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ASTRO

TARGETING CANCER CARE

November 30, 2011

Dr. Leon S. Malmud
Chair, NRC Advisory Committee on the Medical Use of Isotopes
Dean Emeritus, Temple University School of Med
Temple University Health System
3401 North Broad Street
Philadelphia, PA 19140

Dear Dr. Malmud,

The American Society for Radiation Oncology (ASTRO) is concerned with the revised definition of medical event approved by the Advisory Committee on the Medical Use of Isotopes (ACMUI) on October 18, 2011, and we ask that ACMUI formally reconsider this revised definition.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy.

As you are aware, ASTRO submitted a definition of medical event to the ACMUI at its meeting in April 2011. This definition was discussed at length during that meeting and subsequently was endorsed by the ACMUI. In addition, ASTRO presented this definition at two NRC workshops, where the majority of the participants—including the participating ACMUI representative—supported this definition.

In addition to participation in the public workshops and the ACMUI meeting, ASTRO has discussed our definition with NRC staff, as well as with all of the NRC Commissioners, including Chairman Gregory Jaczko. In October, the Chairman attended our annual meeting where he not only spoke to meeting attendees, but met with a small group of our leadership to better understand our concerns. We believe that all of these meetings and discussions were productive.

At the September 22-23, 2011 ACMUI meeting, the Permanent Implant Brachytherapy Subcommittee agreed to submit a revised committee report on the definition of medical event by October 7, 2011 so that it could be discussed by the full committee on a teleconference on October 18, 2011. It was clear during the discussion on September 23, 2011 that the subcommittee would be making only minor changes to the report (see pages 174-175 and pages 202-203 of the official transcript). However, ASTRO believes that the new definition offered in the revised report differs substantially from the definition endorsed by the ACMUI in April. This new definition is significantly more lenient and complex than the definition endorsed in April. We believe such a complex definition may be difficult to regulate and could cause confusion in practice. ASTRO continues to advocate for a target-based definition (>20 percent of source strength implanted outside the planning target volume) to define medical events for regulatory purposes.

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We believe that the changes to the Permanent Implant Brachytherapy Subcommittee report may have been caused by the lack of appropriate time and a dramatic change in subcommittee membership. These factors did not afford the subcommittee the time and expertise needed to complete the report in a satisfactory manner. In addition, the ACMUI has always afforded stakeholders the opportunity to comment on issues that directly affect them. ASTRO was not given the opportunity to review and provide comments on this new definition prior to the October teleconference.

We applaud the NRC commissioners and staff for, thus far, providing ample opportunity for stakeholders, including ASTRO, to fully comment and participate in the process of redefining medical events. However, we believe the Permanent Implant Brachytherapy Subcommittee's revised definition and ACMUI's approval of that definition represents an exception to what has been, up until now, an open process. We would like to continue to work with both the ACMUI and the NRC to ensure that a definition that is both clinically appropriate and straightforward to regulate is adopted. We request that ACMUI formally reconsider the revised definition, allowing sufficient time for stakeholders to comment and offer input, and that this reconsideration occur in a timely manner so as not to delay NRC rulemaking on this important issue.

We look forward to continuing to work with the ACMUI and NRC on the definition of medical event and look forward to your response. Please contact Cindy Tomlinson, Manager of Regulatory Affairs at cindyt@astro.org or 703.839.7366 should you have any questions.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

Attachments: Statement of Danny Song, MD on behalf of ASTRO, ACMUI Meeting, April 11, 2011
Statement of Ronald Ennis, MD on behalf of ASTRO, NRC Medical Rulemaking Workshop, June 20, 2011
Statement of Bradley Prestidge, MD on behalf of ASTRO, NRC Medical Rulemaking Workshop, August 11, 2011

CC: Honorable Gregory Jaczko, NRC
Bruce Thomadsen, PhD, Vice-Chairman, ACMUI
Jim Welsh, MD, Chair, ACMUI Permanent Implant Brachytherapy Subcommittee
Michael Fuller, Team Leader, Medical Radiation Safety Team, NRC
Ashley Cockerham, Health Physicist, NRC

