Facilities and Management in Radioassay Laboratories
II. Present Situation and Problems
(2) Problems in Laboratories

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A questionair 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 clincial 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 protocals for the radioassay perfrormance.

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 cuasing 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

licences, specific or general license were made clear. A specific license is issued only to named persons upon application and generally allows for a wide range of radioisotope usage which is necessary for the institute to perform most of in vivo procedures using scanner or scintillation camera. On the ohter hand, a general license is very restrictive as to the types and levels of isotopes, although only registration of name, address and location of use is required. By and large most of in vitro procedures is allowed for clinical measurements of hormones and other substances under this license. However labeling of hormones with I-125 could not be performed under this license because of restricted amount of radioactivity. Maximum permissible levels of water concentration and air concentration seem to be 2 to 10 times higher in the states than in Japan. Radioisotope use for medical purposes is not considered to cause elevated concentration of radioactivity in the air in the states. Therefore, the unrestricted designation can normally be applied to a hospital laboratory using radiopharmaceuticals in the states. In Japan, however, a certain percentage of radioactivity is assumed to be vaporized.

As the second part, how radioactive wastes were handled in the states were discussed based on Dr. Katoh's report which was made by his direct interviews with physisists in charge in several institutes in the states. The handling ways of liquid scintillater used, in vitro test tube and HBsAg positive materials and cut-off levels for disposal were tabulated as follows.

Liquid Scintillater (H-3, C-14)

Institute	Storage		Released after Dilution
	Vial	Solution	
A	−	+	−
B*	+	+	−
C	−	+	−
D	+	−	−
E	−	−	+

*Using vermiculite

In vitro test tube

Institute	Tube			Solution	
	with garbage	Storage	Commercial collector	Released after dilution	Commercial collector
A	−	+	+	?	?
B	−	−	+	+	+*
C	−	−	+	−	+*
D	+	−	−	+	−
E	−	−	+	+	−

Cut off Levels for Disposal

Institute	
A	Below background count, Expcept for Tc-99m
B	Solid material . . . Difficult fo determine Liquid Below (MPC) w
C	Below BKG
D	According to the regulation
E	No cut-off level determined

HBsAG positive waste

Institute		
A	Nonradioactive liquid	Disposed after autoclaving
	Radioactive liquid	Solidified after Sterilization by NaCLO
	Plastic beads	Stored in the plastic bag
B	Liquid	NaCLO treatment
C	Nonradioactive liquid	Disposed after autoclaving
	Radioactive	to Commercial collector
D	Autoclaving	
E	Autoclaving Stored and burnt out with other biological waste	
F	Autoclaving	
G	No specific attention	