[別紙１]

- Education of medical students and others at the initial professional training stage is important;
- Training modules should contain sufficient general information to ensure that an appropriate perspective on radiation risks is maintained (i.e., for the purpose of justification when the benefits of proper diagnosis and treatment of an individual outweigh dramatically the minor stochastic risks of exposure to radiation for society at large);
- Continuing education is very important;
- Consideration should be given to further development of distance learning packages and the use of the Internet (see further discussion on this below);
- Video modules and CD's could be made available either on the Web or to the professional societies to achieve greater distribution and hopefully, impact;
- It would be useful to catalogue currently available appropriate information and courses from various organizations and list them on the Agency's Web sites.

In developing training materials and documents, it would be helpful to have feedback from the professional societies and experts.

Action: *to arrange for a review of the syllabus for the Agency training courses in medical radiation physics by appropriate professional bodies and to publish the results.*

The syllabus, entitled "Review of Radiation Oncology Physics: A Handbook for Teachers and Students", has been revised and published as working material (in May 2003), and the electronic version is available from the web page of the Division of Human Health. Revisions are being incorporated and endorsements sought from the relevant professional societies.

Recommendation by the Panel: the Panel noted the progress and considered that this action is almost complete.

Information exchange

Action: *to collect and disseminate, using the Agency's International Reporting System for Unusual Radiation Events (RADEV), information about accidental medical exposures, including, as far as possible, information about events that did not have clinical consequences but from which prevention-relevant lessons can be drawn.*

Information about accidental exposures in radiotherapy has been collected and collated, and a draft package for the dissemination of this information has been prepared. The package has been used at two regional workshop held in Latin America and one for African Member States held in 2003. Further regional events are planned for 2004, for English speaking Africa, Europe, Latin America, and Asia. The audience of the workshops is composed of radiotherapy staff (radiation oncologists, medical physicists and radiotherapy technologists) and regulators.

Recommendation by the Panel: The Panel agreed that the dissemination of information on lessons from incidents and accidents should continue and recommended that:

- Consideration should be given to mechanisms by which such information can be widely disseminated. The accident reports should be available on the Internet and methods should be found for drawing the attention of professionals to them;
- Some members of the Panel felt that many more accidental medical exposures almost certainly occur than are reported. The Panel would encourage the reporting of such events;
- It was suggested that following return to their home countries, workshop participants make presentations with the material provided and that this be used as a measure of impact of the workshops since significant reduction in incidents and accidents is not likely to be measurable due to the rarity of their reporting;
- It was noted that under dosage accidents are very difficult to detect and there may be purposeful prescription of lower doses for a number of reasons including too much emphasis on the over dosage accidents;
- Impact of accident reports may be evaluated through use of citation index of published documents and, in the future, the information exchange via Internet.

It was noted that the issue of confidentiality of information would need consideration in the reporting of incidents and accidents.

Assistance

Action: *to support Member States in the gradual transition from the basic to advanced stages of implementation of the BSS.*

The Secretariat has developed a modular, step-by-step approach to technical assistance in the area of radiation protection in radiology and has organized missions based on this approach as a pilot exercise. The approach was recently incorporated into the plan of work for technical assistance for Asia, is going to be incorporated in Latin America and other regions will follow.

Recommendation by the Panel: the Panel agreed that this action should continue. Methods should be found of measuring the impact of the work being undertaken by the Agency.

Action: *to promote the formal recognition of medical physicists responsible for the radiological protection of patients as health professionals.*

The Agency has been assisting the IOMP to identify countries that have recognized medical physicists as professionals in health care and thereby, to gain support for an overture to the International Labour Organization.

[別紙 1]

Recommendation by the Panel: the Panel agreed that recognition of medical physicists as health professionals was important and felt that IOMP should continue taking the lead in negotiating with ILO and informing other organizations and societies how they may help, including the necessary methods and contact information.

Action: to continue current activities in radiotherapy concerned with the traceability of dose measurements and with audit services, including the development of local expertise, and to extend these services to diagnostic radiology and nuclear medicine.

In the field of dosimetry, the Secretariat has continued providing secondary standards dosimetry laboratories (SSDLs) and hospitals in Member States with calibration and audit services relating to external beam radiotherapy, brachytherapy, mammography and radiation protection. A code of practice for dosimetry in diagnostic radiology has been drafted. In the field of nuclear medicine, the provision of calibration and audit services for SSDLs and hospitals is under development.

