 measured at the storage temperature of the unit;

(c) Measurement of actual plasma volume;

(d) One per cent of the total platelets prepared shall be tested for sterility;

(e) The tests for functional viability of the platelets shall be done by swirling movement before issue;

(f) If the results of the testing indicate that the product does not meet the specified requirements, immediate corrective action shall be taken and records maintained;

(v) Compatibility Test: Compatible transfusion for the purpose of variable number of Red Blood Cells, A, B, AB and O grouping shall be done if the platelets concentrate is contaminated with red blood cells.

(2) GRANULOCYTE CONCENTRATES:

(i) Storage: It shall be kept between 20 degree centigrade to 24 degree centigrade for a maximum period of 24 hours.

(ii) Unit of granulocytes shall not be less than 1×10^{10} (i.e. 1×10 raised to the power of 10) when prepared on cell separator.

(iii) Group specific tests/HLA test wherever required shall be carried out.

(4) FRESH FROZEN PLASMA:

Plasma frozen within 6 hours after blood collection and stored at a temperature not warmer than minus 30 degree centigrade, shall be preserved for a period of not more than one year.

(5) CRYOPRECIPITATE:

Concentrate of anti-hemophilic factor shall be prepared by thawing of the fresh plasma frozen stored at minus 30 degree centigrade.

(a) Storage: Cryoprecipitate shall be preserved at a temperature not higher than minus 30 degree centigrade and may be preserved for a period of not more than one year from the date of collection.

(b) Activity: Anti-hemophilic factor activity in the final product shall be not less than 80 units per bag. One per cent of the total cryoprecipitate prepared shall be tested of which seventy five percent of the unit shall conform to the said specification.

An area of 10 square metres shall be provided for apheresis in the blood bank.

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The blood banks specifically permitted to undertake the said apheresis on the donor shall observe the criteria as specified in item H relating to Criteria for blood donation under the heading. "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part. The written consent of the donor shall be taken and the donor must be explained the hazards of apheresis. The Medical Officer shall certify that donor is fit for apheresis and it shall be carried out by a trained person under supervision of the Medical Officer.

(A) PLASMAPHERESIS, PLATELETPHERESIS AND LEUCAPHERESIS:

The donors subjected to plasmapheresis, plateletpheresis and leucopheresis shall, in addition to the criteria specified in item H relating to the CRITERIA FOR BLOOD DONATION, under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part being observed, be also subjected to protein estimation on post-pheresis/first sitting whose results shall be taken as a reference for subsequent pheresis/sitting. It shall also be necessary that the total plasma obtained from such donor and periodicity of Plasmapheresis shall be according to the standards described under validated Standard Operating Procedures.

NOTE:

(i) At least 48 hours must elapse between successive apheresis and not more than twice in a week.

(ii) Extracorporeal blood volume shall not exceed 15% of donor's estimated blood volume.

(iii) Platelet pheresis shall not be carried out on donors who have taken medication containing Asprin within 3 days prior to donation.

(iv) If during plateletpheresis or leucapheresis, RBCs cannot be re-transfused then at least 12 weeks shall elapse before a second cytapheresis procedure is conducted.

(B) MONITORING FOR APHERESIS;

Before starting apheresis procedure, haemoglobin or haematocrit shall be

* Schedule M, Part I, Para 1.1.4 of the Drugs and Cosmetics Rules 1945:

1.4 Disposal of waste:

- (1) The disposal of sewage and effluents (solid, liquid and gas) from the manufactory shall be in conformity with the requirements of Environment Pollution Control Board.
- (ii) All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 1996.
- (iii) Additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of wate.

(iv) Provisions shall be made for the proper and safe storage of waste materials awaiting disposal.
Hazardous, toxic
substances and flammable materials shall be stored in suitably designed and segregated, enclosed
areas in conformity
with Central and State Legislations.

1. Ins by GSR 40 (E) dt 29.1.2001 (w.e.f. 1.6.2001)

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(C) COLLECTION OF PLASMA:

The quantity of plasma separated from the blood of a donor shall not exceed 500 ml. Per sitting and once in a fortnight or shall not exceed 1000 ml. Per month.

SCHEDULE F

PART XII-C

I. REQUIREMENTS FOR MANUFACTURE
OF BLOOD PRODUCTS

The blood products shall be manufactured in a separate premises other than that meant for blood bank. The requirements that are essential for grant or renewal of licence to manufacture blood products such as Albumin, Plasma Protein Fraction, Immunoglobins and Coagulation Factor Concentrates, shall be as follows, namely:

A. GENERAL REQUIREMENTS:

1. Location and surroundings, buildings and water supply: The requirements as regards location and surrounding, buildings and water supply as contained in paragraphs 1.1.1, 1.1.2, 1.1.3 of Part I of Schedule M shall apply mutatis mutandis to the manufacture of blood products.

2. Disposal of waste and infectious materials:

- (i) The requirement as regards disposal of waste and infectious materials as contained in paragraph 1.1.4 of Part I of Schedule M* shall apply mutatis mutandis to the manufacture of blood products.
- (ii) Proper facility shall also be provided for potentially infectious materials, particularly HIV I & HIV II, Hepatitis B 1(surface antigen and Hepatitis C Virus antibody) through autoclaving, incineration or any other suitable validated methods.

3. Health, clothing and sanitation of personnel:

- (i) The requirement as contained in paragraph 3 of Part I of Schedule M shall be complied with
- (ii) The personnel working in the manufacturing areas shall be vaccinated against Hepatitis B virus and other infectious transmitting diseases.

4. Requirements for manufacturing area for Blood Products:

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- (i) For the manufacture of blood products, separate enclosed areas specifically designed for the purpose shall be provided. These areas be provided with air locks for entry and shall be essentially dust free and

ventilated with an air supply. Air supply for manufacturing area shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas.

The filters shall be checked for performance on installation and periodically thereafter, and records thereof shall be maintained.

(ii) Interior surfaces (walls, floors and ceilings) shall be smooth and free from cracks, they shall not shed matter and shall permit easy cleaning and disinfection. Drains shall be excluded from aseptic areas.

Routine microbial counts of the manufacturing area shall be carried out during manufacturing operations. The results of such counts shall be checked against well documented in-house standards and records maintained.

Access to the manufacturing areas shall be restricted to a minimum number of authorised personnel. Special procedures for entering and leaving of the manufacturing areas shall be prominently displayed.

(iii) Sinks shall be excluded from aseptic areas. Any sink installed in other clean areas shall be of suitable material such as stainless steel, without an overflow, and be supplied with water of potable quality. Adequate precautions shall be taken to avoid contamination of the drainage system with dangerous effluents and airborne dissemination of pathogenic micro-organisms.

(iv) Lighting, air-conditioning ventilation shall be designed to maintain a satisfactory temperature and relative humidity to minimise contamination and to take account of the comfort of personnels working with protective clothing.

(v) Premises used for the manufacture of blood products shall be suitably designed and constructed to facilitate good sanitation.

(vi) Premises shall be carefully maintained and it shall be ensured that repair and maintenance operations do not present any hazard to the quality of products. Premises shall be cleaned and, where applicable, disinfected according to detailed written validated procedures.

(vii) Adequate facilities and equipments shall be used for the manufacture of blood products derived from blood plasma.

(viii) All containers of blood products, regardless of the stage of manufacture, shall be identified by securely attached labels. Cross-contamination shall be prevented by adoption of the following measures,

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- (a) processing and filling shall be in segregated areas;
- (b) manufacture of different products at the same time shall be avoided;
- (c) simultaneous filling of the different products shall be avoided;
- (d) ensure transfer, containers/materials by means of airlocks, air extraction, clothing change and careful washing and decontamination of equipment;
- (e) protection containers/materials against the risk of contamination caused by re-circulation of untreated air or by accidental re-entry of extracted air;
- (f) using containers that are sterilised or are of documented low "bioburden".
 - (ix) Positive pressure area shall be dedicated to the processing area concerned.
 - (x) Air-handling units shall be dedicated to the processing area concerned.
 - (xi) Pipe work, valves and vent filters shall be properly designed to facilitate cleaning and sterilisation. Valves on fractionation/reacting vessels shall be completely steam-sterilisable. Air vent filters shall be hydrophobic and shall be validated for their designated use.

Ancillary Areas:

- (i) Rest and refreshment rooms shall be separated from other areas.
- (ii) Facilities for changing and storing clothes and for washing and toilet purposes shall be easily accessible and appropriate for the number of users. Toilets shall not be connected directly with production or storage areas.
- (iii) Maintenance workshops shall be separated from production areas. Wherever parts and tools are stored in the production area, they shall be kept in rooms or lockers reserved for that use.
- (iv) Animal houses shall be well isolated from other areas, with separate entrance.

2. Subs by GSR 40(E) dt. 29.1.2001 (w.e.f. 1.6.2001)

3. Subs by GSR 40(E) dt. 29.1.2002 (w.e.f. 1.6.2001)

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B. COLLECTION AND STORAGE OF PLASMA FOR FRACTIONATION:

(a)

Collection:

- (1) Plasma shall be collected from the licensed Blood Banks through a cold chain process and stored in frozen condition not warmer than minus twenty degree centigrade.
- (2) Individual plasma shall remain in quarantine till it is tested for 2(Hepatitis B and Hepatitis C Virus antibody), HIV I and HIV II.
- (3) A sample from pooled-lot plasma of about 10-12 units of different donors shall be tested for 3(Hepatitis B and Hepatitis C Virus antibody), HIV I and HIV II and if the sample is found negative, only then it shall be taken up for fractionation.

(b)

Storage Area:

- (1) Storage areas shall be of sufficient space and capacity to allow orderly storage of the various categories of materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned, or recalled products.
- (2) Storage areas shall be designed or adopted to ensure good storage conditions. In particular, they shall be clean, dry and maintained within temperature required for such storage and where special storage conditions are required (e.g. temperature, humidity), these shall be provided, checked and monitored.
- (3) Receiving and dispatch bays shall protect materials and products from the weather and shall be designed and equipped to allow containers of incoming materials to be cleaned, if necessary, before storage.
- (4) Where quarantine status is ensured by storage in separate areas, these areas shall be clearly marked and their access restricted only to authorised personnel.
- (5) There shall be separate sampling area for raw materials. If sampling is performed in the storage area, it shall be conducted in such a way so as to prevent contamination or cross-contamination.
- (6) Segregation shall be provided for the storage of rejected recalled, or returned materials or products.
- (7) Adequate facility shall be provided for supply of ancillary materials, such as ethanol, water, salts and polyethylene glycol. Separate facilities shall be provided for the recovery of organic solvents used in fractionation.

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C. PERSONNEL

(1) Manufacture: The manufacture of blood products shall be conducted under the active direction and personal supervision of competent technical staff, consisting of at least one person who shall be a whole time employee, with one year practical experience in the manufacture of blood products/plasma fractionation and possesses -

(a) Post-graduate

degree in Medicine -M.D. (Microbiology/
Pathology/Bacteriology/Immunology/Biochemistry); or

(b) Post-graduate degree in Science (Microbiology); or

(c) Post-graduate degree in Pharmacy (Microbiology)

From a recognised University or Institution.

2. Testing: The head of the testing unit shall be independent of the manufacturing unit and testing shall be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who shall be a whole time employee. The Head of the testing unit shall have eighteen months practical experience in the testing of drugs, especially the blood products and possesses -

(a) Post-graduate

degree in Pharmacy or Science (
Chemistry/Microbiology/Bio-chemistry); or

(b) Post-graduate degree in Medicine - M.D. Microbiology/Pathology/Biochemistry),
from a recognised University or Institution.

D. PRODUCTION CONTROL:

(1) The production area and the viral inactivation room shall be centrally air-conditioned and fitted with HEPA Filters having Grade C (Class 10,000) environment as given in the Table below.

(2) The filling and sealing shall be carried out under aseptic conditions in centrally air-conditioned areas fitted with HEPA Filters having Grade A or, as the case may be, Grade B (Class 100) environment given in the said Table.

TABLE

AIR CLASSIFICATION SYSTEM FOR MANUFACTURE
OF STERILE PRODUCTS

Maximum number of particles permitted per m³

MAXIMUM NUMBER OF MAXIMUM NUMBER

PARTICLES PERMITTED OF VIABLE
PER m³ MICROORGANISM
PERMITTED PER m³
GRADE 0.5-5 micron Less than 5 micron
A (Class 100) 3500 None Less than 1
Laminar - Airflow
Workstation)
B (Class 100) 3500 None Less than 5
C (Class 10000) 3,50,000 2000 Less than 100

(3)The physical and chemical operations used for the manufacture of plasma fractionation shall maintain high yield of safe and effective protein.

(4)The fractionation procedure used shall give a good yield of products meeting the in house quality requirements as approved by the Licensing Authority and Central Licence Approving Authority reducing the risk of microbiological contamination and protein denaturation to the minimum.

(5)The procedure adopted shall not affect the antibody activity and biological half-life or biological characteristics of the products.

E. VIRAL INACTIVATION PROCESS:

The procedure used by the licensee to inactivate the pathogenic organisms such as enveloped and non-enveloped virus, especially infectivity from HIV I & HIV II, Hepatitis B surface antigens 4(and Hepatitis C Virus antibody), the viral inactivation and validation methods adopted by the licensee, shall be submitted for approval to the Licensing Authority and Central Licence Approving Authority.

4. Ins by GSR 40(E) dt 29.01.2001 (w.e.f. 1.6. 2001)

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(1) No preservation (except stabiliser to prevent protein denaturation such as glycine, sodium chloride or sodium caprylate) shall be added to Albumin, Plasma Protein Fraction, Intravenous Immunoglobulins or Coagulation Factor Concentrates without the prior approval of Licensing Authority and Central Licence Approving Authority.

