SUPREME COURT JUDGEMENT REGARDING APPLICATION OF SECTION OF NEGLIGENCE TO DOCTORS

CASE NO. :
Appeal (crl.)]44-145 of 2001
PETITIONER:
Jacob Mathew
RESPONDENT:
State of Punjab & Anr.
DATE OF JUDGEMENT: 05/08/2005
BENCH:
CJI R.C. LAHOTI~G.P. MATHUR & P.K BALASUBRAMANYAN
JUDGMENT:
JUDGMENT
R.C. LAHOTI, CJ 1

Ashok Kumar Sharma, the respondent no.2 herein filed a First Information Report with police station. Division No.3, Ludhiana, whereupon an offence under Section 304A read with Section 34 of the Indian Penal Code (for short "the IPC") was registered. The gist of the information is that on 15.2.1995, the informant's father, late Jiwan Lar Sharma was admitted as a patient in a private ward of CMC Hospital, Ludhiana. On 22.2. I995 at about 11 p.m. Jiwan La! felt difficult), in breathing. The .complainant's elder brother, Vijay Sharma who was present in the room contacted the duty nurse, who in her turn called some doctor to attend to the patient. No doctor turned up for about 20 to 25 In minutes. Then, Dr. Jacob Mathew, the appellant before us and Dr. Allen Joseph came to the room of the patient. An oxygen cylinder was brought and connected to the mouth of the patient but the breathing problem increased further. The patient tried to get up but the medical staff asked him to remain in the bed. The oxygen cylinder was found to be empty. There was no other gas cylinder available in the room. Vijay Sharma went to the adjoining room and brought a gas cylinder there from. However,there was no arrangement to make the gas cylinder functional and in-between, 5 to 7 minutes were wasted. By this time, another doctor came who declared that the patient was dead. The latter part of the FIR states (as per the translation in English as filed by the complainant):

"The death of my father was occurred due to the carelessness of doctors and nurses and non availability of oxygen cylinder and the empty cylinder was fixed on the mouth of my father and his breathing was totally stopped hence my father died. l sent the dead body of my father to my village for last cremation and for information I have come to you. Suitable action be done Sd/- .....As per statement of imitator the death of Jiwan Lal Sharma has occurred due to carelessness of doctors and nurses concerned and to fit empty gas cylinder:"

On the above said report, an offence' under Section 304A/34 IPC was registered and investigated. Challan was filed against the two doctors.

The Judicial Magistrate First Class, Ludhiana framed charges under Section 304A, lPC against the two accused persons, both doctors. Both of them filed a revision in the Court

of Sessions Judge submitting that there was no ground for framing charge against them . The revision dismissed. The appellant filed a petition in the High Court under Section 482 of the Code of Criminal Procedure praying for quashing of the FIR and all subsequent proceedings.

It was submitted before the High Court that there was no specific allegation of any act of omission or commission against the accused persons in the entire plethora of documents comprising the challan papers filed by the police against them. The learned single Judge who heard the petition formed an opinion that the plea raised by the appellant was available to be urged in defence at the trial and, therefore a case for quashing the charges was not made out Vide order dated 18.12.2002, the High Court dismissed the petition. An application for recalling the. above said order was moved which too was dismissed on 24.1.2003. Feeling aggrieved by these two orders, the appellant has filed these appeals by special leave.

According to the appellant, the deceased Jiwan Lal was suffering from cancer in an advanced stage and as per the information available, he was, in fact, not being admitted by any hospital in the country because "his being a case of cancer at terminal stage. He was only required to be kept at home and given proper nursing, food, care and solace coupled with prayers. But as is apparent from the records, his sons are very influential persons occupying important positions in Government. They requested the hospital authorities that come what may, even on compassionate grounds their father may be admitted in the hospital to regulated medical treatment and proper management of diet. It was
abundantly made clear to the informant and his other relations who had accompanied the deceased that the disease was of such a nature and had attained such gravity, that peace and solace could only be got at home. But the complainant could prevail over the doctors and hospital management and got the deceased admitted as an inpatient. Nevertheless, the patient was treated with utmost care and caution and given all the required medical assistance by the doctors and para- rnedical staff. Every conceivable effort was made by all tile attending staff comprising of doctors and nurses and other para-medicals to give appropriate medical treatment and the whole staff danced attendance on the patient but what was ordained to happen, did happen. The complainant and his relations, who were misguided or were under mistaken belief as to the facts, lodged police repol1 against the accused persons wholly unwarranted and uncalled for.

The matter came up for hearing before a Bench of two learned judges of this Court. Reliance was placed by the appellant on a recent two-judge Bench decision of this Court in Dr. Suresh Gupta v. Govt. of NCT of Delhi and Anr. (2004) 6 SCC 422. The Bench hearing this appeal doubted the correctness of the view taken in Dr. Suresh Gupta's case and vide order dated 9.9.2004 expressed the opinion that the matter called for consideration by a Bench of three Judges. This is how the case has come up for hearing before this Bench.

In Dr. Suresh Gupta's case, the patient, a young man with no history of any heart ailment, was subjected to an operation performed by Dr. Suresh Gupta for nasal deformity. The

operation was neither complicated nor serious. The patient died. On investigation, the cause of death was found to be "not introducing a cuffed endotracheal tube of proper size as to prevent aspiration of blood from the wound in the respiratory passage". The Bench formed an opinion that this act attributed to tile doctor, even if accepted to be true, could be described as an act of negligence as there was lack of due care and precaution. But, the Court categorically held "for this act of negligence he may be liable in tort, his carelessness or want of due attention and skill cannot be described to be so reckless or grossly negligent as to make him criminally liable".

The referring Bench in its order dated 9.9.2004 has assigned two reasons for their disagreement with the view taken in Dr. Suresh Gupta's case which are as under:-
(I) Negligence or recklessness being 'gross' is not a requirement of Section 304A of IPC and if tile view taken in Dr. Suresh Gupta's case is to be followed then the word 'gross' shall have to be read into Section 304A IPC for fixing criminal liability on a doctor. Such an approach cannot be countenanced.

(2) Different standards cannot be applied to doctors and others. In all cases it has to be seen whether tile impugned act was rash or negligent. By carrying out a separate treatment for doctors by introducing degree of rashness or negligence, violence would be done to the plain and unambiguous -language of section 304A. If by adducing evidence it is - proved that there was no rashness or negligence involved, the trial court dealing with tile matter shall decide appropriately. But a doctor cannot be placed at a different pedestal for finding out whether rashness or negligence was involved.

We have heard the learned counsel for the appellant, the respondent-State and the respondent complainant. As the question of medical negligence arose for consideration, we thought it fit to issue notice to Medical Council of India to assist the Court at the time of hearing which it has done. In addition, a registered society 'People for Better Treatment', Kolkata; Delhi Medical Council, Delhi Medical Association and Indian Medical Association sought for intervention at the hearing as the issue arising for decision is of vital significance for the medical profession. They too have been heard. Mainly, the submissions made by the learned counsel for the parties and the intervenors have centered around two issues :.
(i) Is there a difference in civil and criminal law on. the concept of negligence?; and (ii) whether a different standard is applicable for recording a finding of negligence when a professional, in particular, a doctor is to be held guilty of negligence? -

With the awareness in the society and the people in general gathering consciousness about their rights, actions for damages in tort are on the increase. Not only civil suits are filed, the availability of a forum for grievance redressal under the Consumer Protection Act, 1986 having jurisdiction to hear complaints against professionals for' deficiency in service', which expression is very widely defined in the Act, has given rise to a large number of complaints against professionals, in particular against doctors, being filed by the persons feeling aggrieved.

Criminal complaints are being filed against doctors alleging commission of offences punishable under Section 304A or Sections 336/337/338 of the lPC alleging rashness or negligence on the part of the doctors resulting in loss of life or injury (of varying degree) to the patient. The present one is such a case. The order of reference has enabled us to examine the concept of, negligence', in particular 'professional negligence', and as to when and how it do give rise to an action under the criminal law. We propose to deal with the issues in the interests of settling the law. We propose to deal with the issues in the interest of settling the law.

Negligence as a tort

The jurisprudential concept of negligence defies any precise definition. Eminent jurists and leading judgments have assigned various meanings to negligence. The concept as has been acceptable to Indian jurisprudential thought is well-stated in the Law of Torts, Ratanlal & Dhirajlal (Twenty-fourth Edition 2002, edited by Justice G.P. Singh). It is stated (at p.441-442).

"Negligence is the breach of a duty caused by the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs would do or doing something which a prudent and reasonable man would not do. Actionable negligence consists in the neglect of the use of ordinary care or skill towards a person to whom the defendant owes the duty of observing ordinary care and skill, by which neglect the plaintiff has suffered injury to his person or property. The definition involves three constituents of negligence: (1) A legal duty to exercise due care on the part of the party complained of towards the party complaining the former's conduct within the scope of the duty (2) breach of the said duty; and (3) consequential damage. Cause of action for negligence arises only when damage occurs; for, damage is a necessary ingredient of this tort.".

According to Charlesworth & Percy on Negligence (Tenth Edition, 2001), in current forensic speech, negligence has three meanings. They are: (i) a state of mind, in which it is opposed to intention; (ii) careless conduct; and (iii) the breach of duty to take care that is imposed by either common or statute law. All three meanings are applicable in different circumstances but anyone of them does not necessarily exclude the other meanings. (Para 1.01) The essential components of negligence, as recognized, are three: "duty", "breach" and "resulting damage", that is to say :-
I. the existence of a duty to take care, which is owed by the defendant to the complainant; -
2. the failure to attain that standard of care, prescribed by the law, thereby committing a breach of such duty; and
3. damage, which is both causally connected with such breach and recognized by the law, has been suffered by the complainant. (Para 1.23)

If the claimant satisfies the court on the evidence that these three ingredients are made out, the defendant should be held liable in negligence. (Para I.24)

Negligence as a tort and as a crime

The term ‘negligence’ is used for the purpose of fastening the defendant with liability under the Civil Law and, at times, under the Criminal Law. It is contended on behalf of the respondents that in both the jurisdictions, negligence is “negligence, and jurisprudentially no distinction can be drawn between negligence under civil law and negligence under criminal law. The submission so made cannot be countenanced in as much as it is based upon a total.’ departure from the established terrain of thought running ever since the beginning of the emergence of the concept of negligence upto the modern times. Generally speaking, it is the amount of damages incurred which is determinative of the extent of liability in tort; but in criminal law it is not the amount of damages but the amount and degree of negligence that is determinative of liability. To fasten liability in Criminal Law, the degree of negligence has to be higher than that of negligence enough to fasten liability for damage in Civil Law. The essential ingredient of mens rea cannot be excluded from consideration when the charge in a criminal court consists of criminal negligence. In R. V. Lawrence, [1981] I AlI ER 974 (HL), Lord Diplock spoke in a Bench of five and the other Law Lords agreed with him. He reiterated his opinion in R. v. Caldwell 198 I (I) A II ER 96 I (HL) and dealt with the concept of recklessness as constituting mens rea in criminal law. His Lordship warned against adopting the simplistic approach of treating all problems of criminal liability as soluble by classifying the test of liability as being “subjective” or “objective”, and said “Recklessness on the part of the doer of an act does presuppose that there is something in the 9ircumstances that would have drawn the attention of an ordinary prudent individual to the possibility that his act was capable of causing the kind of serious harmful consequences that the section which creates the offence was intended to prevent, and that the risk of those harmful consequences occurring was not so slight that an ordinary prudent individual would feel justified in treating them as negligible. lt is only when this is so that the doer of the act is acting ‘recklessly’ if, before doing the act, he either fail to give any thought to the possibility of there being any such risk or, having; recognized that there was such risk, he nevertheless goes on to do it.”

The moral culpability of recklessness is not located in a desire to cause harm. It resides in the proximity of the reckless state of mind to the state of mind present when there is an intention to cause harm. There is, in other words, a disregard for the possible consequences. The consequences entailed in the risk may not be wanted, and indeed the actor may hope that they do not occur, but this hope nevertheless fails to inhibit the taking of the risk. Certain types of violation, called optimizing violations, may be motivated by thrill-seeking. These are clearly reckless.

In order to hold the existence of criminal rashness or criminal negligence it shall have to be found out that the rashness was of such a degree as to amount to taking a hazard knowing that the hazard was of such a degree that injury was most likely imminent. The element of criminality is introduced by the accused having run the risk of doing such an act with recklessness and indifference to the consequences. Lord Atkin in his speech in Andrews v. Director of Public Prosecutions, [1937] A.C. 576, stated, “Simple lack of care such as will constitute civil liability is not enough; for purposes of the criminal law

there are degrees of negligence; and a very high degree of negligence is required to be proved before the felony is established." Thus, a clear distinction exists between "simple lack of care" incurring civil liability and "very high degree of negligence" which is required in criminal cases. Lord Porter said in his speech ill the same case ." A higher degree of negligence has always been demanded in order to establish a criminal offeoce than is sufficient to create civil liability. (Charlesworth & Percy, ibid, Para 1.13)

The fore-quoted statement of law in Andrews has been noted with approval by this Court in Syad Akbar v. State of Karnataka (1980) I SCC 30. The Supreme Court has dealt with and pointed out with reasons the distinction between negligence in civil law and in criminal law. Their Lordships have opined that there is a marked difference as to the effect of evidence, viz. the proof, in civil and criminal proceedings. In civil proceedings, a mere preponderance of probability is sufficient, and the defendant is not necessarily entitled to the benefit of every reasonable doubt; but in criminal proceedings, the persuasion of guilt must amount to such a moral certainty as convinces the mind of the Court, as a reasonable man, beyond all reasonable doubt. Where negligence is an essential ingredient of the offence, tile negligence to be established by the prosecution must be culpable or gross and not the negligence merely based upon an error of judgment.

Law laid down by Straight, J. in the case Reg v. Idu Beg (1881)3 All. 776, has been held good in cases and noticed in Bhalchandra Waman Pathe v. State of Maharashtra 1968 Mh. L.J. 423? a three-Judge Bench decision of this Court. It has been held that while negligence is an omission to do something which a reasonable man, guided UPOI) those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do; criminal negligence is the gross and culpable neglect or failure to exercise that reasonable and proper care and precaution to guard against injury either to the public generally or to an individual particular, which having regard to all the circumstances out of which the charge has arisen, it was the imperative duty of the accused person to have adopted.

In our opinion, the factor of grossness or degree does assume significance while drawing distinction in negligence actionable in tort and negligence punishable as a crime. To be latter, the negligence has to be gross or of a very high degree.
Negligence by professionals

In the law of negligence, professionals such as lawyers, doctors, architects and others are included in the category of persons professing some special skill or skilled person generally. Any task which is required to be performed with a special skill would generally be admitted or undertaken to be performed only if the person possesses the requisite skill for performing that task. Any reasonable man entering into a profession which requires a particular level of learning to be called a professional of that branch, impliedly assures the person dealing with him that the skill which he professes to possess shall be exercised and exercised with reasonable degree of care and caution. He does not assure his client of the result. A lawyer does not tell his client that the client shall win the case in all circumstance. A physician would not assure the patient of full recovery ill

every case. A surgeon cannot and does not guarantee that the result of surgery would invariably be beneficial, much less to the extent of 100% for the person operated on. The only assurance which such a professional can give or can be understood to have given by implication is that he is possessed of the requisite skill in that branch of profession which he is practicing and while undertaking the performance of the task entrusted to him he would be exercising his skill with reasonable competence. This is all what the person approaching the professional call expect. Judged by this standard, a professional may be held liable for negligence on one of two findings: either he was not possessed of the requisite skill which he professed to has possessed or he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising ordinary skill in that profession. It is not necessary for every professional to possess the highest level of expertise in that branch which he practices. In Michael Hyde and Associates v. J.D. Williams & Co. Ltd., [2001] P.N.R. 233, CA, Sed ley LJ. said that where a profession embraces a range of views as to what is an acceptable standard of conduct, the competence of the defendant is to be judged by the lowest standard that would be regarded as acceptable. (Charlesworth & Percy, ibid, Para 8.03) .

Oft' quoted passage defining negligence by professionals, generally and not necessarily confined to doctors, is to be found in the opinion of McNair J. in Bolam v. Friem Hospital Management Committee, [1957] I W.L.R. 582, 586 in the following words:

"Where you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not the test of the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art." (Charlesworth & Percy, ibid, Para 8.02) The water of Bolam test has ever since flown and passed under several bridges, having been cited and dealt with in several judicial pronouncements, one after the other and has continued to be well received by every shore it has touched as neat, clean and well-condensed one. After a review of various authorities Bingham LJ. in his speech in Eckersley v. Binnie [1988] 18 Con.L.R. 1, 79 summarised the Bolam test in the following words:- .. "From these general statements it follows that a professional man should ,command the corpus of knowledge which forms part of the professional equipment of the ordinary member of his profession. He should not lag behind other ordinary assiduous and intelligent members of his profession in knowledge of new advances, discoveries and developments in his field. He should have such an awareness as an ordinarily competent practitioner would have of the deficiencies in his knowledge and the limitations on his skill., He should be alert to the hazards and risks in any professional task he undertakes to the extent that other ordinarily competent members of the profession would be alert. He must bring to any professional task he undertakes no less expertise, skill and care than other ordinarily competent members of his profession would bring, but need bring np more. The standard is that of the reasonable average. The law does not require of a professional man that he be a

paragon combining the qualities of polymath and prophet..” (Charlesworth & Percy, ibid, Para 8.04)

The degree of skill and care required by a medical practitioner is so stated in Halsbury’s Laws of England (Fourth Edition, Vol.30, Para 35):-

“The practitioner must bring to his task a reasonable degree of skill and knowledge, and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence, judged in the light of the particular circumstances of each case, is what the law requires, and a person is not liable in negligence because someone else of greater skill and knowledge would have prescribed different treatment or operated in a different way; nor is he guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art, even though a body of adverse opinion also existed among medical men.

Deviation from normal practice is not necessarily evidence of negligence. To establish liability on that basis it must be shown (1.) thai there is a usual8~d normal practice; (2) that the defendant has not adopted it; and (3) that the course in “ fact adopted is one 1m professional man of ordinary skill would have taken had he been acting with ordinary care.”

Above said three tests have also been stated as determinative of negligence in professional practice by Charle.” worth & Percy in their celebrated work on Negligence (ibid, para 8.110)

In the opinion of Lord Denning, as expressed in Hucks v. Cole, [1968] 118 New LJ 469, a medical practitioner was not to be held liable simply because things went wrong from mischance or misadventure or through an error of judgment in choosing one reasonable course of treatment in preference of another. A medical Practitioner would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field.

The decision of House of Lords in Maynard Vs West MidJands Regional Health Authority, [1985] I All ER 635 (HL) by a Bench. consisting of five Law Lords has been accepted as having settled the law on the point by holding that it is not enough to show that there is a body of competent professional opinion which considers that decision of the defendant professional was a wrong decision, if there also exists a body of professional opinion, equally competent, which supports the decision as reasonable in the circumstances. It is not enough to show that subsequent events show that the operation need never have been performed, if at the time the decision to operate was taken, lit was reasonable, in the sense that a responsible body of medical opinion would have accepted it as proper. Lord Scannan who recorded the leading speech with which other four Lords agreed quoted the following words of Lord President (Clyde) in Hunter v. Hanley J 955 SLT 213 at 217, observing that the words cannot be bettered “In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man clearly is not negligent merely because his conclusion differs from that of other professional

men. The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care". Lord Scarman added .'a doctor who professes to exercise a special skill must exercise the ordinary skill of his specialty. Differences of opinion and practice exist, and will always exist, in tile medical as in other professions. There is seldom anyone answer exclusive of all others to problems of professional judgment. A court may prefer one body of opinion to the other, but that is no basis for a conclusion of negligence." His Lordship further added "that a judge's 'preference' for once body of distinguished professional opinion to another also professionally distinguished is not sufficient to establish negligence in a practitioner whose actions have received title seal of approval of those whose opinions, truthfully expressed, honestly held, were not preferred."

