Radiological Safety Division

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Ref. No. AERB/RSD/Med-Xray/Gen/2011/8841

July 20, 2011

Sub: Response to the complaint received by AERB in respect of manufacturers/suppliers of medical X-ray equipment

AERB has recently received an anonymous communication with complaint of "harassment of Diagnostic X-Ray suppliers by AERB officers by endless delay" and "making unnecessary phone calls to companies and demanding irrelevant information or finding other ways to raise objections".

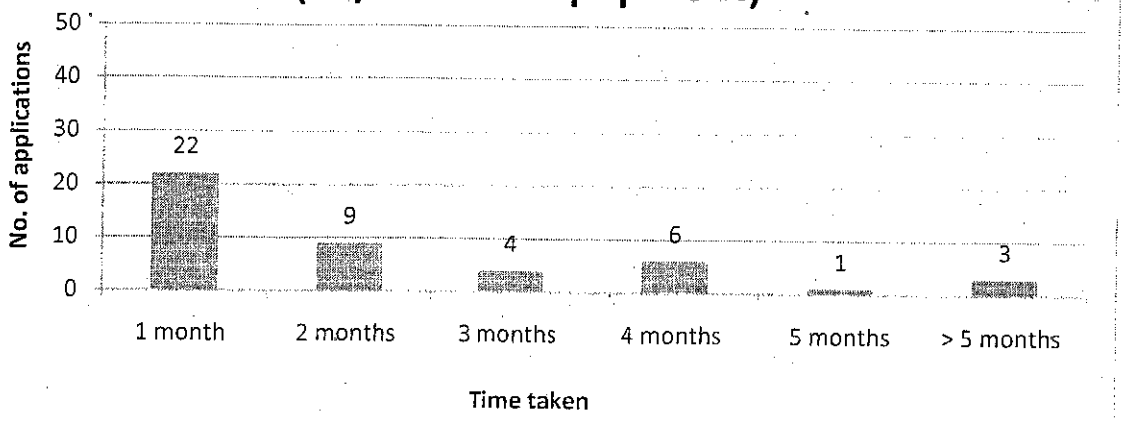
In this regard, we hereby inform you that AERB endeavors to continually improve its regulatory processes and towards this objective takes into account feedback and inputs from all stakeholders. Accordingly in the light of the above communication, an investigation was carried out to locate any short fall for corrective action.

The timeframe for issuance of regulatory consent has been prescribed in Rule 8 of the Atomic Energy (Radiation Protection) Rules, 2004, stipulating one hundred and eighty days from the date of receipt of the application subject to the condition that all the requirements for issuance of the consent have been duly fulfilled.

In case some discrepancies are observed while reviewing the applications, our concerned officers do inform the applicants about the same in writing and communicate on phone mainly to curtail the delay in issuing consent.

As part of the investigation, the status of all applications received for type approvals (TAs) / renewals of TAs/ no objection certificates (NOCs) for CT scan and Cathlab equipment received from January 2010 to June 2011 was reviewed. A total of 55 applications were received during this period and the time taken for completion of these is indicated in the following diagram.

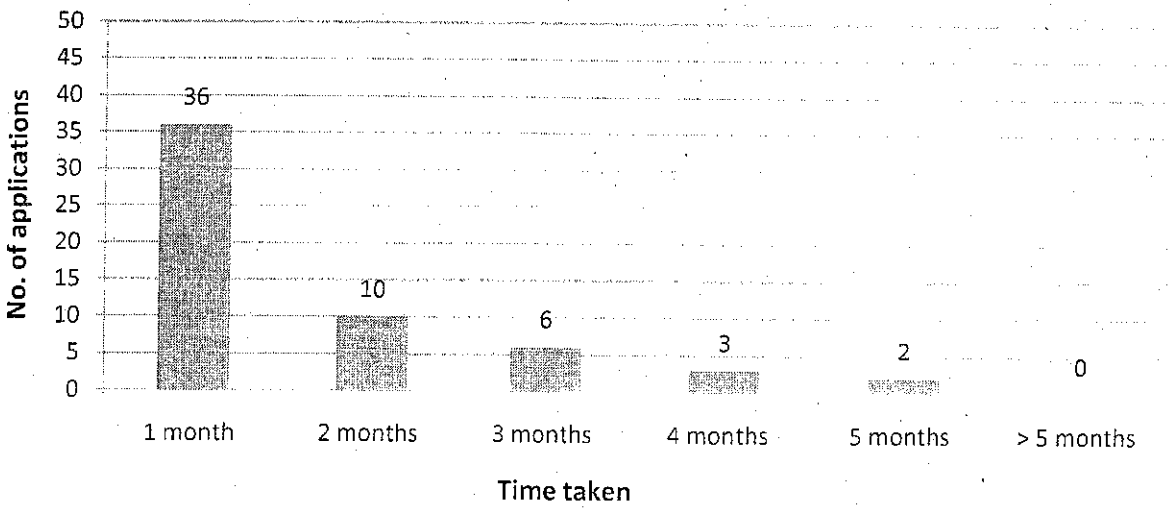
Fig No. 1: Time taken for issuance of consent (CT/Cathlab Equipment)



