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STANDARD
DOSIMETRY
LABORATORIES



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#### EDITORIAL NOTE

The directors of national metrology institutes of thirty-eight Member States of the Metre Convention signed the Mutual Recognition Arrangement (MRA) during the 21<sup>st</sup> "Conférence Générale des Poids et Mesures" (CGPM) held in Paris on 14 October 1999. Prof. Pedro Andreo, Section Head of the Dosimetry and Medical Radiation Physics Section and IAEA Co-Secretary of the IAEA/WHO Network, signed the MRA on behalf of the SSDL Network. An essential element of this agreement is the concept of equivalence in measurements and comparability of national metrology services. The signing of the Mutual Recognition Arrangement places metrology of ionizing radiation in those countries having a laboratory member of the IAEA/WHO Network of SSDLs at the level of international recognition, allowing for the worldwide mutual recognition of their national measurement standards and of the calibration and measurement certificates issued by their laboratories. This, naturally, imposes strict demands on the performance of the SSDLs, and will require a thorough review of the conditions of acceptability of results of the intercomparisons and quality audits organized by the Agency for the Network of SSDLs.

A circular letter with a copy of the signed MRA was sent to all members of the IAEA/WHO Network of SSDLs in December 1999. It is planned to devote a special issue of the SSDL Newsletter to contributions that address specifically practical aspects related to the implementation of the MRA.

Almost 25 years after its foundation, the IAEA/WHO Network of SSDLs comprises 70 members in 59 Member States and is supported by 15 Primary Standards Dosimetry Laboratories and 5 international bodies and committees. The close link between the Network and other metrology bodies has contributed substantially to achieving consistency in the dosimetry of ionizing radiation. Many people both inside and outside the IAEA and WHO have contributed to the success of the Network and Dr. H. Eisenlohr is one of them. He was the IAEA Co-Secretary of the SSDL Network between 1976 and 1987. He was in close contact with competent staff of national and international standards laboratories and commissions, and with his counterparts at WHO, as well as with officials and SSDL staff of developing countries involved in the establishment of such laboratories. He kindly prepared "the SSDL story", the first article of this issue of the SSDL Newsletter so that the "SSDL memory" becomes recorded.

The second article is a report of the Third Research Co-ordination Meeting (RCM) for the Co-ordinated Research Project (CRP E2.10.02) on "the development of a quality assurance programme for SSDLs", held at the IAEA Headquarters from 29 November to 3 December 1999. The objective of the CRP is to prepare practical guidelines to SSDLs for the development of a quality system based on ISO/IEC standards. The main results achieved under this CRP are included in this report and will be published in the form of an IAEA document to be distributed to all SSDL members.

The third article is a report from the SSDL in Tanzania, which describes the quality control programme implemented in the laboratory.

The present staff of the Dosimetry and Medical Radiation Physics (DMRP) Section:

Name	Position/tasks	E-mail address
Andreo, Pedro	Head, DMRP Section IAEA Co-Secretary, SSDL Network	p.andreo@iaea.org
Bera, Pranabes	Laboratory Technician (TLD)	p.bera@iaea.org
Czap, Ladislav	Laboratory Technician (Ionization chamber calibration)	l.czap@iaea.org
Girzikowsky, Reinhard	Laboratory Technician (High dose)	r.girzikowsky@iaea.org
Izewska, Joanna	TLD Officer, Head, Dosimetry Laboratory Unit	j.izewska@iaea.org
Meghzifene, Ahmed	SSDL Officer, Editor, SSDL Newsletter	a.meghzifene@iaea.org
Olko, Pawel	TLD support (TA)	p.olko@iaea.org
Peixoto, J. Guilherme	Physicist, Diagnostic Radiology Dosimetry (TA)	j.peixoto@iaea.org
Pernicka, Frantisek	Diagnostic Radiology Dosimetry Officer (TA)	f.pernicka@iaea.org
Toelli, Heikki	Brachytherapy Dosimetry Officer	h.toelli@iaea.org
Salzer, Anneliese	Secretary	a.salzer@iaea.org
Flory, Rosemary	Secretary	r.flory@iaea.org
DMRP Section		dosimetry@iaea.org <sup>a</sup>

<sup>&</sup>lt;sup>a</sup> This is the general e-mail address of the DMRP Section where all correspondence not related to specific tasks of the staff above should be addressed. Please note also that there is a considerable circulation of the staff of the Agency, so that messages addressed to someone who has left might be lost. All incoming messages to this mailbox are internally distributed to the appropriate staff members.

### SERVICES PROVIDED BY THE IAEA PROGRAMME IN DOSIMETRY AND MEDICAL RADIATION PHYSICS

The IAEA's Dosimetry and Medical Radiation Physics programme is focused on services provided to Member States through the IAEA/WHO SSDL Network and dose quality audits. The measurement standards of Member States are calibrated, free of charge, at the IAEA's dosimetry laboratory. The audits are performed through the IAEA/WHO TLD postal dose assurance service for SSDLs and radiotherapy centres, and the International Dose Assurance Service (IDAS) for SSDLs and radiation processing facilities, mainly for food-irradiation and sterilisation of medical products.

The range of services is listed below.

Se	ervices	Radiation quality
1.	Calibration of ionization chambers (radiotherapy, diagnostic radiology including mammography, and radiation protection, including environmental dose level).	x-rays (10-300kV) and gamma rays from $^{137}$ Cs and $^{60}$ Co
2.	Calibration of well-type ionization chambers for brachytherapy Low Dose Rate (LDR).	γ rays from <sup>137</sup> Cs
3.	Intercomparison of therapy level ionization chamber calibrations (for SSDLs).	γ rays from <sup>60</sup> Co
4.	TLD dose quality audits for external radiotherapy beams for SSDLs and hospitals.	$\gamma$ rays from $^{60}$ Co and high energy x-ray beams.
5.	TLD dose quality audits for radiation protection for SSDLs.	γ rays from <sup>137</sup> Cs
6.	ESR-alanine dose quality audits for radiation processing (for SSDLs and industrial facilities), through International Dose Assurance Service (IDAS).	γ rays from <sup>60</sup> Co, dose range: 0.1-100 kGy
7.	Reference irradiations to dosimeters for radiation protection (for IAEA internal use).	x-rays (40-300 kV) and $\gamma$ rays from $^{137}\text{Cs}$ and $^{60}\text{Co}$

Member States who are interested in these services should contact the IAEA/WHO Network Secretariat for further details, at the address provided below. Additional information is also available through the Internet at the web site: http://www.iaea.org/programmes/nahunet/e3/.

IAEA/WHO SSDL Network Secretariat
Dosimetry and Medical Radiation Physics Section
Division of Human Health
International Atomic Energy Agency
P.O. Box 100
A-1400 Vienna
Austria

Telephone: +43 1 2600 21662 Fax: +43 1 26007 21662 E-mail: Dosimetry@iaea.org



# THE SECONDARY STANDARD DOSIMETRY LABORATORIES (SSDL) STORY

Horst H. Eisenlohr

In 1976, the International Atomic Energy Agency and the World Health Organization formally concluded a Working Arrangement aiming at setting up a world-wide Network of SSDLs under the auspices of the two organizations. It appears that the loose term Working Arrangement was used for this joint undertaking as both IAEA and WHO did not wish to signal, at that time, a deep involvement in the project. Moreover, the two pursued different routes organizations implementing the project. In consequence, it took many years before the programme received adequate technical and financial support. Thus, after years of reluctance, the project was considered important enough to be included into the IAEA's Technical Assistance programme. It then began to thrive though, in the course of time, WHO's initial financial support declined. Now (1999), the SSDL Network comprises 76 laboratories around the world. It is guided by a joint IAEA/WHO Secretariat which, in turn, is advised by an SSDL Scientific Committee. It is supported by 5 Collaborating Organizations (BIPM, ICRU, IEC, IOML, IOMP - see list on page 32), by 15 Affiliated Members, i.e. national Primary Standards Laboratories (Australia, Austria, Canada, France, Germany, Hungary, Italy, Japan, The Netherlands, New Zealand, Russian Fed., Slovakia, Spain, UK and USA), and enjoys full national and international recognition.

Most of the people who initiated, promoted and directed the establishment of SSDLs and the Network have by now retired from their positions in national or international institutions. Some of the early enthusiasts are no longer alive, and the names of many of them were never associated with the project, because staff of, and consultants to, international organizations are expected to work in anonymity.

### THE PRE-CARACAS PERIOD

It is perhaps no longer possible to identify the conceptual origin of the laboratories which are now named SSDLs. However, there is evidence that around 1960 a small group of medical

physicists working at the IAEA in Vienna (particularly M. Cohen and K.C. Tsien) formulated and launched a programme aimed at assisting radiotherapy in Latin America, the only region in the developing world where ionizing radiation was extensively used in medicine at that time. This group and their successors in the sixties (L. Lanzl, R. Loevinger, P. Pfalzner, H. Eisenlohr) also proposed that the organize and perform Agency a intercomparison service by mail using TLD. This proved to be of utmost importance in the following decades. It also figured at the origin of the Agency's Dosimetry Section which was inaugurated in 1967 (R. Loevinger (head), P. Pfalzner, H. Eisenlohr, S. Malo Alvarez, V. Balamutov). It should be noted here that many years before (1959/60) a dosimetry laboratory had been set up at IAEA's headquarters in Vienna (R.G. Jaeger, G. Roth, A. Sanielevici, H. Nagl) with the objective of building an absorbed dose calorimeter for intercomparison measurements with similar instruments at some national laboratories (UK, USSR). The calorimeter was designed by S. Genna (USA), and was intended to serve as a reference standard for developing member states which did not have access to a primary standards laboratory. Unfortunately, the staff of the IAEA dosimetry laboratory and the Dosimetry Section worked in different Divisions of the Agency. Nevertheless, major subjects of discussion between the two groups were implementing and improving the postal dose intercomparison service, planning of international training programmes and drafting of manuals and atlases of typical dose distributions that could improve the quality of radiotherapy (external and internal) in developing countries. It soon became clear that a critical issue was the absence of dosimetry laboratories in those areas of the world. In fact, the group noticed that even in many industrialized countries such national dosimetry services with a direct link to the international measurement system did not exist. As a result of these observations P. Pfalzner discussed, among other issues, the setting up of a regional dosimetry reference centre with colleagues in South America. In his travel report to the Director General of IAEA from February 1968 he proposed the setting up of a regional dosimetry laboratory with IAEA support. Similar proposals were also made by a joint WHO/IAEA Expert Committee on Planning of Radiotherapy Facilities, held in Geneva in 1964; in the report of an IAEA panel on Medical Radiation Dosimetry,

held in collaboration with WHO in Vienna, 1967; and in a joint WHO/IAEA Expert Committee on Medical Radiation Physics, held in Geneva, 1967. (The organization first mentioned in the name of a joint undertaking, i.e. WHO/IAEA, is the one that made the effort to initiate and organize it). It seems evident from what has been said above that both organizations, IAEA and WHO, became aware of the problem of medical radiation physics in the early sixties, and took early initiatives independently. However, due to a wellestablished system of mutual consultations - both organizations maintained a liaison office at the headquarter of the other - such activities soon became joint ventures. While this development was often to the advantage of the project, it would not entirely exclude duplicate action and irritating solo attempts.

