

Guidelines for ultrasound owners and owners of clinics, diagnostic centres, nursing homes and hospitals

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Abstract

These are guidelines that are required for ultrasound owners for registration and use of ultrasound machines and are applicable across India. A brief description of the violations and penalties has also been listed.

Key words: PNDT Guidelines; nursing home; diagnostic centre, rules; violations

Registration and Use of Machines

1. The owner needs to register, *at least 3 months in advance*, all the places where a USG machine, whether a black and white or color Doppler machine, is to be used; this applies to medical/surgical nursing homes/intensive cardiac care unit and wherever a USG machine is used. This registration is compulsory and is regardless of the type of studies intended to be performed on that machine, whether pregnancy scans, abdominal scans, or only 2D echocardiograms. All centers should be registered.
2. All radiologists/sonologists/doctors using USG machines need to have their names entered in the PC-PNDT certificate or on a separate sheet that must be displayed along with the PC-PNDT registration certificate. These doctors should be qualified to perform ultrasound according to their degree/ diploma certificate.
3. No doctor other than the one registered in that particular center may use the machine installed there. Other qualified doctors may use the machine at that Centre only after notifying the appropriate authority (AA).
4. In the case of a locum doctor, the doctor's name and personal details, state council registration number, and his/her degree certificate need to be sent to the AA/ward office, accompanied by a covering letter from the clinic owner requesting permission for the use of the machine by the locum on the specified dates.
4. The USG machine should not be shifted from one Centre to another. One center can have multiple USG machines, but the manufacturer's name and the makes and models of the machines should be noted in the PC-PNDT registration certificate (all ultrasound machines available at that center should be registered on the certificate or on a separate attached sheet).
5. Any changes in the center (e.g., change in machine or place of use) should be intimated to the AA 30 days in advance. Any change of the doctor operating the machine should be intimated to the AA within 30 days. A recent Gazette notification has stated that application for locum to adding a doctor's name to the Registration Certificate needs to be done 30 days in advance; this gazette has been challenged by IRIA in Delhi High Court, and interim relief has been given of 7 days.

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Record Keeping and Information to be displayed at the Clinic

1. All records (including images) of all the patients are to be maintained for a minimum of 2 years. If any legal case against the Centre is pending then the concerned records should be maintained till the same case is disposed of.
2. The PC-PNDT registration certificate has to be displayed

in original in the reception area and the USG room. If there are more than two rooms where sonography is performed, the original has to be displayed in both rooms as well as the reception area (request for more originals can be submitted to the AA/ward office).

3. There should be a board, prominently displayed, with the message in English and the local language that 'sex selection and detection is not done in this Centre and is punishable under the PC-PNDT Act'. This should be displayed in the waiting area and the USG room. No specific size for the message is suggested.
4. A copy of the PC-PNDT Act should be maintained in the center and needs to be displayed in the waiting room/reception area as well as in the USG room.
5. Form 'D' is to be maintained by genetic counseling Centres only.
6. Form 'E' is to be maintained by genetic laboratories.
7. Form 'F' is to be maintained by USG Centres/genetic clinics for pregnant patients only.
 - a. All columns in form 'F' should be filled up; no column should be left blank, write "No" or "Not Applicable" wherever required
 - b. Previous obstetric history of patients, with number of children and the sex of each child should be mentioned in form 'F'
 - c. Form 'F' is to be filled up in duplicate: one copy is to be given to the AA (i.e., Medical Officer of Health of the ward) and one copy has to be kept at the clinic (records to be kept for 2 years). In the case of online submission of form 'F', either a printout of the form with the patient's signature or another form 'F' has to be maintained at the center (i.e., a hard copy has to be preserved at the clinic when form 'F' is submitted online.)
 - d. The name of the referring doctor and the indications and results of the USG examination must be mentioned in the form.
 - e. Form 'F' should be signed by the doctor conducting the sonographic examination and not by the owner of the center.
 - f. As per the Act, before the USG examination, a full explanation of the procedure must be given to the patient in her own language and a declaration of consent must be obtained, signed by both the patient and the doctor.
 - h. All blank areas should be labeled as 'Not Applicable' / 'Nil'.
8. A monthly report should be sent to the AA by the 5th of the month by all PC-PNDT-registered centers. (This is not needed if form 'F' is filled up online.)
9. For renewal of registration, an application has to be sent in advance (preferably 1 month in advance) to the AA. If this is not received the Centre will be considered as unregistered and a penalty of Rs.15,000/- can be charged [Table 1]. The Centre will also have to apply afresh for

registration.

10. Application form 'A' is to be submitted in duplicate, along with the documents of the USG machine and an undertaking, duly notarized, stating sex selection and sex detection will not be done at the center. The undertaking should also state that the center will display a message in English and the local language that sex selection and detection are not done at the center and that the same are punishable under the Act.

Miscellaneous

1. Advertisement of any sort is banned and is punishable under the Act with a fine of up to Rs.1 Lakh and/or imprisonment for 5 years.
2. The sex of the fetus should not be disclosed to the patient, relatives, referring doctor, or anyone else.

FAQ's

1. How important is Form F?

Form F filing is mandatory for all pregnant patients. It goes without saying that it should be complete and without errors. The authority should be able to contact the patient on basis on this form. All columns need to be filled and if any points are not applicable, please write NA or Not Applicable against that column, do not leave it blank. Forms should be maintained properly so that one can easily access it whenever asked for

2. How does one apply for PC-PNDT registration?

All details have been given in guidelines. The new amendment (5 June) states that an intimation of one month prior should be given before starting the clinic, adding new machines.

3. How does one renew PCPNDT registration?

All details have been given in guidelines. One should apply ideally 3 months before expiry of the current registration and certainly before one month of expiry.

