ANNEX

RECORDS ON THE PARTICIPATION OF THE SAN JUAN DE DIOS HOSPITAL IN THE IAEA/WHO TLD POSTAL DOSE CHECK SERVICE

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The IAEA/WHO TLD postal service

The International Atomic Energy Agency (IAEA) operates a facility to verify the calibration of radiotherapy units in hospitals and oncology centres in Member States. This service was established in 1969. Dose quality audits of radiotherapy centres (sometimes referred to as 'intercomparisons') are performed using thermoluminescence dosimeters (TLD) sent by post. The TLDs are provided by the Agency and irradiated by hospital users in predetermined reference conditions, using radiation doses of clinical relevance. The dose absorbed in the dosimeter is determined at the IAEA 's Dosimetry Laboratory and the result compared with the value stated by the user. The service has been used for 30 years to check more than 2600 radiotherapy beams in 850 hospitals, and in many instances significant errors have been detected in the calibration of therapy beams; these have sometimes been related to patient mistreatments. In all instances the service provides an independent and impartial quality audit of the dosimetry procedures used at the hospitals.

The TLD postal service, known as the IAEA/WHO TLD postal service, is conducted through a collaboration between the IAEA, the World Health Organization (WHO) and, in Latin America, the Pan American Health Organization (PAHO). The Dosimetry and Medical Radiation Physics Section of the IAEA's Division of Human Health is responsible for the technical aspects of the TLD system, reference irradiations, and collection and evaluation of the dosimeters. WHO/PAHO oversees the distribution of the TLDs to radiotherapy institutions using WHO national or regional affiliated centres. The IAEA and WHO establish the connection with participants through the health ministries of Member States, which ordinarily have authority over radiotherapy centres.

Originally, the service was developed for Co-60 therapy units. Recently however, it has been extended to high-energy photon and electron beams produced in clinical accelerators. Within this

programme, activities in collaboration with other organizations provide a redundant quality assurance to the laboratory tasks performed at the IAEA. All the TLD procedures receive the support of the Bureau International des Poids et Mesures (BIPM), various Primary Standard Dosimetry Laboratories (BEV in Austria, PTB in Germany, etc.), and certain advanced radiotherapy centres and institutions in Europe and the USA. These institutes provide reference irradiations for the TLD sets, acting as an external quality control arm of the IAEA's TLD dosimetry service.

Important remark

The IAEA/WHO TLD postal service warranties the confidentiality of the results, and only the persons responsible for the radiotherapy departments or for the calibrations have access to the outcome of the verification. The open discussion and dissemination of the results given below constitutes an exceptional case, and the decision to release these results has been adopted in the light of the important social consequences of the accident under consideration.

Results of TLD dose quality audits for the San Juan De Dios Hospital, San José, Costa Rica

The San Juan de Dios Hospital participated 14 times in the IAEA/WHO TLD postal dose check service during the period 1977–1995. During this interval, 17 checks of beam calibrations were

performed: in only four occasions were the results within the acceptance limit of ±5%. The results of the participation in the TLD checks between 1990 and 1995 are set out in the table below.

Year		Beam	Deviation (*)
1990		Co-60/1:	20.5%
1991		Co-60/1:	7.1%
1992		Co-60/1:	26.3%
		Co-60/2:	25.9%
1994		Co-60/1:	68.9%
		Co-60/2:	69.8%
1995		Co-60/1:	38.3%
		Co-60/2:	25.5%
1995	("blind test")	Co-60/1:	-5.9%
	("blind test")	Co-60/2:	-7.2%

(*) relative deviation (%) = 100 x (user stated dose - IAEA measured dose) / IAEA measured dose

In relation to the above table, it should be noted that deviations in positive values indicate that the user stated dose is higher than the value measured by the IAEA; this corresponds to a situation where the patient would receive a dose lower than what is intended. On the contrary, deviations with a negative sign indicate that a patient would receive a dose higher than that intended.

