EXECUTIVE SUMMARY

(a) The decision to implement a new technology for radiation therapy should be based on a thorough evaluation of the expected benefits, rather than being driven by the technology itself. To ensure safe implementation, a step-by-step approach should be followed.

(b) ICRP *Publication 86* (2000) concluded that 'purchasing new equipment without a concomitant effort on education and training and on a programme of quality assurance is dangerous'. Although originally referring to conventional radiation therapy, this conclusion is even more critical for new technologies.

(c) Major safety issues can arise from underestimating the staff resources required to implement and operate a new technology. Resources should be allocated in order to avoid the substitution of proper training with a short briefing or demonstration, from which important safety implications of new techniques cannot be fully appreciated.

(d) Certain tasks, such as calibration, beam characterisation, complex treatment planning, and pretreatment verification for intensity modulated radiotherapy (IMRT), require a substantial increase in staff allocation. The re-assessment of staff requirements, in terms of training and the number of professionals, is essential when moving to new technologies.

(e) Radiation therapy staff and hospital administrators should remain cognisant of the fact that the primary responsibility for the safe delivery of treatment lies with them. This responsibility includes investigating discrepancies in dose measurements before using the beam for patient treatments. Independent verification of beam calibration remains essential.

(f) Hospital administrators of radiation therapy departments should provide a work environment that facilitates concentration and avoids distraction.

(g) Manufacturers should be aware of their responsibility for delivering the correct equipment with the correct calibration files and accompanying documents. They also have a responsibility to provide correct information and advice, upon request, to users. Procedures to meet these responsibilities should be developed and maintained in a quality control environment.

(h) Programmes for purchasing, acceptance testing, and commissioning should not only address treatment machines but also treatment planning systems (TPSs), radiation therapy information systems (RTISs), imaging equipment used for radiation therapy, software, procedures, and entire clinical processes. Devices and processes should be recommissioned after equipment modifications, including software upgrades and updates.

(i) Procedures should be in place to deal with situations created by computer 'crashes', which may cause loss of data integrity and lead to severe accidental exposures.

(j) Protocols for treatment prescription, reporting, and recording, such as found in reports of the International Commission on Radiation Units and Measurements (ICRU), should be revised to accommodate new technologies. They should be

adopted at a national level with the support of professional bodies. Similarly, dosimetry protocols should be developed for small and non-standard radiation fields.

(k) Target dose escalation without a concomitant increase in the probability of normal tissue complications generally implies a reduction of geometrical margins. Such a reduction is only possible with conformal therapy accompanied by precise, image-guided patient positioning and effective immobilisation, together with a clear understanding of the accuracy achieved in clinical practice. Without these features, target dose escalation could lead to severe patient complications.

(l) Unambiguous, well-structured communication is essential, considering the complexity of radiation therapy and the multidisciplinary nature of the healthcare environment. In particular, procedures to notify physicists of maintenance and repair activities, identified as crucial in conventional technology, are even more important with new technologies.

(m) When conventional tests and checks are not applicable or not effective for new technologies, the safety philosophy should aim to identify measures to maintain the required level of safety. This may require the design of new tests, or the modification and validation of existing tests.

(n) Lessons learned from past accidental exposures should be incorporated into training. Radiation therapy facilities are encouraged to share their experiences of actual and potential safety incidents through participation in databases such as the Radiation Oncology Safety Information System (ROSIS). Report formats and analytical tools should be further developed to maximise and facilitate the learning components of such databases.

(o) Prior to the introduction of new techniques and technologies, there is little or no operational experience to share. To maintain safety in this situation, two complementary measures are recommended:

- Prospective safety assessments should be undertaken in order to develop risk-informed and cost-effective quality assurance programmes. Examples include failure modes and effects analysis, probabilistic safety assessment, and risk matrix.
- Moderated electronic networks and panels of experts supported by professional bodies should be established in order to expedite the sharing of knowledge in the early phase of introducing a new technology.

References

ICRP, 2000. Prevention of accidental exposures to patients undergoing radiation therapy. ICRP Publication 86. Ann. ICRP 30 (3).