(2) The licensee shall ensure that the said stabilisers do not have deleterial effect on the final product in the quantity present so as not to cause any untoward or adverse reaction in human beings.

F. QUALITY CONTROL

Separate facilities shall be provided for Quality Control such as Hematological, Bio-chemical, Physico-chemical, Microbiological, Pyrogens, Instrumental and Safety testing. The Quality Control Department shall have inter alia the following principal duties, namely -

- (1) To prepare detailed instructions, in writing for carrying out test and analysis.
- (2) To approve or reject raw material, components, containers, closures, in process materials, packaging material, labelling and finished products.
- (3) To release or reject batch of finished products which are ready for distribution.
- (4) To evaluate the adequacy of the conditions under which raw materials, semi-finished products and finished products are stored.
- (5) To evaluate the quality and stability of finished products and when necessary of raw materials and semi-finished products.
- (6) To review production records to ensure that no errors have occurred or if errors have occurred that they have been fully investigated.
- (7) To approve or reject all procedures or specifications impacting on the identity, strength, quality and purity of the product.
- (8) To establish shelf-life and storage requirements on the basis of stability tests related to storage conditions.
- (9) To establish and when necessary revise, control procedures and specifications.
- (10) To review complaints, recalls, returned or salvaged products and investigations conducted thereunder for each product.

5. Ins by GSR 40 (E) dt 29.01.2001 (w.e.f. 1.6.2001)

6. Ins by GSR 40 (E) dt 29.01.2001 (w.e.f. 1.6.2001)

Appendix 7—Schedule F—Part XII-C of the Drugs & Cosmetics Rules, 1945

(11) To review Master Formula Records/Cards periodically.

G. TESTING OF BLOOD PRODUCTS

The products manufactured shall conform to the standards specified in the Indian Pharmacopoeia and where standard of any product is not specified in the Pharmacopoeia, the standard for such product shall conform to the standard

specified in the United States Pharmacopoeia or the British Pharmacopoeia. The final products shall be tested for freedom from HIV I and HIV II antibodies, Hepatitis B surface antigen 5 (and Hepatitis C Virus antibody).

H. STORAGE OF FINISHED PRODUCT:

- (i) The final products shall be stored between two degree centigrade to eight degree centigrade, unless otherwise specified by the Central Licence Approving Authority.
- (ii) The shelf-life assigned to the products by the licensee shall be submitted for approval to the Licensing Authority and Central Licence Approving Authority.

I. LABELLING:

The products manufactured shall be labelled as specified in the Indian Pharmacopoeia, the British Pharmacopoeia or the United States Pharmacopoeia which shall be in addition to any other requirement stated under Part IX or Part X of these rules. The labels shall indicate the results of tests for Hepatitis B surface antigen 6 (and Hepatitis C Virus antibody), freedom from HIV I and HIV II antibodies.

J. RECORDS:

The licensee shall maintain records as per Schedule U and also comply with Batch manufacturing records as specified in Paragraph 9 of Part I of Schedule M and any other requirement as may be directed by Licensing Authority and Central Licence Approving Authority.

K. MASTER FORMULA RECORDS:

The licensee shall maintain Master Formula Records relating to all manufacturing and quality control procedures for each product, which shall be prepared and endorsed by the competent Technical Staff, i.e. Head of the manufacturing unit. The Master Formula Records shall contain

- (i) the patent or proprietary name of the product along with the generic

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- (ii) a description or identification of the final containers, packaging materials, labels and closures to be used;
- (iii) the identity, quantity and quality of each raw material to be used irrespective of whether or not it appears in the finished product. The permissible overage that may be included in a formulated batch shall be indicated;
- (iv) a description of all vessels and equipments and the sizes used in the process;
- (v) manufacturing and control instructions along with parameters for critical steps such as mixing, drying, blending, sieving and sterilising the product;
- (vi) the theoretical yield to be expected from the formulation at different stages of manufacture and permissible yield limits;
- (vii) detailed instructions on precautions to be taken in the manufacture and storage of drugs and of semi-finished products; and
- (viii)
the requirements in-process quality control tests and analysis to be carried out during each stage of manufacture including the designation of persons or departments responsible for the execution of such tests and analysis.

II. REQUIREMENTS FOR MANUFACTURE OF BLOOD PRODUCTS FROM BULK FINISHED PRODUCTS

Where the blood products, such as Albumin, Plasma Protein Fraction, Immunoglobulins and Coagulation Factor Concentrates are manufactured through the manufacturing activities of filling and sealing the blood products from bulk powder or solution or both, the requirements as they apply to the manufacture of blood products from whole blood shall apply mutatis mutandis to such manufacture of blood products, unless other requirements have been approved by the Central Licence Approving authority.

Appendix 8—Bio Medical Waste (Management and Handling) Rules, 1998

Appendix 8
The Bio-Medical Waste
(Management and Handling) Rules, 1998
Ministry of Environment & Forests

NOTIFICATION

New Delhi, 20th July, 1998

S.O. 630 (E).-Whereas a notification in exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) was published in the Gazette vide S.O. 746 (E) dated 16 October, 1997 inviting objections from the public within 60 days from the date of the publication of the said notification on the Bio-Medical Waste (Management and Handling) Rules, 1998 and whereas all objections received were duly considered..

Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 the Central Government hereby notifies the rules for the management and handling of bio-medical waste.

1. Short Title and Commencement:

- (1) These rules may be called the Bio-Medical Waste (Management and Handling) Rules, 1998.
- (2) They shall come into force on the date of their publication in the official Gazette.

Application:

These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form.

3. Definitions: In these rules unless the context otherwise requires

- (1) "Act" means the Environment (Protection) Act, 1986 (29 of 1986);
- (2) "Animal House" means a place where animals are reared/kept for experiments or testing purposes;
- (3) "Authorisation" means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, disposal and/or any other form of handling of bio-medical waste in accordance with these rules and any guidelines issued by the Central Government.
- (4) "Authorised person" means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, dispose and/or handle bio-medical waste in accordance with these rules and any guide126

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- (5) "Bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Schedule I;
- (6) "Biologicals" means any preparation made from organisms or microorganisms or product of metabolism and biochemical reactions intended for use in the diagnosis, immunisation or the treatment of human beings or animals or in research activities pertaining thereto;
- (7) "Bio-medical waste treatment facility" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment or disposal is carried out;
- (8) "Occupier" in relation to any institution generating bio-medical waste, which includes a hospital, nursing home, clinic dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called, means a person who has control over that institution and/or its premises;
- (9) "Operator of a bio-medical waste facility" means a person who owns or controls or operates a facility for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste;
- (10) "Schedule" means schedule appended to these rules;

4. Duty of Occupier:

It shall be the duty of every occupier of an institution generating bio-medical waste which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called to take all steps to ensure that such waste is handled without any adverse effect to human health and the environment.

5. Treatment and Disposal

- (1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards prescribed in Schedule V.
- (2) Every occupier, where required, shall set up in accordance with the time-schedule in Schedule VI, requisite bio-medical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility.

6. Segregation, Packaging, Transportation and Storage

- (1) Bio-medical waste shall not be mixed with other wastes.
- (2) Bio-medical waste shall be segregated into containers/bags at the point of Appendix 8—Bio Medical Waste (Management and Handling) Rules, 1998

generation in accordance with Schedule II prior to its storage, transportation, treatment

and disposal. The containers shall be labeled according to Schedule III.

(3) If a container is transported from the premises where bio-medical waste is generated to any waste treatment facility outside the premises, the container shall, apart from the label prescribed in Schedule III, also carry information prescribed in Schedule IV.

(4) Notwithstanding anything contained in the Motor Vehicles Act, 1988, or rules thereunder, untreated biomedical waste shall be transported only in such vehicle as may be authorised for the purpose by the competent authority as specified by the government.

(5) No untreated bio-medical waste shall be kept stored beyond a period of 48 hours

Provided that if for any reason it becomes necessary to store the waste beyond such period, the authorised person must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human health and the environment.

7. Prescribed Authority

(1) The Government of every State and Union Territory shall establish a prescribed authority with such members as may be specified for granting authorisation and implementing these rules. If the prescribed authority comprises of more than one member, a chairperson for the authority shall be designated.

(2) The prescribed authority for the State or Union Territory shall be appointed within one month of the coming into force of these rules.

(3) The prescribed authority shall function under the supervision and control of the respective Government of the State or Union Territory.

(4) The prescribed authority shall on receipt of Form 1 make such enquiry as it deems fit and if it is satisfied that the applicant possesses the necessary capacity to handle bio-medical waste in accordance with these rules, grant or renew an authorisation as the case may be.

(5) An authorisation shall be granted for a period of three years, including an initial trial period of one year from the date of issue. Thereafter, an application shall be made by the occupier/operator for renewal. All such subsequent authorisation shall be for a period of three years. A provisional authorisation will be granted for the trial period, to enable the occupier/operator to demonstrate the capacity of the facility.

(6) The prescribed authority may after giving reasonable opportunity of being heard to the applicant and for reasons thereof to be recorded in writing, refuse to grant or renew authorisation.

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(7) Every application for authorisation shall be disposed of by the prescribed authority within ninety days from the date of receipt of the application.

(8) The prescribed authority may cancel or suspend an authorisation, if for reasons, to be recorded in writing, the occupier/operator has failed to comply with any provision of the Act or these rules :

Provided that no authorisation shall be cancelled or suspended without giving a reasonable opportunity to the occupier/operator of being heard.

8. Authorisation

(1) Every occupier of an institution generating, collecting, receiving, storing, transporting, treating, disposing and/or handling bio-medical waste in any other manner, except such occupier of clinics, dispensaries, pathological laboratories, blood banks providing treatment/service to less than 1000 (one thousand) patients per month, shall make an application in Form 1 to the prescribed authority for grant of authorisation.

(2) Every operator of a bio-medical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorisation.

(3) Every application in Form 1 for grant of authorisation shall be accompanied by a fee as may be prescribed by the Government of the State or Union Territory.

9. Advisory Committee

The Government of every State/Union Territory shall constitute an advisory committee. The committee will include experts in the field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration, and any other related department or organisation including non-governmental organisations. The State Pollution Control Board/Pollution Control Committee shall be represented. As and when required, the committee shall advise the Government of the State/Union Territory and the prescribed authority about matters related to the implementation of these rules.

10. Annual Report

Every occupier/operator shall submit an annual report to the prescribed authority in Form 11 by 31 January every year, to include information about the categories and quantities of bio-medical wastes handled during the preceding year. The prescribed authority shall send this information in a compiled form to the Central Pollution Control Board by 31 March every year.

11. Maintenance of Records

(1) Every authorised person shall maintain records related to the generation,

collection, reception, storage, transportation, treatment, disposal and/or any form of handling of bio-medical waste in accordance with these rules and any guide130

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(2) All records shall be subject to inspection and verification by the prescribed authority at any time.

12. Accident Reporting

When any accident occurs at any institution or facility or any other site where

bio-medical waste is handled or during transportation of such waste, the authorised person shall report the accident in Form III to the prescribed authority forthwith.

13. Appeal

Any person aggrieved by an order made by the prescribed authority under these rules may, within thirty days from the date on which the order is communicated to him, prefer an appeal to such authority as the Government of State/Union Territory may think fit to constitute :

Provided that the authority may entertain the appeal after the expiry of the said period of thirty days if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in times.

SCHEDULE II

(see Rule 6)

Colour Coding and Type of Container for
Disposal of Bio-Medical Wastes

Colour Type of Container / Waste Category Treatment options as per

Coding Schedule I

Yellow Plastic bag Cat. 1, Cat. 2, and Cat. 3, Incineration/deep burial
Cat. 6.

Red Disinfected container/plastic bag Autoclaving/Microwaving/
Cat. 3, Cat. 6, Cat.7. Chemical Treatment

Blue/White Plastic bag/puncture proof Autoclaving/Microwaving/
translucent Cat. 4, Cat. 7. Container Chemical Treatment and
destruction/shredding

Black Plastic bag Cat. 5 and Cat. 9 and Disposal in secured
Cat. 10. (solid) landfill

Notes:

1. Colour coding of waste categories with multiple treatment options as defined in Schedule I, shall be selected depending on treatment option chosen, which shall be as specified in Schedule I.
2. Waste collection bags for waste types needing incineration shall not be made of chlorinated plastics.
3. Categories 8 and 10 (liquid) do not require containers/bags.
4. Category 3 if disinfected locally need not be put in containers/bags.

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I

(see Rule 6)

Label for Bio-Medical
Waste Containers/Bags

Handle with Care

Note : Label shall be non-washable and prominently visible.

SCHEDULE IV

(see Rule 6)

Label for Transport of Bio-Medical Waste Containers/Bags

Day Month

Year

Date of generation

Waste category No

Waste class

Waste description

Sender's Name & Address

Receiver's Name & Address

Phone No Phone No

Telex No Telex No

Fax No Fax No

Contact Person Contact Person

.....

In case of emergency please contact

Name & Address :

Phone No.

Note :

Label shall be non-washable and prominently visible.

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SCHEDULE V
(see Rule 5 and Schedule 1)
Standards for Treatment and Disposal
of Bio-Medical Wastes

STANDARDS FOR INCINERATORS:

All incinerators shall meet the following operating and emission standards

A. Operating Standards

1. Combustion efficiency (CE) shall be at least 99.00%.
2. The Combustion efficiency is computed as follows:

%CO₂

C.E. =

$$\frac{\quad}{\%CO_2 + \%CO} \times 100$$

3. The temperature of the primary chamber shall be 800 ± 50 deg. C°.
4. The secondary chamber gas residence time shall be at least 1 (one) second at 1050 ± 50 C°, with minimum 3% Oxygen in the stack gas.