Up until 1995, the person in charge of the dosimetry at the San Juan de Dios Hospital had been informed by the IAEA through PAHO of the results obtained in the different participations in the TLD dose check service. This had been the standard procedure of the IAEA/WHO TLD postal dose check until then, and participants were requested to take steps to improve their beam calibration.

In 1995, as the IAEA observed that the large deviations found remained undiminished, they sent a second set of dosimeters under so-called 'blind test' conditions, where participants are not informed of the exact deviation measured by the IAEA, but only that the results are outside the acceptance limit. The confirmation of an anomalous situation, shown by the inconsistency of the two sets of results, prompted the IAEA to field an expert to investigate the status of the calibration of the beams. Simultaneously, three TLD sets were sent to the Hospital in July 1996 to verify the calibration of the two Co-60 therapy units, a Theratron 80 and an Alcyon. The replacement of the Co-60 sources of the two machines had been planned for July–August 1996. It was requested that

the TLDs be irradiated immediately after the calibration of the machines with the new sources, and before initiating the treatment of patients.

The following provides a short summary of the TLD results for both Co-60 therapy units.

1. Theratron 80

After the source replacement, the calibration of the beam was performed by the IAEA expert, Ms. Castellanos, using dosimetry equipment available in the Hospital. Based on the two calibration factors of the equipment, the expert irradiated two TLD sets on 19 July 1996 and returned them for evaluation to the IAEA 's Dosimetry Laboratory. The TLDs were received on 1 August 1996 and evaluated on 2 August 1996. The results in terms of the deviation of the IAEA measured and user stated dose values (D_{IAEA} and D_{stated}, respectively) were within the acceptance limits of $\pm$5%:

TLD set No SR 96201

D_{stated} = 2.000 Gy

D_{IAEA} = 2.047 Gy

% deviation, relative to the IAEA measured values = -2.3%,

which corresponds to a dose ratio IAEA measured/user stated dose = 1.024.

TLD set No SR 96202

D_{stated} = 2.000 Gy

D_{IAEA} = 2.068 Gy

% deviation, relative to the IAEA measured values = -3.3%,

which corresponds to a dose ratio IAEA measured/user stated dose = 1.034

2. Alcyon

A TLD set to be used with this machine was left in Costa Rica by the expert with instructions for the local physicist to irradiate them immediately after the exchange of the Co-60 source and prior to the initiation of patient treatment. The irradiated TLD set was returned to the IAEA's Dosimetry Laboratory on 18 October 1996, only after the accident had been reported. The TLDs were

evaluated on the day of their arrival. The accompanying data sheet was filled in by Mr. J. Cabezas, the person in charge of the dosimetry in the hospital. He did not indicate the date of the irradiation of the TLDs, but provided only the date of the beam output measurement (calibration) using an ionization chamber, i.e., 22 August 1996.

From the analysis of the accompanying data sheet it was observed that the user stated dose D_{stated} = 2.000 Gy (pertaining to the date of 22 August 1996) corresponded in reality to a depth of 0.5 cm, and not to the depth of 5 cm in water where the TLD capsules had been placed for irradiation. Therefore, the user stated dose had to be decreased by a factor equal to 0.787 (obtained from the Co-60 percentage depth dose data given in Brit J Radiol Suppl 17), corresponding to the attenuation of the beam by 4.5 cm of water. This yielded a 'depth corrected' stated dose D'_{stated} = 1.576 Gy (on 22 August 1996). The shape of the TLD glow curve, however, demonstrated that the TLDs had been irradiated only a few days before their dispatch by post to the IAEA. The above 'depth corrected' stated dose was therefore subsequently modified to account for the decay of the Co-60 source during approximately two months, yielding a more accurate estimate of the user stated dose D''_{stated} = 1.544 Gy.