Recommendation by the Panel: the Panel agreed that the current activities in dosimetry for radiotherapy, diagnostic radiology and nuclear medicine should continue.

The Panel took note that there are additional activities on clinical audits, which are outside the scope of this Action plan and are subject to separate review. It was however agreed that clinical auditing would require the support of organizations such as WHO and PAHO and that the professional societies, such as ISR and IOMP, should be able to provide a cadre of appropriate experts.

Guidance

Action: to finalize the existing draft practice-specific guidance documents, seeking input from professional bodies, international organizations and national authorities responsible for the radiological protection and medical care of patients.

Three practice-specific guidance documents on implementation of the BSS in radiology, nuclear medicine and radiotherapy have been finalized - with input from professional bodies, international organizations and national authorities responsible for the radiological protection and medical care of patients.

Recommendation by the Panel: the Panel agreed that these documents should be published and attention of all relevant organizations drawn to them.

Actions in diagnostic and interventional radiology

Education and training

Action: *to provide for the training of radiographers and radiologists in the optimum management of doses in conventional radiology.*

As indicated above, focus of the Agency's education and training programme is to "train-the-trainers" and to achieve a sustainable training mechanism in Member States. The approach should involve cooperation with national authorities and professional bodies, assisted by the standardized material developed under this Action Plan. Nevertheless a number of courses had already been aimed at the professionals indicated in the action, in order to launch the process and to obtain feedback for improving the standardized training material. Five training courses for radiologists and radiographers were held in 2002 and another 5 in 2003. A total of 250 professionals have been trained. By means of assessment at the beginning and at the end of each course, the trainees' understanding of radiation protection-related issues was evaluated, in order to determine whether there had been an improvement and how useful the training packages had been.

Recommendation by the Panel: the Panel's views on this action are covered above. However, particular note was made of the need for the education of prescribers, students, etc. and the need for continuous professional development as far as radiological protection is concerned.

Appraisals and other services

Action: *to develop a methodology for establishing local guidance (reference) levels for diagnostic radiology, through simple surveys taking into account image quality, to disseminate the methodology, to promote programmes for assessing it and, during the assessments, to help countries with the conduct of quality control tests involving the use of phantoms and patient dose measurements.*

The methodology that has been developed is being applied in a Latin American regional project involving 10 Member States starting in 2004. Pilot projects on image quality improvement and patient dose reduction have been launched in Kazakhstan, Moldova, Jordan and Kuwait. Other countries in the process of starting are Union of Arabic Emirates and Tajikistan. Five countries in West Asia have been provided with equipment through Model Project on Upgrading Radiation Protection Infrastructure to undertake Quality Control in radiology.

Recommendation by the Panel: The Panel agreed that continuing evaluation of reference levels was important.

The Panel noted that PAHO was not involved in the projects in Latin America and therefore, there was the possibility of duplication of grants and/or projects by different organizations. The Panel recommended that all relevant organizations and professional bodies cooperate to make efficient use of limited resources in this area.

[別紙１]

Co-ordinated research

Action: *to co-ordinate research work on exploring the feasibility of establishing guidance (reference) levels for complex procedures in diagnostic and interventional radiology.*

A co-ordinated research project on the feasibility of establishing guidance (reference) levels for complex procedures such as interventional radiology was launched, and the initial results for interventional cardiology procedures were reviewed at a research coordination meeting in October 2003. The review indicates that it may be feasible to establish guidance levels for the diagnostic part of the procedure but that the therapeutic part of it may require the guidance levels to be multiplied by complexity factors. The next and last meeting of this research is planned for early 2005.

Recommendation by the Panel: the Panel noted the progress to date, which is concerned with interventional cardiology. Use of reference levels appears to be possible for coronary angiography but it may require development and definition of complexity indices for the interventional part of the procedure. This may be more difficult for the more complex and less commonly performed interventional procedures (such as in neuroradiology).

Actions in nuclear medicine

Action: *to promote in developing countries - through training and the dissemination of information - the use of existing standards, guidelines, protocols and QA procedures in both diagnostic and therapeutic applications, including radiopharmacy.*

A nuclear medicine manual to promote the use of standards and QA procedures is near finalization. In addition, lectures are being given on the use of existing standards, guidelines, protocols and QA procedures. Further details may be found in the 2003 Annual Report of the Department of Nuclear Applications.