### THE CARACAS PANEL

During this period, the Dosimetry Section at IAEA prepared an experts' meeting on "Dosimetric Requirements of Radiotherapy Centres", to be held in Venezuela. P. Pfalzner and H. Eisenlohr were assigned as scientific secretaries of the panel, which was held in Caracas in April 1968. At this meeting the World Health Organization was represented by W. Seelentag, who had recently joined WHO, together with G.P. Hanson and D.J. Joly representing PAHO.

This Meeting took place at the Instituto Venezolano de Investigaciones Científicas (IVIC), near Caracas, from 22 to 26 April 1968. The meeting had its origin, as already mentioned, in observations and proposals contained in the working programme of IAEA's Dosimetry Section. The following experts were, upon request by IAEA, nominated by their respective countries as members of the panel: E. Bunde (FRG), S. Fedoruk (Canada), M. Gaitan Y. (Colombia), J.B. Massey (UK), E. Meyer (Brazil), H.A. Mugliaroli (Argentina), F. Para Gil (Ecuador), J. Solanas (Venezuela), M. Williams (USA), M. Zaharia (Peru). As this meeting can be considered as the origin of the SSDL programme an extract of the panel report will be reproduced here:

"The Committee notes that in Latin America the development of physics in radiotherapy from the point of view of both personnel and equipment has not kept pace with that of radiotherapy itself. This is evidenced by the extreme shortage, even

complete absence in some cases, of qualified medical radiation physicists in the countries of Latin America. At the same time there exists in these countries a large number of radiotherapy departments, both public and private, many of which are equipped with expensive telecobalt and X-ray units. The absence of adequate physics services seriously limits the effective and safe utilization of this very costly equipment.

"There is no doubt that the solution to this problem lies in the provision of sufficient numbers of full-time qualified medical radiation physicists (see report of the joint IAEA/WHO Expert Committee on Medical Radiation Physics, WHO Tech. Rep. Ser. 1968, 390). For this reason there is an urgent need to establish adequate facilities for the post-graduate training of such physicists.

"There is also an urgent need to establish facilities for the calibration of instruments used in radiation measurements. At present no such facilities exist in Latin America and recourse has to be had to either North America or Europe, which involves great practical difficulties.

"Information available to the panel indicates that in many of the major cities of Latin America an undesirably large number of separate radiotherapy centres are now in existence. Such a situation does not lend itself to the performance and development of high-grade radiotherapy. This latter requires a degree of centralization which will permit the more rapid acquisition of experience, the more effective use of apparatus, a better chance of having a good physics service and the provision of a complete range of radiotherapy facilities. The governments of the countries concerned and all other interested organizations are requested to give their attention to this state of affairs.

"Although this report is presented to the IAEA as the organization responsible for the setting up of this panel meeting, the members of the panel suggest that in carrying out the recommendations the IAEA should consider inviting the complete cooperation of other organizations interested in this field, in particular WHO/PAHO. It is further suggested that this report be circulated to the public health authorities in the countries of Latin America."

The group submitted three detailed recommendations to the IAEA for implementation:

- the preparation of a basic manual of dosimetry

- the organization of regional training courses in radiotherapy physics, and
- the creation of regional dosimetry facilities (in South America).

The third item is of direct relevance to this article. Its full wording is therefore given here:

"Dosimetry, in the medical application of radiation, is concerned with knowing as accurately as possible the dose administered to the patient and the dose received by staff working with generators of ionizing radiation.

"The complete absence of national laboratories for standardizing radiation measurements and the lack of physics departments in most of the radiotherapy centres in Latin America warrants the setting up of one or more regional dosimetry centres with suitable equipment and expert staff.

"The committee therefore suggests that the IAEA, in collaboration with WHO, should take appropriate steps as soon as possible to establish such a centre or centres, the function of which would be primarily:

- To calibrate dosimeters for Latin American institutions.
- To make intercomparisons of dose measurements with all the institutions concerned in Latin America.
- To render local technical assistance to Latin American institutions by means of trained staff, in checking radiation equipment and dosimetry.
- To standardize radiation measurements.
- To make intercomparisons with the findings of other internationally recognized standardization laboratories (NBS, NPL, etc.).
- To provide a personnel dosimetry service to countries in the process of setting up their own local service.
- To co-operate with local personnel dosimetry services.
- To collaborate in the organization and establishment of local dosimetry laboratories and in training the staff to take charge of them.
- To work out research projects related to the centre's purposes.

"The Working Group considers that it would be desirable for the centres to have available the following facilities in carrying out the abovementioned duties:

- a laboratory for absolute measurements,
- a laboratory for checking dosimeters,
- an instrument laboratory equipped with an electronics shop and a precision machine shop,
- a personnel dosimetry laboratory, and
- suitable library facilities."

## WHO REGIONAL DOSIMETRY REFERENCE CENTRES

After submission of the panel report by the two scientific secretaries, the Agency authorized its Dosimetry Section to start implementing the first two recommendations. However, IAEA's management was not prepared to let the Dosimetry Section go ahead with the third and most important proposal, the creation of regional dosimetry laboratories. The rationale behind this decision was clearly the financial consideration. WHO, in contrast, did not hesitate to take immediate action.

As early as November 1968, WHO invited a group of experts and IAEA staff to its Headquarters in Geneva to discuss the need for, and ways improving, radiation dosimetry radiotherapy and radiation protection purposes. This group endorsed the recommendations of the Caracas panel and drafted recommendations which formed the basis of the WHO document "Draft Guidelines for the Setting up of Secondary Standard Dosimetry Laboratories: Their Needs, Duties and Characteristics (Geneva, 1971) signed by W. Seelentag and B. Waldeskog, and with S. Osborn (King's College Hospital, London) as principal author. At the same time, WHO began designating a number of laboratories within radiotherapy centres as WHO Regional Dosimetry Reference Centres (RDRCs), in the framework of a general programme called "WHO Collaborating Laboratories". Whereas credit should be given to the WHO staff in charge for putting into action an explicit recommendation of the Caracas panel, criticisms on WHO's some post-Caracas procedures appear appropriate. Firstly, despite the IAEA's reluctance in the matter, WHO should have officially informed IAEA immediately and in detail on its intended steps. In fact, it was to the IAEA's complete surprise when in December 1968, WHO informed IAEA of the designation of two laboratories (in Bucharest and Buenos Aires) as WHO RDRCs. Indeed, it was not until

December 1974 that the IAEA was regularly consulted prior to such activities. Secondly, WHO pursued the project within the medical field. These laboratories were conceived as adjuncts to radiotherapy centres, fulfilling a special technical task within these departments. While a link to the international measurement system was promised, collaboration among these WHO centres, as well as active support through the existing IAEA dosimetry laboratory, was not foreseen. In a circular letter to the governments WHO stated that "the work of the WHO Regional Centres will be harmonized by WHO Headquarters with the assistance of the BIPM and one or two national standardizing institutions which will act as international reference centres". However, a later inquiry revealed that neither the BIPM nor any other PSDL were officially approached by WHO in this matter at that time. Moreover, no means were foreseen for a periodic and compulsory check of the working conditions of the RDRCs, nor was any clear route of responsibility stipulated within the relevant local administrations.

### IAEA DOSIMETRY LABORATORY BECOMES PART OF THE DOSIMETRY PROGRAMME

In 1971 the Agency's Dosimetry Section became responsible for the working programme of its dosimetry laboratory which, as mentioned earlier, had been a separate group within another Division of the IAEA. At times, this strange situation had caused confusion and inefficiency. From now on, manpower and facilities of the laboratory could be fully utilized for the section's programme. At that time, contacts were established between the Dosimetry Section and staff of national Primary Standards Laboratories. In a joint effort with R. Loevinger (NBS), W. A. Jennings (NPL), K. Zsdanszky (OMH), H. Reich (PTB) and others a concept of Secondary modern Standard Dosimetry Laboratories (SSDLs) was elaborated, with close links to other national standards laboratories and the BIPM. Also, the Agency's dosimetry laboratory was designated to serve as a coordinating laboratory for the SSDLs, and as a training centre for SSDL staff. The postal dose intercomparison programme using TLDs, which had already proved its value in improving the reliability of dose measurements in radiotherapy centres, should be extended to periodically serve the SSDLs, and PSDLs should be asked to

regularly participate in this programme. In the course of these discussions a need was seen for some formal structure beyond WHO, harmonizing the work of the SSDLs and providing access to the international measurement system. Thus, the idea of a Network of SSDLs took shape and it was felt that another open meeting might help to make a breakthrough towards the establishment of SSDLs and an SSDL Network, as part of the international metrology system and in accordance with the concepts developed by the IAEA and its experts.

### RIO PANEL

Consequently, another IAEA/WHO panel on SSDL Activities was prepared and held in Rio de Janeiro in December 1974. It was attended by 6 representatives from national Primary Standards Laboratories (NRC, LMRI, PTB, ETL, NPL and NBS), 4 from SSDLs/RDRCs, 2 from WHO and 1 each from PAHO, IOMP, BIPM, EURATOM and GSF). Scientific Secretaries were H. Eisenlohr from IAEA and W. Seelentag from WHO.

The panel recommended the establishment of a Network of SSDLs, its Secretariat function being vested in the IAEA and WHO. An Advisory Council should assist the Secretariat in all matters concerning the Network. The panel also identified the responsibilities of the Secretariat, the Council, the SSDLs and PSDLs within the Network. Pending approval of the IAEA and WHO Secretariats, the panel also elected 4 panel participants to serve on the Council in its first term.

The majority of the participants expressed their preference of the IAEA concept of an SSDL Network based on and closely linked to the international measurement system in preference to the WHO scheme of Collaborating Laboratories. It was felt that the latter structure had been used previously because it was an existing structure, but established for quite different purposes. The following are quotations from the report of the IAEA secretary of the panel, and from working papers submitted by participants:

"There are at present about 20 National Primary Standards Laboratories operating in the world. They are linked together by the International Bureau of Weights and Measures (BIPM) in Paris. Their main task is to maintain and operate primary standards and to calibrate secondary standards against them.

"In most countries now having expanding nuclear programs, calibration of radiation measurement equipment is not possible because adequate calibration facilities are lacking. Even in technically advanced countries, the Primary Standard Dosimetry Laboratories (PSDLs) are not able to calibrate and check all instruments used in radiotherapy, industry and radiation protection, because the number of these instruments is too large. As, however, in most countries such calibrations are now obligatory, many developed countries are going to set up calibration centres on the secondary standard level; their task will be to calibrate and check tertiary and field instruments in daily use.