Because of the lack of clarity in the information provided for the TLD irradiation procedure, two results are given below, one relative to the user stated dose D_{stated}, and another relative to the best estimate of the user stated dose D''_{stated}:

TLD set No SR 96203

D_{stated} = 2.000 Gy (user stated dose)

D_{IAEA} = 2.812 Gy

% deviation, relative to the IAEA measured values = -28.9%

which corresponds to a dose ratio IAEA measured/user stated dose = 1.406

D''_{stated} = 1.544 Gy (IAEA estimated user stated dose)

D_{IAEA} = 2.812 Gy

% deviation, relative to the IAEA measured values = -45.1%,

which corresponds to a dose ratio IAEA measured/estimated user stated dose = **1.821**.

From the above data it can be concluded that the TLD results for the Alcyon machine indicate an overexposure of the order of 80%, which applies exclusively to the reference conditions used in the beam calibration (10cm x 10cm field size, 5 cm depth in water). The overexposure of patients will vary from this amount depending on the conditions used for radiotherapy treatments (field size, secondary collimation, use of wedges, etc.). The estimated overexposure for the reference conditions agrees well (within the uncertainties of the TLD system, estimated to be 2.5%, k=1) with the result measured by PAHO for the same configuration, using a calibrated ionization chamber.

ADENDUM

INTRODUCTION

The report reproduced in this Safety Report was delivered by the Director General of the IAEA to the Government of Costa Rica on 26 September 1997.

As stated in the findings and conclusions of the Data on Patients of Appendix II, a further evaluation of doses to normal tissue was desirable for some of the patients. To make this evaluation, a two dimensional reconstruction of the dose distributions made using a computerized treatment planning system (TPS) was undertaken by the Secretariat, in co-operation with P. Binder of the General Hospital in Vienna, Austria, and with the advice of C. Serrano, Hospital Ramón y Cajal, Madrid, Spain. In addition, an estimation of the biologically equivalent dose for late effects, if administered at 2 Gy/fraction, based on the Lineal Quadratic (LQ) model, was made in collaboration with G.G. Steel of the Institute of Cancer Research, United Kingdom and J.F. Fowler, Belgium and United Kingdom.

METHOD AND DISCUSSION

Cross-sectional images for the actual patients in the area of interest that were suitable for clinical dosimetry were only available in a few cases (indicated by CT in the tables of this addendum). Therefore, most of the dose reconstruction had to be made using 'standard' images taken from anatomy atlases.

The images were entered into the TPS by means of a television camera and the scale was fitted digitally to the actual body thickness of the patient, taken from the patients' charts. The influence of anatomical differences on the uncertainties introduced when selecting the isodose curve that crosses a given tissue is estimated to be within ±10%, in view of the fact that the distance between two consecutive isodose curves (drawn in steps of 10%) is about 2 cm.

The data for a Co-60 beam available in the TPS of the General Hospital in Vienna correspond to those for a Theratron 780. Differences with the ALCYON II are not significant except in the penumbra region. Calculation of doses to tissue within the penumbra of the beams has therefore been avoided.

The dose reconstruction was made for the patients falling into the following groups:

- 4 patients alive, with severe or catastrophic effects from radiation;
- 16 patients alive, with marked effects and with a high risk of future effects from radiation;
- 3 patients deceased, considered to have radiation as the major factor in their cause of death;
- 4 patients deceased, considered to have radiation as a a substantial contributor to death

The two dimensional relative dose distributions were calculated in planes containing the centre of the beam. The absolute dose values to organs and tissues at risk were obtained by the usual methods of clinical dosimetry, as explained in the following.

Determination of the absolute doses to organs and tissues at risk

Dose received by the tissue of interest before the source change

The dose to organs at risk was estimated from the prescribed dose to the target by applying a conversion factor. The conversion factor was obtained by comparison of the isodose from the TPS, which correspond to the tumour with the isodose corresponding to the organ at risk (d<) .See Table A.I.

Dose received after the source change

The dose to organs at risk was estimated from the actual treatment time (from patients' charts), the time to deliver 1 Gy to the 100% isodose and the relative dose distributions from the TPS.

