This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Thirty-third Report

Annex 3

REQUIREMENTS FOR THROMBOPLASTINS AND PLASMA USED TO CONTROL ORAL ANTICOAGULANT THERAPY

(Requirements for Biological Substances No. 30)
(Revised 1982)

CORRIGENDUM

(September 1984)

Page 102, **Example:**

Delete: Using the data from Table 1, the calculated value for $C_{IRP,WRP}$ is 1.033. The International Sensitivity Index for RBT/79 is 1.4. Thus, the International Sensitivity Index for the working reference preparation is estimated as $1.033 \times 1.4 = 1.446$.

The standard error for $C_{IRP,WRP}$ is calculated as 0.077. Thus, S.E. $(ISI_{WRP}) = 0.077 \times 1.4 = 0.108$. The coefficient of variation for the ISI of the working reference preparation is $100 \times 0.108/1.446 = 7.5\%$. The coefficient of variation is large because Table 1 contains data from only eight plasmas, i.e., one day's tests. In practice, tests would be conducted on several days and the coefficient of variation using the combined data would be smaller.

(*see over*)

Insert: Using the data from Table 1, the calculated value for $C_{IRP,WRP}$ is 0.968. The International Sensitivity Index for RBT/79 is 1.4. Thus, the International Sensitivity Index for the working reference preparation is estimated as $0.968 \times 1.4 = 1.355$.

The standard error for $C_{IRP,WRP}$ is calculated as 0.077. Thus, S.E. $(ISI_{WRP}) = 0.072 \times 1.4 = 0.100$. The coefficient of variation for the ISI of the working reference preparation is $100 \times 0.100/1.335 = 7.4\%$. The coefficient of variation is large because Table 1 contains data from only eight plasmas, i.e., one day's tests. In practice, tests would be conducted on several days and the coefficient of variation using the combined data would be smaller.

Page 103, **Example:**

Delete: Using the data from Table 2, the calculated value for $C_{WRP,b}$ is 1.004. The International Sensitivity Index for the working reference preparation is given as 1.05. Thus, the ISI for the batch is estimated as $1.05 \times 1.004 = 1.054$.

The standard error for $C_{WRP,b}$ is 0.008. If the standard error of the ISI of the working reference preparation, determined at the time of its calibration, is 0.018, the total standard error of the ISI of the batch taking account of the imprecision of both ISI_{WRP} and $C_{WRP,b}$ is

$$[(1.05 \times 0.008)^2 + (1.004 \times 0.018)^2]^{1/2} = 0.020$$

The coefficient of variation for the ISI of the batch is $100 \times 0.020/1.054 = 1.9\%$.

Insert: Using the data from Table 2, the calculated value for $C_{WRP,b}$ is 0.996. The International Sensitivity Index for the working reference preparation is given as 1.05. Thus, the ISI for the batch is estimated as $1.05 \times 0.996 = 1.046$.

The standard error for $C_{WRP,b}$ is 0.008. If the standard error of the ISI of the working reference preparation, determined at the time of its calibration, is 0.018, the total standard error of the ISI of the batch taking account of the imprecision of both ISI_{WRP} and $C_{WRP,b}$ is

$$[(1.05 \times 0.008)^2 + (0.996 \times 0.018)^2]^{1/2} = 0.020$$

The coefficient of variation for the ISI of the batch is $100 \times 0.020/1.046 = 1.9\%$.

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

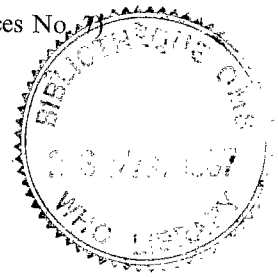
Thirty-third Report

Annex 4

REQUIREMENTS FOR POLIOMYELITIS VACCINE (ORAL)

(Requirements for Biological Substances No. 7)

(Revised 1982)



CORRIGENDUM

(March 1987)

Page 155 (Appendix 4). In the first paragraph, the 3rd and 4th lines should read:

> .... 1.3 g of sodium bicarbonate and 20 ml of fetal bovine or calf serum per litre, with penicillin (120 mg/l) and streptomycin (100 mg/l).

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