4. Do MRI machines need to be registered?

Yes, they need to be registered and all changes to be notified to the AA

5. Do CT scan machines need to be registered?

Yes, they need to be registered and all changes to be notified to the AA

6. What is the current status of Video recording devices in Maharashtra and across the country?

Video recording devices have not been installed in Maharashtra except in Kolhapur district. They are being installed in Rajasthan and in some pockets of Punjab. There is no order for their implementation, but they are being installed at local level by collectors.

Table 1: Violations and Penalties*

| Violations | Section/Rule of the PC-PNDT Act | Penalties |
|---|---|---|
| Non-availability of copy of the PC-PNDT Act in the registered center | Rule No. 17 (2) | Case may be launched in the court under Section 23/25 of the Act.. |
| Non-display of the registration certificate in the Centre. | Rule No. 6 (2) | |
| Non-display in the premises of a board in English and the local language stating 'Disclosure of the sex of the fetus is prohibited under law.' | Rule No. 17 (1) | or show cause notice under Section 20 (1), (2) for temporary suspension of registration. or Under Section 20 (3) |
| Advertisement relating to preconception and prenatal determination of sex | Section 22 (1), (2). | Under Section 22 (3) of the PC-PNDT Amendment Act, imprisonment that may extend up to 3 years and with fine which may extend up to Rs. 10,000/-. Case is to be launched in the court under Section 28 of the Act |
| Unregistered Centres. It includes all such centers where any portable equipment capable of detecting sex before or after conception is used. The owner of such equipment may be having a registered facility somewhere else. | Section 3 | Case is to be launched in the court under Section 23 of the Act. |
| Irregularities in registered center | | The AA or person authorized thereupon may: |
| Owner/employee conducting the ultrasonography not qualified. | Section 3 (2) and Rule 3 (b). | Issue show cause notice under Section 20 (1) (2) of the Act and, with the endorsement of the advisory committee, may suspend (for a reasonable period) or cancel the registration, according to the magnitude of the violation. May take <i>suomoto</i> action under Section 20 (3) and suspend the registration without issuing show cause notice. |
| Not all doctors registered | Under Rule 4.6 and as per form 'A', Sr. No. 8 | |
| Minor deficiency in record keeping. | Under Rule 9. | During the period of suspension of registration, the equipment needs to be sealed and signed and kept with the owner. After cancellation of the registration, the equipment has to be sealed and seized. Anybody aggrieved by the above decision may appeal to the higher-level AA within 30 days of the action. The appeal has to be disposed of by the higher authority within 60 days of its receipt. |
| Irregularities in record keeping (form 'F') | Sections 4 and 29 and Rule9. | Contravention of provision of Sections 5 and 6 of the Act and punishable under Section 23 (1) of the PC-PNDT Act. |
| Sex selection | Section 3A. 4 (5). 6 read with Section 2 (0) | Violation of Sections 5 and 6 of the Act and punishable under Section 23 of the Act. |

*Section 23:

*Source: pcwndt.gov.in

1. Contravening this provision of the Act shall be punishable with imprisonment for a term, which may extend up to 3 years and with fine which may extend up to Rs. 10,000 and, on any subsequent conviction, with imprisonment which may extend up to 5 years and with fine which may extend up to Rs. 50,000.
2. The name of the practitioner shall be reported by the AA to the State Medical Council, which will take necessary action that could include suspension of the registration if charges are framed by the court, the suspension to last till the case is disposed of. In case the doctor is convicted, the punishment could include removal of his/her name from the register of the council for a period of 5 years for the first offence, and then permanently for a subsequent offence.

7. What does one do when officials come for inspection. What are the papers required during the inspection?

One should be ready with all paperwork and form F copies. All certificates should be displayed in reception and suite area as mentioned in the guidelines. One needs to be co operative.

8. Is there a restriction on portable ultrasound devices ?

Based on the dismissal of writ filed in high court by Maharashtra State Branch of IRIA, ultrasound machine cannot be used as a portable device. Though it's use is not explicitly prohibited in the PC PNDT act, there are clauses to suggest that one cannot transport it from place

to place, even though those centres may be individually registered.

9. Is there a restriction on the number of places a Sonologist can visit ?

As per the recent gazette dated 5 June 2012, a sonologist can visit only 2 places in one district. This gazette has been challenged in Delhi High Court by IRIA and ad-interim stay has been obtained. It has also been challenged in Mumbai High Court by Dr Rajeev Zankar, and ad-interim stay has been given until next hearing in October.

10. Can one arrange for a locum sonologist when one is on leave or vacation?

One has to give one month notice for the same to local AA with a letter, and copy of certificates of that doctor. This has been reduced to 7 days in the ad-interim relief given by Delhi High Court in July 2012, until the next hearing or there-after. However, it is probable that the 2 place rule as mentioned in the previous FAQ may also apply to the locum doctor.

11. Are training courses authorised by the Govt of India?

Medical Council of India has been given guidelines by the Central Supervisory Board in their meeting held in Mumbai in Jan 2012, to create a 6 month Level I training course in Ultrasound for MBBS doctors. This process is still a work in progress.

12. What should one do when renewal papers are not processed?

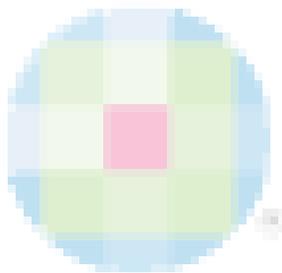
If papers are not processed in 90 days, the centre is considered registered. One must however still inform the authorities once again once the 90 day period is over through a written letter stating the same.

13. What are the steps one needs to take to desal their machines?

If a show cause notice has been issued by authorities and the machine sealed, one needs to release the machine through the courts only.

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