It is seen that with the exception of four applications, all others were completed within a period of 4 months with majority of them being cleared within 2 months period.

Similarly, with regard to applications received during the same period for type approvals(TAs) / renewals of TAs/ no objection certificates (NOCs) for conventional medical diagnostic X-ray equipment, out of the 67 applications received, most were completed within the target timeframe as indicated in the following diagram.

Fig. No. 2: Time taken for issuance of consent (Conventional Medical X-ray Equipment)



The brief analysis of information depicted in Fig No. 1 & 2 on number of applications received and time taken for issuance of regulatory consents is summarized below:

- It may be noted that 22 applications of CT/Cathlab equipment and 36 applications of conventional medical X-ray equipment were reviewed and regulatory consents issued within a period of one month. The actions could be initiated well within the stipulated time frame on account of receipt of applications satisfying all the applicable requirements such as applications were completely filled-in along with all the relevant documents, e.g. technical catalogue of X-ray equipment, Quality Assurance (QA) Tests Report and CE/BIS Certificate (as applicable).

- The regulatory consents were issued within a period of two months for 9 applications of CT/Cathlab equipment and 10 applications of conventional medical X-ray equipment. The reason for time period of two months is mainly the incomplete application and non submission of requisite technical document(s).

- 4 applications of CT/Cathlab equipment and 6 applications of conventional medical X-ray equipment were reviewed and regulatory consent issued within a period of three months. This was mainly due to repeated communications from AERB with Applicant(s) requesting for providing technical documents and the list of end-users to whom X-ray equipment have been supplied by the Applicant(s), in accordance with the terms and condition of TA certificate.

- 6 applications of CT/Cathlab equipment and 3 applications of conventional medical X-ray equipment were reviewed and regulatory consent issued within a period of four months. This was mainly because of the non- procurement of QA kit by Applicant(s) and non availability of service engineers with Applicant(s), in addition to the reasons cited above.

- 1 application of CT/Cathlab equipment and 2 applications of conventional medical X-ray equipment were reviewed and regulatory consent issued within a period of five months. The reasons for this were mainly the delay in completing the regulatory inspection process for demonstration of TA tests and non availability of X-ray machine for TA testing, in addition to the reasons cited above.

- In case of 3 applications of CT/Cathlab equipment, the time taken was found to be beyond reasonable delay. In this regard, we have already taken corrective actions involving re-assignment of responsibilities.

If there are more specific complaints pertaining to individual applications, AERB will certainly look into them. It is needless to say that the processing of various applications get facilitated for speedy disposal if all the technical requirements and requisite information are submitted in the first instance itself.

AERB has organized discussion meets on several occasions on issues raised by the manufacturers / suppliers / vendors on implementation of regulatory requirements. AERB has also organized awareness programs and workshops for manufacturers / suppliers / vendors of medical X-ray equipment. All these programs have witnessed good participation and interactions with manufacturers. The detailed requirements for obtaining NOC / TA from AERB and the responsibilities of manufacturers have been emphasized in such programs. Hence all the manufacturers of X-ray equipment in the country are well informed about the applicable regulatory requirements.

Detailed information (also in the form of flow-chart) on the procedure for obtaining NOC/Type Approval for X-ray machine, Guidelines for obtaining regulatory consents by end users and manufacturers/suppliers is available on AERB website including the list of Type Approved X-ray equipment.

20-7-11
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To Webmaster: To publish on website.

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