B. Emission Standards

Parameters Concentration mg/Nm³ at (12% CO₂ correction)

(1) Particulate matter

150

(2) Nitrogen Oxides

450

(3) HCl

50

(4) Minimum stack height shall be 30 metres above ground

(5) Volatile organic compounds in ash shall not be more than 0.01%

Note :

I Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the above emission limits, if necessary.

I Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.

I Chlorinated plastics shall not be incinerated.

I Toxic metals in incineration ash shall be limited within the regulatory quantities as defined under the Hazardous Waste (Management and Handling Rules,)

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Only low sulphur fuel like L.D.0dLS.H.S.1Diesel shall be used as fuel in the
incinerator.

Standards for Waste Autoclaving:

The autoclave should be dedicated for the purposes of disinfecting and treating
bio-medical waste,

(I) When operating a gravity flow autoclave, medical waste shall be subjected
to :

- (i) a temperature of not less than 121 C° and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes; or
- (ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or
- (iii) a temperature of not less than 149 C° and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.

(II) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following:

- (i) a temperature of not less than 121 C° and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or
- (ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;

(III) Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicator indicates that the required temperature, pressure or residence time was not reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

(IV) Recording of operational parameters

Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

(V) Validation test

Spore testing :

The autoclave should completely and consistently kill the approved biological

indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be Bacillus stearothermophilus spores using vials or spore Strips; with at least 1X10⁴ spores per millilitre. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121 C° or a pressure less than 15 psi.

(VI) Routine Test

A chemical indicator strip/tape the changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved

Standard for Liquid Waste:

The effluent generated from the hospital should conform to the following

limits

PARAMETERS PERMISSIBLE LIMITS

PH 6.3-9.0

Suspended solids 100 mg/l

Oil and grease 10 mg/l

BOD 30 mg/l

COD 250 mg/l

Bio-assay test 90% survival of fish after 96 hours in 100% effluent.

These limits are applicable to those, hospitals which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

Standards of Microwaving

- 1 Microwave treatment shall not be used for cytotoxic, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items.
2. The microwave system shall comply with the efficacy test/routine tests and a performance guarantee may be provided by the supplier before operation of the limit.
3. The microwave should completely and consistently kill the bacteria and other pathogenic organisms that is ensured by approved biological indicator at the

maximum design capacity of each microwave unit. Biological indicators for
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Standards for Deep Burial

1. A pit or trench should be dug about 2 meters deep. It should be half filled with waste, then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil.
2. It must be ensured that animals do not have any access to burial sites.
Covers of galvanised iron/wire meshes may be used.
3. On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.
4. Burial must be performed under close and dedicated supervision.
5. The deep burial site should be relatively impermeable and no shallow well should be close to the site.
6. The pits should be distant from habitation, and sited so as to ensure that no contamination occurs of any surface water or ground water. The area should not be prone to flooding or erosion.
7. The location of the deep burial site will be authorised by the prescribed authority.
8. The institution shall maintain a record of all pits for deep burial.

FORM I

(see rule 8)

APPLICATION FOR AUTHORISATION

(To be submitted in duplicate.)

To

The Prescribed Authority
(Name of the State Govt/UT Administration)
Address.

1. Particulars of Applicant

(i) Name of the Applicant

(In block letters & in full)

(ii) Name of the Institution:

Address:

Tele No., Fax No. Telex No.

2. Activity for which authorisation is sought:

(i) Generation

(ii) Collection

- (iii) Reception
- (iv) Storage
- (v) Transportation
- (vi) Treatment
- (vii) Disposal

(viii) Any other form of handling

3. Please state whether applying for fresh authorisation or for renewal:

(In case of renewal previous authorisation-number and date)

4. (i) Address of the institution handling bio-medical wastes:

(ii) Address of the place of the treatment facility:

(iii) Address of the place of disposal of the waste:

5. (i) Mode of transportation (in any) of bio-medical waste:

(ii) Mode(s) of treatment:

6. Brief description of method of treatment and disposal (attach details):

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- (i) Category (see Schedule 1) of waste to be handled
- (ii) Quantity of waste (category-wise) to be handled per month

8. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date : Signature of the Applicant

Place : Designation of the Applicant

FORM II
(see rule 10)
Annual Report

(To be submitted to the prescribed authority by 31 January every year).

1 . Particulars of the applicant:

(i) Name of the authorised person (occupier/operator):

(ii) Name of the institution:

Address

Tel. No

Telex No.

Fax No.

2. Categories of waste generated and quantity on a monthly average basis:

3. Brief details of the treatment facility:

In case of off-site facility:

(i) Name of the operator

(ii) Name and address of the facility:

Tel. No., Telex No., Fax No.

4. Category-wise quantity of waste treated:

5. Mode of treatment with details:

6. Any other information:

7. Certified that the above report is for the period from

Date Signature
Place..... Designation.....

FORM III
(see Rule 12)
Accident Reporting

1. Date and time of accident:
 2. Sequence of events leading to accident
 3. The waste involved in accident :
 4. Assessment of the effects of the accidents on human health and the environment,.
 5. Emergency measures taken
 6. Steps taken to alleviate the effects of accidents
 7. Steps taken to prevent the recurrence of such an accident
- Date Signature

Place..... Designation.....

[F.No.23-2/96-HSMD]
VIJAY SHARMA, Jt.Secy.

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Blood Donors infected with HIV+, their legal rights and duties

Interestingly the question of whether a Doctor is prohibited from disclosing that a blood donor is HIV + or whether such disclosure violates the right of privacy of the donor arose recently before the Supre Court of India in the case of Mr. 'X' versus Hospital 'Z'. Mr 'X' a medical Doctor had donated blood which tested to be HIV+. He was engaged to marry Miss 'Y', but the marriage was called off when hospital 'Z' (where we had donated blood) disclosed that he had tested positive for HIV. He sought his remedy before the National Commission under the consumer Protection Act 1986 but without success. The matter was taken to the Supreme Court of India by way of appeal. It was pleaded that the hospstital, by disclosing his HIV(+) status, had violated its duty to maintain confidentiality, which in turn had invaded his right of privacy; thus making the hospital liable to pay damages to him. In its judgement the court went into the legal sanction behind medical ethics as well as the right of privacy under the Indian Constitution and ultimately concluded that there was no breach of confidentiality or privacy especially when the rights of a third party, the fiancee of Mr 'X', were involved. It was also noticed that under Sections 269 and 270 of the Indian Penal Code any negligent act or malignant act likely to spread infection or disease dangerous to life was a criminal offence.

Soon thereafter certain Non Government Organisations (NGO's) working in the field of AIDS prevention filed a writ petition in the Apex Court challenging the afore-mentioned decision on the ground that no opportunity of hearing was given to bodies representing HIV+ or AIDS infected persons to present their views. The Court treated the said writ petition as an application for clarification of its earlier order and ultimately by judgement dated 10.12.2002 virtually nullified the conclusions recorded in the earlier judgement.

The vital issues concerning blood donors infected with HIV+, their legal rights and duties to themselves and to others, still remain to be settled.

Both the judgements of the Supreme Court of India are reproduced below:

* The text of the judgement has been taken from (1998) 8 Supreme Court Cases 296 Appendix 9—Mr. "X" v. Hospital "Z" — I

*(Before S. Saghir Ahmad and B.N. Kirpal, JJ.)

Mr 'X' ... Appellant;

Versus
HOSPITAL 'Z' ... Respondents.

Civil Appeal No. 4641 of 1998, decided on September 21, 1998

The Judgement of the Court was delivered by:

S. SAGHIR AHMAD, J.—Infringement of “suspended right to marry” cannot be legally compensated by damages either in torts or common law, is our answer to the problem raised in this appeal which is based on the peculiar facts of its own.

2. The appellant after obtaining the Degree of MBBS in 1987 from Jawaharlal Institute of Postgraduate Medical Education and Research, Chandigarh, completed his internship and junior residence at the same College. In June 1990, he joined the Nagaland State Medical and Health Service as Assistant Surgeon Grade I. Thereafter, the appellant joined the MD Pharmacology course though he continued in the Nagaland State Service on the condition that he would resume his duties after completing the MD Course. In September 1991, the appellant joined the further Course of Diploma in Ophthalmology which he completed in April 1993. In August 1993, he resumed his duties in the Nagaland State Health Service as Assistant Surgeon Grade I.

3. One Itokhu Yepthomi who was ailing from a disease which was provisionally diagnosed as aortic aneurism was advised to go to 'Z' Hospital at Madras and the appellant was directed by the Government of Nagaland to accompany the said patient to Madras for treatment. For the treatment of the above disease, Itokhu Yepthomi was posted for surgery on 31.5.1995 which, however, was cancelled due to shortage of blood. On 1.6.1995, the appellant and one Yehozhe who was the driver of Itokhu Yepthomi were asked to donate blood for the latter. Their blood samples were taken and the result showed that the appellant's blood group was A(+ve). On the next date, namely, on 2.6.1995, Itokhu Yepthomi was operated for aortic aneurism and remained in the Hospital till 10.6.1995 when he was discharged.

4. In August 1995, the appellant proposed marriage to one Ms 'Y' which was accepted and the marriage was proposed to be held on 12.12.1995. But the marriage was called off on the ground of blood test conducted at the respondents' Hospital in which the appellant was found to be HIV(+). The appellant went again to the respondents' Hospital at Madras where several tests were conducted and he was found to be HIV (+). Since the marriage had been settled but was subse146

5. The appellant then approached the National Consumer Disputes Redressal Commission for damages against the respondents, on the ground that the information which was required to be kept secret under medical ethics was disclosed illegally and, therefore, the respondents were liable to pay damages. The Commission dismissed the petition as also the application for interim relief summarily by order dated 3.7.1998 on the ground that the appellant may seek his remedy in the civil court.

6. Learned counsel for the appellant has vehemently contended that the principle of "duty of care", as applicable to persons in the medical profession, includes the duty to maintain confidentiality and since this duty was violated by the respondents, they are liable in damages to the appellant.

7. Duty to maintain confidentiality has its origin in the Hippocratic oath, which is an ethical code attributed to the ancient Greek physician Hippocrates, adopted as a guide to conduct by the medical profession throughout the ages and still used in the graduation ceremonies of many medical schools and colleges. Hippocrates lived and practised as a physician between the third and first centuries BC. He has been referred to by Plato as a famous Aesculapiad who had a philosophical approach to medicine. His manuscripts, the Hippocratic Collection (Corpus Hippocraticum), contained the Hippocratic oath which is reproduced below:

"I swear by 'Z' the physician and Aesculapius and health and all heal and all the gods and goddesses that according to my ability and judgement I will keep this oath and this stipulation—to reckon him who taught me this art equally dear to me as my parents, to share my substance with him and relieve his necessities if required, to look upon his offspring in the same footing as my own brothers and to teach them this art if they shall wish to learn it without fee or stipulation and that by precept, lecture, and every other mode of instruction I will impart a knowledge of the art to my own sons and those of my teachers and to disciples bound by a stipulation and oath according to the law of medicine but to none others. I will follow that system of regimen which according to my ability and judgement, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked nor suggest any such counsel, and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practise my art. I will not cut persons labouring under the stone but will leave this to be done by men who are practitioners of this work. Into

whatever house I enter, I will go into them for the benefit of the sick and will abstain from every voluntary act of mischief and corruption, and further, from the seduction of females or males, of freemen and slaves.

Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge as reckoning that all such should be kept secret. While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times, but should I trespass and violate this oath, may the reverse be my lot.”

8. The Hippocratic oath consists of two parts. The first, or covenant, is the solemn agreement concerning the relationship of apprentice to teacher and the obligations enjoined on the pupil. The second part constitutes the ethical code.

9. It is on the basis of the above that the International Code of Medical Ethics has also laid down as under:

“A physician shall preserve absolute confidentiality on all he knows about his patient even after his patient has died.”

10. Here, in this country, there is the Indian Medical Council Act, 1956 which controls the medical education and regulates the professional conduct. Section 20-A which was inserted by the Indian Medical Council (Amendment) Act, 1964 provides as under:

“20-A. Professional conduct:—(1) The Council may prescribe the standards of professional conduct and etiquette and a code of ethics for medical practitioners.

(2) Regulations made by the Council under sub-section (1) may specify which violations thereof shall constitute infamous conduct in any professional respect, that is to say, professional misconduct, and such provision shall have effect notwithstanding anything contained in any law for the time being in force.”

At the same time, that is, by the same Amending Act, clause (m) was also introduced in Section 33 and this clause provides as under:

“33. Power to make regulations—The Council may, with the previous sanction of the Central Government, make regulations generally to carry out the purposes of this Act, and, without prejudice to the generality of this power, such regulations may provide for—

(a)-(l) ***

(m) the standards of professional conduct and etiquette and code of ethics to be observed by medical practitioners.”

11. It is under these provisions that the Code of Medical Ethics has been made by the Indian Medical Council which, inter alia, provides as under:

“Do not disclose the secrets of a patient that have been learnt in the exercise of your profession. Those may be disclosed only in a court of law under orders of

12. It is true that in the doctor-patient relationship, the most important aspect is the doctor's duty of maintaining secrecy. A doctor cannot disclose to a person any information regarding his patient which he has gathered in the course of treatment nor can the doctor disclose to anyone else the mode of treatment or the advice given by him to the patient.

13. It is contended that the doctor's duty to maintain secrecy has a correlative right vested in the patient that whatever has come to the knowledge of the doctor would not be divulged and it is this right which is being enforced through these proceedings.

14. It is the basic principle of jurisprudence that every right has a correlative duty and every duty has a correlative right. But the rule is not absolute. It is subject to certain exceptions in the sense that a person may have a right but there may not be a correlative duty. The instant case, as we shall presently see, falls within the exceptions.

