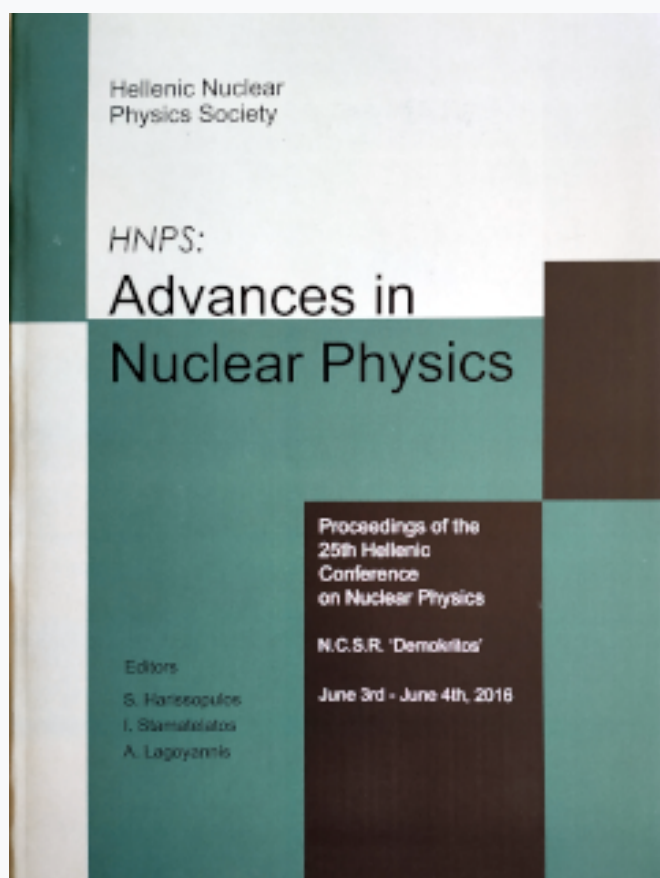


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Radiotherapy (RT) innovative Technology combined with Hospital/Home-Care Standards and Medical Protocols and Guidelines: A collective Compendium

B. Spyropoulos*, M. Adamopoulou, S. Arbis, G. Bouboukiotis, G. Chatziavazis, K. Chatzigeorgiadis, K. Golfinopoulos, A. Golfinopoulou, A. Kalfas, S. Karatzetzos, D. Kavadas, E. Kefalidis, G. Kotsinonos, P. Koukoularis, C. Kyriazopoulos, D. Linardatos, S. Makri, M. Marinis, K. Monocholias, S. Roumeliotis, I. Stathopoulos, K. Stavridis, T. Stergiou, M. Tsantoulis, O. Tsitsigrionis

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Abstract A heuristic “3-dimensional” project is presented, accomplished by the 24 post-graduate students of our Department’s MSc. Course “Advanced Biomedical Technology”. The project has addressed, first, RT innovative Technology as reflected on Industrial Property (IP) docs, second, cardinal patient-care and medical-managerial aspects and finally, their combination with relevant Medical Protocols, Guidelines & Standards. Parts of the three modules of the 4th-trimester, i.e. “Large Therapeutic and Diagnostic Facilities Safety, Radiation Protection and Quality Assurance” (PMS_BIT_2.4.), “Biomedical Technology (BMT) of Home-Surveillance, Health-Care Management and Online Health Services” (PMS_BIT_2.5.) and “BMT-Quality Assurance, Industrial Property Rights, Technical Standards and Medical Protocols and Guidelines” (PMS_BIT_2.6.), taught by the first author, have been combined and each student has prepared and orally presented a “3-D” paper. Around 1000 pages of relevant content (over 1 GB) with numerous Figures and Tables are included in the produced Compendium. The quality of the students’ papers and presentations corroborate the need of introducing novel, contemporary and creative examination methods, attracting their interest and promoting their self-confidence.

Keywords Radiotherapy, RT Accelerators & Isotopes, Technical Standards, Medical Protocols & Guidelines, Industrial Property Rights

INTRODUCTION

A collective project is presented, accomplished by the 24 post-graduate students of our Department’s MSc. Course “Advanced Biomedical Technology”. The project has addressed:

- The Radiotherapy (RT) innovative Technology as it is reflected on Industrial Property Documents, as Patent Applications and granted Patents (IP-docs).
- The cardinal patient-care and medical-managerial aspects.
- Finally, their combination with relevant Medical Protocols, Guidelines & Standards.