"There is general agreement among the experts concerned that it is neither necessary nor desirable for every individual country to maintain primary standards for radiation dosimetry. However, it has been recommended at several occasions, for the first time at the IAEA panel on Dosimetric Requirements of Radiotherapy Centres, Caracas, 1968, that regional or local SSDLs be established in developing areas. Since then, seven such SSDLs were set up, six (RDRCs) being designated by WHO "in cooperation with IAEA" (Argentina, Iran, Mexico, Romania, Singapore, Thailand), and one by IAEA "in agreement with WHO" (Brazil).

"When setting-up SSDLs one must keep in mind that the goal is a metrological, not a health, organization. It must be tied to the international measurement system, which can only be accomplished by relating to the primary laboratories. It will probably be most useful to tie individual secondary laboratories to particular primary laboratories, in order to develop long-term working relationships.

"If the network is to be effective on a world wide scale, we must expect a growing number of secondary laboratories. It is hardly possible to predict what the number will be. In any event, it will be necessary to assign the secondary laboratories to five or six primary laboratories.

"There will be need for some central coordinating organization with responsibility for establishing criteria of competence, accuracy, institutional responsibility, long term continuity, etc. This coordinating organization must establish mechanisms for deciding when a secondary

laboratory meets these criteria, for bestowing some form of certification, for periodically checking that the criteria continue to be met, and at least in principle for withdrawing certification if the criteria are no longer satisfied.

"The certification of a secondary laboratory should imply recognition of high quality performance, so that it bestows a status in which the laboratory can take pride. This will be an important element in maintaining high morale, which is necessary to attract and hold the competent individuals necessary to a satisfactory long term operation.

"Certification should not be given until a secondary laboratory has demonstrated its competence over a period of a year or so. Thus, existing secondary laboratories are not a barrier to creation of a network of metrological laboratories, but are rather a necessary first step (from R. Loevinger's working paper).

"Representatives from BIPM, NBS, NPL, PTB and LMRI pointed out that the institution of "WHO Collaborating Centres" in the framework of which 6 of the 7 existing SSDLs have been set up cannot be considered as completely adequate for an SSDL network. In contrast to institutes in other fields of collaboration with WHO (e.g. in nuclear medicine), most SSDLs (or rather RDRCs) at the time of their designation by WHO are in early planning stage only. By the act of designation they cannot therefore automatically fulfil the requirements that a calibration centre must meet in order to be accepted by the PSDLs for calibration of their secondary standards. Another formal procedure therefore appeared to be necessary by which an SSDL would receive recognition of its qualification as an "accepted" SSDL. It was the main objective of the panel to propose such a procedure acceptable to all parties involved, the SSDLs, the PSDLs, IAEA/WHO. The BIPM stated that it assumes responsibility at the primary standard level only."

There is no doubt that the Rio panel paved the way for the future development of the SSDL network. For the time being, however, the principle instigator of the panel report, the IAEA's Secretariat, was still not prepared to include the project into its main programme. But there was now hope for progress.



Photo: H.H. Eisenlohr, W.A. Jennings, W. Seelentag (from left to right) at the IAEA/WHO panel at Rio de Janeiro, Brazil, December 1974.

### IAEA/WHO SSDL TASK FORCE

Indeed, in 1975 IAEA and WHO formed an SSDL Task Force with H. Eisenlohr (IAEA) and W. Seelentag (WHO) as members who were to consider the technical and financial implications of the Rio recommendations. The work of this Task Force resulted, in April 1976, in a document entitled Working Arrangement between IAEA and WHO on a Network of SSDLs in which the essential ideas of the Rio recommendations, with some modifications, were laid down.

#### THE SSDL NETWORK

Thus, in 1976, the Directors General of IAEA and WHO formally announced by circular letters to their respective member states the establishment of the IAEA/WHO Network of SSDLs. In these letters which were accompanied by revised (but still preliminary) Criteria for the establishment of a Secondary Standard Dosimetry Laboratory, it

was stated that, for the time being, WHO would function as secretariat of the Network, while the IAEA would be responsible for its technical and scientific development.

At that time there existed 8 laboratories which had been designated by WHO during the period 1968 -76. Another laboratory had been set up by the Brazilian Government in collaboration with the Government of the Federal Republic of Germany (G. Drexler, Gesellschaft für Strahlen und Umweltforschung, Munich) and IAEA. In response to the circular letters, the number of member laboratories in the network rose to over 30 within 15 months. In addition, 11 National Primary Standards Laboratories (ARL, NRC, LMRI, DAMW, PTB, OMH, RIV, NRL, VNIIFTRI, NPL, NBS) became affiliated members, and 5 international organizations/ commissions (BIPM, ICRU, IEC, IOML, IOMP) joined the network as collaborating organizations. This development was taken as a clear signal that the course pursued by the Agency's dosimetry staff was right.

# THE FINAL DOCUMENT ON CRITERIA FOR ESTABLISHING AN SSDL

In November 1984, an Advisory Group at IAEA Headquarters considered the present status and the future of the SSDL Network. The meeting was attended by representatives of primary and secondary standard laboratories, the BIPM, IOML, ICRU and WHO. In its report the Group stressed the value of joining the SSDLs together into a network. "Such an alliance assists individual members in carrying out their functions involving the measurement of ionizing radiation, the creation of expertise in applied dosimetry and its transfer to the users of ionizing radiation, and training of radiation workers. importantly, the network serves as a means of achieving worldwide coherence in radiation measurements which can be traced back to the measurement standards of the BIPM and the Primary Standard Dosimetry Laboratories.

"Equipment and techniques are now available that should enable an SSDL to provide calibrations comparable in accuracy to those provided by PSDLs. The strongest possible metrological links should be established within the network. Those provide traceability to the which international measurement system, should not be concentrated all at one place, but should be spread out to provide a wide net. Many PSDLs should be drawn into active participation, and the SSDLs should intercompare dosimetry measurements as widely as possible among themselves". It was agreed that it would be highly desirable for the Agency's dosimetry laboratory to have its dosimetry standards calibrated at the BIPM. The Group noted that when SSDL personnel visit the Agency's laboratory for training, they can bring their standards for comparison. This will help to maintain a high level of assurance about the coherence of the network standards.

Prior to the meeting R. Loevinger (NBS), S. Ellis (NPL) and the IAEA secretary had drafted a revised Criteria Document to be discussed and finalized by the SSDL Advisory Group. The final version was then officially approved by IAEA and WHO and published in an IAEA booklet entitled "Secondary Standard Dosimetry Laboratories: Development and Trends", Vienna 1985. As the revised Criteria are still in use they are

reproduced in SSDL Newsletter 37, Appendix 61.

It can be said that towards the end of the eighties the SSDL Network became an established and consolidated international venture. For this achievement high credit must be given to the heavily engaged members of the standing SSDL Scientific Committee, formed in Membership consists of one representative from the BIPM, the ICRU, one PSDL, one SSDL and (at least) two other scientists from metrological community. Specifically, Committee advises on techniques for dose metrological intercomparisons; consistency within the Network; measurement traceability to the BIPM; and the provision of technical information to, and training of, SSDL staff. It also assists in the appraisal of the performance of SSDLs by evaluating their annual reports submitted to the network secretariat. The Committee meets biennially and prepares a report to the Directors General of the IAEA and WHO which is subsequently circulated to Member States through the SSDL Newsletter<sup>2</sup>.

Also in 1986 Guidelines for Member States concerning the designation of Secondary Standard Dosimetry Laboratories were drafted by the IAEA Secretary of the network and distributed through the SSDL Newsletter no. 25. These guidelines are a necessary complement to the Criteria document, issued in 1985, and are reproduced in SSDL Newsletter 37, Appendix 5<sup>3</sup>.

In 1987, an International Code of Practice on Absorbed Dose Determination in Photon and Electron Beams was published in the IAEA Technical Report Series (no. 277), with P. Andreo, J.R. Cunningham, K. Hohlfeld and H. Svensson as principal authors. In order to maintain and improve the working standards in SSDLs, workshops, training courses, seminars, symposia and dose intercomparisons have been and are being performed at increasing frequency. One therefore may conclude that the SSDL Network is now in a position to provide access to radiation standards traceable to the international

<sup>&</sup>lt;sup>1</sup> Included as Appendix 6 in the SSDL Network Charter <sup>2</sup> Initially called SSDL Circular Letters - they were initiated in 1973 by W. Seelentag (WHO) and the author and distributed through WHO channels. With No. 25 (October 1986), the Circular Letter was presented with a new format and new name and has been produced and distributed, since then, by the IAEA SSDL Network Secretariat.

<sup>&</sup>lt;sup>3</sup> Included as Appendix 5 in the SSDL Network Charter.

measurement system to practically all countries having radiotherapy facilities.

**CONCLUDING REMARKS** 

This account of the development of the IAEA/WHO Network of SSDLs naturally reflects its evolution as seen by the author. However, he was in a position to use information and documents at first hand, all of which may not be available elsewhere. What appeared, 30 years ago, to be a rather modest project in terms of international input developed into not only one of the IAEA's largest technical co-operation projects but also into "one of the IAEA's most humanitarian activities", as the Director General of WHO recently called it.

One person must be mentioned here because of his outstanding and never declining efforts in assisting SSDLs on location, and because his name is rarely mentioned in printed documents, namely J. Haider, senior technician of the Agency's dosimetry laboratory. He was an ingenious maid-of-all-work, who spent most of his working time at numerous SSDLs and was (and still is) of invaluable assistance to the entire SSDL community.

### Acknowledgement

The author wishes to thank Dr. W.A. Jennings for his encouraging suggestions and valuable comments.

#### **Related Publications**

H. Eisenlohr: The IAEA/WHO Network of Secondary Standard Dosimetry Laboratories and its Function within the Metrology System. I. J. Appl. Rad. & Isot. 29 (1978), 707-711.

Secondary Standard Dosimetry Laboratories: Development and Trends. IAEA publication, Vienna, 1985.

- H. Eisenlohr: The SSDL Network, radiation protection and the principle of measurement traceability. Letter to the Editor of Rad. Prot. Dosimetry, 18/2, 113, 1987.
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### About the Author

Dr. Horst H. Eisenlohr. Post-doctorate and assistant professor in atomic physics at University Freiburg, 1955-1958.

Appointment with IAEA 1963. Head of the IAEA Dosimetry Section, 1971-1987.

IAEA Co-Secretary of the SSDL Network, 1976-1987.

# DEVELOPMENT OF A QUALITY ASSURANCE PROGRAMME FOR SSDLs

Report of the third Research Co-ordination Meeting (326-E2-RC-641.2), 29 November - 3 December 1999, IAEA, Vienna

A. Meghzifene, Scientific Secretary Dosimetry and Medical Radiation Physics Section Division of Human Health, IAEA

H. Jarvinen, STUK, Finland

J. Morales, SSDL, Cuba

J. Diaz, SSDL, Venezuela

Z. Limin, SSDL Shangai, China

The report of the First Research Co-ordination Meeting (RCM) related to this Co-ordinated Research Project (CRP) was published in the SSDL Newsletter No. 38 (January 1998). The scientific background and scientific scope of the CRP were given in that report. For completeness, a brief summary of the scope is included in this report.