Recommendation by the Panel: the Panel was not in a position to comment on this action because the document had not been made available to it at the time of the meeting.

Action: *to complete the task of developing a technical document on the quality control of PET systems.*

The work on a technical document on the quality control of PET systems is still under way.

Recommendation by the Panel: the Panel was not in a position to comment on this action because the document had not been made available to it at the time of the meeting.

Actions in radiotherapy

Information exchange

Action: to maintain the Directory of Radiotherapy Centres (DIRAC).

The Directory of Radiotherapy Centres (DIRAC), an Agency-WHO database which contains information relating to - inter alia - teletherapy machines, brachytherapy sources and devices, dosimetry equipment, treatment planning systems, quality assurance programmes and staffing, is verified and updated regularly and is available for internal use by the Secretariats of the Agency and WHO. An Internet version is in preparation.

***Recommendation by the Panel*:** the Panel felt that it may be possible to include UNSCEAR survey data in the database and professional societies should encourage their members to provide information through the Internet. The Panel also felt that it was unlikely that manufacturers would be willing to supplement the data in DIRAC by providing information on their own installed equipment. It also felt that data provided by manufacturers would be incomplete because of the difficulty of obtaining information on second hand equipment.

Assistance

Action: *to follow up on abnormal results of the postal dose quality checks and assist in the establishment of national and regional dosimetry programmes.*

The Secretariat has followed up on such abnormal results with the help of local experts and, when necessary, of external experts specially recruited by it. It has published guidelines for the preparation of a manual for checking dosimetry quality in radiotherapy. It has helped several Member States to establish TLD quality audit programmes and, wherever possible, is establishing links between those programmes and the Agency's Dosimetry Laboratory.

Recommendation by the Panel: the Panel agreed that this activity is very valuable and should be continued

Guidance

Action: *to continue to develop and disseminate codes of practice for dosimetry.*

The Secretariat has developed an International Code of Practice for Dosimetry Based on Standards of Absorbed Dose to Water (Technical Reports Series No. 398). To provide practical guidance on its implementation at hospitals, it is now preparing a technical document (IAEA-TECDOC) on the testing of the procedures recommended for using different types of radiation beams and ionization chambers and comparing the results obtained

with the existing protocols. It has organized a regional workshop, in Africa, on practical aspects of implementing the Code of Practice at hospitals and SSDLs and is planning similar workshops for other regions.

Recommendation by the Panel: the Panel agreed that the activity should continue. It noted that translation of the material into Spanish is being done and recommended that it should be translated into other languages , as necessary, to increase its dissemination.

Action: *to develop guidance on commissioning equipment and accessories involved in simulation and treatment, including TP systems, and on QA of the whole radiotherapy process.*

The Secretariat has prepared an IAEA-TECDOC on the commissioning and quality assurance of computerized radiation treatment planning systems. This is being circulated but it is going to be published in the Agency's Technical Report Series. In addition, IAEA-TECDOC 1040 (entitled "Design and implementation of a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects" and published in 1998) is being revised, and its scope being extended to include linear accelerators and brachytherapy.

Recommendation by the Panel: the Panel noted progress, and proposed that it should continue. In particular, it felt that the material should first be put on the Web for comment before publication.

ACTIONS THAT HAVE NOT BEEN IMPLEMENTED

These actions are:

Action: *to explore the potential uses of information technology and distance learning, identifying application areas and types of information technology.*

This action is included in the cycle 2004/2005 and is being started in 2004. It is noted that this approach has already been used by the IAEA for the education and training on nuclear medicine and radiation oncology.

Action*: to explore mechanisms for widely disseminating information related to the protection of the patient.*

This action is included in the cycle 2004/2005 and is being started in 2004.

Recommendation by the Panel: in its comments on the above two actions, the Panel suggested that the following information might be included in a Web site:

Training modules (including CD's and slide sets);
Syllabi;
Statements on various topics by various authoritative groups;

Appropriateness criteria;
Answers to common questions;
Available courses in radiation protection;
Manuals on radiation protection in medicine.
Etc.....etc..

It felt that the terms of reference for this website and its specification will require the advice of a consultants' group. Consideration will need to be given to the identification of key words that will facilitate access through search engines (for example, a search for "pregnancy and medical radiation" using a search engine such as Google should lead to this website).