15. "Right" is an interest recognised and protected by moral or legal rules. It is an interest the violation of which would be a legal wrong. Respect for such interest would be a legal duty. That is how Salmond has defined "right". In order, therefore that an interest becomes the subject of a legal right, it has to have not merely legal protection but also legal recognition. The elements of a "legal right" are that the "right" is vested in a person and is available against a person who is under a corresponding obligation and duty to respect that right and has to act or forbear from acting in a manner so as to prevent the violation of the right. If, therefore, there is a legal right vested in a person, the latter can seek its protection against a person who is bound by a corresponding duty not to violate that right.

16. The Hippocratic oath as such is not enforceable in a court of law as it has no statutory force. Medical information about a person is protected by the code of Professional Conduct made by the Medical Council of India under Section 33(m) read with Section 20-A of the Act. The relevant provisions of the code of Medical Ethics have already been reproduced above which contain an exception to the general rule of confidentiality, inasmuch as it provides that the information may be disclosed in a court of law under the orders of the Presiding Judge. This is also the law in England where it is provided that the exceptions to this rule permit disclosure with the consent, or in the best interests, of the patient, in compliance with a court order or other legally enforceable duty and, in very limited circumstances, where the public interest so requires. Circumstances in which the public interest would override the duty of confidentiality could, for example, be the investigation and prosecution of serious crime or where there is an immediate or

1. A.I.R. 1963 S.C. 1295

2. (1975) 2 SCC 148

3. 94 US 113:24 L Ed 77 (1877)

future (but not a past and remote) health risk to others.

17. The General Medical Council of Great Britain in its guidance on HIV infection and AIDS has provided as under:

“When diagnosis has been made by a specialist and the patient after appropriate counselling,, still refuses permission for the general practitioner to be informed of the result, that request for privacy should be respected.

The only exception would be when failure to disclose would put the health of the health-care team at serious risk. All people receiving such information must consider themselves to be under the same obligations of confidentiality as the doctor principally responsible for the patient’s care. Occasionally the doctor may wish to disclose a diagnosis to oa third party other than a health-care professional. The Council think that the only grounds for this are when there is a serious and identifiable risk to a specific person, who, if not so informed would be exposed to infection...A doctor may consider it a duty to ensure that any sexual partner is informed regardless to the patient’s own wishes.”

(emphasis supplied)

18. Thus, the Code of Medical Ethics also carves out an exception to the rule of confidentiality and permits the disclosure in the circumstances enumerated above under which public interest would override the duty of confidentiality, particularly where there is an immediate or future health risk to others.

19. The argument of the learned counsel for the appellant, therefore, that the respondents were under a duty to maintain confidentiality on account of the Code of Code of Medical Ethics formulated by the Indian Medical Council cannot be accepted as the proposed marriage carried with it the health risk to an identifiable person who had to be protected from being infected with the communicable disease from which the appellant suffered. The right to confidentiality, if any, vested in the appellant was not enforceable in the present situation.

20. Learned counsel for the appellant then contended that the appellant’s right of privacy has been infringed by the respondents by disclosing that the appellant was HIV(+) and, therefore, they are liable in damages. Let us examine this contention.

21. Right to privacy has been culled out of the provisions of Article 21 and other provisions of the Constitution relating to the Fundamental Rights read with the Directive Principles of State Policy. It was in this context that it was held by this Court in *Kharak Singh v. State of U.P.*¹ that police surveillance of a person by domiciliary visits would be violative of Article 21 of the Constitution. This decision was considered by Mathew, J. in his classic judgement in *Gobind v. State of M.P.* ²

5. (1981) 1 SCC 420

6. (1994) 6 SCC 632

7. 410 US 113

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The Blood Bankers' Legal Handbook Appendix 9—Mr. "X" v. Hospital "Z" — I

3, Wolf v. Colorado⁴ and various articles were considered

and it was laid down ultimately, as under: (SCC p. 157, para 31)

"31. Depending on the character and antecedents of the person subjected to surveillance as also the objects and the limitation under which surveillance is made, it cannot be said surveillance by domiciliary visits would always be unreasonable restriction upon the right of privacy. Assuming that the fundamental rights explicitly guaranteed to a citizen have penumbral zones and that the right to privacy is itself a fundamental right, that fundamental right must be subject to restriction on the basis of compelling public interest."

22. Kharak Singh v. State of U.P.¹ and Gobind v. State of M.P.² came to be considered again by this Court in Malak Singh v. State of P & H⁵ and the view taken earlier on the right of privacy was reiterated.

23. In another classic judgement rendered by Jeevan Reddy, J., in R.

Rajagopal v. State of T.N.⁶ the right of privacy vis-a-vis the right of the Press under Article 19 of the Constitution was considered and in the research-oriented judgement, it was laid down, inter alia, as under: (SCC pp. 649-50, para 26)

"26. (1) The right to privacy is implicit in the right to life and liberty guaranteed to the citizens of this country by Article 21. It is a 'right to be let alone'. A citizen has a right to safeguard the privacy of his own, his family marriage, procreation, motherhood, child-bearing and education among other matters. None can publish anything concerning the above matters without his consent—whether truthful or otherwise and whether laudatory or critical. If he does so, he would be violating the right to privacy of the person concerned and would be liable in an action for damages. Position may, however, be different, if a person voluntarily thrusts himself into controversy or voluntarily invites or raises a controversy."

24. In an American decision, Jane Roe v. Henry Wade⁷ the Supreme Court of United States said that:

"Although the Constitution of the USA does not explicitly mention any right of privacy, the United States Supreme court recognizes that a right of personal privacy, or a guarantee of certain areas or zones of privacy does exist under the Constitution, and that the roots of that right may be found in the First Amendment, in the Fourth and Fifth Amendments, in the penumbras of the Bill of Rights, in the Ninth Amendment, and in the concept of liberty guaranteed by the first section of the Fourteenth Amendment and that the 'right' to privacy is not absolute."

25. Reference may, at this stage, be made to Article 8 of the European

Convention on Human Rights which defines this right as follows:

(1) Everyone has the right to respect for his private and family life, his home and his correspondence.

(2) There shall be no interference by a public authority with the exercise of this right except such as in accordance with the law and is necessary in democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals or for the protection of the rights and freedoms of others.”

(emphasis supplied)

26. As one of the basic Human Rights, the right of privacy is not treated as absolute and is subject to such action as may be lawfully taken for the prevention of crime or disorder or protection of health or morals or protection of rights and freedoms of others.

27. Right of privacy may, apart from contract, also arise out of a particular specific relationship which may be commercial, matrimonial, or even political. As already discussed above, doctor-patient relationship, though basically commercial, is, professionally, a matter of confidence and, therefore, doctors are morally and ethically bound to maintain confidentiality. In such a situation, public disclosure of even true private facts may amount to an invasion of the right of privacy which may sometimes lead to the clash of one person's "right to be let alone" with another person's right to be informed.

28. Disclosure of even true private facts has the tendency to disturb a person's tranquillity. It may generate many complexes in him and may even lead to psychological problems. He may, thereafter, have a disturbed life all through. In the face of these potentialities, and as already held by this Court in its various decisions referred to above, the right of privacy is an essential component of the right to life envisaged by Article 21. The right, however, is not absolute and may be lawfully restricted for the prevention of crime, disorder or protection of health or morals or protection of rights and freedom of others.

29. Having regard to the fact that the appellant was found to be HIV(+), its disclosure would not be violative of either the rule of confidentiality or the appellant's right of privacy as Ms 'Y', with whom the appellant was likely to be married was saved in time by such disclosure, or else, she too would have been infected with the dreadful disease if the marriage had taken place and consummated.

30. We may now examine the right based on confidentiality in the context of marriage.

31. Marriage is the sacred union, legally permissible, of two healthy bodies of opposite sexes. It has to be mental, psychological and physical union. When two souls thus unite, a new soul comes into existence. That is how life goes on and on this planet.

32. Mental and physical health is of prime importance in a marriage, as one

"13. (1) Any marriage solemnized, whether before or after the commencement of this Act, may, on a petition presented by either the husband or the wife, be dissolved by a decree of divorce on the ground that the other party—

(i)-(iv)

(v) Has been suffering from venereal disease in a communicable form."

(emphasis supplied)

33. So also Section 2 of the Dissolution of Muslim Marriages Act, 1939 sets out that if the husband is suffering from a virulent venereal disease, a woman married under Muslim law to such person shall be entitled to obtain a decree for dissolution of her marriage.

34. Under the Parsi Marriage and Divorce Act 1936, one of the grounds for divorce set out in Section 32 is that the defendant has, since the marriage, infected the plaintiff with venereal disease.

35. Under the Indian Divorce Act 1869, the grounds for dissolution of a marriage have been set out in Section 10 which provides that a wife may petition for dissolution if her husband was guilty of incestuous adultery, bigamy with adultery or of rape, sodomy or bestiality.

36. Under Section 27 of the Special Marriage Act, 1954 the party to a marriage has been given the right to obtain divorce if the other party to whom he or she was married was suffering from venereal disease in a communicable form.

37. The emphasis, therefore, in partially all systems of marriages is on a healthy body with moral ethics. Once the law provides the "venereal disease" as a ground for divorce to either husband or wife, such a person who was suffering from that disease, even prior to the marriage cannot be said to have any right to marry so long as he is not fully cured of the disease. If the disease, with which he was suffering, would constitute a valid ground for divorce, was concealed by him and he entered into marital ties with a woman who did not know that the person with whom she was being married was suffering from a virulent venereal disease, that person must be enjoined from entering into marital ties so as to prevent him from spoiling the health and, consequently, the life of an innocent woman.

38. The contention of the learned counsel that every young man or, for that matter, a woman, has a right to marry cannot be accepted in the absolute terms in which it is being contended. Having regard to the age and the biological needs,

a person may have a right to marry but this right is not without a duty. If that person is suffering from any communicable venereal disease or is impotent so that marriage would be a complete failure or that his wife would seek divorce from him on that ground, that person is under a moral, as also legal duty, to inform the woman with whom the marriage is proposed that he was not physically healthy and that he was suffering from a disease which was likely to be communicated to her. In this situation, the right to marry and duty to inform about his ailment are vested in the same person. It is a right in respect of which a corresponding duty cannot be claimed as against some other person. Such a right, for these reasons also, would be an exception to the general rule that every "right" has a correlative "duty". Moreover, so long as the person is not cured of the communicable venereal disease or impotency, the right to marry cannot be enforced through a court of law and shall be treated to be a "suspended right".

39. There is yet another aspect of the matter.

40. Sections 269 and 270 of the Indian Penal Code provide as under.

"269 Negligent act likely to spread infection of disease dangerous to life.—
Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease, dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both.

270. Malignant act likely to spread infection of disease dangerous to life.—
Whoever malignantly does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both."

41. These two sections spell out two separate and distinct offences by providing that if a person, negligently or unlawfully, does an act which he knew was likely to spread the infection of a disease, dangerous to life, to another person, then, the former would be guilty of an offence, punishable with imprisonment for the term indicated therein, if a person suffering from the dreadful disease "AIDS", knowingly marries a woman and thereby transmits infection to that woman, he would be guilty of offences indicated in Sections 269 and 270 of the Indian Penal Code.

42. The above statutory provisions thus impose a duty upon the appellant not to marry as the marriage would have the effect of spreading the infection of his own disease, which obviously is dangerous to life, to the woman whom he marries apart from being an offence.

8. 107 S Ct 1123 (1987)

9. (9th circuit 1988) 840 2F 2d 701

10. (SDA Fla 1986) 639 F Supp 654

11. 261 Cal Rep. 197 (1989)

Can the appellant, in the face of these statutory provisions, contend that quently, dismissed. the respondents, in this situation, should have maintained strict secrecy? We are afraid, the respondents' silence would have made them particeps criminis.

44. Ms 'Y', with whom the marriage of the appellant was settled, was saved in time by the disclosure of the vital information that the appellant was HIV(+). The disease which is communicable would have been positively communicated to her immediately on the consummation of marriage. As a human being, Ms 'Y' must also enjoy, as she obviously is entitled to all the Human Rights available to any other human being. This is apart from, and in addition to, the Fundamental Right available to her under Article 21, which, as we have seen, guarantees "right to life" to every citizen of this country. This right would positively include the right to be told that a person, with whom she was proposed to be married, was the victim of a deadly disease, which was sexually communicable. Since "right to life" includes right to lead a healthy life so as to enjoy all the faculties of the human body in their prime condition, the respondents, by their disclosure that the appellant was HIV(+), cannot be said to have, in any way, either violated the rule of confidentiality or the right of privacy. Moreover, where there is a clash of two Fundamental Rights, as in the instant case, namely, the appellant's right to privacy as part of right to life and Ms 'Y's right to lead a healthy life which is her Fundamental Right under Article 21, the right which would advance the public morality or public interest, would alone be enforced through the process of court, for the reason that moral considerations cannot be kept at bay and the Judges are not expected to sit as mute structures of clay in the hall known as the courtroom, but have to be sensitive, "in the sense that they must keep their fingers firmly upon the pulse of the accepted morality of the day". (See Allen : Legal Duties)

45. "AIDS" is the product of undisciplined sexual impulse. This impulse, being a notorious human failure if not disciplined, can afflict and overtake anyone howsoever high or, for that matter, how low he may be in the social strata. The patients suffering from the dreadful disease "AIDS" deserve full sympathy. They are entitled to all respect as human beings. Their society cannot, and should not be avoided, which otherwise, would have a bad psychological impact upon them. They have to have their avocation. Government jobs or services cannot be denied to them has been laid down in Some American decisions. (See : School Board of Nassau contry. Floria v. Airline⁸, Chalk v. USDC CD of Cal⁹. Shuttleworth v. Broward Cty.¹⁰; Raytheon v. Fair Employment and Housing Commission, Estate of Chadbourne¹¹. But "sex" with them or the possibility thereof has to be avoided

as otherwise they would infect and communicate the dreadful disease to others.