## SCOPE OF THE CO-ORDINATED RESEARCH PROJECT

The traceability of dose measurements to the international measurement system in a few developed countries is ensured through national hierarchies of primary and secondary standards dosimetry laboratories, and in the rest of the world through the network of SSDLs maintained by the IAEA and WHO. The role of the SSDLs is crucial in providing traceable calibrations with the goal of achieving an uncertainty of the therapy level calibration factors of the order of about 1%. The SSDLs should also play an important role in the global efforts to provide quality audits to radiotherapy centres.

Besides the obvious needs of radiotherapy, accurate calibrations are needed for reliable measurements in diagnostic radiology and radiation protection. The requirements for traceable and reliable calibrations are also becoming more important for international trade where radiation products are manufactured within strict quality control systems in order to conform to given safety and performance criteria.

While every SSDL would be expected to run an

appropriate quality system, the quality standards require that this system should be well documented in the form of a quality manual. A documented quality system will clearly be a requirement when a laboratory wishes to apply for the accreditation of its calibration and testing activities or for the certification of its quality system.

The quality system of an SSDL should cover all the work carried out by the laboratory, whether this is the calibration of dosimeters, measurements for quality audits at radiotherapy clinics or for other demands of, for example, industrial customers. The implementation of the quality system requires high commitment of all staff members of the SSDL and can only be achieved through well organized and documented team work.

The quality system cannot be copied from other organizations. It must reflect the organizational specificity, directives and policies pertinent to each organization. However, many features can be identified which are common to laboratories with similar tasks, equipment and responsibilities. The experience gained in the implementation of the quality system obtained in one laboratory can be utilized for the design of a quality system for another laboratory.

A Co-ordinated Research Project (CRP E2.10.02) was initiated by the Agency with the objective to develop guidelines for SSDLs of the IAEA/WHO network. The guidelines should cover the establishment of a quality system and practical recommendations for the preparation of a quality manual, following ISO/IEC Standards. In addition, a harmonized programme for quality control of the standards, calibration equipment and calibration procedure will be proposed.

### MAIN POINTS DISCUSSED

The main points discussed during the meeting were to review the work done since the last RCM held in June/July1998 (Vienna), mainly:

- the contributions of all participants to the document on "guidelines to SSDLs to develop a quality system" and the exchange of information on experience gained by all participants,
- the results of the trial internal quality control programme and the establishment of action levels, and

 the estimation of uncertainties related to therapy and protection level calibrations achievable at the participating SSDLs.

In addition, the participants were informed by Mr. Pedro Andreo, Section Head, Dosimetry and Medical Radiation Physics Section, that a Mutual Recognition Arrangement (MRA) was signed by representatives of national Metrology Institutes and by two international organizations at BIPM in Paris on 14 October 1999. Mr. Andreo had been appointed by the Agency to sign the MRA on behalf of the IAEA/WHO Network of SSDLs.

The Network is considered as a Regional Metrology Organization (RMO) in the MRA. The RMOs are expected to play an important role in the MRA. They have the responsibility to carry comparisons within their network or regions and develop mechanisms to support confidence and mutual recognition in the validity of calibrations and certificates issued by their members. The SSDLs, members of the IAEA/WHO network, provide traceable calibration services in their countries. Their integration into the MRA through the Agency would not only give more confidence to the end users in the country but could provide a technical basis for extending their services to other countries. The MRA spells out explicitly the need for each participating laboratory to implement a quality system that meets the requirements of ISO/IEC 25<sup>4</sup> [1, 2] in order to establish the necessary mutual confidence.

### RESULTS OF THE PROJECT

As a result of the presentations made by the participants, their contributions and subsequent discussions, the following points are considered to have the maximum relevance for the Co-ordinated Research Project (CRP).

## DEVELOPMENT OF A QUALITY SYSTEM FOR SSDLs

The development of a quality system, with an appropriate quality manual, is a major effort and needs a very good understanding from all staff and a firm commitment from the management. It is then of crucial importance that extra time and resources are allocated to this task.

Typically, the process of developing and implementing a quality system will involve a preliminary phase, a build-up phase, an implementation and a consolidation phase. This is the basic framework used for developing a quality system at the participating SSDLs.

For the sake of clarity, the four phases are detailed below.

### Preliminary phase

### Project team and planning activities

At the beginning, the head of the laboratory should appoint a project team. Care should be taken to ensure that all categories of staff are represented. The team should preferably be lead by a quality manager, or the head of the laboratory.

Then, careful planning must be done and should cover activities in all phases needed for the development of the quality system. An approximate time schedule should be tentatively set up, even if it is modified later.

### Definition of the policy

The quality policy should be defined at this early phase. The quality level required for an SSDL is well defined in IAEA documents [3, 4] while general guidelines are mainly given in ISO/IEC Guide 25.

The definition should include a statement about the quality level that is intended for the laboratory activities.

### Informing and motivating staff

It is of prime importance to inform all staff members about the project to develop a quality system. Clear and complete information about the objectives and the methodology should be transmitted to all staff, preferably through meetings. A wide consensus should be obtained and all staff should feel responsible. All should contribute development of the quality system, as that is the best way to ensure their full commitment to the success of the project. Every effort should be made to convince staff that their work will not end up with a report, but should be an instrument for daily practice to achieve high quality in calibration services.

#### Task assignments

The design, development and implementation of a quality system represents a tremendous amount of

<sup>&</sup>lt;sup>4</sup> This is expected to be soon superseded by ISO/IEC Standard 17025.

work. It unavoidably needs the collaboration and commitment of all the laboratory staff, who should discuss all material and human resources available and the magnitude of the task. The project team should prepare a work plan that should include specific duties for all staff members and specific deadlines to accomplish the tasks.

The head of the laboratory or the authority responsible for developing and implementing the system should bear in mind the normal workload of staff. Great care should be taken to ensure that staff are not excessively loaded, as this may in turn affect quality.

Each laboratory has specific constraints, so no general procedure can be given. Some laboratories will work with tasks assigned to a project team while others will give this responsibility to a particular staff member. In all cases, it should not be perceived as the sole work of the head of the laboratory.

### **Build-up phase**

### Collection of information and inventory of existing system

To design a quality system compatible with international standards, information is of prime importance. One of the first tasks to be accomplished by the project team is to collect experience from other similar SSDLs that have already started with the development of a quality system. The Secretariat of the IAEA/WHO Network of SSDLs is a good source of information. In addition, international guidelines and recommendations (from BIPM, ISO/IEC, IAEA, etc.) should also be available.

At the local level, the laboratory should make an exhaustive list of every task and service that is performed. Every laboratory has some sort of basic empirical quality system even if it is neither exhaustive nor properly documented. The existing system may consist of control methods, protocols, forms, etc. All should be collected and will form a starting point for the development of the quality system. This will probably save a lot of time and work in later phases.

### Training of staff

The quality system can only be developed and operated by well-trained staff who have consciously adhered to and are committed to the quality policy.

Courses, seminars, or conferences should be

planned to instruct every staff member on the organizational and technical aspect of the quality system, with the aim to make clear to all staff the nature all aspects of the project.

### Preparing procedures and working instructions

With the quality objectives previously defined and taking into account the inventory of existing documents and procedures, the laboratory staff must prepare or complete the different procedures and working instructions that will document and standardize every activity performed at the laboratory.

This work involves important editorial work and needs to be carefully checked before it is approved.

Each procedure and working instruction should be written by a qualified staff member, but formal approval should be obtained from the head of the laboratory.

The set of procedures and working instructions being developed for the quality system will form the fundamental parts of the quality manual that needs to be prepared in connection with the implementation of the quality system.

### Implementation phase

### Putting into use

The implementation of the quality system is normally a gradual process that is applied step by step. In this process, each procedure implemented and included as a part of the whole system has to be checked in order to verify its compliance with the quality policy. The time needed to check the implementation of a given procedure will depend on the procedure itself, competence of staff and local conditions.

### Testing for suitability

A newly implemented quality system probably will have some inconsistencies, problems or weakness that will have to be identified during the initial period of its application. It is the responsibility of the head of the laboratory to ensure that adequate solutions are found and applied to correct all identified problems.

During this phase, all efforts should be made to ensure that procedures and working instructions are put into use and tested extensively.

### Consolidation phase

#### Validation

In the long term, validation is the process that will allow the laboratory to be confident with its implemented quality system.

The validation of the quality system may be understood as the overall sum of the validation of the multiple procedures and working instructions successfully implemented in the SSDL.

In the process of validation, the laboratory should practice internal audits with the understanding that they are an integral part of the quality system. The internal audits have to be practiced on a routine basis with a frequency that takes into account the workload and the procedures being audited.

External audits are essential to ensure confidence in the maintenance of the measurement standards to the international measurement system. Examples of external audit services provided by the IAEA for the network of SSDLs are the TLD postal dose service (for radiotherapy and radiation protection level dosimetry) and intercomparison of ionization chamber calibration factors.

### Reviews and feedback from users

The periodic reviews are an integral part of the quality system and should be planned and carried out accordingly.

The feedback from staff and/or end users usually contains useful comments that should be used to improve the quality system.

# PRACTICAL GUIDELINES FOR THE PREPARATION OF A QUALITY MANUAL

#### Recommended structure

The structure of the quality manual is not a key aspect, but a coherent approach facilitates its reading and understanding by the staff, end users and possible auditors. For the process of certification or accreditation, it is most important that the quality manual describes the organization and procedures in full accordance with ISO/IEC Guide 25 requirements.

The quality manual should be composed of a relatively short and concise basic document (preferably not exceeding about 30 pages) and a series of supplementary documents (see Appendix

1). The basic document should include brief recordings of all possible elements of the quality system, with references to supplementary documents for further details. Detailed guidance on quality control procedures, methods of measurement and calibration, operating instructions of radiation sources and other equipment, record keeping etc. should be given in the series of Procedure Manuals (see Appendix 1). This form of presentation makes it easy to manage the overall documentation of the quality manual. It will also be easier to check that all relevant topics of ISO/IEC Guide 25 are covered while minimizing unnecessary overlapping of presentations when this Guide is applied.

The extent to which details are described in a given procedure may vary significantly. To avoid omitting details in the preparation of the procedures, it is necessary to formalize the entire process of preparing the procedures. For simplicity and ease of work, it is a good practice to prepare the standardized forms before the procedures are written. There are several aspects which should be considered in the preparation of the standardized forms.

The first page should contain the title and the reference number of the procedure (or working instruction). The level of the document should be identified in the reference number. The issue number and the date should be shown. The computer file name can also be displayed to facilitate its retrieval.

The name(s) of the drafter(s), quality manager and the approval line should be indicated.

The total number of pages should be displayed in a way that would indicate clearly any missing page (e.g. page 1 of 10)

The purpose of the procedure should be clearly and briefly defined.

The definitions of specific terms used in the procedure should be defined in a separate section.

The main technical and scientific references used in the procedure should be compiled.