When more than one field is applied, in the present case two opposite equally weighted parallel fields, the time obtained corresponds to one of the fields, e.g., 0.5 min/Gy indicates that 0.5 min for each field (in total 1 min) are necessary to produce 1Gy.

The steps were:

1. The time/Gy (T) for the Theratron 780 to deliver 1 Gy were converted to the time/Gy (A) for the ALCYON II source, given the dose rate from both sources.
2. The actual treatment time was taken from the patients' charts.
3. From both values, and from the isodose that crosses the tissue at risk, the dose per fraction (d>), e.g. the daily dose, is obtained.
4. The total dose with the new source (D>) is obtained from the number of fractions indicated in the patients' charts.

Determination of the biologically equivalent 2Gy/fraction dose, (D(2)).

The dose per fraction to tissues at risk were higher than normal for the following main reasons:

- The miscalibration of the beam leading to doses higher than prescribed (both a higher dose per fraction and a higher total dose);
- The prescription of higher fractional doses and a lower number of fractions;
- The use of alternating fields instead of both fields every day.

The effect of these factors has been explored in the example/trial presented in Tables A.II (a) to (d).

Effect of higher dose per fraction.

The effect of a higher dose per fraction and a-lower number of fractions, with the same total dose is shown in Table A.II(a). In the range of doses relevant to this report, the use of three instead of five fractions per week, during the whole treatment, leads to an increase of more than 30% in D(2). The use of two, rather than five fractions, with the same total dose, leads to an increase of about 75% in D(2).

If not only a higher dose per fraction but also the total dose is increased, which was the effect of the miscalibration, the increase in D(2) is accordingly higher, depending of the proportion of the treatment that was conducted with the new source.

These two effects are reflected in the results in Table A.I: instead of a single α/β value for each tissue, the following ranges of values have been used:

1.5–2.5 for brain and spinal cord;

2-4 for all other tissues.

These ranges lead to ranges of values for D(2) as presented in the four last numeric columns of Table A.I. The D(2) values are usually higher than the estimated absorbed dose delivered (D).

Effect of alternating fields versus both fields every day.

Finally the effect of applying alternating fields every other day, instead of treating both fields every day (for two opposite parallel fields), has been explored.

Tissues located at mid-depth receive the same daily dose regardless of whether the treatment has been applied with both fields every day, or alternating fields. Therefore, the biological effect of treating both fields every day or not is not significant, since d and D would be the same.

The largest difference would be expected for tissues that one day are close to the beam entrance and the following day close to the exit. Examples of these tissues are subcutaneous tissue (at D_{max}) and tissue from skin folds, rectum, bladder, thoracic and lumbar spinal cord

The results of the calculation experiment are shown in Table A.II(b), (c) and (d). In this table, the value d1 stands for the dose received when the tissue is located closer to the beam entrance and d2 stands for the dose received when closer to the beam exit. The table shows that the biological effect of using alternating fields is about 5–6%, except for skin in the abdominal region, for which the ratio between entrance dose and exit dose may become as much as 3–4, depending on the body thickness of the patient and D(2) increases by about 10% or more.

This consideration was therefore only applied to the skin folds and subcutaneous tissue for patients treated in the abdominal region with parallel opposite fields, alternating every other day, namely patients Nos 8, 52 and 78. The results are presented in Table A.III.