The Court cannot assist that person to achieve that object.

46. For the reasons stated above, the appeal is without merits and is, conse*
The text of the judgement has been taken from Judgements Today 2002 (10) 214
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S. RAJENDRA BABU, P. VENKATARAMA REDDI & ARUN

KUMAR, JJ

Dt. 10.12.2002

APPEARANCES

Mr Kirit Raval, Solicitor General Mr. Jayant Das, Senior Advocate, Ms Meenakshi Arora, Mr Anand Grover, Mr. S. Ravindra Bhat, Mr. Naveen R. Nath, Ms. Lalit Mohini Bhat, Ms. Hetu Arora, Mr. Shiv Kumar Suri, Mr. Sanjay Parikh, Ms. Sumita Das, Mr. S. Santhanan Swaminadhan, Mr. Maninder Singh, Mr. A. Mariarputham, Mr. Ankur Talwar, Ms. Prathiba M. Singh, Ms. Rekha Pandey, Mr. Ajit Pudussery, Mr. K. C. Ranjeet, Mr. E.C. Vidya Sagar, Mr. S. Murlidhar, Ms. Flavia Agnes, Ms.

V. Mohana, Ms. Veena Gowda, Mr. Dayan Krishnan, Mr. Trideep Pais and Mr. Shreyas Jayasinha, Advocates with them for the Appearing parties.

RAJENDRA BABU, J.

1. Civil Appeal no. 4641 of 1998 arose out of an order made by the National Consumer Disputes Redressal Commission (for short 'the Commission') dismissing a petition and also an application for interim relief summarily by an order made on 3.7.1998 on the ground that the appellant should seek his remedy in a civil court.

2. The case that arose for consideration before this Court, in brief, is as follow: The appellant completed his studies leading to degree of MBBS from Jawaharlal Institute of Post Graduate Medical Education and Research, Chandigarh in the year 1988. In June, 1990 he joined the Nagaland State Medical and Health Service assistant surgeon grade-1 and thereafter he was selected for admission to MD Pharmacology. However, he was continued in service on the condition that he would join his duties after completing his studies. Later on, he was given admission in diploma in ophthalmology in September 1991 and he completed that course in April 1993 and rejoined his service in the Nagaland State as assistant surgeon grade-1 as junior specialist. He was deputed to accompany his uncle who was a minister of transport and communication to the respondent hospital at Chennai and who was diagnosed as suffering from aortic aneurism. As the patient

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was aneemic, the surgery was postponed. The appellant and his driver offered to donate blood and blood samples of the appellant were sent for testing. In the

meanwhile, the patient was operated upon for aortic aneurism and was discharged from the hospital on 10.6.1995 and the appellant and his driver took him to Dimapur. The appellant was engaged to be married which was scheduled to be held on 12.12.1995. The appellant, his fiancée and his mother-in-law left for Darjeeling and Kolkata to do some shopping and thereafter on 18.10.1995 they returned to Kohima. On 12.11.1995 the minister of transport and communication called the appellant's brother-in-law and sister to his residence and informed that the appellant's marriage was being called off; that the appellant's blood was tested at hospital; that it was found to be HIV positive; that this information had been furnished to him by a doctor [who was impleaded as respondent no. 2]; that he had of his own accord re-confirmed the appellant's HIV status by personally calling the respondent no. 2 and was informed by him of the same. Therefore, the marriage of the appellant was called off on account of his HIV positive status by his brother-in-law. Next day the appellant went to the hospital for further confirmation and it was confirmed that he was HIV positive. The appellant tried to contact the director of the hospital to enquire about the unauthorised disclosure by the hospital about his HIV status as he was unable to obtain any information from the management regarding the said disclosure. As a result thereof, he was forced to leave Kohima as several people including the appellant's own family members and certain other members of the community were now aware of the appellant's HIV positive status and he was socially ostracised. Aggrieved by the unauthorised disclosure and on the basis that the hospital had a duty to maintain the confidentiality of personal medical information of the appellant, he filed a petition before the commission seeking compensation from the respondents for breach of their duty to maintain confidentiality and consequential discrimination, loss in earnings and social ostracism. For interim relief an interlocutory application was also filed. In those circumstances, the commission dismissed the petition summarily and directed him to initiate civil proceeding for an appropriate relief.

3. A special leave petition was filed before this Court. This Court made an order on 21.9.1998 dismissing the said petition. However, in the course of the order several findings have been given, particularly those relating to "suspended right to marry". In that proceeding, this Court heard only the appellant and there was no issue of notice to any other person nor this Court had occasion to hear any of the persons representing the HIV or AIDS infected persons or their rights, much less any of the non government organisations which are doing work in the field were heard. In those circumstances, a writ petition was filed under Article 32 of the Constitution before this Court for setting aside the said judgement. However, in the proceedings dated 7.2.2000 it was noted that prayer was deleted and the other prayer which indirectly concerned the correctness of the judgement already

application for clarification or direction in the case already decided by this Court.

In the course of the order it was observed that:

“We direct the office shall not treat this as a writ petition filed under Article 32, but shall register it separately as an IA for clarification/directions in C.A. No.

4641/1998.

Notice of this IA returnable within two weeks shall be issued to National Aids Control Organisation, Union of India and Indian Medical Association which is already represented in IA nos. 2-3. Notice shall also go to Medical Council of India. Dasti service is permitted in addition.”

4. By an order dated 2.9.2001, it has been further directed that the I.As should be listed before a three judge bench.

5. In I.A. 2/1999 filed by the impleaded petitioner, the petitioner has raised the question whether a person suffering from HIV(+) contracting marriage with a willing partner after disclosing the factum of disease to that partner will be committing an offence within the meaning of section 269 and 270 IPC. In substance, the petitioner wants the court to clarify that there is no bar for the marriage, if the healthy spouse consents to marry in spite of being made aware of the fact that the other spouse is suffering from the said disease.

6. The various organisations to which the notice was issued have also entered their appearance before this Court and filed plethora of material giving their respective stands. The practical difficulties in ensuring disclosure to the person proposed to be married or in monitoring such cases are pointed out. It is unnecessary to examine these matters in any detail inasmuch as in our view this Court had rested its decision on the facts of the case that it was open to the hospital or the doctor concerned to reveal such information to persons related to the girl whom he intended to marry and she had a right to know about the HIV positive status of the appellant. If that was so, there was no need for this Court to go further and declare in general as to what rights and obligations arise in such context as to right to privacy or confidentiality or whether such persons are entitled to be married or not or in the event such persons marry they would commit an offence under law or whether such right is suspended during the period of illness. Therefore, all those observations made by this Court in the aforesaid matter were unnecessary, particularly when there was no consideration of the matter after notice to all the parties concerned.

In that view of the matter, we hold that the observations made by this Court, except to the extent of holding as stated earlier that the appellant's right was not affected in any manner in revealing his HIV positive status to the relatives of the fiancée are uncalled for. We dispose of these applications with these observations.

Appendix 10

Legal Standards for Blood Bags - A case study

In early 2002, the Haryana Aids Control Society floated tenders for the purchase of 25,000 blood bags for supplying to blood centers throughout the state of Haryana. The notice invited manufacturers and their agents from all over the country to tender their bids for blood bags that conformed to all applicable standards including ISO 9000 and ISO 9001.

As expected, a number of companies sent in their tender bids and ultimately the bid of M/s Innovol Medical, a company based in Kunnam, Tamil Nadu was accepted. The company started delivering the blood bags to the society as per the agreed schedule.

Interestingly however, around the same time, a few newspaper reports came to the surface alleging that the blood bags being supplied by the successful bidder company through a New Delhi based dealer were in fact substandard and were not suitable for the collection and preservation of blood.

Perhaps as a result of the newspaper reports, a writ was filed in the Punjab and Haryana High Court by a public spirited non-governmental organization called Ahsaas.

In its writ petition, the NGO leveled some very serious allegations against the manufacturer company and against the state of Haryana. The writ repeated the allegations contained in the newspaper reports and prayed that the High Court intervene in the matter to get to the root of what could well be a very serious matter.

When the writ petition came up for hearing in the High Court, the Division Bench hearing the petition requested the author to act as Amicus Curiae - a friend of the court - in order to assist the court. The question before the court was whether the blood bags were safe for use or not. The respondent company filed a veritable pile of documents including certification from various institutes, test reports etc., including reports from medical officers of the State of Haryana declaring the blood bags to be usable quality and as per requirements.

But before this crucial issue could be discussed in court, the respondent manufacturing company tried to show to the court that the writ petition was in fact not

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The court, being ever sensitive to the possibility of the platform of Public Interest Litigation being misused for settling business scores, posed a direct query to the petitioner NGO and asked it to produce its credentials. However by way of abundant caution, and in order not to jeopardize an enquiry into this critical issue, the petitioner requested for permission to withdraw the writ petition.

While allowing Ahsaas to withdraw its petition, the Division Bench at the same time took suo moto notice of the allegations contained in the petition and ordered that proceedings continue with the author assisting the court in arriving at the correct picture. The court also granted time to the respondent company and the state of Haryana to file detailed affidavits and reports clarifying the situation.

Relying on a lot of support from the Blood Bank Society Chandigarh, PGI's Department of Blood Transfusion and Immunohaematology and from the Chandigarh Aids Control Society, the author was able to present the court with considerable material on the subject of blood bags and standards prescribed for them.

In the meantime, the fresh test reports that had been ordered were placed before the court. These reports showed that the blood bags were clearly unsuitable for a number of reasons.

- a. The blood bags were of 450ml capacity instead of the required capacity of 350ml
- b. In order to pass off the bags as 350ml bags, the manufacturers/suppliers had pasted new labels on top of the original labels.
- c. The rubber tubing connecting the needles to the blood bags were sticky and not as they ought to be
- d. Most seriously, however, the quantity of the anti-coagulant present inside the blood bags was less than the prescribed amount. In fact, although the bags were of 450ml capacity, the amount of anti-coagulant was less than what was required for even a 350ml bag.

An attempt was made by Innovol to extricate itself from the sticky mess it found itself in by claiming that the labels originally pasted on the bags were from a previous batch of 450ml bags and since there hadn't been enough time to get fresh labels printed, the suppliers had pasted the new 350ml labels on top of the original labels. The rubber tubing was sticky only because of the lubricant used to keep them usable etc. The court was however not satisfied with this defence.

A request was also made by Innovol that it be allowed to replace all 25,000 blood bags with fresh blood bags, a request supported by the state of Haryana. The court granted this request with the rider that the new bags be tested again before use and the test reports be placed on the court's file.

A month later, Innovol was back in court seeking a month's extension to replace the bags. This request too, was granted.

At the next date of hearing, seeing the way the court had reacted to this attempt to play with the life of innocents, the State of Haryana informed the court that it had been corresponding with Innovol through its Delhi-based dealer. But now interestingly, the company requested yet again that it be allowed an extension for some months since its plant was not capable of manufacturing blood bags conforming to standards and that since it was upgrading its plants to bring them in line with international specifications.

A strange request indeed from a company that just a few months ago had bid for a tender and provided sheaves of documents testifying to its capabilities.

The court declined the request. The state of Haryana was asked to take a day to crystallize its stand in view of this implied admission that the blood bags supplied earlier were of sub-standard quality. As Amicus, the author once again led the court through the chain of events and pointed out the various provisions of law as well as the potential fallout from the use of the bags already supplied.

The very next day, the State of Haryana informed the court that the tender had been cancelled; that the Deputy Drugs Controller of the state was in court and stated that a formal complaint under Section 27 of the Drugs and Cosmetics Act was going to be filed against Innovol and its dealer.

But what took the cake by far was the volte-face by the respondent company. In an incomprehensible somersault, the counsel for the respondent denied that he owed any liability for the actions of Innovol. Rather, he stated that he was representing only the Delhi based dealer, M/s Insignia and as such sought to distance himself from Innovol who he stated, was outside his control and refusing to communicate with him on the subject anymore.

This was the stand of the respondent who had earlier filed a written reply in court on behalf of M/s Innovol as its duly authorized signatory; who had tendered a bid claiming to be the agent of the manufacturer. The court rejected this contention

"7. Mr, M.L. Sarin, learned Senior Counsel assisting the court, contended that having regard to the facts and circumstances apparent from the records neither the manufacturing company M/S Innovol Medical India Limited nor its dealer M/S Insignia International, New Delhi can escape rigour of law; that from a bare perusal of the Written Statement filed on behalf of Respondent No. 3, it is clear that its deponent Mr. Gian Kataria is an authorized signatory on behalf of Respondent No. 3 M/S Innovol Medical India Limited and thus the stand taken by Mr. Pawan Girdhar that he does not represent M/S Innovol Medical India Limited is not correct. He also requests implemement of the Director, Drugs Controller, Tamil Nadu and the Drugs Controller, Government of India as Respondents.

8. Having heard learned counsel representing the different parties, we find substance in the contention of Mr. Sarin and accept the same and having regard to the avowed object of Article 21 of the Constitution of India, we for the present awaiting launching of the prosecution under Section 32 of the Drugs and Cosmetics Act, 1940 against M/S Innovol Medical India Limited, Kunnam, Tamil Nadu - 631604 and its dealer M/S Insignia International, New Delhi of which Mr. Gian Kataria is its proprietor besides an authorized signatory of the former, issue Rule nisi to the Director, Drugs Controller, Tamil Nadu, Chennai as well as the Drugs Controller General of India, Nirman Bhawan, New Delhi impleading them as Respondents No. 4 and 5 respectively to this writ proceedings from whom we would like to know what action they had taken or intend to take against Respondent No. 3."