The classical statement of law in Bolam's case has been widely accepted as decisive of the standard of care required both of professional men generally and medical practitioners in particular. It has been invariably cited with approval before Courts in India and applied to as touchstone to test the pleas of medical negligence. In tort, it is enough for the defendant to show that the standard of care and the skill attained was that of the ordinary competent medical practitioner exercising an ordinary degree of professional skill. The fact that a defendant charged with negligence acted in accord with the general and approved practice is enough to clear him of the charge. Two things are pertinent to be noted. Firstly, the standard of care, when assessing the practice as adopted, is judged in the light of knowledge available at the time (of tile incident), and not at the date of trial. Secondly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that point of time on which it is suggested as should have been used.

A mere deviation from normal professional practice is not necessarily evidence of negligence. Let it also be noted that a mere accident is not evidence of negligence So also an error of Judgment on the part of a professional is not negligence per se. Higher the acuteness in emergency and higher the complication, more are the chances of error of judgment. At times, the professional is confronted with making a choice between the devil and the deep sea and he has to choose the lesser evil. The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure, involving lesser risk but higher chances of failure. Which course is more appropriate to follow, would depend on the facts and circumstances of a given case. The usual practice prevalent nowadays is to obtain the consent of the patient or of the person incharge of the patient if the patient is not be in a position to give consent before adopting a given procedure. So long as it can be found that the procedure which was in fact adopted was one which was acceptable to medical science as on that date) the medical practitioner cannot be held negligent merely because the chose to follow one procedure and not another and the result was a failure.

No sensible professional would intentionally commit an act or omission which would result in loss or Injury to the patient as the professional reputation of the person is at stake. A single failure may cost him dear in his career.

Even in civil jurisdiction, the rule of res ipsa loquitur is not of universal application and has to be applied with extreme care and caution to the cases of professional negligence and in particular that of the doctors.' Else it would be counter productive, Simply because a patient has not favorably responded to a treatment given by a physician or a surgeon has failed, the doctor can not be held liable per Se by applying the doctrine or res ipsa loquitur.
Res ipsa loquitur is a rule of evidence which in reality belongs to the law of torts. Inference as to negligence may be drawn from proved circumstances by applying the rule if the cause of tile accident is unknown and no reasonable explanation as to the cause is coming forth from the defendant In criminal proceedings, tile burden of proving negligence as an essential ingredient of the offence lies on the prosecution. Such ingredient cannot be said to have been proved or made out by resorting to the said rule (See Syad Kabar v. State of Karnataka (1980) I SCC 30). Incidentally, it may be noted that in Krishnan and Anr. v. State of Kerala (1996) 10 SCC 508 the Court has observed that there may be a case where the proved facts would themselves speak of sharing of common intention and while making such observation one of the learned judges constituting the Bench has in his concurring opinion merely stated "res ipsa loquitur'. Nowhere it has been stated that the rule has applicability in a criminal case and an inference as to an essential ingredient of an offence can be found proved by resorting to the said rule. In our opinion, a case under Section 304A IPC cannot be decided solely by applying the rule of res ipsa loquitur.

A medical practitioner faced with an emergency ordinarily tries his best to redeem the patient out of his suffering. He does not gain anything by acting with negligence or by omitting to do an act. Obviously, therefore, it will be for tile complainant to clearly make out a case of negligence before a medical practitioner is charged with or proceeded against criminally. A surgeon with shaky hands under fear of legal action cannot perform a successful operation and a quivering physician cannot administer the end-dose of medicine to his patient.

If the hands be trembling with the dangling fear of facing a criminal prosecution in the event offailure for whatever reason D whether attributable to himself or not, neither a surgeon can successfully wield his life-saving scalper to perform an essential surgery, nor can a physician successfully administer the life-saving dose of medicine. Discretion. being better part of valour, a medical professional would feel better advised to leave a terminal patient to his own fate in the case of emergency where the chance of success may be 10% (or so), rather than taking the risk of making a last ditch effort towards saving the subject and facing a criminal prosecution if his effort fails. Such timidity forced upon a doctor would be a disservice to the society.

The purpose of holding a professional liable for his act or omission, if negligent, is to make the life safer and to eliminate the possibility of recurrence of negligence in future.

Human body and medical science both are too complex to be easily understood. To hold in favour of existence of negligence, associated with the action or inaction of a medical professional, requires an in-depth understanding of the working of a professional as also the nature of the job and of errors committed by chance, which do not necessarily involve the element of culpability.

The subject of negligence in the context of medical profession necessarily calls for treatment with a difference. Several relevant considerations in this regard are found mentioned by Alan Merry and Alexander McCall Smith in their work "Errors, Medicine and the Law" (Cambridge University Press, 2001). There is a_ marked tendency to look for a human actor to blame for an untoward event a tendency which is closely linked with the desire to punish. Things have gone wrong and, therefore, somebody must be found to answer for it. To draw a distinction between the blameworthy and the blameless, the notion of mens rea has to be elaborately understood. An empirical study would reveal that the background to a mishap is frequently far more complex than may generally be assumed. It can be demonstrated that actual blame for the outcome has to be attributed with great caution. For a medical accident or failure, the responsibility may lie with the medical practitioner and equally it may not. The inadequacies of the system, the specific circumstances of the case, the nature of human psychology itself and Sheer chance may have combined to produce a result in which the doctors contribution is either Relatively or completely blameless. Human body and its working is nothing less than a highly Complex machine. Coupled with the complexities of medical science, the scope for misimpressions, misgivings and misplaced allegations against tile operator i.e. the doctor, cannot be ruled out. One may have notions of best or ideal practice which are different from the reality of how medical practice is carried 011 or how in real life the doctor functions. The factors i}f pressing need and .limited resources cannot be ruled out from consideration. Dealing with a case of medical negligence needs a deeper understanding of the practical side of medicine.

At least three weighty considerations can be pointed out which any forum trying the issue of medical negligence in any jurisdiction must keep in mind. These are: (i) that legal and disciplinary procedures should be properly founded on firm, moral and scientific grounds; (ii) that patients will be better served if the real causes of harm are properly identified and appropriately acted upon; and (iii) that many incidents involve a contribution from more than one person, and the tendency is to blame the last identifiable element in the chain of causation the person holding the 'smoking gun'.

Accident during the course of medical or surgical treatment has a wider meaning. Ordinarily, an accident means an unintended and unforeseen injurious occurrence; something that does not occur in the usual course of events or that could not be reasonably anticipated (See, Black's Law Dictionary, 7th Edition). ~are has to be taken to see that the result of an accident which is exculpatory may not persuade the human mind to confuse it with the consequence of negligence.

Medical Professionals in Criminal Law

The criminal law has invariably placed the medical professionals on a pedestal different from ordinary mortals. The Indian Penal Code enacted as far back as in the year 1860 sets out a few vocal examples. Section 88 in the Chapter on General Exceptions provides exemption for acts not intended to cause death, done by consent in good faith for person's benefit. Section 92 provides for exemption for acts done in good faith for the benefit of a person without his consent though the acts cause harm to a person and that person has not consented to suffer such harm. There are four exceptions listed in the Section which is not necessary in this context to deal with. Section 93 saves from criminality certain communications made in good faith. To these provisions are appended the following illustrations :-

Section 88
A, a surgeon, knowing that a particular operation is likely to cause the death of Z, who suffers under a painful complaint, but not .intending to cause Z's death and intending in good faith, Z's benefit, performs that operation on Z, with Z's consent. A has committed no offence.

Section 92
Z is thrown from his horse, and is insensible. A, a surgeon, finds that Z requires to be trepanned. A, not intending. Z's death, but in good faith, for Z's benefit, performs the trepan before Z recovers his power of judging for himself. A has committed no offence.

A, a surgeon, sees a child suffer an accident which is likely to prove fatal unless an operation be immediately performed. There is no time to apply to the child's guardian. A performs the operation in spite of the entreaties of the child, intending, in good faith, the child's benefit. A has committed no offence.

Section 93
As a surgeon, in good faitl1, communicates to a patient his opinion that he cannot live. The patient dies in consequence of the shock. A has committed no offence, though he knew it to be likely that the communication might cause the patient's death.

It is interesting to note what Lord Macaulay had himself to say about Indian Penal Code. We are inclined to quote a few from his speech to the extent relevant for our purpose from "Speeches and Poems with the Repoltand Notes on the Indian Penal Code" by Lord Macaulay (Houghton, Mifflin and Company, published in 1874).

"Under the provisions of our Code, this case would be very differently dealt with according to circumstances. If A kills Z. by administering abortives to her, with the knowledge that those abortives are likely to cause her death, he is guilty of voluntary culpable homicide, which will be voluntary culpable homicide by consent, if Z. agreed to run the risk, and murder if Z. did not so agree. If A causes miscarriage to Z., not intending to cause Z.' death, nor thinking it likely that he shall cause Z.'s death; but so rashly or negligently as to cause her death, A. is guilty of culpable homicide not voluntary, and will be liable to the punishment provided for the causing of miscarriage, increased by imprisonment for a term not exceeding t,>,o years. Lastly, if A took such

precautions that there was no reasonable probability that Z.'s death would be caused, and if the medicine were rendered deadly by some accident which no human sagacity could have foreseen, or by some! peculiarity in Z.'s constitution such as there was no ground whatever to expect, A. will be liable to no punishment whatever on account of her death, but will of course be liable to the punishment provided for causing miscarriage. It may be proper for us to offer some arguments in defence of this part of the Code.

It will be admitted that where an act is in itself innocent, to punish the person who does it because bad consequences, which 1)" .1uman wisdom could have foreseen, have followed from it, would be in the highest degree barbarous and absurd." (P.419)

"To punish as a murderer every man who, while committing a heinous offence, causes death by pure misadventure, is a course which evidently adds nothing to the security of human life. No man can so conduct himself as to make it absolutely certain that he shall not be so unfortunate as to cause the death of a fellow-creature. The utmost that he can do is to abstain from eve~ thing which is at all likely to cause death. No fear of punishment can make him do more than this; and therefore, to punish a man who has done this can add nothing to the security of human life. The only good effect which such punishment can produce will be to deter people from committing any of those offences which turn into murders what are in themselves mere accidents. It is in fact an addition to the punishment of those offences, and it is an addition made in the very worst way." (p.421)
"When a person engaged in the commission of an offence causes death by rashness or negligence, but without either intending to cause death, or thinking it likely that he shall cause death, we propose that he shall be liable to the punishment of the offence which he was engaged in committing, superadded to tl1e ordinary punishment of involuntary culpable homicide.

The arguments and illustrations which we have employed for the purpose of showing that the involuntary causing of death, without either rashness or negligence, ought, under no circumstances, to be punished at all, will, with some modifications, which will readily suggest themselves, serve to show that the involuntary causing of death by rashness or negligence, though always punishable, ought, under no circumstances to be punished as murder." (P.422)
The following statement of law on criminal negligence by reference to surgeons, doctors etc. and unskillful treatment contained in Roscoe's Law of Evidence (Fifteenth Edition) is classic: "Where a person, acting as a medical man, &c. whether licensed or unlicensed, is so negligent in his treatment of a patient that death results, it is manslaughter if the negligence was so great as to amount to a crime, and whether or not there was such a degree of negligence is a question in each case for the jury. "In explaining to juries the test which they should apply to determine whether the negligence in the particular case amounted or did not amount to a. crime, judges have used many epithets, such a", 'culpable,' 'criminal', 'gross', 'wicked', 'clear', 'complete.' But whatever epithet be used and whether an epithet be used or not, in order to establish criminal liability the facts must be such that, in tile opinion of the jury, the negligence of the accused went beyond a mere matter of compensation between subjects and showed such disregard for the life and

safety of others as to amount to a crime against tile State and conduct deserving punishment." (p. 848-849)

xxx xxx xxx

"whether he be licensed or unlicensed, if he display gross ignorance, or gross inattention, or gross rashness, ill his treatment, he is criminally responsible. Where a person who, though not educated as an accoucheur, had been ill the habit of acting as a man-midwife, and had unskillfully treated a woman who died in childbirth, was indicted for the murder, L. Ellenborough said that there was no evidence of murder, but the jury might convict of man-slaughter. "To substantiate that charge the prisoner must have been guilty of criminal misconduct, arising either from the grossest ignorance or the [most?] criminal inattention. One or other of these is necessary to make him guilty of that criminal negligence and misconduct which is essential to make out a case of manslaughter." (p.849)

A review of Indian decisions on criminal negligence.

We are inclined to, and we must -as duty bound, take note of some of the relevant decisions of the Privy Council and of this Court. We would like to preface this discussion with the law laid down by the Privy Council in John Oni Akerele v. The King AIR 1943 PC 72. A duly qualified medical practitioner gave to his patient the injection of Sobita which consisted of sodium bismuth tartrate as given m the British Pharmacopoea. However, what was administered was an overdose of Sobita. The patient died. The doctor was accused of manslaughter, reckless and negligent. act. He was convicted. The matter reached in appeal before the House of Lords. Their Lordships quashed the conviction. On a review of judicial opinion and an illuminating discussion on the points whi.ch are also relevant before us, what their Lordships have held can be summed up as under :-

(i) The a doctor is not criminally responsible for a patient's death unless his negligence or incompetence went beyond a mere matter of compensation between subjects and showed such disregard for life and safety of other as to amount to a crime against the State

(ii) That the degree of negligence required is that it should be gross, and that neither a jury or a court can transform negligence of a lesser degree into gross negligence merely by giving it that appellation. There is a difference in kind between the negligence which gives a right to compensation and the negligence which is a crime.

(iii)lt is impossible to define culpable or criminal negligence, and it is not possible to make the distinction between actionable negligence and criminal negligence intelligible, except by means of illustrations drawn from actual judicial opinion. The most favourable view of the conduct of an accused medical man has to be taken, for it would be most fatal to the efficiency of the. medical profession if no one could administer medicine without a halter round his neck.
"(emphasis supplied)

Their Lordships refused to accept the view that criminal negligence was proved merely because a number of persons were made gravely ill after receiving an injection of Sobita from the appellant coupled with a finding that a high degree of care was not exercised. Their Lordships also refused to agree with the thought that merely because too strong a mixture was dispensed once and a number of persons were made gravely ill, a criminal degree. of negligence was proved.

The question of degree has always been considered as relevant to a distinction between negligence in civil jaw and negligence in criminal law. In Kurban Hussein Mohamedalli Rangawalla v. State of Maharashtra (1965) 2 SCR 622, while dealing with Section304AoflPC, the following statement of law by Sir Lawrence Jenkins in Emperor v. Ornkar Rampratap 4 .Bom LR 679, was cited with approval :- "To impose criminal liability under Section 304-A, Indian Penal Code, it is necessary that the death should have been the direct result of a rash and negligent act of the accused, and that act must be the proximate and efficient cause without the intervention of another's negligence.. It must be the causa causans; it is not enough that it may have been the causa sine qua non." .

K.N. Wanchoo, J. (as he then was), speaking for the Court, observed that the above said view.oftlle law has been' generally followed by High Courts in India and was tile correct view to take of the meaning of Section 304A. The same view has been reiterated in Kishan Chand & Anr. v. The State of Haryana (1970) 3 SCC 904. In Juggankhan v. The State of Madhya Pradesh (1965) I SCR 14, the accused, a registered Homoeopath, administered 24 drops of stramonium and a leaf of dhatura to the patient suffering from guinea worm.' The accused had not studied the effect of such substances being administered to a human being. The poisonous contents of the leaf of dhatura, were not satisfactorily established by the prosecution. This Court exonerated the accused of the charge under Section 302 IPC.

However, on a finding that stramonium and dhatura leaves are poisonous and in no system of medicine, except perhaps Ayurvedic system, the dhatura leaf is given as cure for guinea worm, the act of the accused who prescribed poisonous material without studying their probable effect was held to be a rash and negligent act. It would be see V that the profession of a Homoeopath which the accused claimed to profess did not permit use of the substance administered to the patient. The accused had no knowledge of the effect of such substance being administered and yet he did so. In this background, the inference of the accused being guilty of rash and negligent act was drawn against him. In our opinion, the principle which emerges is that a doctor who administers a medicine known to or used in a particular branch of medical profession impliedly declares that he has knowledge of that branch of science and if he does not, in fact, possess that knowledge, he is prima facie acting with rashness or negligence.

Dr Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole and Anr (1969)I SCR 206 was a case under Fatal Accidents Act, } 855, It does not make a reference to any other decided case, The duties which a doctor owes to his patients came up for consideration. The Court held that a person who holds himself out ready to give medical advice and

treatment impliedly undertakes that he is possessed of skill and knowledge for that purpose. Such a person when consulted by a patient owes him certain duties, viz., a duty of care in deciding whether to undertake the case a duty of care in deciding what treatment to be given or a duty of care in the administration of that treatment. A breach of any of those duties gives a right of action for negligence to the patient. The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of case and competence judged in the light of the particular circumstances of each case is what the law requires. The doctor no doubt has a discretion in choosing treatment which he proposes to give to the patient and such discretion is relatively ampler in cases of emergency. In this case, the death of patient was cased due to shock resulting from reduction of the fracture attempted by doctor without taking the elementary caution of giving an aesthetic to the patient. The doctor was held guilty of negligence and liability for damages in civil law. We hasten to add that criminal negligence or liability under criminal law was not an issue before the Court as it did not arise and hence was not considered.

In the year 1996, there are 3 reported decisions available. Indian Medical association Vs V.P. Shantha and Ors. (1995) 6 SCC 651 is a three -Judge Bench decision. The principal issue which arose for decision by the Court was whether a medical practitioner renders" service" and can be proceeded against for " deficiency in service" before a forum under the Consumer Protection Act, 1986, The Court dealt with how a profession differs from an "occupation: especially in the context of performance of duties and hence the occurrence of negligence. The Court noticed that medical professionals do not enjoy any immunity from being sued in contract or tort (i.e. in civil jurisdiction) on the ground of negligence. However, in the observation made in the context of determining professional liability as distinguished from occupational liability, the Court has referred to authorities, in particular, Jackson & Powell and have so stated the principles, partly quoted from the authorities :-

"In the matter of professional liability professions differ from occupations for the reason that professions operate in spheres where success cannot be achieved in every case and very often success or failure depends upon factors beyond the professional man's control. In devising a rational approach to professional liability which must provide proper protection to the consumer while allowing for the factors mentioned above, the approach of the Courts is to require that professional men should possess a certain minimum degree of competence and that they should exercise reasonable care in the discharge of their duties. In general, a professional man owes to his client a duty in tort as well as "in contract to exercise reasonable care in giving advice or performing services. (See: Jackson & Powell on Professional Negligence, 3rd Edn., paras 1-04, I -OS, and 1-56)."

In Poonam Verma v. Ashwin Patel and Ors., (1996) 4 SCC 332 a doctor registered as medical practitioner and entitled to practice in Homoeopathy only, prescribed an allopathic medicine to the patient. The patient died. The doctor was held to be negligent and liable to compensate the wife of the deceased for the death of her husband on the ground that the doctor who was entitled to practice in homoeopathy only, was under a

statutory duty not to enter the field of any other system of medicine and since he trespassed into a prohibited field and prescribed the allopathic medicine to the patient causing the death, his conduct amounted to negligence per se actionable in civil .Law. Dr. Laxman Balkrishna Joshi's case (supra) was followed. Vide para 16, the test for determining whether there was negligence on the part of a medical practitioner as laid down in Bolam's case (supra) was cited and approved.