Parts of the three modules of the 4th-trimester, i.e. “Large Therapeutic and Diagnostic Facilities Safety, Radiation Protection and Quality Assurance” (PMS_BIT_2.4.), “Biomedical Technology (BMT) of Home-Surveillance, Health-Care Management and Online Health Services” (PMS_BIT_2.5.) and “BMT-Quality Assurance, Industrial Property

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Rights, Technical Standards and Medical Protocols and Guidelines” (PMS_BIT_2.6.), taught by the first author, have been combined and each student has prepared and orally presented a “3-D” paper. Around 1000 pages of relevant content (over 1 GB) with numerous figures and tables are included in the produced Compendium.

In Table 1 the outline of the three major components of the formed Compendium are presented and the 3D-“vectors” assigned to each student are formed.

Nr.	IP/Patent-Documents relevant to RT Systems	Hospital and Homecare needed for CA-patients	Medical Protocols, Guidelines & Standards
1	Image-guided RT	Ambulant treatment?	Techniques & strategies
2	Linac Bladder CA	Chemotherapy (cis-Pt, MCV)	Adjuvant Radiotherapy
3	CyberKnife	Lung tumors	Trial reports
4	Endometrial CA Combined Tele- & Brachytherapy	HDR, MDR and LDR After-loading systems	Treatment planning for both methods
5	Stereotactic Radiosurgery	In/out Hospital Care	Metastatic Brain Tumors
6	Gamma Knife	Small-cell Lung CA Metastases	Retrospective analysis
7	Chronic Leukemia RT	Leukemia: Remission and Rehabilitation needed	Stem cell transplants
8	Intensity Modulated RT	Safety considerations	Dosimetry verification
9	Stereotactic Ablative Body RT	Lung-Liver-Prostate metastases	Quality assurance (SABR)
10	¹³⁷ Cs, ¹⁹² Ir, ⁶⁰ Co After-loading Uterus	Oncology supportive Care	Staff Radiation Protection
11	Microtron RT	In- and out-patients RT	PET-CT ¹¹ C Radioactivity
12	Image guidance; the 6-D skull	Prostate Cancer	Da Vinci vs. Cyber- knife
13	High LET Radiation	Side Effects and Homecare	High-LET RT Si-Dosimetry
14	X-Knife Stereotactic RT and Radiosurgery (RS)	Prediction of Radio-surgery complications	Clinical Isodose-curves for γ-Knife vs. X-Knife
15	Stereotactic body RT	Side effects: Stereo- RT/RS	Patient Dosimetry
16	Betatron: Kidney CA	Haemodialysis	Infections
17	Fiducial points in RT	Photon/Proton RT	Metallic implants, LEDs
18	Linac- colorectal CA	CEA Diagnosis	Radio-embolization
19	3-D conformal RT	Prostate side effects	Dosimetry
20	Partial breast Brachytherapy	Palliative RT	Brachytherapy Staff RP
21	Proton Cyclotron Therapy PT	Radiation Protection	Fluence & Dosimetry
22	Proton Radiography & target	Dose and exposure	Treatment planning
23	The Bragg peak in PT	Risks & side effects	Tissue Protection
24	Tomotherapy	PT side effects	Dosimetry methods

Table 1: The outline of the three major components of the formed Compendium.

The principal goal of this project is to attempt an interdisciplinary approach aiming to:

- Achieving Safety, Radiation Protection and Quality Assurance in modern Large Radio-Therapy and the directly associated major Diagnostic Imaging Facilities.
- Ensuring Quality Assurance in Biomedical Technology (BMT), by disclosing important Industrial Property aspects, Technical Standards, Medical Protocols and Guidelines.

- Enabling the increased involvement of patient-surveillance and health-care at home technologies, as well as, web-based Health-services management.

The quality of the students' papers and presentations corroborate the need of introducing novel, contemporary and more creative examination methods, attracting their interest and promoting their self-confidence.

