Experiences of PNRI Interaction with Licensees in Nuclear Regulatory Information Conferences

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ABSTRACT

The Philippine Nuclear Research Institute (PNRI) initiated various nuclear regulatory conferences with its licensees in the years 1995 and 1996. The purpose of these conferences was mainly to reach a common understanding of the provisions of the Code of PNRI Regulations (CPR) and foster openness between PNRI and licensees.

Each conference was designed for a specific category of licensees, i.e., commercial, medical, industrial (nuclear gauges), industrial radiography, research and teaching. The regulatory group of PNRI discussed the applicable regulations to each category of licensees including experiences in implementation and enforcement. This was followed by licensees’ feedback on experiences in dealing with the regulatory group and complying with applicable regulations.

The outcome of these conferences brought out generic and specific issues and concerns. Majority of the general issues and concerns were directed towards PNRI. This brought to the realisation that although safety is the primary responsibility of the licensees, PNRI as the only competent authority on radioactive material and radiation safety matters, carries the bigger share of preparing the licensees for this kind responsibility.

1. Introduction

The need for collective and more focused interaction between the PNRI and its licensees has grown over the years as the number of rules and regulations the PNRI has promulgated increases. In 1959, a year after the establishment of the then Philippine Atomic Energy Commission by Republic Act 2067, the first set of regulations entitled “Rules and Regulations on the Acquisition, Possession, and Use of Radioactive Materials” was promulgated. This was followed by the promulgation of the “Rules and Regulations on the Safe Transport of Radioactive Materials in the Philippines” in 1966 and then the “Standards for Protection Against Radiation” in 1976. The first set of regulations was revised in 1989 and has evolved into various specific rules and regulations that provide requirements for licensing and safe use of radioactive materials in medicine, industry, research, and teaching.

The participation of the affected groups of licensees was rather limited to providing written comments of draft regulations. Consultative meetings with licensees and public hearings were not integral in the rule making process. Through the years, however the level of awareness in rule making has improved which can be attributed largely to the technical assistance provided by the International Atomic Energy Agency (IAEA) in the form of training, seminars, experts, safety series publications, etc.
In line with the continuing effort of PNRI to improve the regulatory system so as to be consistent with global standards, various reforms are underway. The holding of nuclear regulatory information conferences with licensees is one of these. These conferences are being held to get direct feedback, suggestions, criticisms, recommendations and opinions.

2. The Philippine rules and regulations

The Philippine regulations for licensing and safe use of radioactive materials are compiled in the Code of PNRI Regulations (CPR). The CPR consists of parts in chronological order with specific subject matter as follows:

Part 2 - Licensing of Radioactive Material
Published in Official Gazette (O. G.), Vol. 86, No. 29, 16 July 1989, pp. 5337-5355

Part 3 - Standards for Protection Against Radiation
Published in O. G., Vol. 72, No. 14, 05 April 1976, pp. 3736-3751.

Part 4 - Rules & Regulations on the Safe Transport of Radioactive Materials in the Philippines

Part 6 - Rules of Procedure for the Licensing of Atomic Energy Facilities in the Philippines

Part 7 - Licensing of Atomic Energy Facilities
Published in O. G., Vol. 70, No. 22, 08 June 1974, pp. 4435-4438.

Part 11 - Licenses for Industrial Radiography and Radiation Safety
Requirements for Radiographic Operations
Published in O. G., Vol. 86, No. 28, 09 July 1990, pp. 5123-5131.

Part 12 - Licenses for Medical Use of Sealed Radioactive Sources in Teletherapy

Part 13 - Licenses for Medical Use of Radiopharmaceuticals

Part 14 - Licenses for Medical Use of Sealed Radioactive Sources in Brachytherapy

Part 15 - Licenses for Large Irradiators
Published in O. G., Vol. 89, No. 46, 15 November 1993, pp. 6686-6702.

In addition to the above rules and regulations, IAEA Safety Series Nos. 6 and 9, Regulations for The Safe Transport of Radioactive Materials, 1973 revised edition and Basic Safety Standards for Radiation Protection, 1982 edition, respectively were adopted through an Administrative Order in 1983, for use whenever applicable.

The PNRI has recently issued policies on internal regulatory control of the radiation facilities it operates in accordance with international basic safety principles as well as standards for radiation protection.


The PNRI has only about 250 licensees involved in the use of radioactive materials in medicine, industry, research and teaching. Table 1 shows the distribution of licensees according to classification and geographical distribution.