In Achutrao Haribhau Khodwa and Ors. v. State of Maharashtra and Ors. (1996) 2 SCC 634 the Court noticed that in the very nature of medical profession, skills differs from doctor to doctor and more than one alternative course of treatment are available, all admissible. Negligence cannot be attributed to a doctor so long as he is performing his duties to the best of his ability and with due care and caution. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession. It was a case where a mop was left inside the lady patient's abdomen during an operation. Peritonitis developed which led to a second surgery being performed on her, but she could not survive. Liability for negligence was fastened on the surgeon because no valid explanation was forthcoming for the mop having been left inside the abdomen of the .lady. The doctrine of res ipsa loquitur was held applicable in a case .like this'.

M/s Spring Meadows Hospital and Al1r. v. Harjol Ahluwalia through K.S. Ahluwalia and Anr. (1998) 4 SCC 39 is again a case of liability for negligence by a medical professional in civil law. It was held that an error of judgment is not necessarily negligence. The Court referred to the decision in Whitehouse & Jorden, [1981] I ALL ER267, and cited with approval the following statement of law contained in the opinion of Lord Fraser determining when an error of judgment can be termed as negligence:-

"The true position is that an error of judgment may, or may not, be negligent, it depends on the nature of the error.If it is one that would not have been made by a reasonably competent professional man professing to have the standard and type of skill that the defendant holds himself out as having, and acting with ordinary care, then it is negligence. it, on the other hand, it is an error that such a man, acting with .ordinary care, might have made, then it is ,not negligence".

In State of Haryana and Ors. v. Smt. Santra, (2000) 5 SCC 182 also Bolam's test has been approved. This case too refers to liability for compensation under civil law for failure of sterilization operation performed by a surgeon. We are not dealing with that situation in the case before us and, therefore, leave it to be dealt within an appropriate case.

Before we embark upon summing up our conclusions on the several issues of law which we have dealt with hereinabove, we are inclined to quote some of the conclusions arrived at by tile learned authors of , 'Errors, Medicine and the Law" (pp. 241-248), (recorded at the end of the book in the chapter titled 'Conclusion') highlighting the link between moral fault, blame and justice in reference to medical, profession and negligence. These are of significance and relevant to the issues before us. Hence we quote :-

(i) The social efficacy of blame and related sanctions in particular cases of deliberate wrongdoings maybe a matter of dispute, but their necessity D in principle D from a moral point of view, has been accepted. Distasteful as punishment may be, the social, and possibly moral, need to punish people for wrongdoing, occasionally in a severe fashion, cannot be escaped. A society in which blame is overemphasized may become paralyzed. This is not only because such a society will inevitably be backward-looking, but also because fear of blame inhibits the uncluttered exercise of judgment in relations between persons. If we are constantly concerned about whether our actions will be the subject of complaint, and that such complaint is likely to lead to legal action or disciplinary proceedings, a relationship i of suspicious formality between persons is inevitable, (ibid, pp. 242-243)

(ii) Culpability may attach to the consequence of an error in circumstances where substandard antecedent conduct has been deliberate, and has contributed to the generation of the error or to' its outcome. In .case of errors, the only failure is a failure defined in terms of the normative standard of what should have been done. There is a tendency to confuse the reasonable person with the error-free person. While nobody can avoid errors on the basis of simply choosing not to make them, people can choose not to commit violations. A violation is culpable, (ibid, p. 245).

(iii) Before the court faced with deciding the cases of professional negligence there are two sets of interests which are at stake: tile interests of the plaintiff and the interests of the defendant. A correct balance of these two sets of interests should ensure that tort liability is restricted to those cases where there is a real failure to behave as a reasonably competent practitioner would have behaved. An inappropriate raising of the standard of care threatens this balance, (ibid, p.246). A consequence of encouraging litigation for loss is to persuade the public that all loss encountered in a medical context is the result of the failure of somebody in the system to provide the level of care to. which the patient is entitled. The effect of this on the doctor-patient relationship is distorting and will not be to the benefit of the patient in the long run. It is also unjustified to impose on those engaged in medical treatment an undue degree of additional stress and anxiety in the conduct of their profession. Equally, it would be wrong to impose such stress and anxiety 011 any other person performing a demanding function in society, (ibid, p.247). While expectations from the professionals must be realistic and the expected standards attainable, tllis implies recognition of the nature of ordinary human error and human limitations in the performance of complex tasks, (ibid, p. 247).

(iv) Conviction for any substantial criminal offence requires ,that the accused person should have acted with a morally blameworthy state ,of mind..Recklessness and deliberate wrongdoing, are morally blameworthy, but any conduct falling short of that should not be the subject of criminal liability. Common- Law system have traditionally only made negligence the subject of criminal sanction 'when the-level of negligence has been high a standard traditionally described as gross negligence. In fact, negligence at that level is likely to be indistinguishable from recklessness, .(ibid, p.248).

,..

(v) Blame is a powerful weapon. Its inappropriate use distorts tolerant and constructive relations between people. Distinguishing between (a) accidents which are life's misfortune for which nobody is morally responsible, (b) wrongs amounting to culpable conduct and constituting grounds for compensation, and (c) those (i.e. wrongs) calling for punishment on account of being gross or of a very high degree requires and calls for careful, morally sensitive and scientifically informed analysis; else there would be injustice to the larger interest of the society, (ibid, p. 248)." Indiscriminate prosecution of medical professionals for criminal negligence is counter- productive and does no,service or good to the society.

Conclusions summed up

We sum up our conclusions as under:-

I) Negligence is the breach of a duty caused by omission to do something which a reasonable man guided by those considerations which ordinarily regulate the conduct of human affairs would do, or doing something which a prudent and reasonable man would not do. The definition of negligence as given in Law of Torts, Ratanlal & Dhirajlal (edited by Justice G.P. Singh), referred to hereinabove, holds good. Negligence becomes actionable on account of injury resulting from the act or omission amounting to negligence attributable to the person sued. The essential components of negligence are three: 'duty', 'breach' and 'resulting damage'.

2) Negligence in the context of medical profession necessarily calls for a treatment with a difference. To infer rashness or negligence on the part of a professional, in particu1ar a doctor, additional considerations apply. A case of occupational negligence is different from one of professional negligence. A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, He cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed. When it comes to the failure of taking precautions what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial. Similarly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that particular time (that is, the time of the incident) at which it is suggested it should have been used.

3) A professional may be held liable for negligence on one of the two findings: either he was not possessed of the requisite skill which he professed to have possessed, or, he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising ordinary skill

in that profession. It is not possible for every professional to possess the highest level of expertise or skills in that branch which he practices. A highly skilled professional may be possessed of better qualities, but that cannot be made the basis or the yardstick force judging the performance of the professional proceeded against on indictment of negligence. ‘

4) The test for determining medical negligence as laid down in Bolam’s case [1957] I W.L.R. 582,586 holds good in its applicability in India.

5) The jurisprudential concept of negligence differs in civil and criminal law. What may be negligence in civil law may not necessarily be negligence in criminal law. For negligence to amount to an offence, the element of mens rea must be shown to exist. For an act to amount to criminal negligence, the degree of negligence should be much higher i.e. gross or of a very high degree. Negligence which is neither gross not of a higher degree may provide a ground for action in civil law but cannot form the basis for prosecution.

6) The word ‘gross’ has not been used in Section 304A of IPS: yet it is settled that in criminal law negligence or recklessness, to be so held, must be of such a high degree as to be ‘gross’. The expression’ rash or negligent act’ as occurring in Section 304A of the IPC has to be read as qualified by the word ‘grossly’.

7) To prosecute a medical professional for negligence under criminal law it must be shown that the accused did something or failed to do something which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do. The hazard taken by the accused doctor should be (If such a nature that the injury which resulted was most likely imminent.

8) Res ipsa loquitur is only a rule of evidence and operates in the domain of civil law specially in cases of torts and helps in determining the onus of proof in actions relating to negligence. It cannot be pressed in service for determining per se the liability for negligence within the domain of criminal law. Res ipsa loquitur has, if at all, a limited application in trial on a charge of criminal negligence
.
“In view of the principles laid down hereinabove and the preceding discussion, we agree with the principles of law. ‘laid down in Dr. Suresh Gupta’s case (2004) 6 SCC 422 and re-affirm the same. Ex abundallti cautela, we clarify that what we are affirming are the legal principles laid down and the law as stated in Dr. Suresh Gupta’s case. We may not be understood as having expressed any opinion on the question whether on the facts of that case the accused could or could not have been held guilty of criminal negligence as that question is not before us. We also approve of the passage from Errors, Medicine and the Law by Alan Merry and Alexander McCall Smith which has been cited with approval in Dr. Suresh Gupta’s case (noted vide para 27 of the report).

Guidelines re: prosecuting medical professionals

As we have noticed hereinabove that the cases of doctors (surgeons and physicians) being subjected to criminal prosecution are on an increase. Sometimes such prosecutions are filed by private complainants and sometimes by police 011 an FIR being lodged and cognizance taken. The investigating officer and the private complainant cannot always be supposed to have knowledge of medical science so as to determine whether the act of the accused medical professional amounts to rash or negligent act within the domain of criminal law under Section 304-A of IPC. The criminal process once initiated subject the medical professional to serious embarrassment and sometimes harassment. He has to seek bail to escape arrest, which mayor may not be granted to him. At the end he may be exonerated by acquittal or discharge but the loss which he has suffered in his reputation cannot be compensated by any standards.

We may not be understood as holding that doctors can never be prosecuted for an offence of which rashness or negligence is an essential ingredient. All that we are doing is to emphasis tile need for care and caution in the interest of society; for, the service which the medical profession renders to human beings is probably tile noblest of all, and hence there is a need for protecting doctors from frivolous or unjust prosecutions. Many a comp1airiant prefers recourse to criminal process as a tool for pressurizing the medical professional for extracting uncalled for or unjust compensation.

Such malicious proceedings have to be guarded against.

Statutory Rules or Executive Instructions incorporating certain guidelines need to be framed and issued by the Government of India and/or the State Governments in consultation with the Medical Council of India. So long as it is not done, we propose to lay down certain guidelines for the future which should govern the prosecution of doctors for offences of which criminal rashness or criminal negligence is an ingredient. A private com plaint may not be entertained unless the complainant has produced prima facie evidence before the Court in the form of a credible opinion given by another competent doctor to support the charge of rashness or negligence on the part of the accused doctor. The investigating officer should, before proceeding against the doctor accused of rash or negligent act or, omission, obtain an independent and competent medical opinion preferably from a doctor in government service qualified in that branch of medical practice who can normally be expecte1 to give an impartial and unbiased opinion applying Bolam’s test to the facts collected in the investigation. A doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been leveled against him). Unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigation officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested, the arrest may be withheld.

Case at hand

Reverting back to the facts of the case before us ,we are satisfied that all the averments made in the complaint, even if held to be proved, do not make out a case of criminal rashness or negligence on the part of the accused appellant. It is not the case of the

complainant that the accused, appellant was not a doctor qualified to treat the patient whom he agreed to treat. It is a case of non-availability of oxygen cylinder either because of the hospital having failed to keep available a gas cylinder or because of the gas cylinder being found empty. Then, probably the hospital may be liable in civil law (or may not he-D we express no opinion thereon) but the accused appellant cannot be proceeded against under Section 304A IPC on the parameters of ,Bolam's test. Result.

The appeals are allowed. The prosecution of the accused appellant under Section 304A1341PC is quashed. AI! the interlocutory applications be treated as disposed of.

THE DELHI NURSING HOMES REGISTRATION ACT, 1953
N.O .VI OF 1953.
22nd April, 1953.

An act to provide for the registration and inspection of Nursing homes in the state of Delhi and for certain purpose connected therewith.

Be it enacted as follows:-

1. Short title, extent and commencement

(i) This Act may be called the Delhi Nursing Homes Registration Act, 1953.

(ii) It extends to the whole of the union territory of Delhi.

(iii) It shall come into force on such date as the Chief Commissioner may by notification in the official
Gazetted appoint.

2. Definitions: In this act, unless the context otherwise requires-

(i) 'Chief Commissioner' means the Chief Commissioner of the Union Territory of Delhi.

(ii) 'Local Authority' means a municipal committee, district board or other authority legally entitled to or entrusted .by the Government with the control of management of a municipal or local fund; ,

(iii) 'Maternity Home' means any premises used or intended to be used for the reception of pregnant women or of women in or immediately after child birth;

(iv) 'Nursing Home means any premises used or intended to be used for the reception of persons suffering from any sickness injury or infirmity and the providing of treatment al)d nursing for them and includes a maternity home, and the expression 'carry on nursing home means to receive persons in a nursing home for, any of the aforesaid purposes and to provide treatment or nursing for them.

(v) "Prescribed" means prescribed by rules made under this act. (v)' qualified medical practitioner' means a medical practitioner registered in any state or Union Territory in India under a law for the registration of
.medical practitioners:

(vi) 'qualified midwife' means a midwife registered in any state or Union Territory in India under a law for the registration of midwives;

(vii) 'qualified nurse' means a nurse registered in any state or Union Territory in India under a law for the registration of nurses;

(viii) 'register' means to register under section 5 of this Act and the expression 'registered' and registration' shall be construed accordingly;

(ix) 'rules means rules made under this Act;

(x) 'Supervising authority' means the person or authority appointed by the Chief Commissioner, by notification in the Official Gazette,

(xi) to perform all or any of the functions of the supervising authority under this Act.

3. Prohibition to carry on nursing home without registration -No person shall carry on a nursing home unless he has .been duly registered in respect of such nursing home and the registration in respect has not been cancelled under section 7.

.
Provided that nothing in this section shall apply in the case of a nursing home which is in existence at tile date of the commencement of this Act, for a period of 3 months from such date or if an application for registration is made within that period in accordance with the provisions of section 4 until such application is finally disposed of.

4. Application for registration -
(i) Every person intending to carry on a nursing home shall make every year an application for registration of title renewal of registration to the supervising authority.

Provided, that in tile case of a nursing home which is in existence at the date of tile commencement of this Act an application for registration shall be made within three months from such date.

(ii) Every application for registration or the renewal of registration shall be made on such date and in such farm and shall be accompanied by such fee, as may be prescribed.

5. Registration -
(I) subject to the provisions of this Act and the rules,. the supervising authority shall on the receipt of an application for registration, register the applicant in respect of the nursing home named in the application and issue to him a certificate of registration the prescribed form;
Provided that the supervising authority may refuse to register the applicant if it is satisfied:-
(a) That the applicant, or any person employed by him at the nursing home, is not a fit person to carry in or to be employed at a nursing home of such a description as the nursing home named in the application; or
(b) That the nursing home is not under the supervision of a person who is a qualified medical practitioner and he or a qualified nurse is not resident in the home, or that there is not a proper proportion of qualified nurses among the persons having the superintendence of or employed in the nursing of the patients in the home; or
(c) That in the case of a maternity home it has not got its staff a qualified midwife and a qualified medical practitioner; or
(d) That for reasons connected with the situation, construction, accommodation, staff of equipment, the nursing home or any premises used in connection therewith is or are not fit to be used for a nursing home of such a description as the nursing home mentioned in the application or that the nursing home or premises is or are used or to be used for purposes which are in any way improper or undesirable in the case of such nursing home. -
(2) A certificate of registration issued under the section shall, subject to-the provisions of section 7, is in force and shall be valid until the 31st day of March next following the date on which such certificate was issued.

(3) The certificate of registration issued in respect of ‘ ‘a nursing home” shall be kept affixed in a conspicuous place in the nursing home.

6. Penalty for non-registration -whoever contravenes the provisions of section 3 shall, on conviction, be punished with fine which may extend to five hundred rupees, or in case of, a second or subsequent offence, with imprisonment for a term which may extend to three months or with fine which may extend to five hundred rupees or with both.

7. Cancellation of registration - Subject to the Provision of this Act, the supervising authority may at any time cancel the registration of a person respect of an nursing home on any ground which would entitle it to refuse an application for the registration of a person in respect of that home, or on the ground that the person has been convicted of an offence, under this Act or that any other person has been convicted of such an offence in respect of that home.

8. Notice of refusal or of cancellation of registration.
(I) Before making an order refusing an application for registration or an order canceling any registration, the supervising authority shall give to the applicant or to the person registered, as the case may be, not less than one” calendar months notice of its intention to make such an order; and every such notice shall state the grounds on which the supervising authority intends to make the order and shall contain an intimation that if within a calendar month after the receipt of the notice the applicant or person registered informs the authority in writing that he desires so to do, the supervising authority shall, before making the order give him (in person or by a representative) an opportunity of showing cause why the order, should not be made.

(2) If the supervising authority after giving the applicant or the person registered an opportunity of showing cause as aforesaid, decides to refuse the application for registration or to cancel the registration, as the case may be, it shall make an order to that effect and shall send a copy of the order by registered post to the applicant or the person registered.

(3) Any person aggrieved by an order refusing an application for registration or cancelling any registration -may, within a calendar month after the date on which the copy of the order was sent to him appeal to the -Chief Commissioner against such order of refusal The decision of the Chief Commissioner on any such appeal shall be final.

.(4) No such order shall come into force until after the expiration of a calendar month from the date on which it was made or, where notice of appeal is given. against it, until the appeal has been decided or withdrawn.
9. Inspection of nursing Home-
(1) The supervising authority or any officer empowered by it in this behalf may, subject to such general or special orders as may be made by the

Chief Commissioner, enter and inspect any premises which are used or which the supervising authority or the officer empowered by, it has reasonable cause to believe to be used, for the purpose of nursing home, and inspect any records required to be kept in accordance with the provisions of this Act.

(2) If any person refuses to allow the supervising authority or the officer empowered by it to enter or inspect any such premises as aforesaid or to inspect any such records as aforesaid or obstructs the supervising authority or the officers empowered by it in the execution of the powers under this section, he shall be guilty of an offence, under this Act.

10. Credit of fee and fines -Any fees received or fines paid under this Act shall be credited to the Consolidated Fund of the state.

11. Expenses of Supervising authority -All expenses incurred by the supervising authority under and for the purpose of this act and the rules made there under may be paid out of the consolidated Fund of the State.

12. Penalty for offences under the Act whoever contravenes any of the provisions of this Act or of any rules shall, if no other penalty, is elsewhere provided in this act or the rules for such contravention, on conviction, be punished with fine which may extend to hundred rupees and in the case of continuing offence to a further fine of 25 rupees," in respect of each day on which the offence continues after such conviction.

13. Offences by Corporations -If the person contravening any of the provisions of this Act is a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct. of the business of tile Company, as well as the company shall, be deemed to be guilty of the contravention and shall i be liable to be proceeded against and punished accordingly.

Provided that nothing contained in this section shall render any such person liable to any punishment provided, in", this Act, If he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

14. Court competent to try offences under this Act -No court inferior to that of a Magistrate of the first class shall try any offence punish under this Act.

15. Protection of action taken m good faith -No Suit, prosecution or other legal proceedings shall lie against any 81 person for anything which is in good faith done or intended to be done in pursuance of this Act or of any rules made there under.