The responsibility line should be shown.

If specific instructions are prepared in conjunction with the procedure, their reference numbers should be clearly indicated.

### Level 1 document: the basic document of the quality manual

Detailed guidance for writing the level 1 document of the quality manual was partially prepared during the CRP. Additional work is needed to complete it. A full report will be published by the IAEA. Reference to the relevant sections of ISO/IEC Guide No. 25 (ISO 17025<sup>5</sup>) will be included in order to assist in checking the compliance of the text with ISO requirements.

### Level 2 documents: procedure manuals

The level 2 documents contain the procedures needed to implement the policies stated in the level 1 document. A complete quality manual usually includes a large number of procedures, but the exact number depends on the various activities carried out at the SSDL.

### Level 3 documents: working instructions

The level 2 document does not generally contain all details needed to implement a given procedure. One can easily check this level of detail by ensuring if it is sufficient for competent new SSDL staff to carry out all the procedures without any further help. In general, working instructions are needed to spell out all the details and those are referred to in a level 3 document.

## MINIMUM QUALITY CONTROL PROGRAMME FOR SSDLs

One of the basic objectives of the Co-ordinated Research Project on "Development of a Quality Assurance Programme for SSDLs" was to develop an Internal Quality Control Programme (IQCP) that might be implemented by SSDLs who are members of the IAEA/WHO Network of SSDLs. Previous recommendations on that topic were already published [3], but it was considered appropriate to complement the information given in that publication with the experience on methods, frequency of the tests and action levels used by the five participating SSDLs in the CRP. It was agreed to focus the attention of the IQCP only on calibration services of photon beams provided at therapy and protection levels. A basic proposal on a minimum IQCP was discussed during the 1st Research Co-ordination Meeting organized in Vienna in December 1996. Results derived from the 3 year-implementation of the proposed IQCP by the five SSDLs (China-Shanghai, Cuba, Finland,

Turkey and Venezuela), together with the recommendations that arose from its implementation, are presented below.

### Design aspects of a minimum quality control programme for SSDLs

Basic information for setting up action levels and frequencies for the control of instrumentation used in calibration services at therapy level is described in TRS-374 [3]. To some extent, that information is also applicable to protection level calibrations. These action levels are consistent with the requirement that the overall combined standard uncertainty expected for the calibrations performed at SSDL for therapy levels and protection level dosimetry should be less than 1% and 2% (at one standard deviation), respectively. It was, however, appropriate to check how these basic action levels using the different types were met instrumentation available at the SSDLs taking part in the CRP.

It was clear from the beginning that the frequencies of the tests have to be optimized, taking into account the human resources and workload available at the SSDLs. The basic principle used for designing the minimum IQCP was to keep in balance the need for detecting unwanted measurement errors and the extra work needed to implement the tests.

The minimum IQCP which has been under trial is presented in Appendix 2. Nine parameters were tested. The method used for the quality control, the frequency and the action levels are reported. The action levels were derived from the set of data supplied by the participants, using statistical tools.

#### Conclusions and recommendations

### Re-calibration of reference and working standards

Results of comparisons of old and new calibration factors for therapy level reference standards recalibrated during the trial suggest that an action level of 0.7% could be envisaged. However, a wide spread of the results among all participants was also observed. For this reason, the participants have decided not to make a specific recommendation for an action level. Instead, SSDLs are encouraged to establish their own action levels based on the results of long term stability of their reference standards. If a significant difference is found (between the old and the new calibration factors), the SSDL should carry out further investigations in order to explain the deviation. Efforts should be made to spell out

<sup>&</sup>lt;sup>5</sup> A draft version of the new standard was used. Changes in the relevant section numbers may occur when the final version is published.

any mistakes or misunderstandings, and to confirm that the deviation is caused by an actual change of the standard or by recognized change of the calibration parameters or procedures. If needed, the PSDL or IAEA dosimetry laboratory where the calibration was performed should be contacted to help reconcile the deviation.

Re-calibration of reference standards should be planned at about three year intervals [3]. It is recognized that this period depends on the long-term stability of the instrument. Taking into account the results of long-term stability of reference standards used by most SSDLs, and the risk of loosing or damaging the standard during transportation, the interval between calibrations can be increased to 5 years without a major decrease in quality.

Working standards are usually reference class instruments and thus of the same quality as the reference standards. This suggests that action levels for working standards and reference standards should be at about the same level. Results obtained in the trial IOCP confirmed this assumption. Recalibration ofthe working standards recommended to be carried out every year. The new calibration factors obtained after each re-calibration are used if the change (between previous and new factors) exceeds twice type A uncertainty of the calibration. The working standard should always be re-calibrated at the SSDL after the calibration of the reference standard (done at a PSDL or the IAEA dosimetry laboratory).

# Stability tests of reference and working standards by measurements at a fixed position in a gamma or x-ray beam and by check source measurements

These tests check the stability of the reference standards and the calibration set-up maintained at the SSDL. The action levels that were set for the measurement standards of both therapy and protection level are consistent with the typical uncertainty related to the long term stability of the reference and working standards.

Action levels recommended for plane parallel chambers were suggested by only one participating SSDL and should be considered with care.

### Control of the charge measuring assembly

Ionization chambers can be calibrated alone (in terms of charge) or as part of a whole system that also includes the electrometer. The calibration of the system as a whole is provided in terms of scale readings. It is strongly recommended that SSDLs

send the whole system to the PSDL or IAEA dosimetry laboratory for calibration at 5-year intervals. It is the practice of some PSDLs to compare the SSDL reference electrometer with the PSDL's current measuring system. At the IAEA, the calibration of the reference chamber alone (connected to IAEA reference electrometer) and the calibration of the whole system (reference SSDL chamber connected to SSDL electrometer) are carried out. This will give an indication of the accuracy of the reference SSDL electrometer. The SSDL can in turn check the calibration in terms of charge of other working standards or field class electrometers. Another alternative is to use a precision current source in order to check the calibration of electrometers. Such current sources (designed and produced at the IAEA's Laboratories) can be borrowed<sup>6</sup> from the IAEA. A check of the electrometer calibration factor, using a strontium check source, was carried out by one participating SSDL during the trial IQCP. The results obtained were not satisfactory. Other participants carried out the tests with a Co-60 therapy beam instead of using a radioactive check source. The typical Type B uncertainty for measurement of the ionization current (at therapy level calibration) in terms of charge was found to be about 0.1%. Accordingly, the action level of 0.1% is proposed. It is recommended that SSDLs use the calibration factor of the whole system when a higher value is found.

### Check of working thermometers, barometers, and hygrometers

Mercury thermometers are proposed as reference thermometers for SSDLs [3]. It is recommended to check their calibration once a year in a national calibration laboratory. It is, however, anticipated that some SSDLs may have problems getting access to such calibration laboratories. The alternative is to carry out a check of the reference thermometer at 0 °C in the ice bath. Differences larger than 0.2 °C are considered excessive and should be corrected for

The action level for barometer stability is derived from the experimental standard deviation found in the trial IQCP. It is considered not necessary to recalibrate the reference mercury barometer unless visible damage is observed. Electronic barometers can be used as working standards, provided they are calibrated against mercury barometers.

The accuracy of hygrometers was not considered

<sup>&</sup>lt;sup>6</sup> Interested SSDLs are invited to send a request to the Secretary of the IAEA/WHO Network of SSDLs.

important, unless the typical relative air humidity in the SSDL is at the edge of the acceptable range of 20-80%.

A monthly frequency for the controls of thermometers and barometers was used in the IQCP. However, the stability showed by the significant numbers of thermometers and barometers under test suggests that the actual frequency of controls can be reduced to 2 or 3 times a year.

### Beam irradiation characteristics: geometry, uniformity and timer correction

Few data were collected on beam irradiation characteristics from the SSDLs participating in the trial. However experimentally estimated action levels for those parameters checked during the trial IQCP were consistent among the participants.

### Comments

- Action levels proposed in the present IQCP are considered as minimum values that should be used by the SSDLs in order to guarantee an acceptable degree of accuracy for the calibrations performed at therapy and protection levels. They are defined at the 95% confidence level.
- If the results of a given test fall outside the action level, it is recommended to repeat the test. Further investigations are carried out only after the deviation is confirmed.
- SSDLs are encouraged to review and if necessary update action levels from time to time (e.g. as part of a general review of the quality system).
- If an action level set by an SSDL is significantly greater (compared to that proposed in the present IQCP), special attention should be paid to the measurement conditions (ambient, operational), type of equipment and human factor.

## ESTIMATION OF UNCERTAINTY OF CALIBRATIONS

As a part of the quality objectives specified in the quality system of an SSDL, the level of accuracy (limits of uncertainties) to be aimed at for the various types of calibrations at the SSDL should be defined. The next step is then to ensure that the resulting uncertainties in calibrations are properly

evaluated and that all efforts are made to achieve and maintain the accuracy requirements. The estimated uncertainties should form the background data for all operations in the laboratory, including the setting of action levels for quality control and the evaluation and follow-up of the results of all measurements. The requirements in terms of accuracy should be clearly recognized by all SSDL staff members, including the detailed uncertainties pertinent to equipment used and procedures applied in calibrations and testing.

The mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes (including SSDLs of the IAEA/WHO Network) calls upon, among other requirements, successful participation by each institute in appropriate supplementary comparisons. The analysis of the consistency of results, or the degrees of equivalence between standards, is based on the declared uncertainties of the results given by the participants. The evaluation of uncertainties thus becomes a prerequisite for participating in the intercomparisons, and a key point in external auditing of the SSDLs' operation and effectiveness of their quality system.

The estimation of uncertainties is, therefore, an important part in the development of an SSDL quality system in order to comply with the standard requirements. In TRS-374 [3], the theoretical basis and a general example of estimation of uncertainties of calibration are given. Within this CRP, these basic principles were tested in detail, by collecting and analyzing the estimated uncertainties for the most common types of calibrations in all of the participating SSDLs. The range of values of uncertainties of various types of calibrations, estimated by the participating SSDLs, is given below:

### • Therapy level:

- For air kerma calibrations of thimble chambers: 0.3 to 1.2% (Co-60)
- For absorbed dose to water calibrations of thimble chambers: 0.4 to 0.5% (Co-60)
- For air kerma calibrations of thimble and plane parallel chambers: 0.5 to 1.5% (x-rays)
- Protection level (survey meters)
  - For ambient dose equivalent: 1.3-4.0% (Co-60 and x-rays), depending on the type of survey meter.