It may not be out of place to point out that apart from the many penalties provided under the Drugs and Cosmetics Act, even the Indian Penal Code provides for very strict punishment against those who endanger the lives of others in the guise of selling medicines or medical aids.

The case at hand is still pending before the Punjab and Haryana High Court and it seems unlikely that the judicial and human conscience of the court will let the guilty get away. One hopes that this case stands out as a deterrent and a warning to anyone else intending to embark on a similar misadventure.

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Plastics collapsible containers for human blood and blood components
Poches en plastique souple pour is sang et les produits du sang

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ISO 3826:199

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, government and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote. International Standard ISO 3826 was prepared by Technical Committee ISO/TC 76, Transfusion, infusion and injection equipment for medical use. Annexes A and B form an integral part of this International Standard. Annex C is for information only.

Introduction

In some countries national pharmacopoeia or other government regulations are legally binding and these requirements may take precedence over this International Standard. The manufacturers of the plastics container or the suppliers are expected to disclose in confidence to the national control authority, if requested by them, full details of the plastics material(s) and the components of the materials and their methods of manufacture, details of manufacture of the plastics containers including the chemical names and quantities of any additives, whether incorporated by the manufacturer of the containers or present in the raw material, as well as full details of any additives that have been used.

Plastics collapsible containers for
human blood and blood components

1. Scope

1.1 This International Standard specifies requirements, including performance requirements for di-(2 ethylhexyl) phthalate (DEHP) plasticized poly(vinyl chloride) (PVC) for plastics collapsible, non-vented, sterile containers complete with collecting tube outlet port(s), integral needle and with optional transfer tube(s), for the collection, storage, processing, transport, separation and administration of blood

and blood components. The containers may contain anticoagulant and/or preservative solutions, depending on the application envisaged. These requirements are intended to

a) ensure that the quality of blood and blood components is maintained as high as possible;

b) make possible efficient and safe collection, identification, storage, separation and transfusion of the contents, with special attention to reducing to a minimum the risks resulting from

—contamination, in particular microbiological, contamination,
—air embolism,

—errors in identification of containers and any representative samples of

contents

—interaction between the container and its contents;

c) ensure functional compatibility when used in combination with transfusion sets as specified in ISO 1135-4;

d) provide maximum resistance to breakage and deterioration in a package of minimal mass and volume.

1.2 The requirements specified in this international Standard also apply to multiple units of plastics containers, e.g. to double, triple or quadruple units.

1.3 The term "plastics containers" is used throughout this International Standard to mean the container complete with collecting tube and needle, port(s) anticoagulant and/or preservative solutions and transfer tube(s) and associated container(s), where applicable.

1.4 Unless otherwise specified, all tests specified in this International Standard apply to the plastics container as prepared ready for use.

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Normative references

The following standards contain provisions which through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 247:19 Rubber - Determination of ash.

ISO 1135-3:1986, Transfusion equipment for medical use - Part 3: Blood-taking set

ISO 1135-4:1987, Transfusion equipment for medical use - Part 4: Transfusion sets for single use.

3. Dimensions and designation

3.1 Dimensions

See figure 1 and table 1, Only the dimensional values shown in figure 1 are binding; the dimensions given in table 1 are for guidance purposes only.

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Notes:

1. The figure illustrates the components of a plastics container and, apart from the dimensions shown, does not form part of the requirements of this International Standard.
2. For guidance, additional dimensions are given in table 1. These dimensions are optional and are not requirements of this international Standard.

Table 1 - Dimensions for plastics containers, label areas and nominal capacity (for guidance purposes only)

Dimensions in millimetres

Nominal

Inside

Inside

Size of label area

Capacity

width

height

MI

$b2 \pm 5$

$h2 \pm 5$

b1

h1

100

75

120

60

85

250

120

130

90

85

400

120

170

100

100

500

120

185

100

100

3.2 Designation example

Designation example of a plastics collapsible container with a nominal capacity of 500 ml complying with the requirements specified in this International Standard.

Plastics container ISO 3826-500

4. Design

4.1 General

The design of the plastics container shall provide for the safe and convenient collection, storage, processing, transport, separation and administration of whole blood and blood components. The design and manufacture shall not adversely affect the preservation of blood and blood components. The container shall permit the preparation of plasma or centrifuged or resuspended cellular components with a minimal hazard of contamination by microorganisms. The container shall be functionally compatible with the transfusion set specified in ISO 1135-4, its design shall also ensure that it can be used in a centrifuge cup.

4.2 Air content

4.2.1. The total volume of air contained in the blood collection pathway and the container used for the collection of blood and for each transfer container and its associated tubing shall not exceed 10 ml. The volume of air contained in each additional transfer container and associated tubing shall not exceed 10 ml.

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When used in accordance with the manufacturer's instructions, the plastics container shall be capable of being filled with blood without air being introduced.

4.3 Emptying under pressure

The plastics container filled with a volume of water at a temperature of $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ equal to its nominal capacity and connected to a transfusion set as specified in ISO 1135-4 inserted in an outlet port (see 4.8) shall empty without leakage within 2 min when gradually squeezed between two plates to an internal pressure of 40 kPa above atmospheric pressure.

4.4 Pilot samples

The plastics container shall be designed so that pilot samples of unmistakable identity can be collected for the performance of appropriate laboratory tests without the closed system of the container being penetrated.

4.5 Rate of collection

4.5.1 The plastics container shall be designed so that it is capable of being filled to its nominal capacity in less than 8 min when tested in accordance with B.2.

4.6 Collecting and transfer tube(s)

4.6.1 The plastics container may be provided with one or more collecting or transfer tube(s) to allow the collection and separation of blood and blood components. The transfer tube shall be fitted with a device, which acts first as a seal and, when broken, permits the free flow of blood components in either direction.

4.6.2 The tubes shall be such that they can be sealed hermetically and do not collapse under normal use.

4.6.3 The plastics container, filled with water (see note 4 under 5.2.8) to its nominal capacity and sealed, and the tubes connected to the plastics container, shall form a hermetic seal and a tight leakproof joint which will withstand, without leakage occurring, a tensile force of 20 N, applied to the tubing for 15 s. The tensile force shall be applied at right angles to the edge of the joint and in the longitudinal axis of the plane of the container at a temperature of $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

There shall be no leakage at the junctions and the container shall also conform to the requirements specified in 5.2.8.

4.6.4 Under visual inspection, the tubing shall not display any cracks, blisters, kinks or other defects.

4.7 Blood taking needle

The needle shall be integral with the collecting tube and covered by a protective cap. The protective cap shall prevent leakage of anticoagulant and/or preservative

solution from the plastics container during storage, shall maintain the sterility of the fluid path and shall be readily removable. The protective cap shall be tamper-evident and manufactured so that either it is impossible to replace or any attempt at manipulating it is blatantly obvious.

The blood-taking needle, as specified in ISO 1135-3, shall withstand, without working loose from the assembly, a tensile force of 20N applied along the longitudinal axis of the tubing for 15 s.

4.8 Outlet port(s)

4.8.1 The plastics container shall be provided with one or more outlet ports for the administration of blood and blood components through a transfusion set. The port(s), which shall have a puncturable, non-resealable closure, shall allow connection of a transfusion set without leakage on insertion or during conditions of use, including emptying under pressure (see 4.3). To ensure functional interchangeability, the port(s) shall be of such size and design to allow insertion of a transfusion set having a closure-piercing device in accordance with ISO 1135-4. Before the closure is pierced by the point of the closure-piercing device, the outlet port(s) shall be tightly occluded by the closure-piercing device.

4.8.2. Each outlet port shall be fitted with a hermetically sealed, tamper-evident protector to maintain the sterility of the internal surface.

4.9 Suspension

The plastics container shall have adequate means of suspension or positioning, which do not interfere with use of the container during collection, storage, processing, transport and administration. The means of suspension or positioning shall be capable of withstanding a tensile force of 20 N applied along the longitudinal axis of the outlet port(s) for 60 min at a temperature of $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ without breaking.

5. Requirements

5.1 General

The plastics container shall be transparent, virtually colourless (see 5.3.2.), flexible, sterile, non-pyrogenic, free from toxicity (see 5.4) and non-frangible under conditions of use (see 5.2.5). It shall be compatible with the contents under nor

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The plastics container shall be stable biologically, chemically and physically with respect to its contents during its shelf-life and shall not permit penetration of microorganisms. Any substances leached from the container by the anticoagulant and/or preservative solution, blood and blood components by either chemical interaction or physical dissolution, shall be within the limits specified.

In many countries there are national pharmacopoeias, government regulations or standards detailing suitable tests for assessing such chemical or physical interactions. However, if no such regulations are provided, the test methods indicated in table 2 shall be used.

5.2 Physical requirements

5.2.1. Conditions of manufacture

All processes involved in the manufacture, assembly and storage of the plastics container shall be carried out under clean and hygienic conditions in compliance with the appropriate national authorities in accordance with the relevant legislation and international agreements. Every practicable precaution shall be taken at all stages to reduce the risk of adventitious contamination by microorganisms or foreign matter.

5.2.2 Sterilization

5.2.2.1 The plastics container shall have been sterilized by autoclaving or any other method approved by the national control authority.

5.2.2.2 The method of sterilization used shall not adversely affect the materials or contents nor cause any loosening of joints and deterioration of welds in the plastics material nor any major alteration in the shape of the plastics container.

5.2.2.3 The manufacturer shall be able to produce evidence acceptable to the national control authority of the effectiveness of the sterilization process actually used. If required by the national control authority, positive controls to check the effectiveness of sterilization shall be included in each sterilization lot.

5.2.3 Transparency

When tested with the suspension as specified in B-1, the opalescence of the suspension shall be perceivable when viewed through the plastics container com-

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pared with a similar container filled with water.

5.2.4 Coloration

The material of the plastics container shall not be coloured to such an extent that

assessment of the colour of the blood is adversely affected.

5.2.5 Thermal stability

The plastics container, filled to half of its nominal capacity with purified water, shall withstand storage at -80°C for 24 h, subsequent immersion in water at $50^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 20 min, and returning to room temperature. The plastics container shall meet the requirements of 4.6.3, 4.9, 5.2.7 and 5.2.8.

NOTE 3 If a refrigerant solution is used, the plastics container may be enclosed in a protective bag to avoid direct contact between the refrigerant solution and the plastics container.

5.2.5 Vapour transmission

The plastics container, without an over-package, shall be filled with the labelled volume of anticoagulant and/or preservative solution, if any, and with a volume of sodium chloride solution ($\text{NaCl} = 9 \text{ g/l}$) equal to the nominal capacity, sealed and labelled ready for use. The plastics container shall then be capable of being stored in still air conditions for six weeks at a temperature of $5^{\circ}\text{C} \pm 1^{\circ}\text{C}$ and a maximum relative humidity of 55% without loss of more than 2% (m/m) of water from the solution.

5.2.7 Resistance of distortion

When centrifuged, the plastics container filled with water to its nominal capacity shall withstand an acceleration of 5000g for 30 min at temperatures of 4°C and 37°C without becoming permanently distorted.

5.2.8 Resistance to leakage

When filled to nominal capacity with purified water and sealed, the plastics container shall not develop leaks under conditions of centrifugation at 5000g for 30 min at 4°C followed by 30 min at 37°C . In addition, the container, similarly filled to nominal capacity and sealed, shall show no leakage on being gradually squeezed between two plates, lined with indicator paper, to an internal pressure equivalent to 100kPa above atmospheric pressure at $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ reached within 1 min and maintained for 10 min.

NOTE 4 When the plastics container is filled with anticoagulant solution, such as an ACD solution or other solutions with similar pH, leakage may be detected by pressing the container against sheets of blue litmus paper and observing the

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5.2.9 Permanence of marking and labelling

Any attempt to peel the label off shall result in the label being destroyed.
When tested in accordance with B.3, the label(s) shall not separate from the containers after removal from water. Printing on the label or on the container shall remain legible.

5.3 Chemical requirements

5.3.1 Requirements for extract

The limits specified in table 2 shall not be exceeded when the appropriate tests are carried out on the extract obtained in accordance with A.2 and A.3.9.

5.3.2 Requirements for plastics material

When plastics materials are tested by the methods given in column 3 of table 3, the limits shown in column 2 of the table shall not be exceeded.

Table 2 - Chemical limits on extracts

Characteristics	Limit
Oxidizable matter	≤ 2 ml of $c(0.5 \text{ Na}_2\text{S}_2\text{O}_3) = 0.01$ mol/l
Ammonia (NH ₃)	≤ 2 mg/1
Chloride ions (Cl)	≤ 4 mg/1
Acidity or alkalinity	0.4 ml of $c(\text{NaOH}) = 0.01$ mol/l, or 0.8 ml of $c(\text{HCl}) = 0.01$ mol/l
Residue on evaporation	3 mg/100 ml
Opalescence	Slightly opalescent, but not more pronounced than that of reference suspension 2
Coloration	No coloration
Ultraviolet (UV) Extinction	≤ 0.2 in the range of 230 nm absorption to 360 nm
Extractable	
Di(2-ethylhexyl)	≤ 10 mg/100 ml
Test method in	
	A.3.1
	A.3.2
	A.3.3
	A.3.4
	A.3.5
	A.3.6

A.3.7

A.3.8

A.3.9

Characteristics

Ash

Elements Ba, Pb

Cd, Sn

Vinyl chloride

Limit

$\leq 1 \text{ mg/g}$

1 mg/kg

$\leq 0.6 \text{ mg/kg}$

$\leq 1 \text{ } \mu\text{g/g}$

Test method in

A.4.1

A.4.2.1

A.4.2.2

A4.3

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Phthalate (DEHP)

Table 3 - Chemical limits on plastics material

Monomer

5.4 Biological requirements

The plastics container shall not release any substances which may adversely affect the therapeutic effectiveness of blood and blood components, including those substances which may exhibit toxic, cytotoxic, bacteriostatic, bactericidal, pyrogenic or haemolytic reactions.

