

Facilities and Management in Radioassay Laboratories

II. Present Situation and Problems

(2) Problems in Laboratories

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A questionnaire survey for radiation control and quality control in radioassay laboratories was made on 43 university hospitals and 27 community hospitals in Japan.

1) LICENSE CONDITION:

All hospital laboratories desiring to perform radioassays for clinical use are required to obtain the approval of Department of Health and Welfare. In addition, for every hospital desiring to use radionuclides such as ^{125}I for labelling procedure, it is necessary to be certified by Department of Scientific Technology. At present, about 15% of the hospitals were licensed by Department of Scientific Technology for using the radionuclides defined as chemical reagents and not as approved radiopharmaceuticals by law.

2) FACILITIES

Routine radioassay was performed in a single centralized laboratory in 74% of the university hospitals and in 96% of the community hospitals. However, all hospitals feel it necessary to centralize the assay laboratories scattered in a hospital to one laboratory which performed all routine clinical assays, from the view of quality control of the assays and radiation control as well.

3) Radiation control service:

Radiation control service which included purchasing of radionuclides, radiological survey,

personnel monitoring, waste disposal etc. was carried out by personal of department of radiology department of nuclear medicine in 80% of the or hospitals. At present, only 10% had an independent organization for radiation control service. However, more than 30% feel it necessary to have a well qualified independent organization for radiation control service.

4) Quality control:

More than 90% of the laboratory had a specific quality control program for radioassay. Main causes for errors they had encountered were in the order of problems in commercial kits, handling of samples, instrument performance, technical and clerical errors. To prevent these errors it was thought important to establish the detailed protocols for the radioassay performance.

5) Waste disposal:

All ^{125}I -solid wastes were collected in containers and shipped to the Japan Radioisotope Association in 60% of the hospitals. While in 34%, more than half of the ^{125}I -solid wastes were stored for decay out and then discarded as general waste. ^{125}I -liquid waste was collected and shipped to the Japan Radioisotope Association or collected, stored for decay and disposed of down the regular drains after dilution in accordance with regulations in all the hospitals surveyed.

Regulations for Medical Use of Radioisotopes and for Disposal of Radioactive Wastes in Foreign Countries

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Increasing numbers of radioimmunoassay have been causing the problems of handling of radioactive materials and wastes. In order to discuss these problems faced in Japan in comparison with

those in foreign countries, were reported the current regulation of radioactive use for medical purpose and treatment methods of radioactive wastes.

As the first part, differences of two kinds of