The Panel noted that this task will require considerable dedication, even a full time person but is of the utmost importance. It also noted that attention would need to be given to the means of disseminating information about the existence of the website.

Action: *to promote - through the provision of advice about the functions, responsibilities and training of technologists - recognition of the impact of technologists involved in day-to-day procedures on the radiological protection of patients.*

In the regional and national training courses described above, substantial emphasis has been given to inclusion of technologists in the courses. Typically $1/3^{rd}$ to half of the participants in regional courses and half or even $2/3^{rd}$ in national courses are technologists. A separate action on recognition of the impact of technologists has not been started. With regard to this action, it remains to be clarified as to what type of promotion and advice should be provided to obtain the recognition of the impact of technologists.

Recommendation by the Panel: the Panel noted that the Syllabus and Modules may need to be tailored to the particular needs of technologists and it recommended that the Agency's documents should specifically mention the role of technologists and recognize the full scope of competencies of the technologists. The CDs on training should be provided to the ISRRT and the Society should be involved in the review of the material. The Panel also noted that ISRRT would be the appropriate body to act as a conduit of the material to national organizations that serve the needs of technologists.

Actions: *to provide guidance to donors, recipients and NGOs on the safety issues related to the transfer of second-hand equipment.*

This action is included in the cycle 2004/2005 and is being started in 2004. It should be noted that similar recommendations emerged from the International Symposium on Standards and Codes of Practice in Medical Radiation Dosimetry, held in November 2002. In particular, a recommendation says that *"WHO advice that provides guidance to organizations donating technologies to the developing countries should be disseminated widely". (This document is generic, and there is a need for more specific guidance for radiation equipment for diagnosis and therapy)*

[別紙１]

Recommendation by the Panel: the Panel recommended that a group should be convened to prepare this guidance, which should be concise. The group should include the other international organizations and Standards Organizations such as IEC and the initial focus should be on radiotherapy machines. Account should be taken of the relevant documents of WHO, IEC, and EC, and IAEA-TECDOC 1040. The guidance should cover acceptance and constancy tests, the availability of spare parts, and the local services required for maintenance and training. It should also outline the responsibilities of both donors and recipients.

The Panel requested the Proceedings of the International Conference on Standards and Codes of Practice in Medical Radiation Dosimetry be made available to it as electronic files. (The proceedings will on the web in the coming weeks.)

Action: *to provide for training in the application of digital techniques for staff at facilities which are in transition from conventional to digital equipment, with a view to ensuring the proper management of patient exposure.*

This action is included in the cycle 2004/2005 and is being started in 2004.

Recommendation by the Panel: the panel recommended that this action should be changed to read 'to produce training material for the transition from conventional to digital techniques ...'. The ICRP document on Managing Doses in Digital Radiology should be used for the preparation of training materials and the module developed should be provided to professional bodies for presentation at their congresses and meetings, in editorials in journals, and in refresher courses. The relevant organizations should be involved in the process of preparation of this material with comments and input being sought through use of the website discussed above.

The Panel stressed that the important and practical aspects should be especially emphasized in the material.

Action: *increase - through training and information exchange - the awareness of users of CT techniques (including conventional, helical and multi-slice) regarding radiation dose and image information and to promote the use of paediatric CT protocols.*

This action is included in the cycle 2004/2005 and is being started in 2004. It should be noted that some recommendations emerging from the International Symposium on Standards and Codes of Practice in Medical Radiation Dosimetry, held in November 2002 are relevant to this action. In particular, recommendations from the Symposium state that *"Appropriate methods for quality assurance and quality control in digital and interventional radiology should be developed urgently"* and that *"new dosimetry methods should be developed to meet the needs of current and future X ray diagnostic methods."* (As mentioned above, the proceedings will soon be available on the Agency's web site.)

Recommendation by the Panel: the Panel noted that referral criteria should play a key role in this. It recommended that particular attention should be placed in the material on paediatric CT and requested that the training module including the referral criteria should be available by the time of the next meeting of the Panel. Again, the Panel noted that, once the CD containing the material had been produced, a distribution mechanism would be necessary, and the professional bodies should be instrumental in this. Attention to the material could be drawn through use of mechanisms such as the publication of articles in journals.

