



**Statement of  
Leonard L. Gunderson, M.D., M.S.  
Chairman of the Board of Directors  
on Behalf of the American Society for Radiation Oncology (ASTRO)  
Before the House Committee on Energy and Commerce Subcommittee on Health  
June 8, 2012**

Chairman Upton, Ranking Member Waxman, Subcommittee Chairman Pitts, Subcommittee Ranking Member Pallone and members of this distinguished committee, good morning and thank you for the opportunity to testify at today's hearing on the standards for radiation therapy technologists. High quality radiation therapy requires not only highly skilled and well trained radiation oncology physicians (radiation oncologists), but also an entire team of medical physicists, dosimetrists, and radiation therapists (technologists). ASTRO and its over 10,000 members applaud the bipartisan leadership of Reps. Whitfield and Barrow -- along with 20 Members of the full committee and 10 from the health subcommittee -- for supporting the Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act (HR 2104). **ASTRO strongly supports immediate passage of the CARE Act, a key component of our *Target Safely* patient safety initiative, to help ensure the safety of radiation therapy.**

I am an Emeritus Professor and Consultant in Radiation Oncology at the Mayo Clinic, where I served in leadership positions for over 21 years. I've practiced as a board certified radiation oncologist for more than 35 years, and had 10-30 patients per day under treatment during that time. My medical education was at the University of Kentucky, and my residency/fellowship was at the Latter-Day Saints (LDS) Hospital/Intermountain Health Care Inc. (IHC) in Salt Lake City, Utah, including a rotation at the MD Anderson Cancer Center in Houston, Texas and other institutions. After completing my training, I was on staff at LDS Hospital/IHC for 2 years, followed by Massachusetts General Hospital/Harvard Medical School for nearly 5 years and subsequently at the Mayo Clinic for 28.5 years.

My clinical research has focused on external beam radiation therapy as a component of multimodality treatment for patients with gastrointestinal (GI) cancers (colorectal, gastric, pancreas, biliary, anus, esophagus) and soft tissue sarcomas. I have worked closely with colleagues in surgery, medical oncology and other specialties to develop consensus on both diagnostic and treatment pathways in the care of patients.

Leadership positions I have held include Chair of Radiation Oncology and subsequently Chair of the Department of Oncology at the Mayo Clinic in Rochester, Minnesota (I was the only radiation oncologist to serve as chair of the Department of Oncology). At Mayo Clinic in Arizona, I was Chair of Radiation Oncology and Deputy Director for Clinical Affairs at Mayo Clinic Cancer Center Arizona. I also have been a leader in the Radiation Therapy Oncology Group (RTOG) clinical cooperative group for 14 years, including Chair of the RTOG Gastrointestinal (GI) Cancer Committee/GI Steering Committee and Vice-Chair for Disease

Sites. I am proud of my more than 30 years of service to ASTRO, which includes a leadership position as a member of the Board of Directors for 8 years. I currently serve as Chairman of the Board of Directors of ASTRO, which I am representing today.

I have personally witnessed the great benefits of radiation therapy for cancer patients. I care deeply about my profession and care even more deeply about the health and safety of my patients. I look forward to telling you why we support the CARE Act, how radiation therapy works, ASTRO's longstanding efforts to improve quality and patient safety, as well as ASTRO's plans to further enhance patient protections.

I believe my testimony is critical to help Congress and the public understand that radiation therapy is a very safe treatment with a long track record of effectively curing cancer with minimal side effects (alone or in conjunction with surgery and chemotherapy or other systemic therapy). We believe passage of the CARE Act – in concert with ASTRO's many patient safety initiatives and the important projects being undertaken by our close partners in physics, radiation oncology technology and device manufacturing – will contribute to our efforts to improve patient care and prevent errors.

As you know, radiation oncology is an important tool in the fight against cancer. Over the last 25 years, the five-year survival rate for cancer patients has increased steadily. For example, in the mid-1970s, the five-year survival rate for breast cancer was 75%, for prostate cancer it was 69%. Today, the five-year survival rate has increased to 90% for breast cancer and 99% for prostate cancer. While these are important gains for some of the most common cancers, progress lags for other cancers such as lung, ovarian, brain and pancreatic cancer where the five-year survival rate remains below 50%. While progress has been made in some areas, more scientific research funding is still needed to continue to improve cancer survival.