16. Power to make rules -

(1) The Chief Commissioner may, by notification in the official Gazette, make rules to carry out all or any of the purposes of this Act. .,
(2) Without prejudice to the generality of the forgoing power, such rules may provide for all or any of the following matters namely:- .;
a) The form of the application to be made under section 4, the date on which such application is to be paid for such registration or renewal of registration;
b) the form of the certificate of registration to be issued under section 5;
c) the records to be kept of the patients received into a nursing home, and in the case of the maternity home of miscarriages, abortions or still births occurring in the nursing home and of the children born therein and of the children so born who are removed from the home otherwise than to the custody or case of any parent, guardian or relative.
d) The notification required to be given of any death occurring in the nursing home;
e) The power to make rules under this section shall be subject to the condition of previous publication in the official gazette.

(17) Savings -Nothing in this Act shall apply to –

(i) any nursing home carried on by Government or a authority; and
(ii) any asylum for lunatics or patients suffering from mental diseases, within the meaning of the Indian Lunacy Act (IV of 1912).

No.F.32(9)/53-MT & CE :- In exercise of the powers conferred by Section 16 of the Delhi Nursing Homes Registration Act,1953 (V -I of 1953} the Chief Commissioner, Delhi is pleased to make the following rules the same having been previously published with his notification No.F. 7(253)/51-MT&CE, dated the 22nd September, 1953.

RULES

1. GENERAL

Short title:- These rules may be called the Delhi Nursing Homes Registration Rules, 1953.
Definitions :;. In these rules, unless there is anything repugnant in the subject or context.
a) Act means the Delhi Nursing Home Registration Act; 1953.
b) Form means a form appended to these rules..
c) Infectious Diseases means a disease, which a registered medical practitioner is required to notify to the medical officer of health of his area under the law for the time being in force.
d) Keeper of Nursing Home means a person who has been duly registered by. the supervising authority in respect of a nursing home under Section 5 of the Act and whose registration has not been cancelled under section 7 of the Act.
e) Section' means a section of the Act.
3. Register:- The supervising authority shall maintain a register in form 'a' showing the name or persons registered under section 5 of the Act.

4. Application for registration:- Any person intending to Carry on a nursing home shall make an application to the supervising authority in Form 13' at least one month before the date on which he intends to canyon such nursing home. Such applications shall be accompanied by a fees prescribed under sub rule (1) of rule 7.

5. Grant of certificate of registration: -The supervising authority shall, if satisfied that there is no objection to registration, register the applicant and issue to him, a certificate of registration in form ‘C’.

6. Renewal of registration :- (i) An application for the renewal of registration shall be made every year in advance in form ‘B’ in the month of January and shall be accompanied by the fee prescribed in sub-rule(2) or rule ii) On receipt of an application made under sub-rule(l)the supervising authority shall if satisfied that the application is in order, issued a fresh certificate of registration in Form ‘C’.

7. (a) Fees for registration end renewal of registration:-

The fees to be paid for registration and renewal of registration shall be charged as under:

I) Rs. 30(- in respect of a nursing home having not more 10 beds.

2) Rs. 50(-in respect of a nursing home having more than 10 beds but less than 25 beds.

3) Rs. I 00/-in,respect of a nursing home having 25 beds and over. .

b) Failure to deposit fee in time as required under rule 6 of Delhi Nursing Homes Registration Rule, 1953 i.e. by. 31 st January, a penalty of Rs. 10 p.m. or part thereof shall be charged.

8. Transfer of ownership etc. of Nursing home: -Immediately after the transfer of the ownership, proprietorship or arrangement of a nursing homes, the transfer and transferee shall jointly communicate the transfer affected to the Supervising Authority and the transferee shall make the application for registration in accordance with the previous Rule.

9.Change of address:- A keeper of the nursing home, shall communicate to the supervising authority and change in his address or ill the situation of the nursing ill respect of which he is registered not later than three days after such change.

10. Change in staff:- Changes in the Medical Nursing or midwifery staff together with the dates on which such changes have taken place shall be communicated to the supervising authority immediately and in any case not later than three days of such changes.

11. Loss of Certificate : In the event of the certificate of registration being lost or destroyed, the holder may apply to the supervising authority for a fresh certificate and the supervising authority, if it thinks fit, issue such certificate upon payment of a fee of Rs.51- A certificate issued under this rule shall be marked duplicate.

12. Record of patients admitted or children horn, in the nursing home -

(1) The keeper of a nursing home shall keep:-

(a) In the Form ‘0’ appended to these rules a register of patients admitted into the nursing home.
(b) A correct alphabetical index of the names of the patient admitted in the nursing home.
(c) Record of health of every patient containing the following information in admission to any other information, that may be required by the supervising authority:-

i) Year.
ii) Registration No.
iii) Name, Slo, 0/0
iv) Occupation
v) Sex
vi) Caste
vii) Age
viii) viii) Date of Admission.
ix) Date of Discharge
x) Disease
xi) Result
xii) xii) Date
xiii) History and Treatment, Diet.

(d) a record of every maternity case admitted into the nursing home and of every child delivered.
(e) A record of all the miscarriages, abortions and still births occurring in the nursing home.

12. Where the register referred to clause (a) of sub rule (1) relates to a woman who has been admitted for delivery and where a child born to such woman is removed with the consent of a keeper of a nursing home and of the parents, or mother of near relative, the keeper of such nursing home shall in addition to the particulars specified in sub-rule (I) also specify in the register the names and address of such person and the date on which and the consideration for which the child was so removed

13. Intimation of death occurring in nursing home:- If any death occurs in tile nursing home, the keeper of the nursing home shall within twenty four hours from the occurrence of the death furnish the following information in respect of such death to the supervising authority together with any other information that may be required by it and to the Medical Officer of Health having jurisdiction over the area in which nursing home is situated.

i) bate of the Death.
ii) Name of deceased (in block Letter).
ii) Name of father or of husband of the deceased (in block .letters).
iii) Male or female:
iv) Age of the deceased.
v) Occupation of the deceased.

vi) Cause of death

FORM 'D' SEE RULE 12

Register of Patients admitted to Nursing Home

S.No.	Reference No. of patient	Full Name and address of patient	Nature of disease at the time of admission	If the patient suffered from an infectious disease during his stay in the home, the nature of such disease and action taken
1.	2.	3	4	5

Date & Hour of deliver or miscarriage or abortion as the case may be	Sex of the child whether born alive dead	The name & address of person attending to delivery	Additional Partiuclar In case of death of maternity cases child Method of feeding each child in the home and the period.
6	7.	8	9 10

Date of discharge of patient from the home ,

Remarks

STANDARD FOR A NURSING HOME MATERNITY HOME

1. BUILDING

The building must comply with the municipal Bye laws. The floor space available for patients should be 120 sq. ft per bed. There should be one lavatory for 1-5 beds.

There should be disinfections and storage arrangements for bed pans.

Isolation arrangements should. be immediately available for septic and infectious cases.

A nurses duty room should be available with facilities for tne nurses to canyon her duties efficiently.

There should be one bath room for 1-5 beds.

,

2. EQUIPEMENT & LINEN

A maternity home should have a proper labour room fitted with all the necessary instruments with a separate room -~
for sterilization.

A Nursing Home where surgical operations are performed must have a well-equipped operation Theatre with a separate room for sterilization. The following essential equipment must be available in every nursing/maternity home.

! (a) High Pressure sterilizer and an instrument sterilizer.
(b) Oxygen cylinder.
(c) Intravenous apparatus.
(d) Modem equipment as is considered essential for running a nursing home/maternity home.

Every nursing home admitting surgical cases should have at least one follow up bed.

Every surgical nursing home should have a properly equipped operation theatre wit:) separate sterilization room.

Bed in the nursing home should be either iron spring beds or iron frames with Niwar.

3. LINEN

Linen should be provided in the following scale.

Bed Sheets	6 Sheets per bed plus 25% reserve
Mattress	I per bed plus 100/0 reserve.
Pillows	2 per bed plus 10% reserve
Blankets	1 per bed plus 10% reserve
Draw sheets	6 per bed plus 25% reserve
Pillow cases	6 per bed plus 25% reserve

4. MEDICINES: Poison Box should be kept under lock and key.
5. STAFF: As per Act.
6. NURSES: One nurse for 3 beds with a minimum of2 nurses in a nursing home/maternity home of 10 beds.
7. MIDWIVES: 2 midwives for I to 10 beds in case of maternity home only.
8. FEES FOR REGISTRATION AND RENEWAL OF REGISTRATION

The fees to be paid for registration and renewal of registration shall be charged as under :

(i) Rs.30/- in respect of a nursing home having not more than 10 beds.
(ii) Rs. 50/- in respect of a nursing home having more than 10 beds but less than 25 beds.
(iii) Rs. 100/- in respect of a nursing home having 25 beds and over.

NOTIFICATION OF DEPARTMENTS OF THE DELHI ADMINISTRATION OTHER THAN NOTIFICATIONS INCLUDED IN PART -1. DELHI ADMINISTRATION, DELHI the 16th. May, 1966

No.F.7(2)/63-M&PH. In exercise of the powers conferred by. section 16 of the Delhi Nursing Homes Registration Act,
1953(VI of 1953) the Chief Commissioner, Delhi is pleased to make after previous publication, the following rules to amend the Delhi Nursing Homes Registration Rule, 1963, namely:-

1. Short title -These rules may be called the Delhi Nursing Home Registration (Amendment)Rule,1965.
“

2. Amendment of rule 2 -In rule 2 of the Delhi Nursing Home Registration Rules, 1953 hereinafter referred to as (the said Rules), after clause (d), the following new clause shall be inserted, namely:-
“(dd)” ‘Schedule’ means the schedule appended to these rules”
3. Substitution of rule 7' For rule 7 of the said rules following rule shall be substituted, namely :-
, 7 Fees for registration and renewal of registration. The fees to be paid for registration and renewal of registration shall be charged as under :-
i) Rs.50/- in respect of a nursing home having not more than 10 beds.
ii) Rs. 100/- in respect-of a nursing home having more than 10 beds but not more than 30 beds.
iii) Rs.200/- in respect of a nursing home having more than 30 beds.
4: Addition of new rule 14- After rule 13 of the said rules, the following new rule shall be added, namely:-
“14. Every nursing home shall comply with the requirements mentioned in the schedule”.
Provided that the nursing homes already registered on the date from which the Delhi Nursing Homes Registration (Amendment) Rule, 1965 come into force shall comply with these requirements within a period of 90 days from
the said date”.
5. Addition of Schedule -To the said rules, the following schedule shall be appended, namely:-

DELHI GAZETTE DELHI ADMINISTRTION: JUNE 2, 1966/SAYISTHA 12,1888.

(See rule 14)

1. Requirements Nursing Home:- ,

(a) Location and surroundings:- The Nursing Home shall “be situated in a place having clean surroundings and shall not be adjacent to an open sewer, drain or public lavatory or to a factory omitting smoke or obnoxious odour.

(b) Buildings:- ..

(i) The building used FOR the nursing home shall comply with the relevant municipal by laws in force from time to time.

(ii) The rooms in the .nursing home shall be well ventilated and lighted and shall be kept In clean and hygienic conditions. Arrangements shall be made for cooling them in summer and heating them in winter.
(iii) The walls of the labour room and operation theatre upto a height of four feet from the floor, shall be of such construction as to render it water proof. The flooring shall be such as not permit retention or accumulation of dust. There shall be no chinks or crevices in the walls or floors.
iv) Aseptic conditions shall be maintained in labour room and the operation room.
(v) Adequate arrangements shall be made for isolating septic and infectious cases.

(c) (i) Space accommodation for the patients etc. :- The floor space in the nursing home shall be 120 sq. ft.
for single bed and additional 80 sq. ft. for every additional bed in single room.
(ii) A Labour/operation theatre shall be provided with, minimum floor space of 180 sq.ft.
(iii) A duty room shall be provided for the “nursing staff on duty.
(iv) Adequate space for, storage of medicines, food articles equipments etc. shall be provided.
(d) Water supply :- The water used in the nursing home shall be pure and of drinkable quality.
2. Health Clothing and sanitary requirements of staff:
yii) The staff employed shall be free from contiguous disease ,and shall be provided with clear uniforms suitable
to the nature of their duties.
viii) The workers shall be medically examined at the time, of employment and periodically so examined thereafter.
The worker shall be vaccinated against on smallpox and inoculated against enteric and cholera. ,
3. The equipment and Lines etc : The nursing home shall provide and maintain :-
i) Adequate number of commodes, bedpans and slop sinks, with flushing arrangements.
ii) High Pressure sterilizer and instrument sterilizer.
iii) Oxygen cylinder and necessary attachment for giving oxygen.
iv) Apparatus for transfusions.
v) Adequate equipments, instruments and apparatus.
vi) Adequate quantity of bed sheets, mattresses, pillows, Blankets, row sheets and other linens and
vii) an almirah under lock and key for poisons.
4. Food:- If the nursing home provides diet to the patients it shall be prepared and served in hygienic conditions.
5. Nursing Staff:- One nurse shall be on duty at all times, for every ten beds or a fraction thereof in the nursing home.
Provided that a part of nursing staff may be substituted with the prior approval of the supervising authority by

other trained staff like midwife, pharmacist, dressers etc according to the specific needs of the nursing home.
6. Records:-Separate stock registers shall be maintained by the nursing home for
(a) equipment
(b) instruments and
(c) Linens.

-BY ORDER D.S. FAUJDAR
Under Secretary (Medical & Public Health)
Delhi Administration, Delhi

MEDICAL & PUBLIC HEALTH DEPARTMENT
NOTIFICATION

Delhi, the Ist May 1992.

No.F. 39(1 09)/86-M&PH/516 -In exercise of the power conferred by Section 16 of the Delhi Nursing Homes Registration Act, 1953 {VI of 1953), the Lt. Governor of the Union Territory of Delhi after previous publication is pleased to make the following rules further to amend the Delhi Nursing Homes Registration Rules, 1953 namely: -

RULES

Short title and commencement :-
(i) These rules may be called the Delhi Nursing Homes registration(Amendment) Rules 1992-
(ii) These shall come into force with immediate effect.
2. Substitution of Rule 7-
For Rule 7 of the Delhi Nursing Homes Registration Rules, 1953- (here in after referred to as tile principle rules), the following shall be substituted.
‘,7 Fee for registration and renewal of registration: The fee to be paid for registration and renewal of registration shall be charged as under :- .’,
(a) Rs .500/- in respect of Nursing Homes having not more than 10 beds”
..
(b) Rs .1000/- in respect of Nursing Homes having more than 10 beds but not more than 30 beds.
(c) Rs .2000/- in respect of Nursing Homes having more than 30 beds.
3. Amendment of Schedule appended to tI)e Rules in the Schedule appended to the Principal Rules :-
(i) In item at Serial No. I (Requirement of Nursing Homes):
(a) in clause (b) entitled ‘Building’ for sub clause (i) the following sub-clause shall be substituted, namely:
(i) The building used for the Nursing Homes comply with tile relevant Municipal bye-law as in force and such guidelines as may be framed by the Lt Governor from time to time and the use of the premises shall conform to the land use prescribed under relevant law(S).
(b) In clause (c) entitled ‘Space accommodation etc., for sub clause (ii), the following sub-clause shall substituted, namely:

(ii) A separate labour room and a separate operation theatre shall be provided with minimum floor space of 180 sq. ft. each.
(iii) In item at Serial No.5 (Nursing staff), the following shall be insel1ed at the end, namely' In nursing homes providing Intensive Care Units facilities there shall be at least four nurses provided exclusively for four such beds or fraction thereof.
(iv) After item at serial no. 6 the following new items shall be inserted namely :-

7. Doctor: There shall be one qualified doctor holding a degree recognized by the medical Council of India or the medical Council of a State, round the clock for every 20 beds or fraction thereof, in the nursing home. In case of Nursing Homes providing intensive care facilities, there sha11 be at least two doctors exclusively for intensive care.

8. Provision of Co-operation at the time of Natural Calamity or disaster: In case of any natural calamity or disaster,
(i) the owner or the keeper of every Nursing Home shall, on being requested by the supervising authority, co-operate and provide such reasonable assistance and medical aid as may be considered essential by the supervising authority at the time of natural calamity or disastrous situation.

9. Provision of display of charges. The owner and/of the keeper of the Nursing Home shall ensure that the charges levied by the Nursing home for the various services available in the Nursing Home are permanently displayed
.
10. Provision of stand by generator: The owner and/or the keeper of the Nursing Home shall ensure the provision of stand by generator in case of the power failure in the nursing home.

By order and in the name of
The Lt.-Governor of the Union
Territory of De!hi.
Mrs. Shailaja Chandra, Secretary (Medical).

IWHEREAS 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 16th October, 1997iriviting 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 sections 6,8 and 25 of the Environment (Protection) Act, 1986 the Central Government here by 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.

2. Application -These rules apply to all persons who genera1e, 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) “authorization” 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) “authorized person” means an occupier or operator authorized 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
.guidelines issued by the Central Government;

(5) “bio-medical waste” means any waste which is generated during the diagnosis, treatment or immunization 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

(6) “biologicals” means any preparation made from organisms of micro-organisms or product of metabolism and biochemical reactions intended for use in the diagnosis, immunization or the treatment or 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 process incidental to such treatment or disposal is carried out 2[and includes common treatment facilities]

3[(7;i) “Form” means Form appended to these rules.]

(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
() 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 setup 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 or any other waste treatment facility.
6. Segregation, packaging, transportation and storage -
I) Bio-medical waste shall not be mixed with other wastes. -
2) Bio-medical waste shall be segregated in to containers/bags at the point of generation in accordance with Schedule
II prior to its storage, transportation, treatment and disposal. The container 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 there under, untreated bio-medical waste shall be transported only in such vehicle as may be authorized 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 authorized 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.
[(6) The Municipal body of the area shall continue to pick up the transport segregated non bio-medical solid waste generated in hospitals and nursing homes, as well as duly treated bio-medical wastes for disposal at municipal
dump site.]
7. Prescribed authority –

(1) Save as otherwise provided, the prescribed authority for enforcement] of the provisions of these rules shall be the State pollution Control Boards in respect of States and the Pollution Control committees in respect of the Union territories and all pending cases with a prescribed authority appointed earlier shall stand transferred to the concerned State Pollution Control Board, or as the case maybe, the Pollution Control Committees.]

(IA)The prescribed authority for enforcement of the provisions of these rules in respect of all health care establishments including hospitals, nursing homes, clinics, dispensaries, veterinary institutions Animal houses, pathological laboratories and blood banks of the Armed Forces under the Ministry of Defence shall be the Director General, Armed Forces Medical Services.]
{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 I make such enquiry it deems fit and if it is satisfied that the applicant possesses be necessary capacity to handle bio-medical waste in accordance with these rules, granted renew an authorization as the case may be.
(5) An authorization shal1 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 subsequence authorisation shall be for a period of three years. A provisional authorization 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 being heard to the applicant and for reasons thereof to be recorded in writing refuse to grant or renew authorisation.
(7) Every application for authorization 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 -

(I) 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 I to the prescribed authority for grant of authorisation.

(2) Every operator of a bio-medical waste facility shall make an application in Form I to the prescribed authority for grant of authorisation. .

(3) Every application in Form I for grant of authorisation shall be accompanied by a fee as may be prescribed by the Government of the State or Union Territory.

1[(4) The authorization to operate a facility shall be issued in Form IV, subject to conditions laid therein and such other condition, aw the prescribed authority may consider it necessary.]

9. Advisory committee-

2[(1)] 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. 3[***] 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.