The Panel also noted that the research and guidance and preparation of training material and mechanisms of implementation should be coordinated between the international organizations, with special account being taken of the research being done and guidance being provided by EC and others. The material should emphasize the important and practical aspects and, during development of the training module, the material should be placed on the web for comment.

Action: *to carry out a study on the cost-effectiveness of the various approaches to protection optimization that reduce doses while preserving the diagnostic information and to provide guidance on priorities and strategies for implementation.*

The formal study has not started, however, action on the most obvious ways of reducing doses, such as promoting shifting from conventional to rare earth screens is being started by including technical cooperation activities for assistance to developing Member States.

Recommendation by the Panel: this action is directed toward consideration of what are the most cost-effective methods of dose reduction in diagnostic radiology. The Panel instinctively thought it was training and education. The Panel felt that this action merits consultation with a few experts on this issue and the outcome of the consultation summarized in a short (several page) report.

Action: *to conduct consultations with manufacturers on achieving interconnectivity of computerized imaging equipment and*

Action: *to conduct consultations with manufacturers and standards organizations on standardizing, displaying and recording data related to patient doses for CT, fluoroscopy and interventional techniques.*

These two actions are included in the programme and budget for the cycle 2004-2005 and the first meeting is planned for March 2004.

Some recommendations emerging from the International Symposium on Standards and Codes of Practice in Medical Radiation Dosimetry, held in November 2002 are relevant to this action. In particular, recommendations from the Symposium refer to the harmonization of quantities, and to the use of these quantities in codes of practice, in reference (guidance levels) and to the need for the calibration to be traceable to standards dosimetry laboratories.

Recommendation by the Panel: carry out the consultation as planned particularly to bring the users' requirements and desires regarding patient dose, image projection and possibly age sex and weight into the available digital record. This should be done in a format that would allow import to such databases as Excel for further study and for optimization purposes.

Action: *to facilitate the critical review of research on biological methods of assessing absorbed dose and to disseminate information about such research (radiotherapy).*

Not started.

Recommendation by the Panel: it should be removed from the Action Plan.

Remark to Members of the Panel: the IAEA is preparing a coordinated research programme, which is related to this project. It is suggested that the recommendation to remove this action from the Action Plan be postponed until the next meeting of the Steering Panel.

Other matters

The Panel felt that it is important that a physician in each facility be named as ultimately responsible for radiation protection in medical practice. This is already recognized in the BSS, which explicitly states that: *"medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;"*

The Panel discussed the issue of shortages of qualified experts in radiotherapy and imaging physics, which is relevant in radiation protection, especially in protection of the patient since medical physicists frequently serve as radiation protection officer. It supported efforts to increase the supply. There may be some potential of technologists being trained to help with radiation protection issues. No other major mechanisms were identified other that specific countries developing exchange programmes or committing their own funds for education and training of qualified experts in order to be able to supply the necessary medical services and to comply with the safety standards.

Notes taken on the vision for the radiological protection of patients

1. Recognizing the benefits of and the needs for medical uses of radiation
2. Working in collaboration and coordination with appropriate international organizations and professional societies
3. Promoting radiation protection of the patient without limiting the medical benefits
4. Using the Agency's mechanisms including education and training, ...
5. Assuring that radiation protection is an integral part of medical practice
6. Assuring radiation protection aspects and taking appropriate actions relative to new and evolving technology
7. Plan and actions are periodically reviewed and assessed for efficacy and prioritisation in light of available resources.
8. To aim for sustainability of achievements
9. The level of protection should be commensurate with the level of risk and a plan to implement safety standards established

[別紙３]