The PNRI is engaged in various applications of radioactive materials. But since PNRI is exempt from licensing requirements it is not accounted for in Table 1. These applications include large irradiation facilities, secondary standard dosimetry laboratory, various small research facilities in health physics, chemistry, biomedical, agriculture, and teaching
Table 1. Distribution Of Licensed Users According To Geographical Location And Classification
(As of August 1997)

<table>
<thead>
<tr>
<th>Region</th>
<th>Commercial</th>
<th>Hospital</th>
<th>Industrial Radiography</th>
<th>Research &amp; Education</th>
<th>Physician</th>
<th>Industry</th>
<th>Subtotal</th>
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<td>Muslim Mindanao Autonomous Region</td>
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<tr>
<td>Cordillera Administrative Region</td>
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<td>-</td>
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<td>3</td>
<td>4</td>
</tr>
<tr>
<td>NCR (Metro Manila)</td>
<td>29</td>
<td>49</td>
<td>25</td>
<td>13</td>
<td>2</td>
<td>40</td>
<td>158</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>29</strong></td>
<td><strong>60</strong></td>
<td><strong>26</strong></td>
<td><strong>24</strong></td>
<td><strong>3</strong></td>
<td><strong>115</strong></td>
<td><strong>257</strong></td>
</tr>
</tbody>
</table>

laboratories. The PNRI maintains a research reactor (not operational) and an interim low level radioactive waste repository.

4. Experiences in nuclear regulatory information conferences [2]

The PNRI in 1995 and 1996 conducted a series of regulatory information conferences to provide an opportunity for members of the regulatory staff of the PNRI and licensees to discuss the applicable Parts of the CPR and the problems experienced in implementation and enforcement by regulators and licensees.

These conferences were conducted by sector or specific applications, e.g., radiopharmaceuticals, brachytherapy and teletherapy, industrial radiography, research, etc. to have more focused approach in the discussions.

The conferences usually consisted of various topics presented by the PNRI regulatory group covering current and specific regulations applicable and relevant to the sector or category of licensees, experiences during review and evaluation of license applications, outcome of compliance monitoring discussions on proposed initiatives. Representatives of the licensees, in some cases the relevant professional organisation itself, took an active role in the discussions to facilitate the consolidation of common concerns for that specific applications group. The overall theme focused on enhancing and promoting a better understanding of the various aspects of the regulatory program as well as encouraging participation and feedback from licensees on regulatory matters affecting them.

4.1 General issues and concerns

General issues and concerns raised during the nuclear regulatory information conferences included the accreditation by the PNRI of professional organisations to certify
on the clinical aspect of use of radioactive materials. In addressing this specific issue, the PNRI has initiated the establishment of accreditation criteria for professional societies and agreed to immediately act on a long standing proposal from the Philippine Society of Nuclear Medicine, for example, to be the certifying body of practitioners in the field of nuclear medicine.

Licensees' feedback is an important input in the effort to improve the PNRI regulatory system and the capability to discharge its functions effectively. Some of the common issues and concerns included delayed issuance of licenses, sometimes resulting in expired licenses or unauthorised use of radioactive material. Some requirements were not fully appreciated for what they are worth. Examples of these were certificate of release, a requirement for radioactive consignment to be released by customs authorities, and transport certificate which is a requirement before a licensee can ship or move radioactive materials. The need to leak test sealed sources as often as specified in the regulations in certain cases was being questioned including the cost of the service and related matters.

4.2 Specific issues and concerns

In radiotherapy, the need to have a standardised calibration technique and reporting of results in full calibration of therapy machine and associated instrumentation was discussed. This included the lack of appropriate dosimetry systems for low energy calibration.

The continued use of radium sources in brachytherapy was raised and the efforts taken by the PNRI to discourage the use of these sources, together with an aggressive campaign to change from manual to remote afterloading devices, were highlighted.

The proposed requirement for medical physicists in other medical applications such as in nuclear medicine has gained overwhelming support from concerned users.

5. Regulatory challenges

The experiences gained and the lessons learned from the conduct of the nuclear regulatory conferences indicated that there is a need to continue this activity on a regular basis. The PNRI, therefore, will design another series of conferences in the following years to sustain the enthusiasm and report results of new initiatives.

The PNRI regulatory system will have to be periodically reviewed. Local experiences as well as information on other regulatory bodies' experiences should be studied and appropriately applied to become more effective and efficient.

Current regulations, especially Parts 3 and 4, will have to be reviewed and revised. Better opportunities for consultations and dialogues with present licensees and even prospective license applicants should be provided by PNRI.

References