ID	tissue	% Isod	d<	FX<	D<	min/ Gy (T)	min/ Gy (A)	min/f ield	d>	FX>	D>	D	range of alpha/beta		range of D(2)		Remarks from the medical findings
8	rectum, lower ileum, part of sigmoid colon	100	2	20	40	0 7	0.42	1.29	3.10	5	15.5	55 51	2	4	59 8	58 4	complaint of diarrhoea about three times a week
8	rectum, part of sigmoid colon (from lat fields)	100				1.1	0.72	2 17	3.02	6	18 1	18 13	2	4	22.8	21 2	complaint of diarrhoea about three times a week
18	bowel, cervix, uterus	100				0 7	0 44	1 29	2 93	12	35 1	35 10	2	4	43 2	40 5	colonic haemorrhage with perforation, small bowel petechiae, haemorrhage of cervix and uterus (a)
26	ear (assuming overlap)	80			0	0.5	0.28	2 02	5 70	14	79 8	79.80	2	4	154	129	drainage of the right ear and complete deafness; (since the eye was shielded only a 3 cm anterior field has been included)
39	skin inguinal and subcutaneous tissue (CT)	100				0.8	0 49	2 01	4 09	14	57.3	57.26	2	4	87.2	77.2	severe woody induration anterior
39	femoral head (CT)	80				0.8	0.49	2.01	3 27	14	45.8	45 81	2	4	60.4	55 5	femoral head aseptic necrosis
40	heart (CT)	100				0 6	0 38	1.14	3.02	17	51.3	51 27	2	4	64.3	60	pericardial effusion
40	spinal cord (CT)	100				0 6	0 38	1.14	3 02	17	51.3	51 27	2	4	64.3	60	may have cervical and thoracic spinal cord changes
41	thoracic spinal cord	75				0 8	0 51	2.5	3.67	15	55.1	55 11	1.5	2 5	81 5	75 6	potential spinal cord changes
44	skin folds and subcutaneous tissue	100				0.8	0 50	7 86	15 60	2	31.2	31 19	2	4	137	102	ulceration in the vulva (a)
44	bowel	75				0.8	0.50	7.86	11.70	2	23.4	23 39	2	4	80 1	61 2	blood in stools (a)
46	skin and subcutaneous tissue (from lat. fields)	100	2	5	10	0.6	0.37	1.08	2.96	20	59.1	69 11	2	4	83 2	78 5	facial oedema; (if anterior neck field overlapped, the dose to the face would be about 50 Gy higher)
46	base of the tongue (from lat. fields)	100				0 6	0.35	1 08	3.12	20	62 3	62 34	2	4	79.7	73 9	swelling of the base of the tongue and larynx (if anterior field overlapped and organ shielding was not used the dose would be nearly doubled)
47	brain	100	2	5	10	0.7	0.41	1.05	2 56	23	59.0	68.97	1.5	2.5	78.5	76 4	high risk of neurological sequelae

ID	tissue	% Isod	d<	FX<	D<	min/ Gy (T)	min/ Gy (A)	min/f ield	d>	FX>	D>	D	range of alpha/beta		range of D(2)		Remarks from the medical findings
52	base of tongue, larynx	100	2	9	18	0.6	0 35	1 1	3.17	23	73.0	91.02	2	4	112	105	oedema of the piriform sinuses and fibrous changes
54	brain and spinal cord	100	2	16	32	0.6	0 35	1.06	3.00	9	27 0	59 04	1.5	2 5	66 8	65 1	risk for neurological sequelae
54	thoracic spine	77				0 8	0 51	2.13	3 21	12	38 6	38 57	1.5	2 5	51 9	49	
54	lumbar spine	77				0.8	0 51	2	3 02	15	45.3	45.27	1.5	2 5	58 4	55.5	
57	gastro intestinal	95	1.6	12	19 2	0.7	0.43	0.96	2 10	10	21.0	40.18	2	4	38.8	39.2	hemorrhage gastrointestinal: estimated dose does not seem to match with the medical findings
58	cervical spine	100	2	16	32	0 6	0 35	1.07	3 02	9	27 2	59.17	1.5	2 5	67 1	65 3	risk for neurological sequelae
58	thoracic spine	75				0 8	0.51	2.13	3 13	12	37 6	37 57	1.5	2 5	49.7	47	
58	lumbar spine	75				0 8	0.51	2	2.94	15	44 1	44 09	1.5	2 5	55 9	53.3	
59	trachea	90				0 8	0 49	1 57	2.88	20	57.5	57 51	2	4	70.1	65.9	necrosis of the pharynx, larynx and epilation over posterior fossa, note: according to the patient's chart, a shielding in the centre of the beam was planned from fraction 16th. This would reduce the dose by 14 Gy
60	face: dose from lat left field	70				0.6	0 36	0.91	1 77	24	42.6	42.57	2	4	40.2	41	oedema and some necrosis of the pharynx and trachea.
60	face. dose from lat. right field	70				0.6	0.36	0.37	0 72	24	17.3	17 31	2	4	11 8	13.6	possible overlap with anterior field in the trachea
60	neck anterior field	95				0.8	0.49	1 53	2.96	24	71.0	70.99	2	4	88	82 3	(if the anterior field overlapped, the dose would be approximately doubled)
62	rectum	100				0.7	0 44	1.29	2 93	15	43.9	43.88	2	4	54	50 6	rectal narrowing
66	heart (CT)	105				0.7	0 44	1.36	3 24	11	35.6	35.62	1 5	2 5	48.2	45 4	potential cardiac effects
67	right colon	100				0.5	0 31	0.96	3 11	16	49 8	49.76	2	4	63.6	59	necrosis of the right colon
77	sink and subcutaneous	100	2	7	14	0.5	0 32	0.98	3 11	18	56 0	70.00	1.5	2 5	87.8	83.8	severe skin changes and gastrointestinal complications