### **ASTRO and Radiation Oncology**

Founded in 1958, ASTRO's mission is to advance the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in the rapidly evolving healthcare environment. ASTRO's physicians and medical professionals are found at hospitals and cancer treatment centers around the globe and make up the radiation therapy treatment teams that are critical in the fight against cancer.

Radiation therapy safely and effectively treats cancer and some benign conditions. Doctors use radiation therapy to eradicate cancer, to control its growth or to relieve symptoms, such as pain. It can be used to treat cancer in almost any part of the body, although breast cancer, lung cancer and prostate cancer typically make up more than half of all patients receiving radiation therapy.

New technology and improved techniques allow radiation oncologists to better target radiation in an attempt to eliminate cancer cells while at the same time protecting healthy cells. As highly trained specialists, radiation oncologists know the various forms of radiation therapy – brachytherapy or external beam radiation – their efficacy in specific cases, and the potential side effects and risks.

Radiation oncology practices use sophisticated equipment to provide patients with safe and effective care. Radiation oncologists discuss and agree upon treatment options with patients and their families and plan and deliver that care in conjunction with the patient's other physicians, as well as with the non-physician members of the patient's care team. This team approach assures that the radiation therapy component of a patient's clinical care fits appropriately in the overall patient treatment plan.

Though their uses are very different, radiation therapy is often confused with diagnostic radiology or imaging. Diagnostic radiology is used in preferably low doses to view inside the body in order to diagnose conditions or monitor the spread of cancer. Radiation therapy delivers a targeted high dose of radiation in an attempt to eradicate the cancer/tumor while sparing normal organs and structures. Higher dose often leads to better local tumor control, which has the possibility of translating into higher cure rates. While total dose is important in radiation oncology, other factors are equally important such as the dose of irradiation per treatment and the number of days over which the treatment occurs.

### **Radiation Oncologist Training and Board Certification**

Radiation oncologists complete four years of medical school followed by five years of post-graduate training, including 4 or more years in a radiation oncology residency program. To earn board certification after residency, they must pass three components of a written examination (clinical, radiobiology, and physics) as well as an oral examination. Ninety-eight percent of all practicing radiation oncologists in the United States are board certified. Radiation therapy should only be delivered by physicians who have been specifically trained to deliver this type of treatment.

There are approximately 4,500 board-certified radiation oncologists in the United States, and about half of them must participate in maintenance of certification (MOC) programs to maintain their board-certified status. MOC programs are designed to evaluate six essential competencies on a continuous basis: medical knowledge; patient care; interpersonal and communication skills; professionalism; practice-based learning and improvement; and system-based practice.

In addition to passing an oral exam every 10 years, the MOC process requires radiation oncologists to attain 200 hours of continuing medical education (CME) credits (80 percent of which must be related to radiation therapy or oncology), to take eight self assessment modules (SAMs), and to complete three Practice Quality Improvement (PQI) projects. ASTRO currently offers 37 online SAMs on a wide range of topics. In February 2012, ASTRO launched an American Boards of Medical Specialties Patient Safety Foundation module. This course has been adapted to fit the needs of the radiation oncology team and focuses on communication and the various aspects of patient safety.

In today's environment, medical technology and decision-making are increasingly complex, and rapid changes in diagnosis and care delivery compound the situation. Initial certification and maintenance of certification offer a strong defense against loss of skills and provide continuous and rigorous quality assurance throughout one's medical career. ASTRO's Performance Assessment for the Advancement of Radiation Oncology Treatment (PAAROT) program is an example of our commitment to continuous quality improvement at the physician level. For

PAAROT, physicians select a baseline sample of 10 consecutive medical records and enter data on a series of measures for every medical record in the sample. Performance is computed per measure across the sample of medical records and is compared to aggregate peer data and pre-established performance goals. Next, pursuant to the review of the scores for each measure, physicians select a measure for performance improvement. An improvement plan is developed and implemented over the course of three months. Finally, re-measurement is completed by selecting another sample of 10 consecutive records and re-entering all measures in every record in the sample to assess the impact of the quality improvement plan. All data collected in PAAROT are HIPAA compliant and de-identified. PAAROT meets the American Board of Radiology (ABR) criteria for Practice Quality Improvement as part of the requirements of the ABR Maintenance of Certification Program.