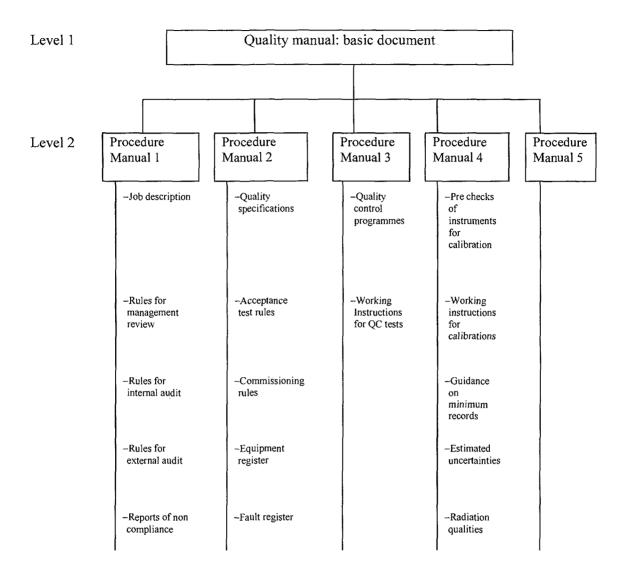
It is emphasized that the range of values given above

should only be considered as an example of the estimation of uncertainties made by some SSDLs. Each SSDL should go through all steps needed to evaluate the uncertainties of measurements, taking into account their own equipment, procedures and experience. The detailed evaluation for the estimation of various component uncertainties will be included in the final report of the CRP and will be distributed to all SSDLs of the Network.

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APPENDIX 1
Recommended structure of the quality manual



APPENDIX 2

RECOMMENDED MINIMUM QUALITY CONTROL PROGRAMME FOR SSDLs

Test No.	Parameter under control	Method of control	Frequency	Action level
1	Reference standard chamber	1.1 Calibration at PSDL or at IAEA laboratory	Every 5 years, unless needed due to results of tests 1.2 and 1.3	No action level is recommended but SSDL should compare with previous calibration factor and contact PSDL when the difference is high.
		1.2 Stability test by measurements at a fixed position in gamma-ray or X-ray beam (this can also test calibration set up)	In connection with every calibration of the working standard chamber or once a year <sup>1</sup>	<ul><li>0.5% therapy level thimble chamber.</li><li>1.0% therapy level plane parallel chamber.</li><li>1.0% protection level chamber.</li></ul>
		1.3 Stability test by check source measurement	In connection with every calibration of the working standard chamber and quarterly.	<ul><li>0.5% therapy level thimble chamber.</li><li>0.8% therapy level plane parallel chamber.</li><li>1.0% protection level chamber.</li></ul>
2	Working standard chamber	2.1 Re-calibration against reference standard	Once a year and always after test 1.1	New calibration factors put to use when the change exceeds 2x estimated type A uncertainty of the calibration and always after calibration of reference standard. Deviations of the calibration factor greater than 0.5% (1% for protection level) should be investigated.
		2.2 Stability test by measurements at a fixed position in gamma-ray or X-ray beam (this can also test calibration set up)	In connection with every calibration of field chambers	<ul><li>0.5% therapy level thimble chamber.</li><li>1.0% therapy level plane parallel chamber.</li><li>1.0% protection level chamber.</li></ul>
		2.3 Stability test by check source measurement	Quarterly and if action level of test 2.2 is exceeded. Only therapy level chambers.	0.5% therapy level thimble chamber.  0.8% therapy level plane parallel chamber.
3	Electrometers	3.1 Reference electrometer comparison with PSDL or IAEA electrometer	In connection with test 1.1	If more than 0.1% the calibration factor of the assembly (chamber plus electrometer) should be used.

Test No.	Parameter under control	Method of control	Frequency	Action level	
		3.2 Working electrometers comparison with reference electrometer with help of constant current source	In connection with test 2.1	If more than 0.1% (measurement at Co-60 beam) the calibration factor of the assembly (chamber plus electrometer) should be used.	
4	Thermometers	4.1 Check of reference thermometer calibration (ice bath)	Once a year	Differences from zero, in ice bath, greater than 0.2 °C should be corrected.	
		4.2 Comparison of working thermometers with reference thermometer	1 month (electronic thermometer) 6 months (mercury)	Differences greater than 0.2 °C should be corrected.	
5	Barometers	5.1 Comparison of working barometers with reference barometer.  Reference mercury barometer needs no re-calibration unless visible damage	1 month <sup>2</sup>	Differences greater than 0.1% should be corrected	
6	Hygrometers	6.1 Check of calibration (e.g. of hair hygrometers)	Once a year	5% RH is only relevant when the SSDL is working at extreme condition (20%, 80%).	
7 Radiation beams		7.1 Check of x-ray beam quality	Once a year	2% therapy level qualities 5% protection level qualities	
		7.2 Check of alignment of radiation beam with laser beam	Once a year	Angle between beams 0.2° for gamma and 0.5° for X-ray.	
		7.3 Check of radiation field size by film exposure	Once a year	5 mm from the expected field size (mechanical or optical indication, therapy level only).	
				(For protection level, ensure that the dosimeter is within uniform area of the field.)	
		7.4 Check of beam flatness and symmetry by film exposure	Once a year	Flatness and symmetry less than 3% for gamma beams.	
				Flatness and symmetry less than 5% for X-ray beam.	
		7.5 Accuracy of timer <sup>3</sup>	Once a year	0.1%	
		7.6 Stability of timer correction	Once a year	0.1 s	

Test No.	No. Parameter under control Method of control		Frequency	Action level
8	Laser beam for distance indicator	8.1 Comparison of laser beam and mechanical distance indicators (mark on the wall or floor, or front pointer)	Before every calibration	1 mm therapy level 2 mm protection level
9	Calibration procedure	9.1 Comparison of calibration factors obtained from two series of measurements by re-positioning of user's chamber	Occasionally	2x Type A combined uncertainty of the calibration.
		9.2 Repetition of whole calibration procedure by another staff member	Once a year in connection with internal audit	2x Type A combined uncertainty of the calibration.

<sup>&</sup>lt;sup>1</sup>Instead of using a working standard for protection level gamma beam measurements, an SSDL may use decay corrected values of the air kerma rate, determined by a reference standard. Annual measurement of air kerma rate in the gamma beam, using the reference standard, is then recommended.

<sup>&</sup>lt;sup>2</sup> A frequency of one month was used in the trial IQCP. The results obtained show that a frequency of 6 months is sufficient.

<sup>&</sup>lt;sup>3</sup>Accuracy of timer shall be verified for all timers during acceptance testing or commissioning. Thereafter, usually only mechanical timers need to be regularly checked for accuracy.



### QUALITY ASSURANCE PROGRAMME AT THE NATIONAL CALIBRATION LABORATORY IN TANZANIA

W.E. Muhogora, O. Yoloye, J. Ngaile and U.S. Lema

National Calibration Laboratory for Ionizing Radiation, Arusha

United Republic of Tanzania

A quality assurance programme at the National Calibration Laboratory for ionizing radiation in Tanzania is described. The programme focuses mainly on regular stability check source and reference output measurements, performance testing of TLD systems as well as some external audit checks. It is found that the stability check source measurements are within  $\pm 1\%$ . Similarly, the air kerma rate measurements agree well with calibration uncertainties, that is  $\pm$  2% for protection level measurements and ± 1.5% for clinical dosimetry. The results of comparison of dose measurements done on site and those obtained from some external audit checks are also within requirements. This shows that the working standards have been kept with good care, and that the traceability to the international measurement system is adequately maintained. Some examples on calibration transfer activities are briefly discussed.

### INTRODUCTION

In the United Republic of Tanzania, the regulatory control of ionizing radiation practices is assigned to the National Radiation Commission (NRC) [1]. In fulfilling this radiation protection responsibility, the dose limitation system [2] is in use to be on an alert against possible trade off. This practical need prompted the NRC, with IAEA technical assistance, to establish the National Calibration Laboratory (NCL) for Ionizing Radiation in 1991. Since 1992, the NCL has been a member of the IAEA/WHO Network of Secondary Standard Dosimetry Laboratories (SSDLs). The basic aim of establishing this laboratory was to improve accuracy in radiation dosimetry in the country. Ever since its establishment, the laboratory therefore maintains and applies dosimetric equipment of the present state of art for the calibration of radiation survey instruments, output of radiation sources and installations in the field as may be required. The

laboratory also provides training and advice to the radiation users up-to-date ionizing on measurement procedures and techniques. The accuracy and reliability in the laboratory measurements are vital; and for this need a quality assurance programme is implemented to ensure that the measurements made using the reference instrument are linked to the international measurement system with an acceptable level of uncertainty. This paper presents the results of quality assurance activities undertaken at the National Calibration Laboratory for ionizing radiation in Tanzania.

### MATERIALS AND METHODS

## CALIBRATION AND DOSIMETRY EQUIPMENT

The calibration facility at NCL consists of <sup>137</sup>Cs (Ser. No. CD 07607), <sup>60</sup>Co (Ser. No. DA 221) STS calibration sources and a Pantak superficial x-ray machine, model HF 160 (tube Ser. No. 68665). The available three sources of radiation can provide a total of eight radiation protection qualities while two clinical calibration qualities may be realized using the x-ray equipment. Two ionization chambers, the protection level, type NE 2575 (Ser. No. 443) and the therapy level, type NE 2581 (Ser. No. 1057) are available. The corresponding stability check sources are NE 2576 (Ser. No. 288) and NE 2503/3 (Ser. No. 2622) respectively. The latter check source belongs to the Ocean Road Cancer Institute (ORCI) the only radiotherapy centre in the country which is located in Dar es Salaam. The electrometer in use is type NE 2570/IB (Ser. No. 937). The calibration of each working standard is traceable to the International Measurement System through the IAEA dosimetry laboratory. The calibration of the working standards was checked against the IAEA's standard in 1996 at the National Radiation Commission premises. A quality assurance (QA) programme based on recommended procedures and the stated conditions during the calibration of the reference instrument [3] is described below.

### REFERENCE CHECK SOURCE AND RADIATION OUTPUT MEASUREMENTS

Reference check source measurements are done monthly in order to assess the long term stability

[4]. The mean annual reference check source determined measurements from respective monthly measurements are of main interest for chamber stability and are analyzed with respect to the standard uncertainty limit of  $\pm 1\%$ . The output in terms of air kerma rate with respect to all ten calibration qualities is also determined monthly in order to confirm good reproducibility of radiation beam and hence the calibration stability of the working standards. The radiation geometry being employed for <sup>137</sup>Cs and <sup>60</sup>Co output measurements is 40 cm field size (FS) at the source to detector distance (SDD) of 300 cm. For x-rays, the FS of 27 cm and SDD of 200 cm are applicable. The air kerma rate (Kair) measurements are analyzed with respect to the uncertainty of  $\pm 2.5\%$  stated in the calibration certificate. The verification of ISO 4037 reference protection level x-ray qualities is also done annually and compared to the typical uncertainty of ±2%. In the case of clinical dosimetry using 60Co beam, a visit is made to ORCI at least once a year to undertake the output measurements of the teletherapy machine, type AECL Theratron 780 (Ser. No. S-4638). The output of interest includes air kerma rate and absorbed dose to water rate (D<sub>w</sub>) measurements in standard geometry. The standard radiation geometry during air kerma rate measurements is the source to surface distance (SSD) of 80 cm, source to chamber distance (SCD) of 85 cm and a 10 x 10 cm<sup>2</sup> FS [4,5]. In both cases, the standard IAEA cubic phantom is employed. The analysis of the measurements is done with respect to the stated calibration uncertainty of ± 1.5% for air kerma rate measurements and  $\pm$  2% for absorbed dose to water rate measurements. Beam scanning, radiation survey of treatment head and check up of proper performance of radiation safety devices are also regularly done at the radiotherapy hospital.