Notes taken on the vision for the radiological protection of patients

患者の放射線防護の将来像に関する覚え書き

１．医療における放射線の使用は必要なものであり、利益をもたらすものであることを認識する。

２．関連した国際機関や学会・団体と協力・協調して活動する。

３．医学的利益を損なうことなく患者の放射線防護を推進する。

４．教育訓練を含む国際原子力機関の（既存の）機構を活用する。

５．放射線防護が医療の欠かせない一部分であることを確実なものとする。

６．新しく進化する技術に対して放射線防護を保証するように適切な活動を行う。

７．利用可能な資源に鑑みて、計画と活動を定期的に見直して効率性と優先度を評価する。

８．持続的に成果が得られるよう努める。

９．放射線防護のレベルは、リスクのレベルがどれだけか、また、定められた安全基準をどのように実施するか、に相応しいものであるべきである。

平成１５年度厚生労働科学研究費補助金

分担研究報告書

医療放射線の防護の最適化及び被ばく線量の低減化方策に関する研究

医療放射線の防護に関する諸外国の法体系に関する研究

－　放射線治療における患者の医療安全　ガイドライン　－

平成１６年３月

分担研究者　吉 川　京 燦

平成１５年度厚生労働科学研究費補助金（医薬安全総合研究事業）研究
「医療放射線の防護の最適化及び被ばく線量の低減化方策に関する研究」

分担研究報告書
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放射線治療における患者の医療安全 ガイドライン

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範囲

この安全指針では、放射線治療とは外部ビーム線源（遠隔治療
ム）と密封放射線源（小線源治療）を患者の治療に使用する行為をいう。
放射線治療は、放射線物理士（医療物理士）及び放射線治療技師の有資格専門家の協力を得て、放射線治療医によって実施される。

正当化

放射線治療の正当化は、BSS（BSS, 付録Ⅱ.4 及びⅡ.8）の基本原則に基づくものでなくてはならない。放射線治療に伴う指示手順の訓練と経験に関する要件を満たす臨床医によって被ばくが指示されること。外科、化学療法などの代替方法を単独・併用した場合の効果、利益、リスクを考慮する。
放射線治療は診断を実施するよりも大きな吸収線量を生じ、通常１回以上の分割照射が行われるが、正常組織への厄介な問題の可能性がある。従ってより適切に正当化された手順が必要である。注意深く各手順の正当化を考慮する必要がある。

医療被ばくに対する防護の最適化

放射線治療の最適化に関するBSSの要件は、「放射線治療における正常組織の被ばくは、計画標的体積に要求される線量の照射の範囲で、合理的に達成できる限り低くする」（BSS、付録Ⅱ.18(a)）ことである。放射線治療の目的が高線量を照射するため、標的体

積の周辺組織に対する副作用は避けられない。その様な副作用の程度は、放射線治療医（または認可された臨床医）が評価する問題である。しかし、その影響が臨床医の予測と大きく異なる場合に規制当局にとって重大な問題となる。更に、事故的に線量が超過したケースでは過失を是正する機会がない。規制当局は、登録者と免許所有者に対し意図したよりも高いか或いは低い線量によって生じる計画外あるいは予想外の結果を報告することを要求すべきである。

BSS の付録Ⅱ.1(d)により、登録者と免許所有者は、放射線治療物理の有資格専門家によって、あるいはその専門家の監督で、BSS に従った校正や線量測定及び QA 要件を実施しなくてはならない。放射線治療の操作上の観点では、放射線腫瘍学者としてや、医療放射線臨床医及び治療に関係する他のスタッフとして、特別な訓練や知識及び経験が求められる。BSS は登録者と免許所有者に、患者が妊娠又はその可能性がある女性の場合に生じるかもしれない正常組織合併症及び胚に起こる傷害を考慮し、適切な治療法を選択することを求めている（Ⅱ.18(a), (b), (d)及び(e)）。患者は起こり得るリスクを知らされなくてはならない。

装 置

放射線治療装置の使用を認可するために、規制当局は、登録者と免許所有者に BSS（BSS, 付録Ⅱ.11　.13 及びⅡ.15）が定めている要件に従うことを要求すべきである。IEC 及び ISO の標準規格、又はそれと同等の国家規格に合致するように特別な注意が払われるべきである。

既存の装置が IEC の国際規格に合致しない場合は、国における対策を立てる必要がある（BSS, 付録Ⅱ.13(a)）。特に、IEC の国際規格が新しいか又は最新の装置を想定している場合は、装置を容易に更新できない場合があり、装置を患者の治療に使用することが許されなければ、利益よりも損害の方が大きい可能性があることを規制当局は認識すべきである。この場合、最適化された解決法が必要である；それは、適切な安全レベルを保証する経過措置期間を設けるべきである。規則は、既存の装置の特徴を IEC の規格要件と比較しながら、安全評価の結果として定めるべきである；例えば、60Co 遠隔照射治療ユニットの照射を終わらせるための二つのタイマーを設ける要件にとって、正式な方法に厳格に従い記録をとってクロノメータを一時的に使用することは、第二のタイマーを設置するまでの安全性を改善するのに役立つであろう。すべての重要部品に対する多重安全防護が、一つの故障が深刻な結果をもたらすことのないようにする目的で使用されるべきである。