4[(2) Notwithstanding anything contained in sub-rule (1), the Ministry f Defence shall constitute in that Ministry, an Advisory Committee consisting of the following in respect of all health care establishments including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories and blood banks of the Armed Forces under the Ministry of Defence, to advise the Director General, Armed Forces Medical services and the Ministry of Defence in matters relating to implementation of these rules, namely :-

(I) Additional Director General of Armed Forces Medical Services……Chairman

(2) A representative of the Ministry of Defence not
below the rank of Deputy Secretary, to be
nominated by that Ministry…….....…Member

(3) A representative of the Ministry. of Environment
and Forests not below the rank of Deputy Secretary
to be nominated by the Ministry…….....…… Member

(4) A representative of the Indian Society of Hospitals
Waste Management, Pune ,…….....……Member

9A. Monitoring of implementation of the rules in Armed Forces Health Care Establishments -

I) The Central Pollution Control Board shall monitor the implementation of these rules in respect of all the Armed Forces health care establishments under the Ministry of Defence.

2) After giving prior notice to the Director General Armed Forces Medical Services, the Central Pollution Control Board along with one or more representatives of the Advisory Committee constituted under sub-rule (2) of rulemay, if it considers it necessary, inspect any Armed Forces health care establishments.

10. Annual report -Every occupier/operator shall submit an annual report to the prescribed authority in Form II by 31st January every year, to include information about the categories and quantities of bio-medlcal wastes handled during the

preceding year. The prescribed authority shall send this information in a compiled form to the Central Pollution control Board by 31st March every year.

11. Maintenance of records-

I) 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 guidelines issued.

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 authorized person shall report the accident in Form III to the prescribed authority forthwith.

13. Appeal -

[(I)] 2[Save as otherwise provided in sub-rule (2), 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 3[in Form V] 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 time.

[(2) Any person aggrieved by an order of the Director General, Armed-Forces Medical Services under these rules may, within thirty days from the date on which the order is communicated to him prefer an appeal to the Central Government in the Ministry of Environment and Forests.].

[14. Common disposal/incineration sites: Without prejudice to rule 5 of these rules, the Municipal Corporations, Municipal Boards or Urban Local Bodies, as the case may be, shall be responsible for providing suitable common disposal/incineration sites for the biomedical wastes generated in the area under their jurisdiction and in areas outside the jurisdiction of any municipal body, it shall be the responsibility of the occupier generating bio-medical waste/operator of a bio medical. waste treatment facility to arrange for suitable sites individual or in association, so as to comply with the provisions of these rules.]

SCHE&ULE- I

(See rule 5)

CATEGORIES OF BIO-MEDICAL WASTE

(Waste Category and Disposal No.1]	Waste Category 2(Type]	1 (Treatment Option]

Category No. I	**Human Anatomical Waste** (Human tissues, organs, body parts.)	Incineration @ deep burial*
Category No.2	**Animal Waste: (Animal tissues, organs, body parts, carcasses** bleeding parts, fluid, blood and " experimental animals used in research, waste" generated by veterinary hospital, colleges, discharge from hospitals, animal houses.)	**Incineration @ deep burial***
Catgory No.3	**Microbiology and Biotechnology Waste** (wastes from laboratory cultures, stocks or specimen of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biological toxins, dishes and devices used for transfer of cultures.)	Local Autoclaving/microwaving/ incineration @
Category No.4	**Waste sharps** (Needles, syringes, scalpels, blades, glass, etc. that may cause puncture and unused sharps)	disinfections (chemical @@/autoclaving/ treatment and cuts.This includes both used microwaving and multilation/shredding##)
Category No.5	**Discarded Medicines and Cytotoxic drugs** contaminated and discarded medicines.)	Incineration @/destruction (Wastes comprising of outdated, and drugs disposal in secured landfills
Category No.6	**[Solied] Waste** (Items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, beddings, other material contaminated with blood.)	incineration@ autoclaving/ microwaving
CategoryNo.7	**Solid Waste** than the waste [sharps] such as catheters, Intra- venous. sets etc.)	disinfection by chemical (Wastes generated from disposable treatmenf@@ Items other autoclaving tubings, microwaving and mutilation/shredding##
Category No.8	**Liquid Waste**	disinfection by chemical (Waste generated from laboratory treatment @@

	and washing, cleaning, house keeping and disinfecting activities.)	and discharge into drains.
Category No. 9	**Incineration Ash** (Ash from incineration of any bio-medical waste.)	disposal in municipal landfill
Category No.10	**Chemical Waste**	chemical treatment @@ and (Chemicals used in production of biologicals, dischargein to drains for chemicals used in disinfection, as insecticides, etc.) liquids and secured landfill for solids.

\+ Options given above are based on available technologies. Occupier/operator wishing to other State-of-the-art technologies shall approach the Central pollution Control Board to the standards laid down to enable the prescribed authority to consider grant of authorization. ‘

@@ Chemicals treatment using at least 1% hypochloride ‘solution or any other equivalent chemical reagent. It must be ensured that chemical. treatment ensures disinfection.

Mutilation/shredding must be such so as to prevent unauthorised re—use

@ There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated.

* Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.

SCHEDULE-II
See rule-6
COLOUR CODING AND TYPE OF CONTAINER FOR DISPOSAL OF BIOMEDICAL WASTES

Colour Coding option	**Type of Container**	**Waste Category**	**Treatment as per Schedule**
Yellow	Plastic bag	Cat.1,2 , 3 and 6	Incineration/deep burial
Red	Disinfected Container	Cate 3,6,and 7	Autoclaving/Microwaving/ Chemical Treatment
Blue/White Translucent	Plastic bag/Punture Proof Container	Cat 4 and 7	Autoclaving/Microwaving/ Chemical Treatment

Black	Plastic bag	Cat 5,8 and 10 Solid	Disposal in Secured Landfill

Notes :

1. Colour coding of waste categories with multiple treatment options as defined in Schedule I, shall be slected depending on treatment optionm chosen, which shall be as specified in Schedule
2. Waste collection bag for waste types needing incineration shall not be made of chlorinated plastics.
3. Categories 8 and 10 (liquid) do not require containers/bags
4. Category3 if disinfected locally need not be put in container/bags.

SCHEDULE III
see rule -6
LABEL FOR BIO MEDICAL WASTE CONTAINERS/BAGS

BIOHAZARD SYMBOL **CYTOTOXIC HARZARD SYMBOL**

figure

SCHEDULE-IV
see rule 6
LABEL FOR TRANSPORT OF BIO MEDICAL WASTE CONTAINERS/BAGS

Day Month
Year

Waste Category No..... Date of generation
Waste class
Waste desription

sender's Name and Address	Receiver's Name and Address
Phone no.	Phone No.
Telex No.	Telex No.
Fax No.	Fax No.
Contact Person	Contact Person

In case of emergency Plase Contact:

Name and Address
Phone no.

Note : Label shall be non-washable and prominently visible.

SCHEDULE V
see rule 5 and schedule I
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. Cobustion Efficiency (CE) shall be at least 99.00%
2. The combustion Efficiency is computed as follows:-

$$C.E. = \frac{\% CO_2}{\% CO_2 + \%CO} X100$$

3. The temperature of the primary chamber shall be 800+- 50 degree C
4. The seondary chamber gas residence time shall be at least 1 (one) second at 1050 +- 50 degree C, with minimum 3% Oxygen in the stack gas.

B. Emission Standards

Parameters	**Concentration mg/Nm^3 at (12% CO_2 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 compunds in ash shall not be more than 0.01%	

Note :

* Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the above emission limits, if necessary.
* Wastes to be incinerated shall be be chemically treated with any chlorinated disinfectants.
* Chlorinated plastics shall not be incinerated.
*Toxic metals in incineration ash shall be limited within the regulation quantities as defined under the Hazardous waste (Management and Handling) Rules 1989.
* Only low sulphur fuel like L.D.O./L.S.H.S. /Diesel shall be used as fuel in the incinerator.

STANDARD FOR WASTE AUTOCLAVING

The autoclave should be decidated for the purposes of disinfecting and treating bio medical waste.

1. When operating a gravity flow autoclave, medical waste shall be subjected to :-
(i) a temperature of not less than 121 degree C and pressure of 15 pounds per sq inch (psi) for an autoclave residence time of not less than 60 minutes; or
ii) a temperature of not less than 135 degree C and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes.
III) a temperature of not less than 149 degree C and a pressure 52 psi for an autoclave residence time of not less than 30 minutes.

2. When operating a vacuum autoclave, medical waste shall be subjected to 4 minimum of one pre-vaccum pulse to purge the autoclave of all air. The waste shall be subjected to the following:

i) a temperature of not less than 121 degree 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 degree C and pressure of 31 psi for an autoclave residence time of not less than 30 minutes.

3. Medical waste shall not be considered properly treated unless the time tempreature and pressure indicators indicate that the required time temperature andpressure were reached during the autoclave process. If for any reasons, time, temperature or pressure indicator indicators 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.

4) Recording of operational parameters: Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time to day, load identification number and opearating parameters throughout the entire length of the autoclave cycle.

5) 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 a least $1X10^4$ spores per milliliter. Under no circumstances will an autoclave have minimum operating parameters less than a residence time ot 30 minutes regardless of temperature and pressure a temperature less than 121 degree C or pressure less than 15 psi.

6) Routine test : A chemical indicator strip/tape that 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 fo the package has been adequately autoclaved.

STANDARDS FOR LIQUID WASTE

The effluent generated from the hospital should conform to the following limits:

Parameters	Permissible limits
pH	6.5-9.0
Suspended solids	100 mg/1
Oil and grease	10 mg/1
BOD	30 mg/1
COD	250 mg.1
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 sweage treatment plant or not connected to public sewers. For discharge into public sewers. For discharge into public sewers with terminal facilities, the general standards as notified 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 unit.
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 microwave shall be Bacillus Subtilis spores using vials or spore stripswith'at least 1 x 104 spores per millilitre.

STANDARDS FOR DEEP BURIAL

1. A pit or trench should be dug about 2 metres deep. It should be half filled with waste, then covered with lime within 50cm 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 perfonned under close and dedicated supervision.

5. The deep burial site should be relatively impermeable and no shallow well should be dose to the site.
6. The pits should be distant from habitation, and sites 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.

SCHEDULE- VI
(See rule 5)
SCHEDULE FOR WASTE TREATMENT FACILITIES LIKE INCINERATOR/AUTOCLAVE MICROWAVE SYSTEM

A. Hospitals and nursing homes in towns with population of30 lakhs and above or earlier	By 30th June, 2000
B. Hospitals and nursing homes .in towns with population of below 30 lakhs	
(a) with 500 beds and above or earlier	By 30th June, 2000
(b) with 200 beds and above but less than 500 bed or earlier	By 31 st Dec 2000
(c) with SO beds and above but less than 200 bed or earlier	By 31st Dec 2001
(d) with less than 50 bed or earlier	By 31 st Dec 2002
C. All other institutions generating bio-medical waste not included in A and B above. or earlier	By 31 st Dec 2002

FQRM -I
(See rule 8)
[APPLICATION FOR AUTHORISATION/RENEWAL OF AUTHORISATION]
(To be submitted in duplicate)

To,
The Prescribed Authority
(Name of the State Govemment/Union Territory Administration)

Address

1. Particulars of the Applicant:
   - (i) Name of the Applicant
     (In block letters and in full)
   - (ii) Name of the Institution.
     Address
     Tel. 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 <;>fthe treatment facility:
   (iii) Address of the place of the disposal of the waste:
5. (i) Mode of transportation (in any) ofbio-medical waste:
   (ii) Mode(s) of treatment :
6. Brief description of method of treatment and disposal (attach details) :
7. (i) Category (see Schedule 1) of waste to be handled:
   (ii) Quantity of waste (categorywise) to be handled per month:
8. Declaration

I do hereby declare that the statement 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 fulfil 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

I. 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 environment:

5. Emergencymeasurestaken: .

6. Steps taken to alleviate the effects of accidents:

7. Steps taken to prevent the recurrence of such an accident:

Date .....

Signature.....

Place..... Designation .....

FORM -IV

[See rule 8(4)]

AUTHORISATION FOR OPERATING A FACILITY FOR COLLECTION, RECEPTION,

TREATMENT, STORAGE, TRANSPORT AND DISPOSAL OF BIOMEDICAL WASTES

I. File No. of authorisation and date of issue .....

2 .....

Of..... is hereby granted an authorisationto operate a facility for collection, reception, storage, transport altd disposal of biomedical waste on the premises situated at .....

3. This authorisation shall be in force for a period of Years from the date of issue.

4. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986

Date.....

Signature.....

Designation .....

TERMS AND CONDITIONS OF AUTHORISATION*

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made thereunder.
2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
3. The person authorised shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. It is the duty of the authorised person to take prior permission of the prescribed authority tolclose down the facility.

* *Additional terms and conditions may be stipulated by the prescribed authority.*

FORM-V

[See rule 13]

APPLICATION FOR FILING APPEAL AGAINST ORDER PASSED BY THE PRESCRIBED AUTHORITY AT DISTRICT LEVEL OR REGIONAL OFFICE OF THE POLLUTION CONTROL BOARD ACTING AS PRESCRIBED AUTHORITY OR THE STATE/UNION TERRITORY LEVEL AUTHORITY

I. Name and address of the person applying for appeal:
2. Number, date of order and address of the authority which passed the order against which appeal is being made (certified copy of order to be attached).
3. Ground on which the appeal is being made.
4. List of enclosures other than the order referred in para 2 against which appeal is being filed.

Signature.....

Date ..... Name and Address .....

THE MEDICAL TERMINATION OF PREGNANCY RULES, 2003

In exercise of powers conferred by section 6 of the Medical Termination of Pregnancy Act, 1971 (34 of 1971), the Central Government hereby makes the following rules, namely :-

1.Short title and commencement -

I) These rules may be called the Medical Termination of Pregnancy Rules, 2003.

2) They shall come into force on the date of their publication in the Official gazette.

2. Definitions -

In these rules, unless the context otherwise requires:

(a) "Act" means the Medical Termination of Pregnancy Act, 1971 (34 of 1971);

(b) "Chief Medical Officer" means the Chief Medical Officer of a District, 'by whatever name called;

(c) "Form" means a form appended to these rules;

(d) "owner", in relation to a place, means any person who is the administrative head or otherwise responsible for the working or maintenance of a hospital or place, by whatever name called, where the pregnancy may be terminated under this Act.

,(e) "Committee" means a committee constituted at the district level under the proviso to clause (b) of section 4 read with rule 3.

3. Composition and tenure of District level Committee -

1) One member of the District level Committee shall be the Gynecologist/ Surgeon/Anesthetist and other members from the local medical profession, non-governmental organizations, and Panchayati Raj Institution of the district:Provided that one of the members of the Committee shall be a woman.

2) Tenure of the Committee shall be for two calendar years and the tenure of the non-Government members shall not be more than two terms.

4. Experience and training under clause (d) of section 2 -

For the purpose of clause (d) of section (2), a registered medical practitioner shall have one or-more of the following experience or training in gynecology and obstetrics, namely :-

:a) in the case of a medical practitioner, who was registered in a State Medical Register immediately before the commencement of the Act, experience in the practice of gynaecology and obstetrics for a period of not less than three years;

(b) in the case of a medical practitioner, who is registered in a State Medical Register:

(i) if he has completed six months of house surgency in gynaecology and obstetrics; or

(ii) unless the following facilities are provided therein, if he had experience at any hospital for a period of not less than one year in the practice of obstetrics and gynaecology; or

(c) if he has assisted a registered medical practitioner in the performance of twenty-five cases of medical termination of pregnancy of which at least five have been performed independently, in a hospital established or maintained, or

a training institute approved for this purpose by the Government.

.(i)'This training would enable the Registered Medical Practitioner (RMP) to do only Ist Trimester terminations (up to 12 weeks of gestation).
(ii) For terminations up to twenty weeks the experience or training as prescribed under sub-rules (a), (b) and (d) shall apply.
(d) in case of a medical practitioner who has been registered in a State Medical Register and who holds a post-graduate degree or diploma in gynaecology and obstetrics, the experience or training gained duri!1g the course of such degree or diploma.

5. Approval of a place -

(I) No place shall be approved under clause (b) of section 4,-
(i) unless the Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions; and ,
(ii) unless the following facilities are provided therein, namely: in case of first trimester, that is, up to 12 weeks of pregnancy : a gynaecology examination/labour table, resuscitation and sterilization equipment, drugs and parental fluid, back up facilities for treatment of shock and facilities for transportation; and in case of second trimester, that is up to 20 weeks of pregnancy:
(a) an operation table and instruments for performing abdominal or gynaecological surgery;
(b) anaestl1etic equipment, resuscitation equipment and sterilization equipment;
(c) drugs and parental fluids for emergency use, notified by Government of India from time to time.

Explanation. In the case of termination of early pregnancy up to seven weeks using RU-486 with Misoprostol, the same may be prescribed by a Registered Medical Practitioner (RMP) as defined under clause (d) of section 2 of the Act and section 4 of MTP Rules, at his clinic provided such a Registered Medical Practitioner has access to a place approved ", under Section 4 of the MTP Act. 1971 read with MTP (Amendment) Act. 2002 and rule 5 of the MTP Rules. For the purpose of access. the RMP should display a Certificate to this effect from the owner of the approved place.
(2) Every application for the approval of a place shall be in Form A and shall be addressed to the Chief Medical Officer of the District.
(3) On receipt of an application under sub-rule (2) the Chief Medical Officer of the District may verify any information contained. in any such application or inspect any such place with a view to satisfying himself that the facilities referred to in sub-rule (1) are provided and that termination of pregnancies may be made under safe and hygienic conditions.
(4) Every owner of the place which is inspected by the Chief Medical Officer of the District shall afford all reasonable facilities for the inspection of the place.
(5) The Chief Medical Officer of the District may, if he is satisfied after such verification, enquiry or inspection, as may be considered necessary that termination of pregnancies may be done under safe and hygienic conditions at
the place recommend the approval of such place to the Committee.
(6) The Committee may after considering the application and the recommendations of the Chief Medical Officer
of the District approve such place and issue a certificate of approval in Form B.
(7) The certificate of approval issued by the Committee shall be conspicuously displaced at the place to be easily visible to persons visiting the place.

(8) The place shall be inspected within 2 months of receiving the application and certificate of approval may be issued within the next 2 months or In case any deficiency has been noted within 2 months of the deficiency having been
rectified by the applicant.
(9) On the commencement of these rules a place approved in accordance with the Medical Termination of Pregnancy Rules. 1975 shall be deemed to have been approved under these rules.

6. Inspection of a place -
(I) A place approved under rule 5 may be inspected by the Chief Medical Officer of the District. as often as may be necessary with a view to verify whether termination of pregnancies is being done therein under safe and hygienic conditions.
(2) If the Chief Medical Officer has reason to believe that there has been death of or injury to a pregnant woman at the place or that termination of pregnancies is not being done at the place under safe and hygienic conditions he may call for any information or may seize any article, medicine, ampoule admission register or other document, maintained, kept or found at the place.
(3) The provisions of the Code of Criminal Procedure. 1973 (2 of 1974). relating to seizure so far as it may; apply to seizure made under sub-rule (2).

7. Cancellation or suspension of certificate of approval-
(I) If after inspection of any place approved under rule 5, the Chief Medical Officer of the District is satisfied that the facilities at such place cannot be made under safe and hygienic conditions, he shall make a report of the fact to the Committee giving the detail of the deficiencies or defects found at the place and the committee may, if it is satisfied, suspend or cancel the approval provided that the Committee shall give an opportunity of making representation to the owner of the place before the certificate issued under rule 5 is cancelled.
(2) Where a certificate issued under rule 5 is cancelled, the owner of the place may make such additions or improvements in the place and thereafter, he may make an application to tile Committee for grant of approval under rule 5.
(3) In the event of suspension of a certificate of approval, the place shall not be deemed to be an approved place during the suspension for the purposes of termination of pregnancy from the date of communication of the order of such suspension.

