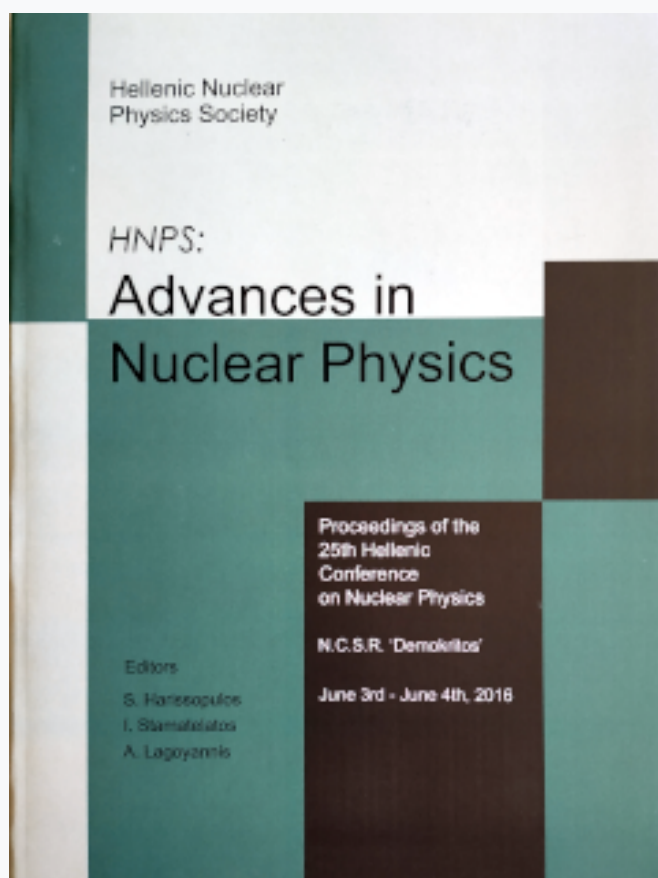


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# **Radiotherapy (RT) innovative Technology combined with Hospital/Home-Care Standards and Medical Protocols and Guidelines: A collective Compendium**

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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 4<sup>th</sup>-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

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## **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 4<sup>th</sup>-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  | <sup>137</sup> Cs, <sup>192</sup> Ir, <sup>60</sup> Co After-loading Uterus | Oncology supportive Care                      | Staff Radiation Protection                              |
| 11  | Microtron RT  | In- and out-patients RT                       | PET-CT <sup>11</sup> 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 $\gamma$ -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

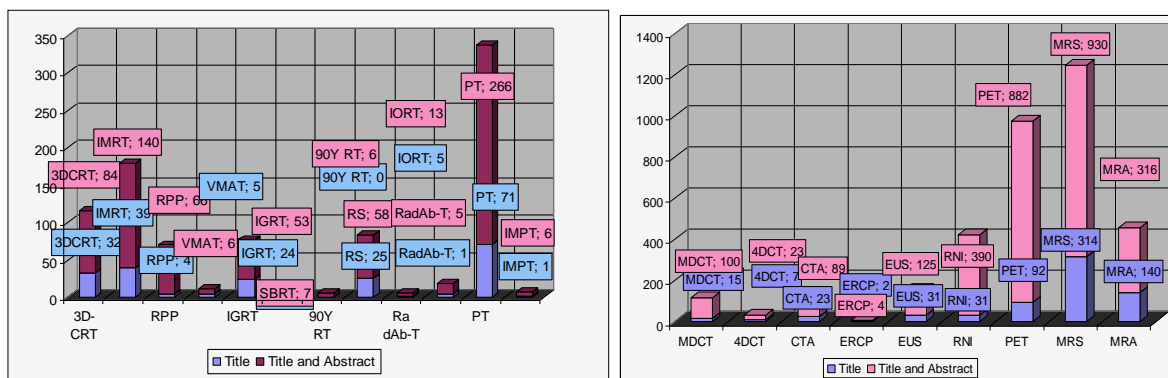
Every one of the 24 students, a specific subject has been assigned, related to a certain Radiotherapy system and/or method. Patents and other IP-Documents relevant to one RT System, a RT-important aspect or a RT-application have been searched for. Following subjects, relevant to RT, as displayed in Table 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  | <sup>137</sup> Cs, <sup>192</sup> Ir, <sup>60</sup> 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.