放射線治療における安全性に対して特に重要なことは、装置の性能とその操作及び保守に関する取扱説明書を理解することである。テキストとその操作及び保守の説明書が外国語であるなら、自国の専門用語で翻訳したものを用意し、操作スタッフがいつでも利用できるようにすべきである。

操作面の考慮

規制当局は、BSS（BSS, 付録Ⅱ.18）の要件に合致する放射線治療照射を行うための方法について、登録申請者が文書化することを要求すべきである。そのような文書化を必要とする理由は、治療の妥当性を評価するためではなく、申請者が治療を実施する場合、治療プロトコールを適用しているかどうかを確認するためである。補助装置と治療部品の適用性について特別な注意が払われるべきである。

規制当局は、患者が動く可能性を少なくするため、治療時間を合理的に短縮するよう、密封線源の取り替えを適時に行うことを奨励すべきである。放射性核種治療のための隔離病室を設けるべきである。

線源の校正

BSS では、外部放射線治療ビームと小線源治療に使用される線源の両方を含む放射線治療線源の校正が、基準線量計測研究所（SDL）とのトレーサビリティを有することを要求している（BSS,付録Ⅱ.19)。我が国では医療被ばくに用いられる線源の校正は日本医学放射線学会医療用線量標準センター（以下、医療用線量標準センター）とのトレーサビリティを有する。放射線治療施設はリファレンス線量計を必ず備えなければならない。リファレンス線量計の校正は、医療用線量標準センターに依頼して、少なくとも年１度の頻度で行うことが望ましい。同センターは、国家標準にトレーサブルな線量計によって決定された ^{60}Coγ線の照射線量標準場を用いて、各放射線治療施設のリファレンス線量計を校正する。

線源校正は、放射線治療物理学における有資格専門家（通常、医療物理士）の管理の下で国が承認した実践コードに従って[38, 39]頻繁に行われるべきである。その校正は、使用開始時、線源交換、大幅な修理や線量計測に影響のあるような何らかの保守行為が行われた後に実施されるべきである（BSS,付録Ⅱ.19(e)）。これらの校正の間隔は、線源と装置の種類によって異なる。

放射線治療線源の誤った校正は、多くの患者に不適切な治療結果をもたらし、深刻な

事態を引き起こす可能性がある。規制当局は、校正の過失を防ぐために、過剰性と多様性をもった「多重防護」の原則を適用することを、登録者と免許所有者に勧めるべきである。

特殊な放射線治療手順（手術的照射、術中放射線治療、血管内放射線治療、定位脳放射線治療、全身照射など）に使用される線源校正に際して、特に注意が必要である

臨床における線量測定と治療計画

規制当局は、登録者と免許所有者に対して BSS（BSS, 付録Ⅱ.20(b), (c), (e) 及びⅡ.21）の要件に従うことを要求すべきである。これらの要件を満たすために、規制当局は、指示、計画、照射線量及び文書が国際的に承認された表現と概念に従うよう要求すべきである：

- 外部照射したすべての患者に対して、放射線腫瘍学臨床医による指示、日付及び署名は、治療前に行わなければならない。これには、次の情報が含まれること：治療部位、総線量、分割線量、分割及び全体的な治療期間。加えて、照射体積内のリスク器官の最大線量が決定されるべきである。あらゆる体積の明確化（全腫瘍体積、臨床標的体積、治療計画体積など）は、ICRU 勧告に従うべきである。
- すべての小線源治療患者に対して、放射線腫瘍学者による指示、日付及び署名が治療前に行われなければならない。これには、次の情報が含まれる：参照点とリスク器官に対する総線量、参照線量の大きさ、線源の数及び線量分布、放射性核種及び基準日における放射性核種及び線源強度。体積と線量の明確化は、ICRU[40]の勧告に従うべきである。

規制当局は、登録者と免許所有者に、臨床上の線量測定の一部としてファントムとインビボ測定を実行することを勧めるべきである。

治療計画システムは、治療の提供に関する不可欠な要素であり、従って、登録者と免許所有者は、それらのシステムにおける委任し許可する過程のすべての記録を有することを保証すべきである。そのような行為は、登録者又は免許所有者の QA プログラムの一部でなければならない。（以下参照）。