8. Review -
(I) The owner of a place, who is aggrieved by an order made under rule 7, may make an application for review of the order to the Government within a period of sixty days from the date of such order:
Provided that the Government may condone any delay in case it is satisfied that applicant was prevented by sufficient cause to make application within time.
(2) The Government may after giving the owner an opportunity of being heard, confirm, modify or reverse the order.
9. Form of consent - The consent referred to in sub-section (4) of section 3 shall be given in Form C.
10. Repeal and saving- The Medical Termination of Pregnancy Rules, 1975, are hereby repealed except as respects things done or omitted to be done before such repeal.

FORM-A
(See sub-rule (2) of rule 5)
FORM OF APPLICATION FOR THE APPROVAL OF A PLACE UNDER CLAUSE (B) OF SECTION 4

Category of approved place:
A Pregnancy can be terminated upto 12 weeks
B Pregnancy can be terminated upto 20 weeks

I. Name of the place (in capital letters)
2. Address in full
3. Non-Governmental/Private/Nursing Home/Other Institutions
4. State, If the following facilities are available at the place

Category A

(i) Gynaecological examination/labour table.
.(ii) Resuscitation equipment.
(iii) Sterilization equipment.
(iv) Facilities for treatment of shock, including emergency drugs.
(“y) Facilities for transportation, if required

Category B

(i) An operation table and instruments for performing abdominal or gynaecological surgery.
(ii) Drugs and parental fluid in sufficient supply for emergency cases.
(iii) Anaesthetic equipment, resuscitation equipment and sterilization equipment.

Place ……
Date……. Signature of the owner of the place

FORM-B
See sub-rule (6) of rule 5)
CERTIFICATE OF APPROVAL
The place described below is hereby approved for the purpose of the Medical Termination of Pregnancy Act, 1971

(34 of 1971).

AS READ WITHIN UPTO…….. WEEKS

Name of the Place……..

Address and other descriptions…….

Name of the owner ……..

Place …….

Date……

To the Government of the ……..

FORM-C
(See rule 9)

I……. daughter/wife of……..aged about……years……..
.(here state the permanent address)
at present residing at …….
do hereby give my consent to termination of my pregnancy at ……
(State the name of place where the pregnancy is to be terminated)

Place…….

Date ……...
(To be filled in by guardian where the woman is a mentally ill person or minor)

I ……..son/daughter/wifeof…….. aged about……, years of……. at present residing at (permanent address)…….. do hereby .give my consent to the termination of the pregnancy of my ward……. who is a minor/lunatic at ……..
(place of termination of my pregnancy)

Place ……..
Date…….

Signature

FORM -II
[See Regulation 4(5)]

I. Name of the state
2. Name of the Hospital/approved place
3. Duration of pregnancy (give total No. only) :
   (a) Up to 12 weeks.
   (b) Between 12 -20 weeks
4. Religion of woman :
   (a) Hindu
   (b) Muslim
   (c) Christian
   (d) Others
   (e) Total
5. Termination with acceptance of contraception:
   (a) Sterlisation.
   (b) I.U.D. -
6. Reasons for termination: -
   (give total number under each sub-head)

(a) Danger to life of the pregnant woman.
(b) Grave injury to the physical health of-the pregnant woman.
(c) Grave injury to the mental health of the pregnant woman.
(d) Pregnancy caused by rape.
(e) Substantial risk that if the child was born, it would suffer from such physical or
mental abnormalities as to be seriously handicapped.
(f) Failure of any contraceptive device or method.

Signature of the Officer Incharge with Date

FORM-III
(Sec Regulation 5)
ADMISSION REGISTER

(To be destroyed on the expiry of five years from the date of the last entry in the Register)

I	2	3	4	5	6	7
S.No.	Name of Admission	Name of the Patient	Religion of	Wife/Daughter	Address	Age

8	9	10	II	12	13	14
Duration of Pregnancy	Reasons on which Pregnancy is formed	Date of termination of Pregnancy	Name of Medical Practitioner (s) by whom Pregnancy is terminated	Date of discharge of Patient	Result and Remarks	Name of Registered Medical Pract.(s) by whom the opinion

THE MEDICAL TERMINATION OF PREGNANCY REGULATIONS, 2003

In exercise of powers conferred by section 7 of the l\1cJical Termination of Pregnancy Act, 1971 (34 of 1971), the Central Government hereby make the following regulations, namely :

1. Short title, extent and commencement

() These regulations may be called the Medical Termination of Pregnancy Regulations, 2003,

(2) They extend to all the Union territories.

(3) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions

In these regulations, unless the context otherwise requires,

(a) “Act” means the Medical Termination of Pregnancy Act; 1971 (34 of 1971);

(b) “Admission Register” means the register maintained under regulation 5; ‘“
(c) “Chief Medical Officer” means the Chief Medical Officer of a District by whatever name called,
(d) “Form” means a form appended to these regulations;
(e) “hospital” means a hospital established or maintained by the Central Government or the Government of Union territory;
(t) “section” means a section of the Act.

3. Form of certifying opinion or opinions

(I) Where one registered medical practitioner forms or not less than two registered medical practitioners form such opinion as is referred to in sub-section (2) of section 3 or 5, he or she shall certify such opinion in Form I,
(2) Every registered medical practitioner who terminates any pregnancy shall, within three hours from the termination of the pregnancy certify such termination in Form I.

4. Custody of forms

(I) The consent given by a pregnant woman for the termination of her pregnancy, together with the certified opinion recorded under section 3 or section 5, as the case may be and the intimation of termination of pregnancy shall ,be placed in an envelope which shall be sealed by the registered medical practitioner or practitioners by whom such termination of pregnancy was performed and until that envelope is sent to the head of the hospital or owner of the approved place or the Chief Medical Officer of the State, it shall be kept-in the safe custody of the concerned registered medical practitioner or practitioners, as the case may be.
(2) On every envelope referred to in sub-regulation (I), pertaining to the termination of pregnancy ‘under section 3, there shall be noted the serial number assigned to the pregnant woman in the Admission Register and the name of the registered medical practitioner or practitioners by whom the pregnancy was terminated and such envelope shall be marked “SECRET”.
(3) Every envelope referred to in sub-regulation (2) shall be sent immediately after the termination of the pregnancy to the head of the hospital or owner of the approved place where the pregnancy was terminated.
(4) On receipt of the envelope referred to in sub-regulation (3), the head of the hospital or owner of the approved place shall arrange to keep the same in safe custody .
(5) Every head of the hospital or owner of the approved place shall send to the Chief Medical Officer of the State, in Form)1 a monthly statement of cases where medical termination of pregnancy has been done.
(6) On every envelope referred to in sub-regulation (1), pertaining to the termination of pregnancy under section 5, there shall be noted the name and address of the registered medical practitioner by whom the pregnancy was terminated and the date on which the pregnancy was terminated and such envelope shall be marked “SECRET”.
Explanation.- The columns pertaining to the hospital or approved place and the serial number assigned to the pregnant woman in the Admission Register shall be left blank in Form I in the case of termination performed under section 5.
(7) Where the Pregnancy is not terminated in an approved place or hospital, every envelope referred to in sub-regulation (6) shall be sent by registered post to the Chief Medical Officer of the State on the same day on which the pregnancy was terminated or on the next working day following the day on which the pregnancy was terminated:

Provided that where the pregnancy is terminated in an approved place or hospital, the procedure provided in sub-regulations (I) to (6) shall be followed.

5. Maintenance of Admission Register

(1) Every head of the hospital or owner of the approved place shall maintain a register in Form III for recording therein the details of the admissions of women for the termination of their pregnancies and keep such register for a period of five years from the end of the calendar year It relates to.

(2) The entries in the Admission Register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number, for example, serial number 5 of 1972 and serial number 5 of 1973 shall be mentioned as 5/1972 and 5/1973.

(3) Admission Register shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person.

6. Admission Register not to be open to inspection

The Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorized by such head or owner and save as otherwise provided in sub-regulation (5) of regulation 4 shall not be open for inspection by any person except under the authority of law:

Provided that the registered medical practitioner on the application of an employed woman whose pregnancy has been terminated, grant a certificate for the purpose of enabling her to obtain leave from her employer: Provided further

that any such employer shall not disclose this information to any other person.

7. Entries in registers maintained in hospital or approved place

No entry shall be made in any case-sheet, operation theater register, follow-up card or any other document or register other than the admission Register maintained at any hospital or approved place indicating therein the name of the pregnant woman and reference to the pregnant woman shall be made therein by the serial number assigned to the, woman in the Admission Register.

FORM -I

[See Regulation-3]

I……..

(Name and qualifications of the Registered Medical Practitioner in block letters)

……

(Full address of the Registered Medical Practitioner)

I……

(Name and qualifications of the Registered Medical Practitioner in block letters)

……

(Full address of the Registered Medical Practitioner) hereby certify that * I/we am/are of opinion, formed in good faith, that it is necessary to terminate the pregnancy of ……(Full name of pregnant woman in blockletters) resident of…….. (Full address of pregnant woman in block letters) for the reasons given below**.

I/We hereby give intimation that * I/We terminated the pregnancy of the woman referred to above who bears the serial No…….. in the Admission Register of the hospital/approved place.

Place …… Signature of the Registered Medical Practitioner

Date …… Signature of the Registered Medical Practitioners

Strike out whichever is not applicable,

**Of the reasons specified items (i) to (v) write the one which is appropriate:

(i) in order to save the life of the pregnant woman, .
(ii) in order to prevent grave injury to the physical and me:1tal health of the pregnant woman,
(iii) in view (If the substantial risk that if the child was born It would suffer from such physical or mental abnormalities as to be seriously handicapped,
(iv) as the pregnancy is alleged by pregnant woman to have been caused by rape,
(v) as the pregnancy has occurred as result of failure of any contraceptive device or methods used by married woman or her husband for the purpose of limiting the number of children.

Note: Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining , whether the continuance of her pregnancy would involve a grave injury to her physical or mental health.

Place …….

Date……

Signature of the Registered Medical Practitioner/Practitioners

FORM-II
[See Regulation 4(5)]

1. Name of the State
2. Name of the Hospital/approved place
3. Duration of pregnancy (give total No. only) :
   (a) Up to 12 weeks.
   (b) Between 12 -20 weeks
4. Religion of woman:
   (a) Hindu
   (b) Muslim
   (c) Christian
   (d) Others

(e) Total

5.Termination with acceptance of contraception:

(a) Sterlisation

(b) I.U.D.

6. Reasons for termination:

(give total number under each sub-head)

(a) Danger to life of the pregnant woman.

(b) Grave injury to the physical health of the pregnant woman.

(c) Grave injury to the mental health of the pregnant woman.

(d) Pregnancy caused by rape, .

(e) Substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.

(f) Failure of any contraceptive device or method.

Signature of the Officer Incharge with Date

THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) RULES, 1996

In exercise of tile power conferred by section 32 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely :-

1. Short title and commencement

1) These Rules may be called the Pro-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.]

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions .

In these rules, unless the context otherwise requires,

(a) "Act" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);

(b) "employee" means a person working in or employed by a 2[Genetic Counselling Centre, Genetic Laboratory,

Genetic Clinic, Ultrasound Clinic and Imaging Centers, and includes those working on part-time, contractual,

consultancy, honorary or on any other basis;

(c) "Form" means a Form appended to these rules;

(e) "Section "means a section of the Act;

(f) words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively assigned to them in the Act.

3. Minimum requirements

The qualifications of the employees, the requirement of equipment etc. for a Genetic Counselling Centre, Genetic

Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall be as under:

(I) Any person being or employing

(i) a gynaecologist or a paediatrician having six months experience or four weeks training in genetic counseling;

or

(ii) a medical geneticists, having adequate space and educational charts/models/equipments for carrying out genetic counselling may set up a genetic counselling center and get it registered as a genetic counseling center.

(2) (a) Any person having adequate space and being or employing

(i) a Medical Geneticist and

(ii) a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate prenatal diagnostic techniques, tests or procedures, may set up a genetic laboratory.

(b) Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, bio-chemical studies and molecular studies :-

(i) Chromosomal studies:

(I) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
(2) Photo-microscope with fluorescent source of light.
(3) Inverted microscope.
(4) Incubator and oven. ,
(5) Carbon dioxide incubator or closed system with 5% CO2 atmosphere.
(6) Autoclave.
(7) Refrigerator
(8) Water bath
(9) Centrifuge
(10) Vortex mixer

(II) Magnetic stirrer
(12) pH Meter.
(13) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
(14) Double distillation apparatus (glass).
(15) Such other equipments as may be necessary.

(ii) Biochemical studies: (requirements according to tests to be carried out) .
(I) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
(2) Inverted microscope.
(3) Incubator and oven.
(4) Carbon dioxide incubator or closed system with 5% CO2 atmosphere.
(5) Autoclave.
(6) Refrigerator.
(7) Water bath.
(8) Centrifuge.
(9) Electrophoresis apparatus and power supply.
(10) Chromatography chamber.
(11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta-counter) or fluorometer-for various bio-chemical tests.
(12) Vortex mixer.
(13) Magnetic stirrer.
(14) pH meter.
(15) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
(16) Double distillation apparatus (glass).
(17) Liquid nitrogen tank.
(18) Such other equipments as may be necessary.
(iii) Molecular studies: -
(I) Inverted microscope.
(2) Incubator.
(3) Oven.
(4) Autoclave. —
(5) Refrigerators (4 degree and minus 20 degree Centigrade).
(6) Water bath.

(7) Microcentrifuge.
(8) Electrophoresis apparatus and power supply.
(9) Vertex mixer.
(I 0). Magnetic stirrer.
(11) pH meter.
(12) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
(13) Double distillation apparatus (glass).
(14) P.C.R. machine.
(15) Refrigerated centrifuge.
(16) U. V. illuminator with photographic attachment or other documentation system.
(17) Precision micropipettes.
(18) Such other equipments as may be necessary.

(3)(1) Any person having adequate space and being or employing:

(a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields; or
(b) a Sonologist, imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning; or
(c) a medical geneticist, may set up a genetic clinic/ultrasound clinic/imaging centre.
(2) The Genetic Clinic/ultrasound clinic/imaging center should have or acquire such of tile following equipments, as may be necessary for carrying out the tests or procedures-
(a) Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist.
(b) An u!tra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography. ‘
(c) Appropriate catheters and equipment for carrying out chorinoic villi aspirations per vagina or per abdomen.
(d) Appropriate sterile needles for amniocentesis or cordocentesis.
(e) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
(f) Equipment for dry and wet sterilization.
(g) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.
(h) Genetic Works Station.

3A. Sale of ultrasound machines /imaging machines

(I) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell, distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Center, laboratory, Clinic, body or person is registered under the Act.

(2) The provider of such machine/equipment to any person/body registered under the Act shall send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/equipment has been provided.

(3) Any organization or person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorising, in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person purchasing or getting authorisation for using such machine/equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.

4. Registration of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres

(1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A, duly accompanied by an Affidavit containing -

(i) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/ Ultrasound Clinic/Imaging Centre/Combination thereof, as the case may be, shall not conduct any test or procedure, by whatever name called for selection of sex before or after conception or for detection of sex of foetus except for diseases specified in section 4(2) nor shall the sex of foetus be disclosed to any body; and

(II) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/Combination thereof, as the case may be shall display prominently a notice that they don not conduct any technique, test or procedure etc by whatever name called, for detection of sex of foetus or for selection of sex before or after conception.

(2) The Appropriate Authority, or any person In his office authorized In this behalf, shall acknowledge receipt of the application for registration, in the acknowledgement slip provided at the bottom of Form A, immediately if delivered
at the office of the Appropriate Authority, or not later .than the next working day if received by post.

5. Application Fee

(I) Every application for registration under rule 4 shall be accompanied by an application fee of:-

(a) Rs. 3000.00 for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging .Centre.

(b) Rs. 4000.00 for an institute, hospital, nursing home, or any place providing jointly the service of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof:

PROVIDED that if an application for registration of any Genetic Clinic/Laboratory/Centre etc., has been rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection: PROVIDED FURTHER that any subsequent

application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

(2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank payable at the headquarters of the Appropriate Authority concerned. The fees collected by the Appropriate Authorities for registration of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre or any other body or person under sub-rule (I), shall be deposited by the Appropriate Authority concerned in a bank account opened in the name of the official designation of the Appropriate Autl1ority concerned and shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and these rules.]

6. Certificate of registration

(1) The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, place the application before the Advisory Committee for its advice.

(2) Having regard to the advice of the Advisory Committee, the Appropriate Authority shall grant a certificate of registration, in a duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres at a conspicuous place at its place of business: PROVIDED that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic Clinic to conduct one or more specified pre-natal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and _standards maintained by such laboratory or clinic.

(3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the .requirements of the Act and these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C.

(4) An enquiry under sub-role Including Inspection at the premises of the Genetic CounsellIng Centre, Genetic Laboratory, Gene/tic Clinic, Ultrasound Clinic and Imaging Centres shall be carried out only after due notice given to the applicant by the Appropriate Authority.

(5) Grant of certificate of registration or rejection of application for registration shall be communicated to the applicants specified in Form B or Form C, as the case may be, within a period or ninety days from the date of receipt of application for registration. -

(6) The certificate of registration shall be non.-transferable. In the event of change of ownership or change of management or on ceasing to function as a [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres both copies, of the certificate of registration shall be surrendered to the Appropriate Authority.

(7) In the event of change of ownership or change of management of the 2[Genetic CouI15eliing Centre, Genetic .Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres, the new owner or fl1anager of such centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration. .

7. Validity of registration -

Every certificate of registration shall be valid for a period of five years from the date of its issue.

8. Renewal of registration

(1) An application for renewal of certificate of registration shall be made in duplicate in Form A, to the Appropriate Authority thirty days before the date of expiry of the certificate of registration. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in sub-rule (2) of rule 4.

(2) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules and having regard to the advice of the Advisory Committee in .this behalf, renew the certificate of registration, as Specified in Form B, for a further period of five years from the date of expiry of the certificate of registration earlier granted.

(3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of it- the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not .complied with the .requirements of the Act and these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and Communicate such rejection to the applicant as specified in Form C.

(4) The fees payable for renewal of certificate of registration shall be one-half of the fees provided in sub-rule (1) of rule 5. (5) On receipt of the renewed certificate of registration in duplicate or on receipt of communication of rejection of application for renewal, both copies of the earlier certificate of registration shall be surrendered. immediately to the Appropriate Authority by the Genetic CounsellIng Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres.

(6) In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shal1 be deemed to have been renewed.

9. Maintenance and preservation of records ,

2[(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic .counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouse or father and the date on which they first report for such counselling, procedure or test.)

(2). The record to be maintained by every Genetic Counselling Centre, in respect of each woman counselled shall be as specified in Form D.

(3) The record to be maintained by every Genetic Laboratory, in respect of each man or woman subjected to any pre- natal diagnostic procedure/technique/test, shall be as specified in Form E.

(4) The record to be maintained by every Genetic Clinic, in respect of each man or woman subjected to any pre-natal diagnostic procedure/technique/test, shall be as specified in Form F.

(5) The Appropriate: Authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place address and equipment installed shall also be preserved as permanent records.