RADIOTHERAPY: EQUIPMENT SAFETY AND INNOVATION

Every one of the 24 students, a specific subject has been assigned, related to a certain Radiotherapy system and/or method. Patents and other IP-Documents relevant to one RT System, a RT-important aspect or a RT-application have been searched for. Following subjects, relevant to RT, as displayed in Table 2, have been investigated and relevant patent documents and important other publications have been retrieved and evaluated.

Radiotherapy methods or aspects			
Image-guided RT	Chronic Leukemia RT	High LET Radiation	3-D conformal RT
Linac Bladder CA	Intensity Modulated RT	X-Knife Stereotactic RT & Radiosurgery	Partial breast Brachytherapy
CyberKnife	Stereotactic Ablative Body RT	Stereotactic body RT	Proton Cyclotrons Therapy PT
Combined Tele- & Brachytherapy	¹³⁷ Cs, ¹⁹² Ir, ⁶⁰ Co After-loading Uterus	Betatron: Kidney CA	Proton Radiography & target Irradiation
Stereotactic Radiosurgery	Microtron RT	Fiducial points in RT	The Bragg peak in PT
Gamma Knife	Image guidance; the 6-D skull	Linac: Colorectal CA	Tomotherapy

Table 2: RT-related subjects searched for Patents and IP-Documents and properly evaluated.

Numerous IP-documents, published during the last 20 years, have been retrieved and evaluated, using the European Patent Office (EPO) and the US Patent and Trademark Office (USPTO) search-engines. Several specific IP-fields have been searched related to imaging and therapeutic techniques. Various Patent-mappings, according to inventor, publication-year dependence, Assignee's Country of origin, Companies etc. have been created from the retrieved data.

The most important of our results are synopsisized in Fig. 1 that displays a significant increase of IP-Docs filing, concerning specific and relevant medical Imaging and Radiotherapy equipment. The time-dependent evolution of imaging related IP-Docs shows that Magnetic Resonance Spectroscopy (MRS) and Positron Emission Tomography (PET) are leading among the Imaging methods, supporting Radiotherapy. On the other hand, Intensity Modulated RT (IMRT), Image-guided RT (IGRT) and Proton Therapy (PT) are the most important fields of the innovation trail, regarding the emerging Radiotherapy Systems.

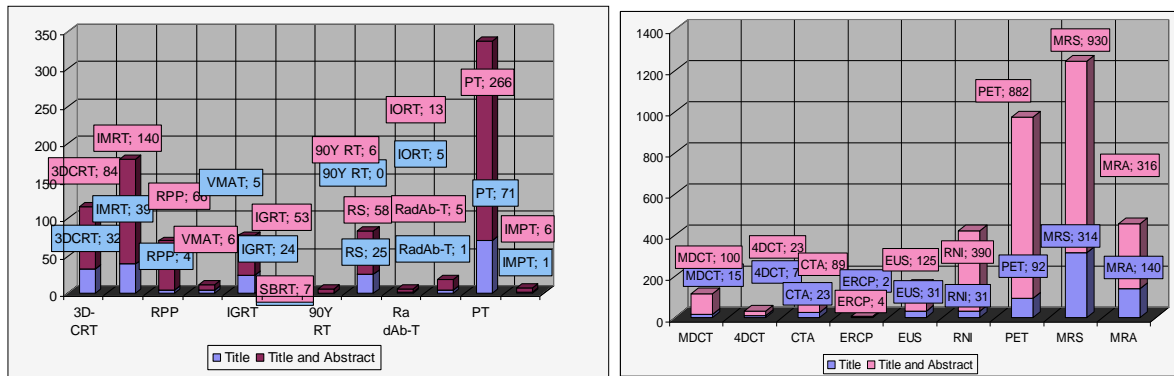


Fig. 1. Left: Indicative numbers of published IP-Docs relevant to Radiotherapy. Right: Indicative numbers of published IP-Docs relevant to Imaging supported RT.

Systems and apparatuses providing for Radiation Therapy particle beams (Protons and Carbon Ions) are the most recent and innovative filed systems in RT. They have a compact design, suitable for a single treatment room. The radiation system comprises a stationary cyclotron coupled to a rotating gantry assembly through a beam line assembly.