Table A.I Dose reconstruction to organs and tissues at risk, using a computerized Treatment Planning System

ID	tissue	% isod	d<	FX<	D<	min/ Gy (T)	min/ Gy (A)	min/f ield	d>	FX>	D>	D	range of alpha/beta		range of D(2)		Remarks from the medical findings
80	spinal cord from lateral fields nasopharynx	100				0 6	0.35	1 12	3 23	16	51.7	51.72	1.5	2 5	69.9	65.9	quadriplegia (if anterior field overlapped and organ shielding was not used, the dose would be nearly doubled)
83	intestine (from AP/PA fields) (CT)	100	2 2	5	11	0 5	0.33	0 94	2.82	20	56 3	67.30	2	4	79.3	75.3	grade 3 GI toxicity initially, weight loss, anaemia, continuous rectal bleeding and diarrhoea, and must wear a diaper
83	rectum (from lateral fields) (CT)	100	2.2	5	11	0.5	0.33	0.94	2.82	20	56.3	67.30	2	4	79.3	75.3	continual rectal bleeding
83	rectum (from lateral fields) (CT)	90				0.9	0.59	1.61	2.47	5	12.4	12.37	2	4	13.8	13.3	continual rectal bleeding
85	rectum	100	2	6	12	0.5	0.30	1.13	3.74	12	44.8	56.84	2	4	76.3	69.8	perirectal ulceration with possible infection/necrosis
95	skin and subcutaneous	100				0.5	0 32	1.08	3 36	14	47 1	47 06	2	4	63 1	57 7	diarrhoea, skin induration
97	cord (from lat fields)	95	1.9	11	20 9	0 5	0 33	1.02	2.94	8	23.5	44.45	1.5	2 5	50 2	48 9	spinal cord demyelination (if the anterior field overlapped and the organ shielding was not used, the dose would be approximately doubled)
106	brain (CT)	100	1.9	13	24.7	0.5	0.34	1	2 94	12	35.3	59.97	1.5	2.5	68.7	66.8	concern about possible radiation necrosis of brain
106	thoracic spinal cord (CT)	88				0.8	0.52	1 88	3 20	10	32.0	32.02	1.5	2.5	43	40.6	
109	temporal lobes	100	2	4	8	0 5	0.33	1 05	3 14	16	50.3	58 31	1.5	2 5	74.8	71.1	lost ability to speak and walk; periventricular leucoencephalopathy, mineralizing microangiopathy, atrophy

Table A.I Dose reconstruction to organs and tissues at risk, using a computerized Treatment Planning System