(6) All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres for a period of two years from the date of completion of counselling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

(7) In case the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinicetic Clinic, Ultrasound Clinic and Imaging Centres maintain records on computer or other eletronic equipment, a printed copy of the record shall be taken and preserved after authentication by a person responsible for such record.

(8) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall send a complete report in respect of all pro-conception or pregnancy related procedures/techniques/tests conducted by them in respect of each month by 5th day of the following month to the concerned Appropriate Authority..

10. Conditions for conducting pre-natal diagnostic procedures ,;

(1) Before conducting pre implantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent,

as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him.

(IA) Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the

pregnant woman to ‘any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.

(2) All the State Governments and Union territories may issue translation of Form G in languages used in tile State or Union Territory and where no official translation in a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands. ,

11. Facilities for inspection

(I) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or test capable of pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorized by the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement therefore or for selection of sex before or after conception or for detection/disclosure of sex of foetus or for detection of cases of violation of the provisions of the Act in any other manner.

(2) The Appropriate Authority or the officer authorised by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organisation if the organisation has not got itself registered under the Act. These machines of the organizations may-be released if such organisation pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception

12. Procedure for search and seizure

(1) The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or more independent witnesses for the purposes of search and examination of any record, register, .document, book, pamphlet, advertisement, or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act.

Explanation: In these rules-

(1). 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an ultrasound centre/imaging centre/nursrng home/hospital/ institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing my procedure technique or test for pre-natal detection of sex of foetus, is used;

(2) 'material object' would include records, machines and equipments; and

(3) 'seize' and 'seizure' would include 'seal' and 'sealing' respectively.

(2) A fist of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres and seized shall be prepared in duplicate at the place of effecting the seizure. Both copies of such .list shall be signed on every page by the Appropriate Authority or the officer authorized in this behalf and by the witnesses to the seizure:

PROVIDED that the list may be prepared, in the presence of the witnesses, at a place other than the place of seizure if, for reasons to be recorded in writing, it is not practicable to make the list at the place of effecting the seizure.

(3) One copy of the list referred to in sub-rule (2) shall be handed over, under acknowledgement, to the person from .whose custody the document, record, register, book, pamphlet, advertisement or any other material object have been seized:

PROVIDED that a copy of the list of such document, record, register, book pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of-the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres. if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seized is available at the place of effecting the seizure.

(4) If any material object seized is perishable in nature, the Appropriate Authority, or the officer authorized in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required:

PROVIDED that the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall be made in the list of seizure.

.

(5) In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangements, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres for safe keeping, isting and removal of documents, records, book or any other material object to be seized, and to prevent any ampering with such documents, records, books or any other material object.

13. Intimation of changes in employees, place or equipment-

Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, UltraSound Clinic and Imaging Centres shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a
period of thirty days of such change.

14. Conditions for ailalysis or test and pre-natal diagnostic procedures

1) No Genetic laboratory shall accept for analysis or test any sample, unless referred to it by a Genetic Clinic.

(2) Every pre—natal diagnostic procedure shall invariably be immediately preceded by locating the foetus and placenta through ultrasonography, and the pre-natal diagnostic procedure shall be done under direct ultrasonographic monitoring so as to prevent any damage to the foetus and placenta.

15. Meetings of the Advisory Committees

The intervening period between any two meetings of Advisory Committees constituted under sub-section (5) of section 17 to advise the Appropriate Authority shall not exceed sixty days.

16. Allowanccs to members ofii.e Central Supervisory Board

(1) The ex-officio members, and other Central and State Government officers appointed to the Board will be entitled to Traveling Allowances and Daily Allowances for attending the meetings of the Board as per the Travailing
Allowances Rules applicable to them.

(2) The non-official members appointed to, and Members of Parliament elected to, the Board will be entitled to Travelling Allowance and Daily Allowance or attending the meetings of the Board as admissible to non-official and Members of Parliament as the case may be, under the Travelling Allowances rules of the Central Government.

17. Public Information

(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to the effect that disclosure of the sex of the foetus is prohibited under law.

(2) At least one copy each of the Act and these rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres and shall be made available to the clientele on demand for perusal.

(3) The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinic and Imaging Centres and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field.

18. Code of Conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, 'Imaging Centres etc.

All persons including the owner.. employee or any other persons associated with Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres registered under the Act/these Rules shall:-

(i) not conduct or associate with, or help in carrying out detection or disclosure of Sex of foetus in any manner;

(ii) not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-natal diagnostic techniques/ procedures, techniques and tests including ultrasonography;

(iii) not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex before or after conception or for detection of sex of foetus except for the purposes specified in sub-section (2) of section 4 of the Act;

(iv) not conduct or cause to be conducted or aid .in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/these Rules;

(v) ensure that no provision of the Act and these Rules are violated in any manner;

(yj) ensure that the person, conducting any techniques or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and these Rules which are punishable offences;

(vii) help the law enforcing agencies in bringing to book the violators of the provisions of the Act and these Rules;

(viii) display his/her name and designation prominently on the dress worn by him/her;

(ix) write his/her name and designation in full under his/her signature;

(x) on no account conduct or allow/cause to be conducted female foeticide;

(xi) not commit any other act of professional misconduct

19. Appeals

(1) Anybody aggrieved by the decision of the Appropriate Authority at sub-district level may appeal to the Appropriate Authority at district level within 30 days of the order of the sub-district level Appropriate Authority.
(2) Anybody aggrieved by the decision of the Appropriate Authority at district level may appeal to the Appropriate Authority at State/UT level within 30 days of the order ,of the District level Appropriate Authority.
(3) Each appeal shall be disposed of by the district Appropriate Authority or by the State/Union Territory Appropriate Authority, as the case may be, within 60 days of its receipt.
(4) IF AN APPEAL IS NOT MADE WITHIN THE TIME AS PRESCRIBED UNDER SUB-RULE (I), (2) OR (3), THE APPROPRIATE AUTHORITY UNDER THAT SUB-RULE MAY CONDONE THE DELAY IN CASE HE/SHE IS SATISFIED THAT APPELLANT WAS PREVENTED FOR SUFFICIENT CAUSE FROM MAKING SUCH APPEAL.

SCHEDULE -I

Refer rule 3(1)

REQUIREMENTS FOR REGISTRATION OF A GENETIC
COUNSELLING CENTRE .

A.PLACE ...

A room with an area of seven (7) square meters.

B. EQUIPMENT

Educational charts/models.

C.EMPLOYEES

Anyone of the following:

(I) Medical Geneticist.

(2) Gynaecologist with 6 months' experience, in genetic counselling, or having completed 4 weeks' training in genetic counselling.

(3) Paediatrician with 6 months' experience in genetic counselling, or having completed 4 weeks' training in' genetic counselling.

SCHEDULE-II

[Refer rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC LABORATORY

A. PLACE

A room with adequate space for carrying out tests.

B. EQUIPMENT

These are categorised separately for each of the under-mentioned studies.

Chromosomal studies:

(I) Laminar flow-hood with ultraviolet and fluorescent light or other suitable culture hood.
(2) Photo-microscope with fluorescent source of light.
(3) Inverted microscope.
(4) Incubator and oven.
(5) Carbon-dioxide incubator or closed system with 5% CO_2 atmosphere. -

(6) Autoclave.
(7) Refrigerator.
(8) Water bath.
(9) Centrifuge.
(10) Vortex mixer.
(1 I) Magnetic stirrer.
(12) pH meter.
(13) A sensitive balance (preferable electronic) with sensitivity of 0.1 miligram.
(14) Double distillation apparatus (glass).
Biochemical studies :
requirements according to tests to be carried out)
(I) Laminar flow-hood with ultraviolet and fluorescent light or other suitable culture hood.
(2) Inverted microscope.
(3) Incubator and oven.
(4) Carbon-dioxide incubator or closed system with 5% CO2 atmosphere.
(5) Autoclave
(6) Refrigerator.
(7) Water bath.
(8) Centrifuge.
(9) Electrophoresis apparatus and power supply.
(10) Chromatography chamber.
(11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests. -.
(12) Vortex mixer
(13) Magnetic stirrer.
(14) pH meter.
(15) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
(16) Double distillation apparatus (glass).
(17) Liquid nitrogen tank.
Molecular studies:
(1) Inverted microscope.
(2) Incubator.
(3) Oven.
(4)Autoclave.
(5) Refrigerators (4 degree and minus 20 degree Centigrade)
(6) Water bath.
(7) Microcentrtifuge.
(8) Electrophoresis apparatus and power supply.
(9) Vortex mixer.
(10) Magnetic stirrer.
(11) pH meter.
(12) A sensitive balance (preferable electronic) with sensitivity of 0.1 miligram.
(13) Double distillation apparatus (glass).
(14) P.C.R. machine
(15) Refrigerated centrifuge.
(16) U. V. illuminator with photographic attachment or other documentation system.

(I7) Precision micropipettes

C. EMPLOYEES
(1) A Medical Geneticist
(2) A laboratory technician having a B.Sc. degree in Biological Sciences or a degree or a diploma in medical laboratory course with at least one year's experience in conducting appropriate pre-natal diagnostic tests.

SCHEDUL- III

[Refer rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC CLINIC

A.PLACE
A room with an area of twenty (20) square metres with appropriate aseptic arrangements.
I
B. EQUIPMENT
(I) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.
(2) Equipment, accessories, necessary for other facilities required for operations envisaged in the Act.
(a) An ultra-sonography machine.
(b) Appropriate cathethers and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.
(c) Appropriate sterile needles for amniocentesis or cordocentesis.
(d) A suitable foetoscope with an appropriate: accessories for foetoscopy, foetal skin or organ'biopsy or foetal blood sampling shall be optional. -j
J) Equipment for dry and wet sterilization.
I) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.
C. EMPLOYEES
(I) A Gynaecologist with adequate experience in pre-natal diagnostic procedures (should have performed at least 20 procedures under supervision of a Gynaecologist experienced in the procedure which is going to be carried out, for example chorionic villi biopsy, amniocentesis, cordocentesis and others as indicated at B above). -.
(2) A Radiologist or Registered Medical Practitioner for carrying out ultrasonography. The required experience shall be 100 cases under supervision of a similarly qualified person experienced in these techniques.

These constitute the minimum requirement of equipment for conducting the relevant procedure.

FORM -A

[Refer rules.4(1) and 8(1)]

(To be submitted in Duplicate with supporting documents as enclosures)

APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF AGENETIC COUNSELLING CENTRE/ GENETIC LA.BORATORY /GENETIC CLINIC/ ULTRASOUND CLINIC/IMAGING CENTRE

1 Name of the applicant.
(Indicate name of the organisation sought to be registered)
2. Address of the applicant
3. Type of facility to be registered
(Please specify whether the application is for registration of a Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Ciinic/lmaging Centre or any combination of these.)
4. Full name and address/addresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre with Telephone/Fax number(s)/Telegraphic/Telex/E-mail address(es).
5.Type of ownership of Organisation (individual ownership/partnership: company/co-operative/any other to be specified). In case type of organization is other than Individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosure.
6. Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Nursing Home/ Private Clinic/Private Laboratory/any other to be stated).
7. Specific pre-natal diagnostic procedures/tests for which procedures/test for which approval is sought
(a) Invasive (i) amniocentesis/chorionic villi aspiration/chromosomal/ biochemical/molecular studies: (b) Non-Invasive Ultrasonography :;
Leave blank if registration is sought for Genetic Counselling Centre only.
8. Equipment available with the make and model of each equipment (List to be attached on a separate sheet).
(a) Facilities available in the Counselling Centre.
(b) Whether facilities are or would be available in the Laboratory/Clinic for the following tests:
(i) Ultrasound
(ii) Amniocentesis
(iii) Chorionic villi aspiration
(iv) Foetoscopy
(v) Foetat biopsy
(vi) Cordocentesis
Whether facilities are available in the Laboratory/Clinic for the following:
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies
(iv) Pre-implantation genetic diagnosis
10. Names, qualifications, experience and registrat1fJn number of employees (may be furnished as an enclosure)
II. State whether the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ultrasound clinic/imaging center qualifies for registration in terms of requirements laid down in Rule 3.

12. For renewal applications only:
(a) Registration No.
(b) Date of issue and date of expiry of existing certificate of registration.
13. List of Enclosures: ...
(Please attach a list of enclosures/supporting documents attached to this application.)

Date:
Place:

Name, designation and signature of the person authorised to sign on behalf of the organisation to be registered.

DECLARATION.

I, Sh./SmtJKum./Dr……. son/daughter/wife of…… aged……. years resident of…….. working as (indicate designation)…….. in (indicate name of the organisation to be registered) ……. hereby declare that I have read and understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.

I also undertake to explain the said Act and Rules to all employees of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ultrasound clinic/imaging centre in respect of which registration is sought and to ensure that Act and Rules are fully complied with.

Date :
Place: . (……)

Name, designation and signature of the person authorized to sign on behalf of tile organisation to be registered

.

SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

ACKNOWLEDGEMENT

[Refer rule-s 4(2) arid 8(1)]

The application in Form A in duplicate for grant*/renewal* of registration of Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic's/Ultrasound Clinic*/Imaging Centre by ……., (Name and address of

applicant) has been received by the Appropriate Authority…… On (date).

*The list of enclosures attached to the application in Form- A has been verified with the enclosures submitted and found to be correct.

.

OR

*On verification it is found that following documents mentioned in the list of enclosures are not actually enclosed.

This acknowledgement does not confer any rights on the applicant for grant or renewal of registration. .

Date:

(……..)

Place: Signature and Designation of Appropriate Authority, or authorised person in the Office of the Appropriate Authority

SEAL

FORM -B

[Refer rules 6(2), 6(5) and 8(2)]

CERTIFICATE Of REGISTRATION

(To be issued in duplicate)

1. In exercise of the powers conferred under section 19(I) of tile Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority……. hereby grants registration to the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound

Clil1ic*/lmaging Centre* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests/ultrasonography under the aforesaid Act for a period of five years ending on ……..

2. This registration is granted subject to the aforesaid Act and Rules. there under and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.

A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.

B.

B. Pre-natal diagnostic procedures* approved for (Genetic Clinic). Non-Invasive
(i) Ultrasound
Invasive
(ii) Amniocentesis
(iii) Chorionic villi biopsy
(iv) Foetoscopy.
(v) Foetal skin or organ biopsy
(vi) Cordocentesis
(vii) Any other (specify)

C. Pre-natal diagnostic tests* approved (for Genetic Laboratory).
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies
D. Any other purpose (please specify)

3. Model and make of equipments being used (any change is to be intimated to the Appropriate Authority under rule 13).
4. Registration No. allotted.
5. Period of validity of earlier Certificate of Registration. (For renewed Certificate of Registration only)

From……..To ……..
Signature, name and designation of the Appropriate Authority

Date:

FORM-C

[Refer rules 6(3),,6(5) and 8(3)]

REJECTION OF APPLICATION FOR GRANT/RENEWAL OF REGISTRATION

In exercise of the powers conferred under section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, the Appropriate Authority hereby rejects the application for grant*/ renewal * of registration of the under mentioned

Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/ Ultrasound Clinic*/Imaging Centre*

1. Name and address of the Genetic Counselling Centre./Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre.

2. REASONS FOR REJECTION OF APPLICATION FOR GRANT/RENEWAL OF REGISTRATION:

Signature, name and designation of
the Appropriate Authority with
SEAL of Office

Date:

Place:

Strike out whichever is not applicable or necessary.

FORM-D

[Refer rule 9(2)]

MAINTENANCE OF RECORDS BY THE GENETIC COUNSELLING CENTRE

1. Name and address of Genetic Counselling centre.
2. Registration No.
3. Patient's name
4. Age
5. Husband's/Father's name
6. Full address with Tel. No., if any
7. Referred by (Full name and address of Doctor(s) with registration No. (s)
(Referral note to be preserved carefully with case papers)
8. Last menstrual period/weeks of pregnancy
9. History of genetic/medical disease in the family (specify) Basis of diagnosis:
(a) Clinical
(b) Bio-chemical
(c) Cytogenetic
(d) Other (e.g. radiological, ultrasonography)
10. Indication for pre-natal diagnosis

A. Previous child/children with:
(i) Chromosomal disorders
(ii) Metabolic disorders
(iii) Congenital anomaly
(iv) Mental retardation
(v) Haemoglobinopathy
(vi)' Sex linked disorders
(vii) Single gene disorder

(viii) Any other (specify)

B. Advanced maternal age (35 years or above)

C. Mother/father/sibling having genetic disease (specify)

D. Others (specify)

11. Procedure advised
(i) Ultrasound
(ii) Amniocentesis
(iii) Chorionic villi biopsy
(iv) Foetoscopy
(v) Foetal skin or organ biopsy
(vi) Cordocentesis
(vii) Any other (specify)
.Laboratory tests to be carried out
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies .
(iv) Pre-implantation genetic diagnosis
13. Result of diagnosis If abnormal give details Normal/Abnormal
14. Was MTP advised?
15. Name and address of Genetic Clinic to which patient is referred.
16. Dates of commencement and completion of genetic counseling.

Name, Signature and Registration No. of the Medical Geneticist/
Gynaecologist/Paediatrician administering Genetic Counselling

Place:

Date:

FORM -E
[Refer rule 9(3)
MAINTENANCE OF RECORDS BY GENETIC LABORATORY

1. Name and address of Genetic Laboratory
2. Registration No
3. Patient’s name
4. Age
5. Husband’s/Father’s name
6. Full address with Tel. No., if any
7. Referred by/sample sent by (full name and address of Genetic Clinic)
(Referral note to be preserved carefully with case papers)
8. Type of sample: Maternal blood/Chorionic -yillus sample/amniotic fluid/Foetal blood or other foetal tissue (specify)

9. Specify indication for pre-natal diagnosis

A. Previous child/children with

(i) Chromosomal disorders -
(ii) Metabolic disorders
(iii) Malformation(s)
(iv) Mental retardation
(v) Hereditary haemolytic anaemia
(vi) Sex linked disorder
(vii) Single gene disorder
(viii) Any other (specify)

B. Advanced maternal age (35 years or above)
C. Mother/father/sibling having genetic disease (specify)
D. Other (specify)

10. Laboratory tests carried out (give details)
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies
(iv) Pre-implantation gentic diagnosis
11. Result of diagnosis If abnormal give detail. Normal/Abnormal
12. Date(s) on which tests carried out.

The results of the Pre-natal diagnostic tests were conveyed to……. On……

Name, Signature and Registration No. of the
Medical Geneticist/Director of the Institute

Place :

Date :

FORM -F

[Refer proviso to section 4(3), rules 9(4) and 10 (IA)]

MAINTENANCE OF RECORD IN RESPECT OF PREGNANT WOMAN BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

1.Name and address of the Genetic Clinic/Ultrasound Clinic/Imaging Centre. .
2.Registration No.
3.Patient's name and her age
4. Number of children with sex of each child
5. Husband's/Father's name ,
6. Full address with Tel.No., if any
7. Referred by (full name and address of Doctor(s)/Genetic Counselling Centre (Referral note to be preserved carefully with case papers)/self referral
8. Last menstrual period/weeks of pregnancy
9. History of genetic/medical disease in the family (specify)
Basis of diagnosis:

(a) Clinical
(b) Bio-chemical
(c) Cytogenetic
(d) Other (e.g. radiological, ultrasonography etc. specify) .
10. Indication for pre-natal diagnosis
A. Previous child/children with:
(i) Chromosomal disorders
(ii) Metabolic disorders
(iii) Congenital anomaly
(iv) Mental retardation
(v) Haemoglobinopathy
(vi) Sex linked disorders .
(vii) Single gene disorder
(viii) Any other (specify) ..'
B. Advanced maternal age (35 years)
C. Mother/father/sibling has genetic disease (specify)
D. Other (specify)
Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.
Non-Invasive
(i) Ultrasound (specify purpose for which ultrasound is to be done during pregnancy) [List of indications for ultrasanography of pregnant women are given in the note below.]
Invasive
(ii) Amniocentesis
(iii) Chorioic Villi aspiration
(iv) Foetal biopsy
(v) Cordocentesis
(vi) Any other (specify)
12. Any complication of procedure -please specify .
13. Laboratory tests recommended
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies
(iv) Pre-implantation genetic diagnosis
14. Result of
(a) pre-natal diagnostic procedure (give details)
(b) Ultrasonography Normal/Abnormal
(specify abnormality detected, if any).
15. Date(s) on which procedures carried out.
16. Date on which consent obtained. (In case of invasive)
17. The result of pre-natal diagnostic procedure were conveyed to…… on……. 18. Was MTP advised/conducted?
19. Date on which MTP carried out

Name, Signature and Registration number of the
Gynecologist/Radiologist/Director of the Clinic

Date:

Place: .

