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DATA PROCESSING AND QUALITY CONTROL OF RADIOASSAY. Y.MIYACHI, Toho University School of Medicine, Tokyo.

Radioimmunoassay was first applied to the measurement of insulin, after which the polypeptide hormones of both large and small molecules have succumbed to this novel form of measurement. Subsequently, radioimmunoassays were developed for non-hormonal substances such as cyclic nucleotides, prostaglandins, tumor associated substances, enzymes, and drugs. As a radioimmunoassay method permits 200-300 samples to be easily measured in one assay, it is inconceivable that a radioimmunoassay should be performed without appropriate mathematical treatment for the processing of assay data and for the validation of the results. Literally a number of mathematical methods have been developed for calculation of radioimmunoassay results. These methods include hyperbola, logit-log, spline and four parameter logistic methods. The dose response curve should be displayed graphically and the display should show the observations, the fitted curve, 95% confidence limits for an observation and 95% confidence limits for the location of the curve. Estimates of potency for each of the unknowns, the minimal detectable dose, ED50, and slope at the ED50 with 95% confidence limits should be provided. Points which appear to be outliers should be marked. In addition to the DATA processing for the unknowns, it is essential that each laboratory have suitable programs

for the quality control of the performance of the radioimmunoassay, which makes the calculations of within- and between-assay variability and of precision profile. Using the computer, we analysed the commercially available radioimmunoassay kits such as  $\alpha$ -fetoprotein, aldosterone, B<sub>2</sub>microglobulin, CEA, cortisol, c-peptide, digoxin, elastase I, ferritin, free T<sub>4</sub>, FSH, gastrin, growth hormone, glucagon, IgE, insulin, LH, PAP, prolactin, PTH, T<sub>3</sub>, T<sub>3</sub> uptake, T<sub>4</sub>, TSH and ACTH. It is true that the coefficient of variation of the assay values was improved year by year, the optimization of the assay kits, especially of ACTH and PTH was strongly pointed out.