Because of the speed of innovation in the field of radiation oncology, ASTRO actively supports physician participation in MOC activities and other continuing medical education to assure that physicians are up-to-date in the approaches for delivering radiation therapy to cancer patients. For example, each spring we offer a “State of the Art” meeting that includes workshops so that our members can be well informed about new advances and to help them anticipate workforce and training needs that will be needed to safely use new, advanced technology.

Additionally, ASTRO provides “eContouring” courses, both online and in person. Contouring is the term used to describe how a radiation oncologist outlines the contours of a tumor, plus nodal areas at risk, to best target them for radiation therapy, while excluding normal organs and structures as much as feasible. These sessions are designed to provide crucial clinical education for physicians and provide an opportunity to practice and discuss core treatment issues. Participants have the opportunity to practice contouring and compare their contours to those of renowned experts in a particular disease site. In addition, participants can take sample cases home with them to continue to practice and further improve their skill.

### **Radiation Oncology Treatment Team**

While the radiation oncologist is ultimately responsible for the patients’ care and safety, a team of highly trained medical professionals is needed to plan and deliver radiation therapy services. These treatment team members perform hands on services to both the complex planning software and machinery that delivers the radiation, and the patients that receive treatment. The team’s training and certification can directly affect safety and treatment outcomes. In addition to the radiation oncologist, the treatment team includes:

- *Medical physicists:* Qualified medical physicists work directly with the radiation oncologist during treatment planning and delivery. They oversee the work of the dosimetrist and help ensure that complex treatments are properly tailored for each patient. Medical physicists are responsible for equipment software and systems acceptance testing, maintenance and commissioning, and for developing and directing quality control programs for equipment and procedures. Medical physicists follow college with additional graduate training in medical physics to receive a master’s or doctoral degree. In some cases, a medical physicist will complete an additional one- or two-year training program at a hospital. Medical physicists preferably are certified by the American Board of Radiology or the American Board of Medical Physics.

- *Dosimetrists*: Dosimetrists carefully calculate the dose of radiation prescribed by the radiation oncologist to make sure the tumor gets the prescribed dosage. Using computers, they develop treatment plans that can best encompass the tumor while sparing normal tissue from radiation. Since treatment plans are often very complex, dosimetrists work with the radiation oncologist and medical physicist to develop a plan that is appropriate for each individual patient. Many dosimetrists start as radiation therapists and then, with on-site training, become dosimetrists. Others are graduates of one- to two-year dosimetry training programs. Dosimetrists may become certified by the Medical Dosimetrist Certification Board.
- *Radiation therapists (technologists)*: Radiation therapists work with radiation oncologists to administer daily radiation treatments under the doctor's prescription and supervision. They are trained in how to properly position a patient to ensure that the radiation is delivered to its intended target. They maintain daily treatment records and, in conjunction with the medical physicist, check the treatment machines to make sure they are working properly. Certified radiation therapists go through a two- to four-year educational program following high school or college. By passing a special examination, radiation therapists may be certified by the American Registry of Radiologic Technologists. Some states require radiation therapists to be licensed but some do not.

### **Patient Safety in Radiation Oncology – The CARE Act**

ASTRO has long advocated for Congress to help us further improve the safety of radiation therapy by establishing minimum education and credentialing standards for radiation therapy personnel through passage of the CARE Act. More than 1 million patients are treated with radiation therapy each year. Having highly skilled radiation therapy professionals on the treatment team is crucial for patient safety.

In some states basic training standards are voluntary, allowing individuals to perform some radiation oncology procedures without any formal education. Without a minimum level of standards, patients are at risk. The CARE bill sets education and certification standards for the radiation therapists, medical physicists and medical dosimetrists who treat Medicare and Medicaid patients. These minimum education and certification standards will help ensure that patients are treated accurately, leading to higher patient survival rates and reduced complications.