DECLARATION OF PREGNANT WOMAN

I, Ms……:
(name of the pregnant .woman) declare that by undergoing
ultrasonography/image scanning etc. I do not want to know the sex of my foetus.

Signature/Thump impression of pregnant woman

DECLARATION OF DOCTOR/PERSON CONDUCTING ULTRASONOGRAPHY/IMAGE SCANNING

I, …….. (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms…… (name of the pregnant woman),

I have neither detected nor disclosed the sex of her foetus to any body in any manner. .

Name and signature of the person conducting
ultrasonography/image Scanning/Director or
owner of genetic clinic/ultrasound clinic/imaging centre.

Important note:

(i) Ultrasound is not indicated/advised/performed to determine the sex of foetus except for diagnosis of sex-linked diseases such as Duchenne Muscular Dystrophy, Haemophilia A & B etc.

(ii) During pregnancy Ultrasonography should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy.

(I) To diagnose intra-uterine and/or ectopic pregnancy and confirm viability. :

(2) Estimation of gestational age (dating)

(3) Detection of number of foetuses and their chorionicity.

(4) Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.

(5) Vaginal bleeding/leaking.

(6) Follow-up of cases of abortion.

(7) Assessment of cervical canal and diameter of internal os.

(8) Discrepancy between uterine size and period of amenorrhoea.

(9) Any suspected adenexal or uterine pathology/abnormality.

(10) Detection of chromosomal abnormalities, foetal structural defects and other abnormalities and their follow-up.

(11) To evaluate foetal presentation and position.

(12) Assessment of liquor amnii.

(13) Preterm labour/pretenn premature rupture of membranes. “

(14) ‘Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retroplacental haemorrhage, abnormal adherence etc.).

(15) Evaluation of umbilical cord-presentation,. insertion, nuchal encirclement, number of vessels and presence of true knot.

(16) Evaluation of previous Caesarean Section scars.
(17) Evaluation of foetal growth parameters, foetal weight and foetal well being.
(18) Colour flow mapping and duplex Doppler studies.
(19) Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. and their follow-up. -
(20) Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, foetal blood sampling, foetal skin biopsy, amnioinfusion, intrauterine infusion, placement of shunts etc.
(21) Observation of intra-partum events.
(22) Medical/ surgical conditions complicating pregnancy.
(23) Research/scientific studies in recognized institutions. .
Person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic/centre in Form-F and any deficiency or inaccuracy found therein & shall amount to contravention of provisions of section 5 or section 6 of the Act, unless contrary is proved by the person conducting such ultrasonography.]

FORM -G
[Refer rule 10]
CONSENT
(For invasive techniques) .

I, ……. wife/daughter of…… Age…….years residing at…….. hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic procedures.

I wish to undergo the preimplantation/pre-natal diagnostic technique/test/procedures in my own interest to find out the possibility of any abnormality (i.e. disease / deformity/disorder) in the child I am carrying.
I Undertake not to terminate the pregnancy if the pre-natal procedure/technique/ test conducted show the absence of disease/deformity/disorder.

I understand that the sex of the foetus will not be disclosed to me.

I understand that breach of this undertaking will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and rules framed there under.

Date: Signature of the pregnant woman
PIace:

(I have explained the contents of the above to the patient and her companion (Name…… Address ……., Relationship ……) in a language she/they understand.

Name, Signature and/Registration
.Number of Gynaecologist / Medical Geneticist/
Radiologist/Paediatrician/Director of
the Clinic/Centre/Laboratory

Date:

Name, Address and Registration number of
Genetic Clinic/Institute
SEAL

FORM -H
[Refer rule 9(S)]
MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS FOR GRANT/REJECTION OF REGISTRATION UNDER THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT, 1994

1. Sl. No.
2. File number of Appropriate Authority.
3. Date of receipt of application for grant of registration.
4. Name, Address, Phone/Fax etc., of Applicant.
S. Name and address(es) of Genetic Counselling Centre*/Genetic Laboratory*/ Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.
6. Date of consideration by Advisory Committee and recommendation of Advisory Committee, in summary.
7. Outcome of application (state granted/rejected and date of issue of orders-record date of issue of order in Form B or Form C).
8. Registration number allotted and date of expiry of registration.
9. Renewals (date of renewal and renewed upto).
10. File number in which renewals dealt.
11. Additional information, if any.

Name, Designation and Signature
Appropriate Authority

Guidance/or Appropriate Authority

(a) Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.
(b) *Means strike out whichever is not applicable.
(c) On renewal, the Registration Number of-the Genetic Counselling Centre/Genetic Laboratory (Genetic clinic/Ultrasound Clinic/imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management.
(d) Registration number shall not be allotted twice.
(e) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre may be allotted a folio consisting of two pages of the Register for recording Form H.
(f) The space provided for ‘additional information’ may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.

(g) Every folio (i.e. pages) of the Register shall authenticated by signature of the Appropriate Authority), with date, and every subsequent entry shall also be similarly authenticated.

Note:

The Principal Notification was published in the Gazette of India vide No. GSR I(E),dt. 1-1-1996 and last Notification No. GSR 109(E), dt. 14-2-2003.

CONSENT FORM PROTOTYPE

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Consent for General Surgery', Anaesthetics and Other Medical Care-

.I …….give my full, free and voluntary consent for the purpose of my surgery/procedure/test/examination ……: (state the nature and extent of the procedure), the nature and consequences of which have been fully explained to me and shall be performed by .Dr……..

II. I consent to the performance of additional procedure(s)/operation than one mentioned above which the doctor or his associates/assistants may consider necessary during the course of the operation.
III. I consent to the administration of such an anaesthetics as may be considered necessary by the doctor with the exception of (mention 'none' / spinal anaesthesia, etc).
V. I consent! do not consent to the photographing or televising and recording of my body, provided my identity is not revealed.
V. I consent to disposal by hospital authorities of any tissues or parts, which may be removed.
VI. I have been fully explained about the alternative methods of treatment, the risks involved, and the possibility of complications. No guarantee or assurance has been given by anyone as to the results that may be obtained.
VII. The above information has been explained to me in a language and/or manner that I understand. My mother tongue is……..

.

Signature of the patient (or person authorized) ……..

Educational Status/Qualification of the patient ……..

Witness…….

CERTIFICATE OF LEAVE FOR ILLNESS. FITNESS CERTIFICATE

As per Indian Medical Council (Professional conduct. Etiquette and Ethics) Regulations, 2002 (Appendix-2), the Medical illness/Fitness Certificate that should be used by every doctor in this country is-

FORM OF CERTIFICATE RECOMMENDED FOR LEAVE OR EXTENSION OR COMMUNICATION OF LEAVE AND FOR FITNESS

Signature of patient

or thulnb impression……..
To be filled in by the applicant in the presence of the Government Medical Attendant, or Medical Practitioner.

Identification marks::-

1……
2…….

I, Dr……. after careful examination of the case certify hereby that……whose signature is given above is suffering from……. and I consider that a period of absence from duty of…… with effect from…… is absolutely necessary for the restoration of his health.

I, Dr…….after careful examination of the case certify hereby that…….. ,on restoration of health is now fit to join service.

Place…… Signature of Medical attendant.
Date …… Registration No……..

Medical Council of India / State Medical Council of …….State)

Note:- The nature and probable duration of the illness should also be specified. This certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.

2. There is no legal language of consent; the law does not provide any standard language of consent. The language, given above is an example and may be used for guidance. It may be modified according to the nature of procedure,
test, surgery, etc.

3. Consent should never be a ‘global consent’ for ‘everything…….’ there is nothing like ‘consent for everything !’

4. The consent should mention the nature and extent of the procedure or operation authorised i.e. it has to be always specific for each & everything’-an operation, a procedure, a sample, an organ donation, etc.,
5. It should be ideally in at least 2 languages- one of which the patient can understand.
6. It must be obtained after the patient is informed about what it is given for, its side-effects if any, any alternatives to the said procedure or test, etc.

7. What is the legal necessity for obtaining consent?

(a) It provides the doctor legal protection in case of an action for negligence, specially in cases where the patient charges the doctor of not disclosing all the facts.
(b) Consent is necessary as per Section 88 IPC which says- ‘ Act not intended to cause death, done by consent in good faith for person’s benefit’.
© An operation without consent but with successful outcome is not a defense in a court of law for a charge of assault or battery by the patient. An operation without consent amounts to assault on the patient.

8. If a patient refuses to treatment then the doctor should obtain this in writing from the patient. A doctor is not responsible for the consequences of any illness that the patient might suffer from. However there are ethical considerations regarding this as a patient cannot be left to die if it endangers the life of the patient because of refusal to treatment.

9. The minimum legal age for giving informed consent in India is 12 years. A child below that age cannot sign any consent form. Below this age the parents’ (natural guardians of the child) consent is needed. A person above 18years of age can give consent for anything i.e. any test or procedure or surgery, etc. Between the ages of 12 to 18 years a person can give consent only for a limited number of situations which do not involve harm to the body in any way.

10. Consent is necessary for blood transfusion, organ transplantation, artificial insemination, sterilization, radiotherapy and all forms of invasive diagnostic and the rapeutic -procedures.
11. Regarding disclosure of information by a doctor to a patient, it is the relevance and not the quantity of information provided that is important. Disclosure should include the provisional diagnosis, differential diagnosis, scope and purpose of investigations being carried out, treatment options available and the benefits and risks with each one of them.

MEDICAL RECORD

As per Indian Medical Council (Professional conduct. Etiquette and Ethics) Regulations 2002, medical record of every patient should be preserved by every doctor in the following format (Appendix-3)-

FORMAT FOR MEDICAL RECORD
(see regulation 3.1)

Name of the patient:
Age:
Sex:
Address:
Occupation:
Date of 1st visit: .
Clinical note (summary) of the case:
Provisional Diagnosis:
Investigations advised with reports:
Diagnosis after investigation:
Advice:

Follow up
Date:
Observations:
Signature in full……..

Name of Treating Physician
Note-I) All medical records should be preserved by the doctor for 3 years from the date of prescription.
2) Provision should be made to maintain the records in electronic form for retrieval at a later date.

WHAT SHOULD I DO IN AN EMERGENCY?

What should a doctor do in case of an Emergency like a death in the hospital/ nursing home/clinic?
Should the police be informed? If a dead body is brought to a hospital of a young person or an old person, in either case-
-with a known illness (which mayor may not be the cause of death)
-without any pre-existing illness,
What is the duty of a doctor regarding information to the police? How to proceed in case of a brought dead patient- whether you have to proceed with cardio-pulmonary resuscitation or just to declare the patient dead because if you start CPR, it may be blamed that the doctor's injections etc. may have caused death.

Answer:
The police needs to be informed in every medico-legal case (MLC). Any case of an unknown admitted to a hospital is a medico-legal case and hence the police needs to be" informed about it.

When a patient has a known illness at the time of admission to the hospital it only helps the doctor to initiate the right treatment without any delay.

While administering treatment to a brought dead patient, the doctor should do whatever is prudent as per the best clinical judgment and whatever is necessary to save the life of the patient without bothering about the allegations that could be made by the patient or patient's relatives. Remember, the doctor's primary duty is to save the life of the patient and not to be deterred from the thought of allegations being put by the patient (or his care givers) for causing negligence or death of the patient. A doctor is held responsible for his actions or may be held guilty of being negligent as- much-as for "giving an injection" as for "not giving an injection when required" as an act of commission or omission, both can be responsible for causing negligence.

If the patient has no history of any pre-existing illness or if the patient with a known history of illness is responding to-treatment, the doctor should proceed on to investigate the patient as per his best clinical judgment and requirements of the case as for a routine 'non-medico legal case'.

.It is better that the doctor is the first one to report to the police in case of a death of a patient in a medico-legal case rather than tI1e patient. It not only gives the impression that the doctor was simply doing his duty as also that he did not have anything to hide.

A case of death due to a pre-existing illness i.e. ‘natural cause of death’ need not be reported to the unless a foul play is suspected to have been responsible in causation of death of the patient.

Any ‘unnatural’ cause of death needs to be reported to the police as it is a medico-legal case.

The standard of care in emergency cases in modem day practice implies three obligation viz. (1) Screening the patient; (2) Stabilizing the patient’s condition; (3) Discharge or transfer of the patient for better treatment.

Answer: .
l) The doctor has the prudence to decide upon the risk that might be concurred in transferring the patient to Ia higher center. The clinical judgment of a doctor in taking a decision in such a matter is definitely considered by a court of law in deciding matters of alleged negligence. If a patient needs transfer to any higher center and cannot be transferred because of his serious/precarious condition, it is left to the judgment of, of the treating doctor in such a matter. After all, any decision is taken in the best interest of the patient. The relatives should always be included in the decision-making in such matters and should be properly informed of the risks of transferring the patient to the higher center. If the relatives are still interested in transferring the patient in such circumstances, a high-risk consent should be taken before the transfer.

A patient should never be refused treatment in an emergency. If the facilities for management of the patient do not exist, he should be given first-aid and then may be referred to a higher center for needful.

A patient should also not be refused for not being able to deposit advance money at the time of admission in an emergency. (Pravat Kumar Mukherjee V s. Ruby General Hospital, National Consumer Commission, April, 2005).

A patient in an emergency should also not be refused treatment on the pretext that that it is a medico-legal case, even if it does not handle medico-legal cases (Supreme Court in Pt. Parmanand Katara V s. Union of India & Ors., AIR 1989 SC 2039).

However if a patient needs to be transferred to a higher center for further treatment, s/he should be transferred/shifted without delay.

An ambulance or other arrangements from the hospital should be available for transfer of the patient. Lack of reasonable facilities for transfer of patient (whenever indicated) to a higher center, by the treating hospital, could go against the favour of doctor/hospital in the court.

Again it could be debatable whether a doctor in a clinic should have 'all the arrangements' needed for transfer of an 'unmanageable patient' to a higher center. Under ordinary circumstances, such facilities of transfer or shifting of the patient to a higher center in an ambulance are not available at a clinic/dispensary. One could be safer in this regard by taking the plea of the fact that such facilities of transfer are not available even at a government run dispensary but that is not an 'excuse' anyway.

Answer

Poisoning whether suicidal or accidental (and obviously homicidal) is a medico-legal case and any medico-legal case needs to be reported to the police.
Attempt to commit suicide is a cognizable offence covered U/S 309 IPC.
(Practical tips -The law enforcing agencies are slightly 'soft' on enforcing this law. The general feeling is that nobody wants to prosecute a person who just survived from the clutches of death. The doctor's duty is primarily to give first-aid at1d treatment to the patient and also provide for psychiatric counseling services to the patient.)

Answer:
I) Consent is NOT necessary in an emergency case. It is implied (as per Sec. 92 IPC).
2) If a doctor has to operate upon a patient in at1 emergency and if the patient is unconscious, s/he need not wait for the patient's consent or the relatives to arrive to give consent for the surgery.
3) A doctor's primary responsibility in an emergency is to save the life of the patient and in this regard s/he is protected by law.
4) Section 92 of the IPC says- Act done in good faith for benefit of a person without consent- Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstance are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing .to be done with benefit:

Provided -

First -That this exception shall not extend to the intentional causing of death, or the attempting to cause death;
Secondly -That this exception shall not extend to the doing of anything which the person doing it knows to be likely to cause death, for any purpose other than the preventing of death or grievous hurt, or the curing of any grievous .disease or infirmity;
Thirdly -That this exception shall not extend to the voluntary causing of hurt, or to the attempting to cause hurt, for any purpose other than the preventing of death or hurt;
Fourthly -That his exception shall not extend to the abetment of any offence, to the committing of which offence it would not extend. –

What it basically means is -"Any harm caused to a person in good faith, even without that person's consent is not an offence, if the circumstances are such that it is impossible for that person to signify consent, or has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done in benefit".

(Practical tips -It is a very old and wrong practice to take the thumb impression of the unconscious patient on the consent form and the case-sheet before proceeding for surgery or a high-risk procedure in case of an emergency. For obvious reasons, such a consent is not valid- in fact it amounts to 'fraud'. Obviously, how can an unconscious patient give his consent for anything? A doctor need not fear in a case of emergency for want of consent. He shoud only take care of the patient and give treatment to him in emergency according to the laid down principles of medicine. Again, the consent should be in the native language of the patient a language that the patient can understand, if he is illiterate it may be in the language that he speaks. Obviously, avoid taking consent in English for a patient who mainly speaks & writes in Hindi. Remember, taking a 'global' consent at tl1e time of patient's admission into the hospital does not suffice in a court of law- consent should be specific f{)r each and every procedure, specifically so stated.)

Answer:

Death on the O. T. table is a medico—legal case and needs to be reported to the police.

A medico-legal autopsy is must in such a case or for that matter in case of death in a medico-legal case.

Answer:

A cause of death due to alleged medical negligence is a medico-legal case and a post-mortem is necessary in every medico-legal case. Similarly 'death on O. T. table' is also a medico-legal case and a post-mortem is necessary.

The fact that a 'high-risk' consent or 'death-on-table' consent has been taken does not mean that a post'-mortem need not be conducted or that any medical negligence aspect has been 'covered'.

There is no 'immunity' from any negligence at the hands of the treating doctor if a 'high-risk' consent or 'D.O.T.' consent has been taken. In any case, doctor should NOT 'avoid' a post-mortem examination (whenever indicated) as it mostly than not, goes in favour of the doctor (speaking from practical experience!).

Mostly, the death(s) in such cases (where a high risk or DOT consent is taken) are due to patient's serious condition or terminal illness or multi-organ failure or therapeutic misadventure, etc and a post-mortem examination if conducted would only consolidate the diagnosis 01 would only help to support these findings. The doctor should 'worry' about a post-mortem examination only if there has been an act of "gross 'negligence'.

Now, the question comes about **'negligence by mistake**' of the doctor. A doctor acting in a cool & composed manner, with a reasoI1able degree of care (which is what is required of him for the patient) is unlikely to commit an act of' gross negligence'. If one is following the laid down principles of medicine (as prescribed & practiced) there is -no question of negligence arising out of a mistake. Mind you, the doctor is not expected to provide a high degree of skill and are but only a reasonable degree of skill and care. It is although easier said: than understood by any doctor. Any gross negligence whether by

mistake or otherwise is negligence nevertheless (if complained about) and shall have to go through the process of law as usual.

In rarest of rare cases, if a mistake does occur, one should seek expert guidance from seniors in the profession and of course a Forensic Medicine specialist.