The most recent and innovative system for Proton RT found, is equipped with a single set of dipole magnets that are installed on the rotating gantry assembly and undertakes the dual functions of beam energy selection and beam deflection. The energy degrader may be exposed to the air pressure. The beam line assembly comprises a rotating segment and a stationary segment that are separated from each other through an intermediate segment that is exposed to an ambient pressure [1], [2].

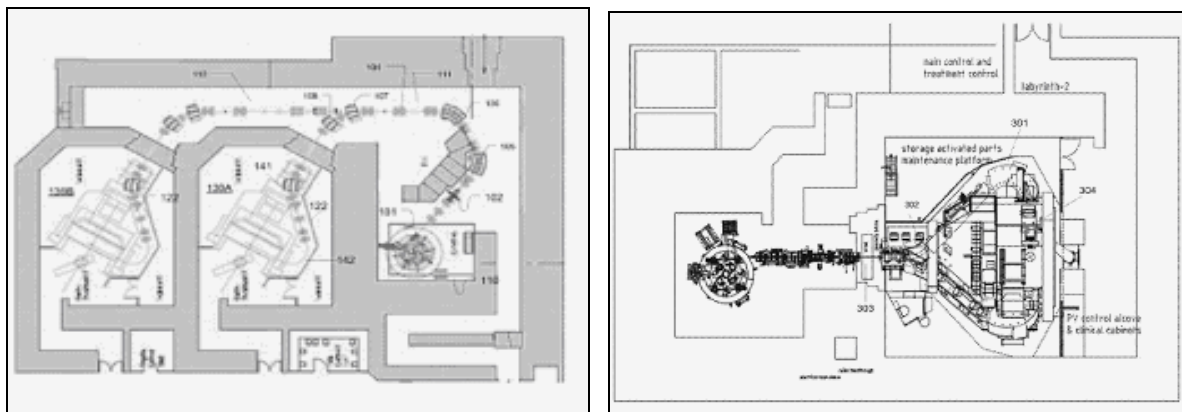


Fig. 2. A compact proton therapy system with energy selection onboard a rotatable gantry [1].

BIOMEDICAL TECHNOLOGY QUALITY ASSURANCE, STANDARDS, MEDICAL PROTOCOLS AND GUIDELINES

Oncology patients need usually Hospital and/or Home-Care support, by interdisciplinary well-trained personnel. There are various complicated and potentially dangerous, for the patients and the personnel, treatment procedures that must be carried-out with caution. Such an example is safety by Hyperthermic Intraoperative Intraperitoneal Chemotherapy (HIIC). Perioperative staff members encounter many occupational exposure hazards in the workplace. Cytotoxic agent exposure is a relatively new hazard that

perioperative staff members are experiencing, as more surgeons use HIIC to treat patients with abdominal-pelvic cavity malignancies. Routes of exposure include inhalation, ingestion, injection, and skin contact. The National Cancer Institute, the Occupational Safety and Health Administration, and the Joint Commission on Accreditation of Healthcare Organizations, provide guidelines for the safe administration and handling of cytotoxic agents. Institutions, in which cytotoxic agents are administered, should use these guidelines to develop policies, procedures, and educational programs, to protect surgical patients and perioperative staff members. Chemotherapy Safety precautions are essential across Practice-settings.