The CARE bill would advance safety and quality by requiring individuals who perform radiation therapy to graduate from a specialized educational program and pass a national certification exam. Personnel would also be required to maintain competency by obtaining continuing education, much like their physician counterparts, which will help ensure that personnel have the skills to perform their duties without error.

The need for federal minimum education and certification standards for radiation therapists, medical physicists and medical dosimetrists is clear. ASTRO is proud to be a member of the Alliance for Quality Medical Imaging and Radiation Therapy, as we agree that consistent and uniform national standards for technical personnel will improve the quality and safety of care,

and reassure patients that their treatments are being assessed, planned, and delivered by highly qualified personnel.

While a critical step, we do not believe that the CARE Act alone can prevent the medical errors that are possible in a complex treatment such as radiation therapy. That is why ASTRO is committed to working with Congress and this Committee on additional efforts to ensure cancer patient safety, particularly in the area of practice accreditation, which is different than credentialing various members of the radiation oncology care team.

However, ASTRO is concerned about proposals to expand the Medicare Improvements for Patients and Providers Act (MIPPA) in lieu of proceeding with the CARE Act. As you know, MIPPA applies *only* to advanced diagnostic imaging services – not radiation therapy services – provided in free-standing centers paid under the Medicare Physician Fee Schedule (MPFS). If MIPPA were simply expanded to include radiation therapy services, we anticipate two problems. First, while MIPPA may have been an effective way to regulate the vast majority of advanced imaging providers, only about one-third of radiation therapy providers operate as free-standing centers paid under the MPFS, so the remaining two-thirds of the radiation oncology providers who are hospital-based would not be covered by newly revised MIPPA requirements. Secondly, only about 10-15% of the radiation therapy centers in the country (both free-standing and hospital-based) are currently accredited. Accreditation done right is resource intensive, involving a full-day onsite inspection by an independent, peer radiation oncologist and medical physicist. A grace period would be needed to allow facilities to come into compliance with the accreditation requirements.

For these reasons, ASTRO believes the more straightforward approach to addressing necessary standards for radiation therapists, dosimetrists and medical physicists is via immediate passage of the CARE Act, which already enjoys vast bipartisan and bicameral support. Following passage of the CARE Act, ASTRO is open to working with the Committee to mandate radiation oncology practice accreditation using the ASTRO/American College of Radiology (ACR) Radiation Oncology Practice Accreditation (ROPA) program that thoroughly assesses the complexity of care processes and safety standards in both hospital and freestanding radiation oncology clinics.

Should the Committee be interested in incorporating this accreditation program into the Medicare program, we would like to work closely with you to ensure that such a program is successful. For instance, we would strongly recommend that such a program be phased-in over sufficient time to ensure that there are an adequate number of radiation oncology physician and medical physicists certified to conduct on-site accreditation reviews to meet the demand of centers seeking accreditation. Because accreditation is labor intensive, our practice accreditation program has struggled with training adequate numbers of reviewers. Medicare would need to account for this workforce challenge with a phased-in approach.

### ***Target Safely Radiation Safety Initiative***

ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments by providing education and professional guidance to our members. A culture of safety and quality control is woven into the very fabric of our field, and there are many checks

and balances, at many levels, to assure that the safest and most effective care is delivered to our patients. Because of the technological advances in our field, radiation therapy treatments are increasingly complex. We have been a leader in efforts to improve patient safety within our specialty, and protecting our patients from potential errors requires constant vigilance.

In 2010, ASTRO's Board of Directors committed to redouble our efforts with respect to quality and safety. We undertook a systemic, 360-degree review of our ongoing patient safety and quality assurance projects and developed an action plan, called *Target Safely*, to improve the safety and quality of radiation therapy and reduce the chance of medical error. Since the plan was established, ASTRO has made great strides in meeting its goals, including:

- Worked with patient support groups, cancer survivors and other medical organizations to create a list of questions patients should ask their physicians and cancer centers when considering radiation therapy as a treatment for their disease. These are designed to help patients better understand the safety checks and balances that are put into place to guard against errors. Those questions are available for download on our patient website [rtanswers.org](http://rtanswers.org) and to view as videos posted on [YouTube](http://YouTube).
- Continued to serve as the chief financial supporter and lead organization in the IHE-RO (Integrating the Healthcare Enterprise -- Radiation Oncology) program. This program brings together radiation oncologists, physicists, other cancer care professionals and the medical device industry to prevent errors by creating an environment of interconnectivity and interoperability where vital clinical information is passed seamlessly from system to system, within and across practices, and made readily available at the point of care. ASTRO is asking all radiation oncologists and hospitals to consider only IHE-RO compliant technologies when selecting new radiation therapy equipment.
- Strengthened the ASTRO/ACR ROPA program with more robust and meaningful measures. ROPA aims to ensure that radiation therapy clinics are fully competent to perform the services they provide. ROPA provides impartial third-party peer review through assessment of daily practices that demonstrate an impact on professional competence according to recognized standards of the scientific community. More than 300 practices have been accredited since 2008. ASTRO strongly supports practice accreditation and encourages its members to participate in the program.
- Developed several white papers on safety considerations in the clinic, including safe use of Intensity-Modulated Radiation Therapy (IMRT) and Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy (SRS/SBRT). Three more white papers on Image-Guided Radiation Therapy (IGRT), High-dose-rate (HDR) brachytherapy and peer review in the clinic are nearing completion.
- Committed to incorporating quality and safety educational content in all ASTRO meetings to ensure attendees have the resources necessary to provide safe and effective patient care.

A centerpiece of *Target Safely* that is becoming a reality is the creation of a national medical error reporting system and patient safety database for radiation oncology. We are proud to report that ASTRO is building on Congress' bipartisan Patient Safety Act of 2005 by beginning work with a federally-certified Patient Safety Organization (PSO) to create an unprecedented

national medical error reporting system for radiation oncology to detect potential problems and identify national error trends. ASTRO greatly appreciates the foresight of Congress, particularly the leadership of this Committee, in passing this legislation that will allow us to efficiently leverage a PSO's experience, expertise, resources, and confidentiality protections to create a radiation oncology-specific error reporting system. We believe that contracting with a PSO will allow us to meet our goal of collecting radiation oncology patient safety data and analyzing it to improve the safety of radiation oncology. In our 2011 ASTRO membership survey, 85% of radiation oncologists and 94% of medical physicists responding said they would use an ASTRO-sponsored confidential reporting system for medical errors and near misses.

While radiation oncology is focused on targeting and delivering maximum doses of radiation directly to the cancer, we remain vigilant of the importance of reducing complications and protecting patients by sparing normal organs and structures as much as feasible from the harmful effects of radiation.

### **Quality Improvement**

Quality assurance and error reporting is only one piece of the puzzle, and ASTRO appreciates this Committee's efforts to promote quality measurement and improvement. ASTRO has devoted significant time and resources to developing clinical guidelines and quality measures for radiation oncology. Over the past four years ASTRO has developed five clinical practice guidelines to improve patient care and reduce treatment variation. These topics include:

- Accelerated partial breast irradiation (APBI),
- Fractionation for whole breast irradiation,
- Palliative radiotherapy for bone metastases,
- Palliative thoracic radiotherapy for lung cancer, and
- Radiotherapeutic and surgical management of newly diagnosed brain metastases.

These five guidelines have all been accepted for inclusion in the National Guideline Clearinghouse sponsored by the Agency for Healthcare Research and Quality. ASTRO also is developing an evidence-based clinical practice guideline on the role of post-operative radiation therapy for endometrial cancer as well as post-operative radiotherapy after radical prostatectomy (joint ASTRO/American Urological Association guideline). Finally, ASTRO is exploring a guideline on radiation therapy in the treatment of lung cancer. In developing clinical practice statements, we have refined our process based on the Institute of Medicine's recommendations in the report *Clinical Practice Guidelines that We Can Trust*.

Since radiation oncology is a specialty that relies on, and has made dramatic advances in effective cancer care through the use of, complex breakthrough technologies, ASTRO has recognized the need for clinical practice statements on the appropriate use of new technologies in the delivery of radiation therapy. Therefore, ASTRO recently launched an initiative to develop and promulgate "Best Practices Statements." These statements will use the Rand Appropriateness Methodology and a modified Delphi approach to address important clinical questions. Experts in the field will engage in consensus deliberations on evidence to determine the appropriateness of different technologies in the treatment of cancer. ASTRO's first such statement is underway, and it will address the appropriate use of different technologies in the treatment of post-operative endometrial cancer.