### CALIBRATION OF TLD SYSTEMS FOR RADIATION PROTECTION AND ENVIRONMENTAL DOSIMETRY

The calibration of the available TLD systems (models 2000 B + C and model 4000 B) are checked monthly using relevant calibration reference radiation qualities [6]. The 60 kV, (0.24mm Cu HVL) x-ray quality is used to calibrate the TLD system in order to evaluate the TLDs employed in monitoring the radiation workers in diagnostic radiology. In the case of TLDs used for individual monitoring of workers

radiotherapy, industrial and institutions, <sup>137</sup>Cs and <sup>60</sup> Co gamma- ray beams are employed as reference qualities depending on which type of radiation quality is closer to the energy of the radiation source in use. Every three months, the sensitivity of the LiF TLDs are checked and the calibration curve determined before using the TLDs. The absorbed dose range is between the reader detection limit of 0.1 mGy and 10 mGy. Normally, the individual doses recorded over three month monitoring periods are less than 3 mSv [7]. A new project to send the control dosimeters (exposed and unexposed TLDs) to selected zonal centres has been started in order to improve the quality control programme. The laboratory also provides the <sup>137</sup>Cs calibration for the CaF<sub>2</sub> TLDs employed in the environmental monitoring of external radiation. The programme is operated by the environmental monitoring department collaboration with the IAEA and the Global Environmental Monitoring Network (GERMON).

### INTERCOMPARISONS

Since 1996, the laboratory has been participating in therapy level postal dose checks organized by the IAEA [8]. The NCL also organizes dose comparisons on site with ORCI at least once a year. During this mission, independent air kerma and absorbed dose water rate measurements are made and are followed by joint discussions between the NCL and ORCI dosimetry staff. Similarly, on site dose comparisons with the Radiation Protection Board (RPB) of Kenya have been planned and will be done in Nairobi. With regard to the protection level dosimetry, the NCL also arranges postal TL dose checks using the blind irradiation method and the counterpart is requested to evaluate them. Three counterparts, namely SSDL Algeria (1997), SSDL Ghana (1997) and IAEA (1994) have so far participated in this exercise. In particular, the national SSDL in Algeria provided the reference TLD 100 calibration curve on which routine re-calibrations based. Formally, the laboratory participated in two postal dose checks organized by the African Cooperative Agreement (AFRA) (1997) and the IAEA (1998). The results are expected in the near future. Regular on site dose comparisons are also planned for radiation protection dosimetry. Already one protection level dose comparison has been done with RPB of Kenya at the NCL premises in 1997.

### RESULTS AND DISCUSSIONS

Figure 1 shows the variability between mean annual check source measurements normalized to the measurements previously taken by the IAEA expert [3] for two ionization chambers from 1991 to 1997. As shown, the mean annual check source measurement is within the acceptance limit of  $\pm$  1%. It is worthwhile to note that the therapy level chamber was acquired in 1995.

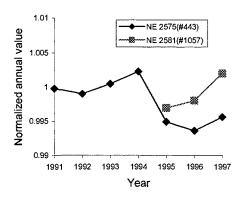


Fig.1: Long term stability of the working standards (normalized to IAEA measurements)

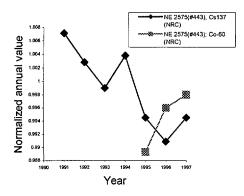


Fig.2: Variation of protection level air kerma rate measurements (reference geometry)

Figure 2 summarizes the air kerma rate measurements which are well within the acceptance limit of  $\pm$  2 %. The air kerma rate measurements along the NCL <sup>137</sup>Cs beam axis have also been found to be within  $\pm$  2% (normalized to the air kerma rate at the standard SCD of 2 m). These results are used to estimate the uncertainty during the calibration of survey instruments and TLD dosimeters.

It can also be seen from Figure 3 that the measurement results are within the acceptance limit of  $\pm 1.5\%$  and  $\pm 2\%$  for  $K_{air}$  and  $D_w$ 

respectively. It is further interesting to note that the experimentally determined half value layer (HVL) measurements over the past two years have been reproducible to within less than 1% within and therefore the acceptable uncertainty. The observed results confirm that the standards working have been adequately maintained over the past 5 year period and therefore the subsequent measurements using the standards are still traceable to the international measurement system.

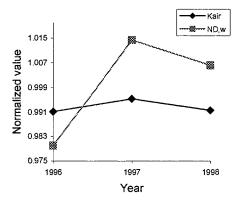


Fig.3: Variation of clinical air kerma and absorbed dose to water rates (reference geometry)

Since 1997 to date, clinical dose comparisons could not be done due to unusual performance observed with ORCI's ionization chamber, NE 2571 (Ser. No. 2404), which was calibrated against the IAEA's standard. It is planned to calibrate the ionization chamber again at the IAEA.

With respect to calibration transfer aspects, the laboratory calibrates gamma radiation survey instruments used all over the country and a few from neighboring countries. Routine calibration of TLD systems as described earlier is further done.

Results from routine calibrations and inter comparisons show that the uncertainty in individual doses as evaluated by NRC is about  $\pm$  50% [6]. Reference TLD irradiations have also been provided to the Radiation Protection Board of Kenya and Victoria hospital in Mauritius. It is further interesting to note that based on our experience, the personal dose equivalent penetrating, Hp(10) for NCL staff is, on average, less than 3 mSv per year.

With respect to the quality assurance on the TLD system, the results are also encouraging. Figures 4 and 5 give typical dose and the energy

dependence of LiF TLDs for indicated radiation qualities as determined in May 1998.

In practice, the TLD batch non-linearity for 0.1-10 mGy dose range is found generally to be less than  $\pm$  20%. The energy response of the TLD batch in use for 33, 48, 65, 83, 100 and 120 keV relative to  $^{137}$ Cs reference energy is within  $\pm$  40%.

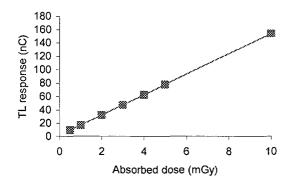


Fig.4: Typical dose dependence of LiF TLDs on Harshaw 2000B+C TLD system using the <sup>137</sup>Cs gamma ray beam

Comparisons are done between NRC and RPB and between NRC and ORCI on site. As can be seen, the performance of the NRC dosimetry system compares well within  $\pm$  2% to the RPB dosimetry system for  $K_{air}$  measurements and

within  $\pm 1.5\%$  and  $\pm 2\%$  to the ORCI dosimetry system.

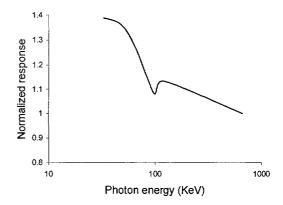


Fig.5: Typical energy response of LiF G-1 TLD (relative to <sup>137</sup>Cs)

The 1996 results of IAEA/WHO postal dose check were -2.1% and -2.5% respectively for each TLD set (of 3 capsules) irradiated to 2 Gy from a <sup>60</sup>Co gamma beam. Table 1 gives the results of parallel dose.

The results from on site comparisons and external audit checks provide further support for adequate consistent measurements.

**Table 1**: On site comparisons in terms of radiation output measurement between the NCL and the indicated institutions

Date	Protection level  K air(NRC)/K air(RPB)	Date	Therapy level  K air(NRC)/K air(ORCI)*	$D_{w \text{ (NRC)}}/D_{w \text{(ORCI)}}^*$
	OB 6	OB 2		
14/10/97	1	23/3/96	1.0084	1.0002
16/10/97	0.9851	6/11/96	0.9980	0.9991

<sup>\*</sup>RPB working standard: NE 2570/1A (Ser. No. 874) with NE 2575 (Ser. No. 416) calibrated by IAEA in 1994.

<sup>\*</sup>ORCI working standard: NE 2620 (Ser. No. 271) with NE 2571 (Ser. No. 2404) calibrated by IAEA in 1996.

Despite the encouraging results, some improvements are necessary for better results. For example, the laboratory needs a reference standard to reduce the frequency for recalibrations of the working standard. The available therapy level standard, which is usually employed for field work at the radiotherapy hospital, is at risk with respect to transport problems that may occur. The recently acquired standard reference check source for the therapy level ionization chamber will improve the related quality assurance programme. Equally important is the need to upgrade the professional level of the dosimetry staff for future improved efficiency.

### **CONCLUSIONS**

The quality assurance programme at the National Calibration Laboratory in Tanzania has been described. Despite its simplistic form, the results from this programme show that the respective recommended acceptance limits have not been exceeded in the past period. More importantly, the laboratory measurements compare well with the measurements done in the external audit check programme. Some limitations have been observed, particularly the lack of a reference standard and the need to upgrade the professional level of dosimetry staff.

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### **ANNOUNCEMENTS**

## FOURTH INTERNATIONAL WORKSHOP ON DOSIMETRY FOR RADIATION PROCESSING

This workshop is sponsored by ASTM and organized in co-operation with the IAEA. It will be held at the Bahia Resort Hotel in San Diego, California on October 22-27, 2000.

The objective is to improve the quality of dosimetry through a better understanding of dosimetry principles, calibration techniques, dosimetry applications (e.g. dose mapping and routine monitoring), and the determination and understanding of dosimetry uncertainties, all based on standards published by ASTM. Other standards on process control and quality systems that may have an impact on dosimetry practices will also be covered.

The workshop format is designed to provide maximum interaction between participants resulting in mutual benefits for all. Experienced discussion leaders whose primary role will be to facilitate the discussions will chair the sessions. To encourage openness, neither the opening presentations nor the workshop discussions will be published. Included will be presentations and round table discussions led by industry experts, laboratory exercises, irradiator site visits, product demonstrations, and poster sessions.

Details of the workshop may be viewed at http://www.astm.org/COMMIT/CUSTOM1/E10.htm.

## MONTE CARLO 2000-ADVANCED MONTE CARLO FOR RADIATION PHYSICS, PARTICLE TRANSPORTS SIMULATION AND APPLICATIONS

The conference is organized by the Instituto Tecnológico e Nuclear (ITN), Ministerio da Ciencia e da Tecnologia of Portugal, in co-operation with the IAEA. It will be held in Lisbon, Portugal on 23-26 October, 2000.

The conference will gather the major experts worldwide working in the field of Monte Carlo methods and techniques and their applications for radiation physics and particle transport simulation.

Details of the Conference may be viewed at http://www.itn.pt/Meetings/MC2000 and can also be obtained from the Dosimetry and Medical Radiation Physics Section, Division of Human Health (IAEA).