In many countries there are national pharmacopoeias, government regulations or standards detailing suitable tests for assessing biological safety and sterility. However, if no such regulations are provided, the test method specified in table

C.1 should be used.

5.4.1 Requirements for type test

The type test shall be established and assessed by an expert(s) in the transfusion field and on toxicology of plastics material. It shall cover the elements in 5.4.1 to

5.4.1.4.

5.4.1.1 General biological safety of plastics container

Materials shall be assessed for biocompatibility by carrying out suitable tests for those properties detailed in table C.1 and the results of the tests shall indicate freedom from toxicity.

5.4.1.2 Compatibility of plastics container with process of manufacture and sterilization

The process of manufacture and sterilization and the prolonged contact with the anticoagulant solution, blood and blood components shall not alter properties of

5.4.1.3 Compatibility of material of plastics container with anticoagulant and/or preservative solution, blood and blood components.

Migration after sterilization and prolonged contact of the constituents or additives of the plastics material shall not alter the properties of the anticoagulant and/or preservative solution, of blood and blood components or cause any toxicological risk for the patient.

5.4.1.4 Biological safety of plastics container with cellular elements of blood and blood components.

The type test shall cover this aspect.

5.4.2 Requirements for lot test

5.4.2.1 Sterility

The plastics container and its contents shall be supplied sterile; guidance on testing for sterility is given in C.3.1.

5.4.2.2 Pyrogens

The plastics container supplied shall be assessed for freedom from pyrogens using a suitable test (guidance on testing for pyrogens is given in C.3.2) and the result shall indicate that the plastics container is pyrogen-free.

6. Packaging

The plastics container shall be placed inside a sealed over-package to meet the requirements specified below.

6.1 The plastics container shall not lose more than 2.5% (m/m) of water from the anticoagulant and/or preservative solution during storage for 1 year at 55% humidity, $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and atmospheric pressure.

6.2 The shelf-life of a plastics container shall be established by the manufacturer on the basis of stability data. When containing anticoagulant and/or preservative solution, the shelf-life shall not be greater than the time during which the water loss equals 5% (m/m), but in any case shall not be less than 2 years.

NOTE 5: For the purposes of this International Standard, the term "shelf-life" refers to the period between the date of fertilization and the date after which the plastics containers should not be used for the collection of blood.

6.3 The interior surface of the over-package should not interact with any of its contents and shall be treated to prevent growth of mould or fungus inside the package.

If chemical fungicides are used, evidence shall be provided to show there has been no harmful penetration of, or deleterious effect on, the plastics container and its contents.

6.4 The over-package shall be sealed in such a manner as to be tamper-evident and to prevent opening or reclosing without displaying signs that the seal has been destroyed.

6.5 The over-package shall be strong enough to resist damage under conditions on normal handling in use.

6.6 The over-package shall be adequately proof, account being taken of the hazards of the region in which it is to be used.

6.7 The plastics container and components arranged in the over-package in a manner which will prevent the collecting tube and connecting [transfer tube(s)] from kinking and acquiring a permanent set.

7. Marking and labelling

Marking and labelling of a plastics container conform to applicable national regulations and include the requirements specified in 7.1 to 7.4.

7.1 Marking on plastics container

The label shall contain the following information:

- a) description of the contents;
- b) nature and volume, in millilitres, or mass, in grams of anticoagulant and/or preservative solution or any other material introduced, and the volume in millilitres, or mass, in grams, of blood and blood components to be collected;
- c) statement: "STERILE AND PYROGEN-FREE";
- d) instruction: "DO NOT USE IF THERE IS ANY VISIBLE SIGN OF DETERIORATION", or precise alternative wording;
- e) instruction: "CONTAINER NOT TO BE RE-USE or precise alternative wording;
- f) instruction: "DO NOT VENT";

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er responsible

i) Lot designation;

j) Expiry date for the unused plastics container occurred by the instruction:

"DO NOT FILL WITH BLOOD AFTER..."

7.2 Marking on over-package

The label shall contain the following information:

a) manufacturer's name and address and/or the name and address of the

supplier responsible;

b) description of the contents;

c) expiry date

d) instruction: "NOT TO BE USED MORE THAN n DAYS AFTER REMOVAL

FROM THE OVER-PACKAGE"

e) lot designation

7.3 Marking on transit container

The label shall contain the following information:

a) manufacturer's name and address and/or the name and address of the

supplier responsible;

b) description of the contents;

c) storage conditions

7.4 Label requirements

The label shall be such that

a) identification of the blood, i.e. ABO and Rh group, and reference number can be recorded on the plastics container, and an appropriate reference number recorded on the pilot tubes; there shall also be adequate space for other entries required by national regulations;

b) by leaving a portion of the plastics container visible and free of markings, the contents can be adequately inspected visually;

c) there is no diffusion of ink from the label into the plastics material of the con

tainer which is harmful to the contents;
d) the printing on the label remains legible at the time of use;
e) a pen or pencil can be used for writing on the label;
f) any adhesive used on the label does not permit or support growth of
microorganisms and has no deleterious effect on the plastics container or its

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contents.

The label attached to the container by the manufacturer should not, prior to filling, make reference to any special information concerning the blood or blood components or the nature of the blood or blood components to be collected.

8. Application of tests

NOTE 6 For guidance purposes only, typical type and lot tests are given in 8.1 and 8.2.

8.1 Type test

On new plastics formulation(s), on already agreed formulation(s) in which any change has been made or on changing of the anticoagulant and/or preservative solution, the full range of chemical tests specified in A.3 and A.4 a series of suitable biological safety tests (guidance on biological testing is given in annex C) and the tests in annex B may be repeated.

8.2 Lot test

On each manufacturing lot of finished plastics containers, tests for the requirements specified in 4.2, 4.3, 4.6.3, 4.7 to 4.9, 5.2.4, 5.2.7 to 5.2.9 and in clauses 7 and 9 shall be carried out. In addition the tests for sterility and freedom from pyrogens (see 5.4.2.1 and 5.4.2.2) shall be carried out on each sterilization lot.

NOTES

7. For plastics containers containing anticoagulant and/or preservative solution, the term "lot" means that quantity of plastics containers prepared, filled from a single batch of anticoagulant solution and sterilized within a continuous working period.

8. For plastics containers not containing anticoagulant and/or preservative solution,

the term "lot" means that quantity of plastics containers prepared within one working day and sterilized in one cycle.

9. Anticoagulant and/or preservative solution

The quality of the anticoagulant and/or preservative solution, if any, shall satisfy the requirements of the national pharmacopoeia and national regulations.

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A.1 General

Take materials for testing from the blood and blood derivatives contact materials of the finished, empty and sterilized plastics containers, i.e. in the state in which they would be used transfusion, collection, separation and administration procedures, including the plastics sheet used for the collecting bag and the plastics tubings used for the collecting tube, transfer tube and any parts that will come into contact with blood and blood components.

A.2 Preparation of extract and blank

A.2.1 Sample preparation

The tests specified in A.3 require a surface area of 1250 cm² of each plastics sample in sheet or tubing form.

A.2.1.1 Sample in sheet form

Use a sample free from printing or label, having a surface area of 625 cm² (total surface area of both sides: 1250 cm²). Cut the samples into pieces of approximately 10 cm² area (one side).

A.2.1.2 Sample in tubing form

Calculate the length required l , in centimetres, as follows:

$$l = \frac{1250}{3,14(d_1 + d_2)}$$

where

d_1 is the inner diameter, in centimetres;

d_2 is the outer diameter, in centimetres

Cut the tubing into sections approximately 5 cm in length.

A.2.2 Preparation of extract

To remove any surface contaminants, particulate matter, lint, anticoagulant and/or preservative solution, etc, place the cut sample in a stoppered glass container with 100 ml of cold distilled water, shake several times and drain off the water. Repeat

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this operation once.

Place the cut sample in a container of borosilicate glass with 250 ml of distilled water and cover the opening of the container. Heat the container in saturated steam at $121^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 20 min, quickly cool to room temperature ($23^{\circ}\text{C} \pm 5^{\circ}\text{C}$) and adjust the volume to 250 ml with distilled water. It is of no significance if the plastics sample tends to stick together slightly.

A.2.3 Preparation of blank

For use as a control make a blank preparation in a corresponding manner, omitting the plastics sample.

A.3 Tests on extract

A.3.1 Oxidizable matter

Add 20 ml of potassium permanganate solution [$c(\text{KMnO}_4) = 0.002 \text{ mol/l}$] and 1 ml of sulfuric acid solution [$c(\text{H}_2\text{SO}_4) = 1 \text{ mol/l}$] to 20 ml of the extract (see A.2.2) in a conical (Erlenmeyer) flask of borosilicate glass. Keep the mixture at room temperature ($23^{\circ}\text{C} \pm 5^{\circ}\text{C}$) for 15 min. Add 0.1 g of potassium iodide and 5 drops of starch solution. Titrate with sodium thiosulfate solution [$c(0.5 \text{ Na}_2\text{S}_2\text{O}_3) = 0.01 \text{ mol/l}$].

At the same time carry out a blank titration.

Determine the difference in the volumes of sodium thiosulfate solution consumed in the two titrations.

A.3.2 Ammonia

The extract shall comply with a suitable limit test for ammonia.

A.3.3 Chloride ions

Add 0.3 ml of silver nitrate solution [$c(\text{AgNO}_3) = 0.1 \text{ mol/l}$] to 0.15 ml of diluted nitric acid. Add the resultant solution to 15 ml of the extract.

Prepare a reference solution in the same way using 12 ml of chloride standard solution (5 ppm of Cl) and 3 ml of water.

Shake the mixtures. After 2 min, the extract shall not be more turbid than the reference solution. Direct daylight shall be avoided.

A.3.4 Acidity or alkalinity

On addition of 2 drops of phenolphthalein solution to 10 ml of the extract, the solution shall not be coloured red. On addition of 0.4 ml of sodium hydroxide solution

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On addition of 0.8 ml of hydrochloric acid [c(HCl) - 0.01 mol/l] the red colour shall disappear. Addition of 5 drops of methyl red solution shall produce an orange colour.

A3.5 Residue on evaporation

Evaporate 100 ml of the extract to dryness on a water-bath and dry at 105°C to constant mass.

Determine the mass of the residue.

A.3.6 Clarity and degree to opalescence

Using identical test tubes of colourless, transparent, neutral glass with a flat base and an internal diameter of 15 mm to 25 mm, compare the liquid to be examined with a reference suspension freshly prepared as described below, the depth of the layer being 40 mm. Compare the solutions in diffused daylight 5 min after preparation of the reference suspension, viewing them vertically against a black background.

The diffusion of light shall be such that reference suspension 1 can readily be distinguished from water and that reference suspension 2 can readily be distinguished from reference suspension 1.

A3.6.1 Reagents

A3.6.1.1 Hydrazine sulfate solution

Dissolve 1g of hydrazine sulfate in water and dilute to 100ml. Allow to stand for 4h to 6h.

A3.6.1.2 Hexamethylenetetramine solution

Dissolve 2.5g of hexamethylenetetramine in 25 ml of water in a 100 ml glass-stoppered flask.

A3.6.1.3 Primary opalescent suspension

Add to the solution of hexamethylenetetramine (A3.6.1.2) 25 ml of the hydrazine sulfate solution (A.3.6.1.1). Mix and allow to stand for 24 h.

This suspension is stable for 2 months, provided that it is stored in a glass container free from surface defects. The suspension shall not adhere to the glass and shall be well mixed before use.

A3.6.1.4 Standard of opalescence

Dilute 15 ml of the primary opalescent suspension (A3.6.1.3) to 1000 ml with water.

This suspension shall be freshly prepared and may be stored for at most 24h.

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A3.6.1.5 Reference suspensions

Prepare the reference suspensions in accordance with table A.1. Mix and shake before use.

Table A.1 - Reference suspensions

Volumes in millilitres

Reference suspension
Standard of opalescence

Water

1

5

95

2

10

90

3

30

70

4

50

50

A3.6.2 Expression of results

A.3.6.2.1 A liquid is deemed to be clear if its clarity is the same as that of water or of the solvent used, when examined under the conditions described above, or if its opalescence is not more pronounced than that of reference suspension 1.

A3.6.2.2 A liquid is deemed to be slightly opalescent if its opalescence is more pronounced than A.3.6.2.1, but not more pronounced than that of reference suspension 2.

A.3.6.2.3 A liquid is deemed to be opalescent if its opalescence is more pronounced than A.3.6..2.2 but more pronounced than that of reference suspension 3.

A.3.6..2.4 A liquid is highly opalescent if its opalescence is more pronounced than

A.3.6.2.3 but not more pronounced than that of reference suspension 4.

A3.7 Degree of coloration

The examination of the degree of coloration of liquids in the range brown-yellowed is carried out by one of the two methods specified in A.3.7.1 and A.3.7.2.

A.3.7.1 Method 1

Using matched tubes of colourless, transparent, neutral glass having an internal diameter of 12 mm, compare 2 ml of the liquid to be examined with 2 ml of water. Compare the colours in diffused daylight viewing them horizontally against a white background.

A3.7.2 Method 2

Using matched tubes of colourless, transparent, neutral glass having an internal diameter of 16 mm, compare 10ml of the liquid to be examined with 10ml of water. Examine the column of liquid down the vertical axis of the tube in diffused daylight against a white background.

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A liquid is deemed to be colourless if it has the appearance of water when examined under the conditions as specified for method 1 or 2.

A3.8 Ultraviolet (UV) absorption

Determine the UV absorption of the extract in a 1 cm cell against the blank. The absorbance is determined in the range from 230 nm to 360 nm.