ASTRO

TARGETING CANCER CARE

Statement of
Danny Song, MD
Associate Professor and Clinical Director
Department of Radiation Oncology and Molecular Radiation Sciences
Johns Hopkins University School of Medicine
On Behalf of the American Society for Radiation Oncology (ASTRO)
Before the Nuclear Regulatory Commission's Advisory Committee on the Medical Use of Isotopes
April 11, 2011

Thank you for the opportunity to make this statement on behalf of the American Society for Radiation Oncology. I am Dr. Danny Song, an Associate Professor and Clinical Director for the Department of Radiation Oncology and Molecular Radiation Sciences at Johns Hopkins University School of Medicine. I am also director of brachytherapy services at Johns Hopkins and have over 7 years' experience in performing prostate as well as endobronchial brachytherapy, and maintain an active brachytherapy service as well as a federally funded research program in prostate brachytherapy.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO believes that the current definition of medical event for permanent implant brachytherapy – one that relies on absorbed dose – is peculiarly problematic and requires practitioners to report events that may very well fall within the range of what is considered to be medically acceptable.

As you know, radiation therapy is the use of various forms of ionizing and in some cases, non-ionizing radiation to safely and effectively treat cancer and other diseases. Radiation Oncologists use radiation therapy to eradicate cancer, to control the growth of the cancer or to relieve symptoms, such as pain. Patients receive radiation therapy in one of two ways: externally or internally. During external beam radiation, a beam of radiation is directed to the tumor and immediate surrounding area in order to destroy the tumor and any nearby cancer cells. Internal radiation or brachytherapy is the placement of radioactive sources in or next to a tumor.

Permanent Implant Brachytherapy and Prostate Cancer

Brachytherapy is a highly effective way of delivering radiation tailored to the shape of the tumor while sparing surrounding normal tissues. Over the last 15 years, sophisticated computerized treatment planning and advances in medical imaging have helped to achieve increased accuracy and superior, optimized dose distribution for cancer patients.

The benefits of brachytherapy vary depending on the patient, their age and diagnosis, stage and preferences. Permanent implant brachytherapy is a cost-effective, minimally invasive outpatient procedure that avoids hospitalization and allows the patient a rapid recovery and rapid return to normal activity. It produces excellent 10-year outcomes with relatively low morbidity. The benefits of using this form of brachytherapy in the treatment of early stage prostate cancer are quite pronounced and include a lower incidence of impotence and incontinence than is commonly

reported with a radical prostatectomy. The high degree of accuracy achievable in prostate implants is partly due to technological improvements, but quality implants still require skill, adequate training, and attention to detail.

Brachytherapy Clinical Practice Guidelines

Permanent prostate brachytherapy, is given by inserting small seeds of radioactive iodine, cesium or palladium directly into the prostate gland. These radioactive sources have relatively low energy levels and half lives of between 10 and 60 days. Patients are under spinal or general anesthesia during this outpatient surgical procedure. The seeds are temporarily radioactive and deliver the radiation to the prostate over several weeks to months. After losing their radioactivity, the seeds remain in the prostate. The seeds are then harmless and should not bother the patient.

It is essential that post-implant dosimetry be performed on all patients undergoing permanent prostate brachytherapy as a quality assessment measure. It is recognized that the dose distributions following implantation are never exactly the same for each patient as those planned prior to the implant because the prostate gland swells and or changes shape during and after the procedure. Because the dose distributions may differ, it is important to document the actual dose that the prostate and normal adjacent tissues will receive over the life of the implant. This can only be determined if a post-implant dosimetric assessment is performed.

The information obtained from post-implant dosimetry is essential for optimal patient care. Significant over-dosing of the prostate may increase the risk of side-effects. Significant under-dosing of the prostate can lead to treatment failure. The latter can potentially be rectified using supplemental external beam radiation therapy or additional seed implants. While the timing may vary in part due to the half-life of the particular isotope involved, post-implant dosimetry scans are generally obtained at intervals varying from one day to one month post-implant.

At the conclusion of the course of treatment, a written summary of the treatment delivery parameters is generated, including the total prescribed dose of brachytherapy and the total dose of external beam therapy if given, treatment technique, treatment volume, acute side effects, clinical course, and patient disposition. Patients treated with brachytherapy should be evaluated after treatment at regular intervals by the radiation oncologist for response and, early and late effects on normal tissues.