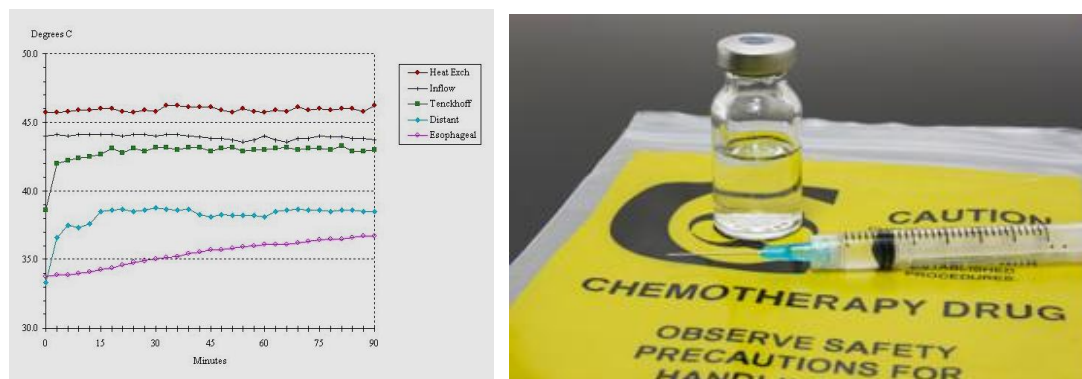


Fig. 3. Left: Patient Temperatures at Three Anatomic Sites, Heat Exchanger and the In-Flow Line [3]. Right: Chemotherapy safety precautions essential across Practice settings [4].

Examples of Oncology patients' Hospital and/or Home-Care needed			
Ambulant treatment?	Leukemia remission/rehabilitation	Side Effects related Homecare	Prostate side effects
Chemotherapy (cis-Pt, MCV etc.)	Safety considerations	Prediction of Radio-surgery complications	Palliative RT
Lung tumors	Lung-Liver-Prostate metastases	Side effects: Stereotactic RT/RS	Radiation Protection
HDR, MDR and LDR after-loading systems	Oncology supportive Care	Haemodialysis	Dose and exposure
In- and off- Hospital Care	In- and out-patients RT	Photon/Proton RT	Risks & side effects
Small-cell Lung CA Metastases	Prostate Cancer	CEA Diagnosis	PT side effects

Table 3: Assignments concerning Oncology patients' Hospital and Home-Care needed.

Another example constitutes the side-effects of Brain-tumor Radiosurgery. There are usually very few immediate side effects from Radiosurgery. A dose of steroids before the treatment, or straight afterwards, help to prevent side effects due to swelling of the brain. The patient may feel sick or faint at first, have a headache or also feel a bit weak and dizzy.

After treatment with a head frame, the patient may have slight bleeding, from the points where the frame was attached to skull. Tingling or itching on the points where the frame was attached is a normal sign of healing. Finally, there is a small risk of light seizures after Radiosurgery, therefore driving is not allowed for at least a month afterwards [4].

HEALTH-CARE AT HOME & WEB-BASED HEALTH-SERVICES MANAGEMENT

Stereotactic Ablative Body Radiotherapy (SABR) is a typical Quality Assurance example. Hypo-fractionated image guided radiotherapy of extracranial targets has become increasingly popular, as a treatment modality for inoperable patients, with one or more small lesions. This report [5] details the results of the physical quality assurance (QA) program used for the first 33 lung cancer SABR 3D-conformal treatment plans. SABR involves one or a few fractions of high radiation dose delivered in many small fields or arcs with tight margins, to mobile targets often delivered through heterogeneous media with non-coplanar beams. Patient-specific QA have been conducted, with particular reference to motion management. Individual patient QA is helpful in setting up the technique and understanding potential weaknesses [5]-[7].

Medical Protocols Guidelines and Standards examples addressed in this study			
Techniques & strategies	Stem cell transplants	Si-Dosimetry for high LET RT	Dosimetry
Adjuvant Radiotherapy	Dosimetry verification	Clinical Isodose-curves for γ -Knife vs. X-Knife	Brachytherapy Staff RP
Trial reports	SABR Quality Assurance	Patient Dosimetry	Fluence & Dosimetry
Treatment planning	Staff Radiation Protection RP	Infections	Treatment planning
Metastatic Brain Tumors	PET-CT 11C-Radioactivity	Metallic implants, LEDs	Tissue Protection
Retrospective analysis	Da Vinci versus Cyber- knife	Radio-embolization	Dosimetry methods

Table 4: Assignments concerning Oncology Medical Protocols Guidelines and Standards.

DISCUSSION AND CONCLUSIONS

We have attempted an interdisciplinary approach in RT based on three pillars:

- Radiotherapy innovative Technology as reflected on IP-Docs.
- Patient-care Medical-managerial aspects of Hospital/Homecare Oncology patients.
- Their combination with relevant Medical Protocols, Guidelines and Technical Standards.

72 discrete topics have been grouped in 24 “case-vectors” handled by 24 students in a complicated, however, creative and interesting “examination”. The results so far, corroborate the trust shown to our students, concerning the outcomes of these projects.

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