# INTERNATIONAL SUMMER SCHOOL IN MEDICAL PHYSICS: RELEVANT TOPICS IN DIAGNOSTIC RADIOLOGY AND NEW TECHNIQUES IN RADIOTHERAPY

The Summer School is organized by the Latin American Association of Medical Physics (ALFIM) and the American Association of Physicists in Medicine (AAPM), in co-operation with the IAEA.

The Summer School will be held in Chicago from 17-21 July 2000 (immediately prior to the World Congress of Medical Physics and Biomedical Engineering, also to be held in Chicago).

Details of the Summer School can be obtained from the Dosimetry and Medical Radiation Physics Section, Division of Human Health (IAEA).

### **COURSES AND MEETINGS TO BE HELD DURING 2000**

### Training courses in the field of dosimetry and medical radiation physics

- Group Training on calibration procedures, 16-17 March 2000, Vilnius, Lithuania (LAT/1/002).
- AFRA Workshop on maintenance of Co-60 units, 20-26 May 2000, Kenya (RAF/4/014).
- Workshop on calibration procedures in radiation protection and radiotherapy level dosimetry, 24-28 June 2000, Algeria (RAF/9/024).
- Regional Training Course on quality assurance in radiotherapy: physical aspects, Australia (November or December 2000, dates to be set) (RAS/6/027).
- Regional Training Course on quality assurance in radiotherapy: physical aspects, 18-29 June 2000, Syria (RAW/6/009-001).

### Other meetings

- Third Project Co-ordinators' Meeting, 24-28 January 2000, Santo Domingo, Dominican Republic (RLA/6/032, ARCAL XXX)
- Research Co-ordination Meeting on radiation therapy dosimetry in developing countries, Vienna,
   6-10 November 2000
- Advisory Group Meeting on evaluation of and recommendation on the dosimetry and medical radiation physics programme, Vienna, 13-17 November 2000
- Research Co-ordination Meeting on transport simulation for photons and electrons in radiotherapy, organized jointly by DMRP and NAPC, Vienna (dates not yet known)
- Research Co-ordination Meeting on EPR biodosimetry, organized jointly by DMRP, ARBR and NSRW, Vienna, 25-29 September 2000
- Consultant Meeting on development of methods for radiotherapy dose calculations and computerized treatment planning systems, Heidelberg, Germany, 23-27 May 2000
- Consultant Meeting on regional education programme in medical radiation physics, Vienna, 5-9
   June 2000
- Consultant Meeting on development of procedures for the determination of absorbed dose with therapeutic photon, electron and proton beams based on measurement standards of absorbed dose to water, Vienna (dates not yet known)
- Consultant Meeting on development of methods to resolve discrepancies for quality audit programmes, Vienna (dates not yet known)
- Consultant Meeting on development of techniques for the dissemination of measurement standards based on absorbed dose to water to SSDLs, Vienna (dates not yet known)
- Consultant Meeting on dosimetry and quality assurance in diagnostic radiology at SSDLs, Vienna (dates not yet known)

### MEMBER LABORATORIES OF THE IAEA/WHO NETWORK OF SSDLs

<u>Country</u> ALGERIA ARGENTINA	City Algiers Buenos Aires	Contact person Mr. M. Arib Ms. M. Saravi	<u>Fax</u> +213 264 8842 +54 14800615	E-mail crsdec@ist.cerist.dz saravi@cae.cnea.gov.ar
AUSTRALIA AUSTRIA	Menai Vienna	Mr. Claudio Tuniz Mr. H. Stadtmann	+612 971732577 +43 22547802502	tuniz@ansto.gov.au hannes.stadtmann@arcs.ac.at
BANGLADESH BELGIUM	Dhaka Gent	Mr. Abdul Jalil Mr. H. Thierens	+8802-863051 +32 92646699	asmollah@dhaka.agni.com hubert.thierens@rug.ac.be
BOLIVIA	La Paz	Mr. Ismael Villca	+592 2433063	ibtn@datacom-bo.net
BRAZIL	Rio de Janeiro	Ms. M. de Araujo	+552 14421605	mmaraujo@ird.gov.br
BULGARIA	Sofia	Mr. Z. Buchakliev	+359 2443114	ivandim@techno-link.com
CANADA	Ottawa	Mr. R. P. Bradley	+1 6139529646	Robert_Bradley@hc-sc.gc.ca
CHILE CHINA*	Santiago	Mr. Oyarzun Cortes Mr. Gan Zeuguei	+56 227318723 +86 1444304	coyarzun@gopher.cchen.cl
CHINA	Beijing TaiYuan, Shanxi	Mr. Chen Mingjun	+00 1444304	
CHINA	Shanghai	Mr. Zhang Limin	+86 2164701810	chph@163.net
CHINA	Beijing	Mr. Li Kaibao	+86 10 62012501	shouzi@public.east.cn.net
CHINA	Hong-Kong	Mr. C. L. Chan	+852 29586654	cchan@ha.org.hk
CHINA	Beijing	Mr. Guo Wen	+86 19357008	gwenssdl@public.east.cn.net
COLOMBIA	Santafe de Bogota	Mr. H. Olaya Davila	+5713153059	icasas@tribolite.ingeomin.gov.co
CUBA	Cuidad Habana	Mr. J. Morales	+53 7331188	tony@cphr.edu.cu
CYPRUS	Nicosia	Mr. S. Christofides	+357 2369170	Cstelios@cytanet.com.cy
CZECH REP. *	Prague	Mr. Kodl	+42 2738330	iiha@ami a-
CZECH REP. CZECH REP.	Prague Prague	Mr. P. Dryák Mr.D. Olejár	+420 2 67008 +42 267311410	iizpraha@cmi.cz hzackova@suro.cz
	_	·		
DENMARK	Bronshoj	Mr. K. Ennow	+45 44532773	klaus.ennow@sis.dk
ECUADOR	Quito	Mr. H. Altamirano	+59 32253097	comecen@suncomecenat.gov,ec
EGYPT	Cairo	Mr. H. M. Eissa	+20 23612339	
FINLAND FRANCE	Helsinki Le Vesinet	Mr. H. Jarvinen	+358 9 75988450	hannu.jarvinen@stuk.fi
GERMANY	Oberschleissheim	Mr. D. F. Regulla	+49 8931873062	regulla@gsf.de
GHANA GUATEMALA	Legon - Accra Guatemala C. A.	Mr. C. Schandorf Mr. J. A.Tovar	+233 21773807 +502 2762007	
		WII. J. A. TOVAI		
HUNGARY*	Budapest 126	Mr. I. Csete	+36 12120147	icsete@omh.hu
HUNGARY	Budapest XII	Mr. G. Kontra	+36 11562402	kontra@oncol.hu
HUNGARY	Paks	Mr. M. Orbán	+36 1551332	
INDIA	Bombay	Mr. V. V Shaha	+91 225560750	vvshaha@apsahra.barc.ernet.in
INDONESIA	Jakarta Selatan	Mr. Susetyo Trijoko	+621 217657950	
IRAN	Karaj	Mr. M. Gavahi	+98 213130676	
IRAN IRAQ**	Teheran Baghdad	Mr. H. Gharaati	+98 216428655	
IRAQ**	Baghdad			
IRELAND	Dublin 14	Mr. P.A Colgan	+353 12697437	rpii@rpii.ie
ISRAEL	Yavneh	Mr. M. Margaliot	+972 8 9434696	
KOREA, REP	Seoul	Mr. Woong Beom Oyum	+82 23513726	pyunwb@mail.gcc.go.kr
LIBYA	Tripoli	Mr Ben Giaber	218213614142	

Country	City	Contact person	<u>Fax</u>	E-mail
MADAGASCAR MALAYSIA MEXICO	Antananarivo Kajang Mexico, D. F.	Mr. Andriambololona Mr. Taiman Bin Kadni Mr. V. Tovar Munoz	+261202235583 +60 3 8258262 +52 53297302	official.mail@instn.mg taiman@ms.mint.gov.my abv@nuclear.inin.mx
NIGERIA** NORWAY	<b>Lagos</b> Osteras	Mr. H. Bjerke	+47 67147407	hans.bjerke@nrpa.no
PAKISTAN PERU PHILIPPINES*	Islamabad Lima Diliman, Quezon	Mr. Salman Ahmad Mr. Tony Benavente Mr. E. S. Caseria	+92 51429533 +51 1 4885233 +63 9201646	pinstech@paknet2.ptc.pk tony@ipencn.gob.pe
PHILIPPINES POLAND PORTUGAL PORTUGAL	Sta. Cruz, Manila Warsaw Sacavem Lisboa	Ms. Nieva O. Lingatong Mr. Bulski Mr. A.F de Carvalho Mr. M. D'Assunçao	+632 711 6016 +48 26449182 +351 19941995 +351 17266307	n.lingatong@hotmail.com w.bulski@rth.coi.waw.pl
ROMANIA	Bucharest	Mr. C. Milu	+40 13123426 +7 812113 0114	cmilu@pcnet.ro trof@dosmet.vniim.spb.su
RUSSIA SAUDI ARABIA	St. Petersburg Riyadh	Mr. V. I. Fominych  Mr. A. Al-Haj	+966 14424777	Abdal@kfshrc.edu.sa
SINGAPORE* SINGAPORE SINGAPORE SLOVAK REP.	Singapore Singapore Singapore Bratislava	Mr. Eng Wee Hua Mr. S. Chong Mr. Chua Eu Jin Ms. V. Laginová	+ 65 7384468 +65 2262353 +65 2221720 +42 7323711	sckmipil@pacific.net.sg euin@sgh.gov.sg vlaginov@ousa.sk
SUDAN** SWEDEN SYRIA	Khartoum Stockholm Damascus	Mr. J-E. Grindborg Mr. M. Takeyeddin	+46 87297108 +963 116112289	jan.erik.grindborg@ssi.se
TANZANIA THAILAND*	Arusha Bangkok	Mr. W.E. Muhogora Mr. K. Bhadrakom	+255 578554 +66 25806013	nrtcz@habari.co.tz
THAILAND THAILAND	Bangkok Bangkok	Mr. S. Srimanoroth Ms. W. Thongmitr	+66 22234674 +66 25613013	siri@dmsc.moph.go.th
TURKEY TUNISIA	Istanbul Tunis	Mr. A. Turer Mrs. L. Bouguerra	+902125482230 +216 571 630/653	yassars@cnaem.nukleer.gov.tr sadok.mtimet@rns.tn
URUGUAY	Montevideo	Mrs. A.F Furth		
VENEZUELA VIETNAM	Caracas Hanoi	Mr. F. Gutt Mr. Dang Duc Nhan	+58 25713164 +8448363958266	fgutt@ivic.ivic.ve vkhkthn@netnam.org.vn
YUGOSLAVIA	Belgrade	Mr. M. Kovacevic	+381 11455943	miljoko@rt270.vin.bg.ac.yu

<sup>\*\*</sup> Provisional Network members

# Collaborating organizations associated with the IAEA/WHO Network of SSDLs International Bureau of Weights and Measures (BIPM) International Commission on Radiation Units and Measurements (ICRU)

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