A3.9 Determination of extractable di-(2 ethylhexyl)phthalate (DEHP)

A3.9.1 Reagents

A.3.9.1.1 Ethanol: from 95.1% (V/V) to 96.6% (V/V) from 0,805 Og/ml to 0.812 3 g/ml.

A.3.9.1.2 Extraction solvent: ethanol water mixture having a density of 0.937 3 gm/l to 0.937 8 g/ml, determined with a pycnometer.

A.3.9.1.3 Di-(2-ethylhexyl)phthalate (C₂₄H₃₈O₂); a colourless, oily liquid insoluble in water, soluble in organic solvents: p from 0982g/ml to 0.986 g/ml, refractive index at 20°C 1.486 to 1.487.

A3.9.2 Preparation of standard solutions

A.3.9.2.1 Solution 1

Dissolve 1g of DEHP (A3.9.1.3) in ethanol (A.3.9.1.1) and dilute to 100 ml with ethanol.

A.3.9.2.2 Solution 2

Dilute 10ml of solution (A.3.9.2.1) to 100 ml with ethanol

A.3.9.2.3 Standard solutions A to E

A: Dilute 20 ml of solution 2(A.3.9.2.2) to 100 ml with extraction solvent (A.3.9.1.2), (DEHP) content 20 mg/100 ml)

B: Dilute 10 ml solution 2 to 100 ml with extraction solvent (DEHP content: 10 mg/100 ml).

C: Dilute 5ml of solution 2 to 100 ml with extraction solvent (DEHP content: 5mg/100 ml)

D: Dilute 2ml of solution 2 to 100 ml with extraction solvent (DEHP content 2mg/100 ml).

E: Dilute 1 ml of solution 2 to 100 ml with extraction solvent (DEHP content: 1 mg/100 ml).

A.3.9.3 Calibration curves

Measure the maximum absorbance of the standard solutions (A.3.9.3) at 272 nm, using the extraction solvent as the reference solution and plot a curve of absorbance against DEHP concentrations.

A.3.9.4 Extraction procedure

Fill the empty plastics container to half of the nominal capacity through the collecting tube with a volume of extraction solvent heated to 37°C. Expel the air completely from the container and seal the collecting tube. Immerse the filled container in a horizontal position in a water-bath maintained at 37°C ± 1°C for 60 min 1 min without shaking. Remove the container from the water-bath, invert it gently ten times and transfer the contents to a glass flask.

Measure the maximum absorbance at 272 nm using the extraction solvent as the reference solution.

A3.9.5 Expression of results

Determine the quantity of extractable DEHP by comparing the result obtained for the plastics container (see A.3.9.4) with the calibration curve of absorbance for the standard solutions (See A3.9.3).

A.4 Tests on plastics material

A.4.1 Determination of ash

Use a sample in sheet form or in tubing form, free from printing or label.

The residue of ash shall be determined in accordance with ISO 247:1990, method B.

A.4.2 Determination of elements

A.4.2.1 Determination of barium and lead content

Ignite 10 g of the plastics material in a silica crucible. Dissolve the residue in 5ml of hydrochloric acid ($\rho = 1,18 \text{ g/ml}$) and evaporate to dryness on a waterbath. Dissolve the residue in 10 ml of hydrochloric acid solution [$c(\text{HCl}) = 1 \text{ mol}$]

Determine the barium and lead content by atomic absorption spectroscopy (AAS).

4.2.2 Determination of tin and cadmium content

Place 5 g of the plastics material in a combustion task. Add 30 ml of sulfuric acid

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Determine the tin content by flameless atomic absorption spectroscopy and the cadmium content by flame atomic absorption spectroscopy (AAS).

A.4.3 Determination of vinyl chloride monomer

A.4.3.1 Reagents

During the analysis, unless otherwise stated, use only reagents of recognized analytical grade.

WARNING - Vinyl chloride is a hazardous substance and is a gas at ambient temperatures.

Vinyl chloride is a carcinogen.

Vinyl chloride should be handled in a well-ventilated fume cupboard and operators should wear gloves made of material, such as neoprene, which does not readily absorb vinyl chloride. Care should be taken in the safe disposal of any solution containing vinyl chloride.

A.4.3.1.1 Purified diethyl ether reagent: Diethylether [(C₂H₅)₂O] purified for use as the internal standard.

A.4.3.1.2 Dimethylacetamide:

(N,N-Dimethylacetamide (C₄H₉NO), Mr = 87,12; a colourless liquid, miscible with water and with many organic solvents, =0.94 g/ml, boiling point = 165°C.

A.4.3.1.3 Vinyl chloride, purity higher than 99.5%.

A.4.3.1.4 Dimethylstearylamine; N,N-Dimethylstearylamine (C₂₀H₄₁NO₂), Mr = 327,5; white or offwhite mass, soluble in many organic solvents, melting point 51°C.

A.4.3.1.5 Polyethyleneglycol 400, M » 400; a colourless or almost colourless, viscous liquid, miscible with water, highly soluble in acetone, alcohol and chloroform.

A.4.3.2 Preparation of internal standard solutions

Using a microsyringe, inject 10 µl of diethyl ether (A4.3.1.1), as the internal standard, into 20 ml of dimethylacetamide (A.4.3.1.2) immersing the tip of the needle

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in the solvent. Immediately before use dilute the solution to 1000 times its volume with dimethylacetamide (A4.3.1.2).

A.4.3.3 Preparation of test solution

Place 1 g of the material to be examined in a 50 ml vial and add 10 ml of the internal standard solution (A.4.3.2). Close the vial and secure the stopper. Shake.

Place the vial in a water-bath at $60^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 2 h.

A.4.3.4 Preparation of vinyl chloride primary solution

Place 50 ml of dimethylacetamide (A.4.3.1) in a 50 ml vial, close the vial and secure the stopper. Weigh the vial and its contents to the nearest 0.1 mg. Fill a 50 ml gas syringe with gaseous vinyl chloride (A.4.3.1.3). Fit a hypodermic needle to the syringe and inject the volume of vinyl chloride slowly into the vial shaking gently and avoiding contact between the liquid and the needle. Reweigh the vial.

The increase in mass is about 60 mg.

1 μl of the solution thus obtained contains about 1.2 μg of vinyl chloride.

A.4.3.5 Preparation of vinyl chloride standard solution

Dilute 5 ml of the vinyl chloride primary solution to 20 ml with dimethylacetamide (A.4.3.1.2).

A.4.3.6 Preparation of reference solutions

Place 10 ml of the internal standard solution (A.4.3.2) in each of six 50 ml vials. Close the vials and secure the stoppers. Inject 1 μl , 2 μl , 3 μl , 5 μl and 10 μl of the vinyl chloride standard solution (A.4.3.5), respectively, into five of the vials.

The six solutions thus obtained contain 0 μg , » 0.3 μg , » 0.6 μg , » 0.9 μg » 1.5 μg and » 2.5 μg of vinyl chloride, Shake, place the vials in a water-bath at $60^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 2 h.

A.4.3.7 Chromatographic procedure

Carry out the chromatographic procedure by using

a) a stainless steel column, 3 m long and with an external diameter of 3 mm, packed with silanized diatomaceous earth for gas chromatography impregnated

with 5% (m/m) of dimethylstearylamine (A.4.3.1.4) and 5% (m/m) of poly

ethyleneglycol 400 (A.4.3.1.5);

b) nitrogen for chromatography as carrier gas at a flow rate of 30 ml/min;

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Maintain the temperature of the column at 45°C that of the injection port at 100°C and that of the detector at 150°C.

Inject 1 ml of the gas phase aspirated from the headspace over the test solution

(A.4.3.3) and from the headspace over the reference solutions (A.4.3.6) into the column.

Determine the amount of vinyl chloride in the test solution.

A.4.3.8 Expression of results

Calculate the amount of vinyl chloride, expressed as micrograms per gram of test material.

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ANNEX B (Normative)

Physical tests

B.1 Transparency test

Fill the empty plastics container equal to its nominal capacity with a volume of the primary opalescent suspension (A.3.6.1.3) diluted to an absorbance of 0.37 to

0.43 at 640 nm (dilution factor about 1:16) in a 1 cm cell.

B.2 Test for rate of collection

From a reservoir containing 500 ml of a fluid at 37°C ± 2°C having a viscosity of 3 x 10⁻⁶ m²/s at 37°C and under pressure of 9.3 kPa, allow the container to fill at a temperature of 23°C ± 2°C through a blood-taking needle with an internal diameter of 1.4 mm in the same hydrostatic plane as the top of the bag. The blood-taking needle shall comply with ISO 1135-3.

NOTE 9 A suitable liquid for use in this test is a solution of glucose in water (400 g/l).

B.3 Test for permanence of labelling

The plastics container, filled to capacity and shall be stored for 5 days at a temperature of 5°C ± 1°C. This initial period shall be followed by a period of 24 h at

a maximum temperature of -40°C , then 24 h at $5^{\circ}\text{C} \pm 1^{\circ}\text{C}$. The labelled and/or printed plastics container shall then be submerged in tap water maintained at a temperature of $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 24 h.

Biological Tests

C.1 General

The biological safety of materials used for plastics containers depends to a large degree on the particular nature of the end-use application. It is not possible to specify a set of biocompatibility test methods which will be necessary and sufficient to establish biological safety for all materials and applications. The area of biological safety testing of materials is a relatively new field with improved methods evolving rapidly, therefore, by necessity, this annex only gives guidelines.

C.2 Type Tests

The biological test methods listed in table C.1 should be considered as minimum requirements. Additional tests may be performed if the current state of the art requires such tests.

The test methods shall be carried out in accordance with requirements as specified in national pharmacopoeias, other government introduction regulations or national standards.

Where national regulations do not exist, these tests may be carried out in accordance with the recommended regulations as listed in table C.1 and shall be assessed by an expert on toxicology of plastics material.

C.3 Lot test

C.3.1 Sterility

Shall be carried out in accordance with the requirements of national pharmacopoeias or national standards detailing suitable sterility tests. However, where no such regulations exist, the test method recommended under C.2.7 in table C.1 should be used.

C.3.2 Pyrogens

It shall be carried out in accordance with the requirements of national pharmacopoeias or national standards detailing suitable sterility tests. However, where no such regulations exist, the test method recommended under C.2.6 in table C.1 should be used.

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C.4 Haemolysis

It is desirable to specify an internationally comparable haemolysis test in this

International Standard because a test for haemolytic effect is not included in most pharmacopoeias and/or standards.

C.4.1 Preparation of erythrocyte suspension

Dilute one volume of freshly prepared human blood, anticoagulated in accordance with the national pharmacopoeia, with five volumes of a sterile solution of sodium chloride [$\rho(\text{NaCl}) = 9 \text{ g/l}$]. Centrifuge for 5 min at 1.500g to 2.000 g in a swing-out centrifuge. Remove the supernatant layer and repeat the treatment of the erythrocytes under the same conditions with the same volume of sodium chloride solution.

Dilute the erythrocytes thus obtained with a sterile solution of sodium chloride [$\rho(\text{NaCl}) = 9 \text{ g/l}$] in the proportion of 1:9. This suspension shall be used within 6 h after its preparation when kept at room temperature.

C.4.2 Procedure

Evaporate 125 ml of the extract (A.2.2) at a temperature of 100°C. Dissolve the residue in 5 ml of a sterile solution of sodium chloride [$\rho(\text{NaCl}) = 9 \text{ g/l}$]. Add 1 ml of the erythrocyte suspension (C.4.1) and suspend the mixture for 20 min at 37°C $\pm 1^\circ\text{C}$. Centrifuge the mixture for 5 min at 1500 g to 2000 g in a swing out centrifuge.

Prepare the blank suspension at the same time under the same conditions, without however adding the dried residue on evaporation of the extract.

NOTE 10 The test described may not detect volatile constituents of the extract; however, it is expected that by concentration of the extract a higher sensitivity is obtained.

Measure the absorbance of the supernatant layer at 540 nm in a 1 cm cell, using the blank suspension as a reference. The absorbance of the test solution should not differ by more than 10% from the blank sample.

Table C.1 - Recommended biological test methods

Reference	Biological Test	Recommended test method to be used where national Regulations do not exist
C.2.1	Cell culture cytotoxicity	ASTM F 813, Practice for Direct Contact cell Culture Evaluation of Materials for Medical Devices French Pharmacopoeia BS 5736, Part 10: Method of test of test for toxicity Of cells in culture of extracts from medical devices
C.2.2	Haemolysis	European Pharmacopoeia or C.4 of this International Standard
C.2.3	Systemic injection	BS 5736, Part 3: Method of test for systemic toxicity (acute toxicity) assessment of acute toxicity of extracts from medical devices European Pharmacopoeia United States Pharmacopoeia
C.2.4	Sensitization	ASTM F 748, Practice for Selecting Genetic Biology Test Methods for Materials and Devices BS 5736, Part 6: Method of test for sensitization. Assessment of the potential of medical devices to Produce delayed contact dermatitis.
C.2.5	Intracutaneous injection (Irritation)	BS 5736, Part 4: Method of test for intracutaneous reactivity of extracts from medical devices United States Pharmacopoeia
C.2.6	Rabbit pyrogen test	BS 5736 Part 5: Method of test for systemic toxicity; Assessment of pyrogenicity in rabbits of extracts From medical devices European Pharmacopoeia
C.2.7	Sterility test	United States Pharmacopoeia United States Pharmacopoeia European Pharmacopoeia

While the authors have made all possible attempts to crosscheck and authenticate the information presented in this handbook, it is possible that some mistakes may have crept in inadvertently. Readers are advised to crosscheck any critical information with government gazettes and/or source documents. This handbook is for educational and informational purposes only.

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