While developing these collaborative guidelines and “Best Practice Statements” is an exhaustive and resource-intensive endeavor, ASTRO is committed to continuing to invest significant time, money and energy into the development of these statements. They also serve as the impetus for the development of quality measures. A newly developed measure, External Beam Radiotherapy for Bone Metastases, is being considered for endorsement by the National Quality Forum (NQF). Given the interdisciplinary team approach to cancer treatment, ASTRO also has partnered with other medical societies to develop multidisciplinary measures. An oncology measure group that was jointly developed with the American Society for Clinical Oncology (ASCO) is being reviewed by the Quality Measurement and Health Assessment Group at CMS. ASTRO has worked closely with the AMA Physician Consortium for Performance Improvement (PCPI) to develop NQF-endorsed quality measures included in the Medicare Physicians Quality Reporting System (PQRS).

ASTRO, in partnership with our foundation -- the Radiation Oncology Institute (ROI) - is developing the National Radiation Oncology Registry (NROR), the first of its kind for radiation oncology. The intent of the registry is to improve the care of cancer patients by capturing real-time reliable information on radiation treatment delivery and health outcomes through a prospective electronic registry infrastructure. The pilot project for this nascent registry is scheduled to begin in the fall of 2012 and will be focused on radiation oncology treatments for patients with localized prostate cancer. The registry will collect numerous data points, including total dose, dose per treatment, and the number of treatments and days required to deliver the total dose. Additionally, other important factors in better understanding cancer patients care will be collected, such as whether radiation therapy is delivered post-operative, pre-operative, or used as the sole therapy. The objectives for NROR are to:

- Collect patient-specific radiotherapy data electronically;
- Determine national patterns of care and gaps in quality of treatment;
- Provide benchmark data and tools to individual practitioners for quality improvement;
- Generate hypotheses linking processes of care and outcomes and identifying subpopulations for which a particular form of radiation therapy is most effective.

This spring, ROI hosted a high-level forum for thought leaders and visionary registry stakeholders to raise awareness of the NROR, gather recommendations from the group, and build longer-term involvement from the community. Forum attendees included radiation oncologists and physicists, representatives from NIH, FDA, and CMS, foundation and professional society participants, private payers, patient advocates, and industry leaders.

While the promise of the data collected by registries, such as NROR, to inform quality improvement efforts and to demonstrate the value (or lack thereof) of particular health care services is great, considerable resources are needed to launch and sustain these efforts. ASTRO strongly supports NCI’s funding for clinical trials conducted through the cooperative groups, as we believe these trials are needed to help us answer key questions. We note, however, that observational data obtained in registries will give us a more complete view of how particular subpopulations (e.g., particular genetic markers, particular comorbidities) respond to treatment outside of a controlled clinical trial environment. We anticipate that the insights gained from this knowledge will have a significant impact on the cost and quality of cancer care. As federal

programs like Medicare will benefit tremendously from this information, we urge Congress to provide federal funding to support registry efforts and to create a regulatory environment that supports these efforts.

### **Conclusion**

In summary, dealing with a cancer diagnosis is hard enough for patients without having the additional burden of worrying about the accuracy and safety of their treatments. With every cancer patient, the goal is to treat and/or cure their disease in the safest and most effective way possible. That is why we're focused completely on ensuring patient safety. We believe that any error is one error too many. ASTRO remains devoted to our patient safety goals and passing the CARE Act is a critical step toward achieving these goals.

ASTRO is also committed to supporting national error reporting, more training, enhanced accreditation, better use of health information technology, patient-centered educational tools and federal advocacy to help protect patients. We share the Committee's concerns about the health and safety of all patients and recognize the importance of maintaining access to high quality cancer treatment. **We urge the Committee to immediately pass the CARE Act, and we look forward to working with you on additional policies that could be implemented to further enhance the quality of care patients receive.**

Thank you again for the opportunity to testify.