品質保証

医療における放射線治療の国際的標準化が求められる今日、日本放射線腫瘍学会（JASTRO）は、当該分野において適切な有資格専門家（放射線腫瘍医、医学物理士、治療認定技師など）の協力を得て、放射線治療精度の確保を目指し、外部放射線治療および密封小線源治療におけるQAシステムガイドラインを作成し、我が国の治療施設のQAシステム構築とその実施における指針となることを切望している。

欧米各国は既に放射線治療のQA、QCプログラムを確立している。QAシステムが確立していない国の治療レベルについては、不信を抱くのは至極当然であり、わが国におけるその導入は急を要する。QAシステムを各施設に導入する一番の理由は、①放射線治療に関する事故の防止②治療行為の手順および状況の明確化③統一した治療レベルの確保にある。

米国においては米国がん研究所（NCI）のもとでRadiological Physics Center（RPC）が約1350施設の物理的QAに関するaudit（ガラス線量計等による郵送調査および訪問調査）を実施している。また、欧州では欧州放射線腫瘍学会（ESTRO）のもとでEuropean Institute for Quality Assurance in Radiotherapy （EQART）が27ヶ国、約450施設に、またInternational Atomic Energy Agency（IAEA）/ WHOが発展途上国を中心に115ヶ国、約1200施設にauditを実施している。しかしながら先進国のなかでも日本のみこのようなaudit体制をもっておらず、日本の放射線治療の質自体が世界的に信頼されていないという深刻な状況にある。このような状況を打開すべく、JCOG（JAPAN CLINICAL ONCOLOGY GROUP）放射線治療委員会による物理的QAに関するauditサーベイを実施し、放射線治療の品質保証の確立をめざしている。

JASTROのQAシステムガイドラインを遵守し、かつJCOGによるauditに積極的に参加することで、万が一出力の多寡が疑われた場合には、有資格専門家が中心となる調査委員会による原因究明の支援を得なければならない。- いかなる状況においてもこれらの検証結果が、十分な校正を実施するための代替を認めてはならない。また、我が国においても、規制当局によるある種の査察制度を導入することが必要不可欠であろう。

訓 練

放射線腫瘍学者や放射線物理学における有資格専門家、放射線治療技師、線量測定者及びメンテナンス関係者のために、規制当局は保健当局や大学及び専門団体に、放射線安全の観点における訓練プログラムの計画及び実施を奨励すべきである。訓練課程は文

献[46 - 48]に刊行されている。資材を提供する病院管理者は、医療被ばくにおける防護と安全に関して自らの決定を示す事ができるよう訓練されるべきである。

BSS の付録Ⅱ.1(f)の条件を満たすために、放射線腫瘍学や医療物理学などの専門組織の助言を得て、規制当局によって訓練基準が明確化又は承認されるべきである。放射線安全の観点では、放射線装置や、施設設計、線源及び線源関連装置の安全特性、線量測定、機器校正、治療計画、放射性廃棄物処分、事故防止、および一般及び緊急医療に対応するための緊急時（医療を含む）対策が含まれるべきである。訓練には、過去の事故的医療被ばくから学んだ教訓が含まれるべきである。

基本的な教育は、特に新しい治療装置や異なる種類の装置が考慮される際に、継続的な教育によって実施されるべきである。

事故的医療被ばくの調査

BSS に準じて、規制当局は、登録者と免許所有者に、BSS の付録Ⅱ.29 及び Ⅱ.30 で要求しているように、事故的被ばくの調査を行うことを要求すべきである。放射線治療においては、事故的被ばくは過小被ばく又は過剰被ばくの両方を考慮すべきである（BSS, 付録Ⅱ.29(a)）。有害な結果は長期の潜伏期間を持つ可能性があるので、規制当局は登録者と免許所有者に、関係する患者の長期追跡調査を行うことを勧めるべきである。

規制当局は、調査や通告及びフィードバックシステムに対する国の方針及び正式な手順を確立すること。このシステムは、製造者、供給者、メンテナンス業者及び使用者の間の情報収集と情報提供が含まれるべきである。

一つの国で蓄積できる経験は限度があるので、それぞれの国は、国際レベルの情報の共有によって利益を得るべきである。