Definition of Medical Event

Under Part 35 section 35.3045 it is deemed to be a medical event if "the total dose delivered differs from the prescribed dose by 20 percent or more." However, ASTRO believes that such a rule is not appropriate for permanent implant brachytherapy. If the NRC definition is rigidly applied, many medically acceptable and appropriate implants will be deemed to be medical events, creating unnecessary patient apprehension. Further, we are concerned the dose-based measure is medically inappropriate and encumbers regulatory bodies (such as the NRC) and the licensees with clinically irrelevant and costly investigations. Hence, a dose-based definition of medical event is not suitable for permanent implant brachytherapy.

One key reason for this is that during the time interval between the initial or preplan volume study and the end of the implant, there are several changes that occur in the treatment volume (e.g., the prostate gland) and the relative position of the radioactive sources within the treatment site which affect the final calculated dose. Further, the prostate volume and therefore the resultant calculated absorbed dose varies upon the post-implant imaging modality used (CT or MRI), observer variability in prostate contouring. An ASTRO working group found that the current definition of medical events was not suitable for permanent implant brachytherapy because the prostate volume (and hence the resultant calculated prostate absorbed dose) depends upon many factors including a) the timing of the imaging; b) the imaging modality

selected; c) the observer variability in prostate contouring (both inter-observer and intra-observer); and d) the planning margins used. If the current dose-based medical event definition remains in force, many properly executed implants would be improperly classified as a medical event leading to a detrimental effect on brachytherapy.

Instead of a rule based on absorbed dose, ASTRO strongly recommends using an activity (i.e., source strength) based rule (>20 percent of source strength implanted outside the treatment site) to define medical events for regulatory purposes. This is because the total source strength implanted within and around the prostate is under control of the authorized user, but the subsequent prostate volume and the resultant dose to the prostate is not. The actual dose and the dosimetric parameters will vary considerably depending upon when and how the images were obtained, how the prostate was contoured, and the amount of swelling or edema. A source strength based criterion, (>20 percent of source strength implanted outside the planning target volume) will correctly identify as medical events cases in which a large number of sources have been improperly implanted outside the treatment site but be less likely to generate spurious medical events than a dose based definition. ASTRO recommends using the source strength-based rule for regulatory purposes.

ASTRO acknowledges one scenario where a source strength-based criterion would not adequately identify a medical event. This would be when all or most of the sources are erroneously implanted within a small region of the target volume, leaving a substantial portion of the treatment site uncovered. Under this circumstance some of the target will be over-dosed and other areas under-dosed. To address this rare event, ASTRO recommends that the authorized user be required to affirm in writing on the written directive, after the implant is completed, that the distribution of the sources within the treatment site was as intended per the pre-implant written directive.

The investigation of the permanent implant brachytherapy procedures at the Philadelphia Veterans Administration has brought attention to this issue, and a Blue Ribbon Panel was assembled to review the cases to determine if the implants were medically inappropriate. This panel found that many of those implants, previously considered to be medical events under the current definition, were, in fact, medically acceptable and proper. Thus, ASTRO is very concerned that if the current dose-based definition for permanent implant brachytherapy medical events remains, many properly executed and medically acceptable implants will erroneously be labeled as medical events.

In the absence of reforming the definition of medical event that relies on dose-based rules, it is difficult to accurately predict exactly how many medically acceptable implants in this country will be mislabeled as medical events. Such a situation would be harmful to the public welfare as it will create undue apprehension in patients and the general public about this safe and effective medical procedure, and it would likely continue to occupy the NRC, state regulatory bodies and the licensees with thousands of man-hours of unnecessary and clinically irrelevant costly investigations. Enforcement of this rule would also lead to decreased patient access to what is well-accepted as a successful and cost-effective treatment which will not be in our patients' best interest.

Written Directive

Another factor compounding the definition of medical event is the revision of medical directives. It is very important that the definition of medical event and the rules surrounding written directives take into account clinical practice realities so that certain medically acceptable implants are not labeled as medical events. Current regulations require that revisions to the written directive be made before implantation begins. The reason the pre-implantation written directive cannot be changed is that the pre-implantation written directive serves as the basis for determining if a medical event has occurred. ASTRO would like to emphasize that many authorized users perform real-time, adaptive, interactive planning, whereby the written directive and the source strength to be implanted are based on the actual volume dynamically determined during the procedure rather than based on the pre-implant volume. ASTRO believes

that real-time planning is a more accurate method of implantation because it takes into account any alterations in the prostate volume and shape. While real-time planning is most developed and most commonly used in the prostate, it can also be used in other brachytherapy procedures as long as the organ is easily imaged in real time.