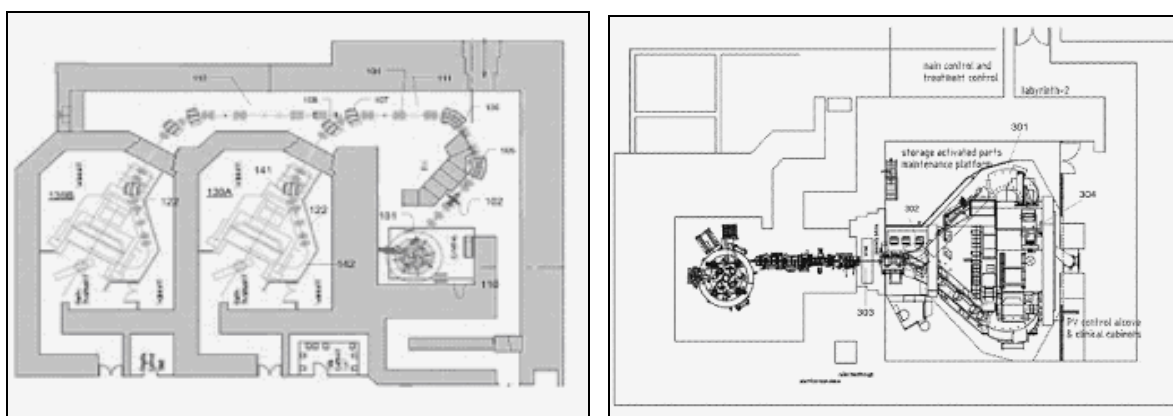
The most important of our results are synopsisized in Fig. 1 that displays a significant increase of IP-Docs filing, concerning specific and relevant medical Imaging and Radiotherapy equipment. The time-dependent evolution of imaging related IP-Docs shows that Magnetic Resonance Spectroscopy (MRS) and 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].

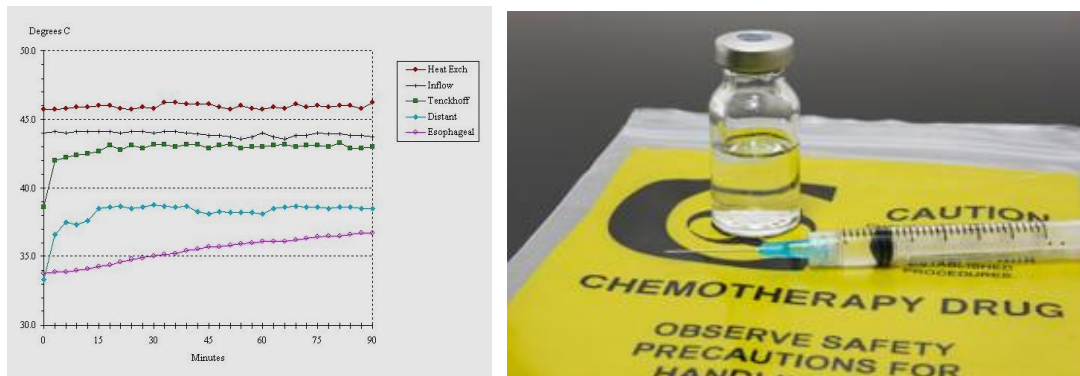


**Fig. 2.** A compact proton therapy system with energy selection onboard a rotatable gantry [1].

## 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 $\gamma$ -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.

## References

- [1] EP 2968980 A1-2016-01-20.
- [2] US 9012866 B2, Applicant: Varian Medical Systems.
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- [4] Brain Radiosurgery side-effects: <http://www.cancerresearchuk.org/about-cancer/type/brain-tumour/treatment/radiotherapy/stereotactic-radiotherapy-for-brain-tumours#sfx>
- [5] <http://www.ncbi.nlm.nih.gov/pubmed/24399615>
- [6] [www.pub.iaea.org/MTCD/publications/PDF/pub1296\\_web.pdf](http://www.pub.iaea.org/MTCD/publications/PDF/pub1296_web.pdf)
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