For those performing real-time adaptive planning implantation, the total source strength to be implanted is determined intraoperatively during the implantation procedure and not pre-implant. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if intraoperatively they find major discrepancies in the gland or organ volume from the volumes determined during the pre-plan. Allowing flexibility to deal with real life clinical situations that become apparent during the operation improves clinical outcomes.

Accordingly, ASTRO recommends that the written directive refer to the total source strength implanted after administration, but before the patient leaves the post-treatment recovery area rather than an arbitrary pre-implantation written directive.

Conclusion

We appreciate both the ACMUI and NRC's deliberations on this issue and look forward to working with the NRC to revise this definition so that patients have access to safe, medically appropriate procedures.

Statement of
Ronald Ennis, MD
Director, Department of Radiation Oncology
St. Luke's-Roosevelt Hospital
On Behalf of the American Society for Radiation Oncology (ASTRO)
At the Nuclear Regulatory Commission Medical Rulemaking Workshop
June 20, 2011, New York, NY

Thank you for the opportunity to make this statement on behalf of the American Society for Radiation Oncology. I am Dr. Ronald Ennis, Director of the Department of Radiation Oncology at St. Luke's-Roosevelt Hospital. I am also an Associate Director of Continuum Cancer Centers of New York, and an Associate Professor at Albert Einstein College of Medicine. I have treated over 1500 prostate cancer patients with permanent implant brachytherapy and have published many articles on prostate cancer, including several on prostate brachytherapy.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO believes that the current definition of a medical event for permanent implant brachytherapy – one that relies on estimates of absorbed dose – is particularly problematic and requires practitioners to report events that are medically acceptable.

Under Part 35 section 35.3045 it is deemed to be a medical event if "the total dose delivered differs from the prescribed dose by 20 percent or more." ASTRO believes that such a rule is not appropriate for permanent implant brachytherapy. If the NRC definition is rigidly applied, many medically acceptable and appropriate implants will be deemed medical events, creating unnecessary patient apprehension about physician quality. Further, we are concerned the dose-based measure is medically inappropriate and encumbers regulatory bodies (such as the NRC) and the licensees with clinically irrelevant and costly investigations. Hence, a dose-based definition of medical event is not suitable for permanent implant brachytherapy.

Normal cells can tolerate radiation better than cancer cells, so some exposure to normal tissues causes no problems. Safe levels of radiation depend on treatment dose, duration of the treatment, tissue size and tissue origin. In addition, there is individual variability of sensitivity to radiation therapy, most of which we still do not understand or know how to predict. The only way to know what is safe or dangerous is to study what happens to patients after a specific type of radiation therapy delivery to a specific part of the body and correlate the discovered toxicities with the doses. In prostate brachytherapy, there are very few serious complications, so there is very little data to guide us, and the quality of the data is very weak.

Prostate tumors are found in the periphery of the gland. A physician can be overly cautious and implant the seeds far away from the periphery, and thus far away from the tumors being treated. This will avoid a medical event, but to the detriment of the patient since the tumor may not be properly treated. This is why physicians define the treatment site – which may be just outside the edges of the prostate – and why it is so important that the seeds reach the intended, physician-determined target.

Permanent implant brachytherapy for prostate cancer is a dynamic procedure and is impacted by changes in prostate size and shape as well as the imaging modalities used. Prior to the procedure, ultrasound is used to determine the size and shape of the prostate. Using this image, the physician will determine the treatment site (or target). The treatment site generally will include a small fraction of space outside of the actual prostate. As mentioned earlier, this is medically acceptable because of the location of the prostate tumors.

Ultrasound is again used during the implant procedure to help guide the radioactive seeds for placement. Because the structure of the prostate may change during the procedure, or even after the initial planning ultrasound was done, changes may have to be made to the number of seeds used, or even the placement of those seeds. Some flexibility must be allowed during the procedure to make these changes, just as flexibility is allowed during traditional surgical procedures.

After the procedure, imaging is again performed, this time using CT or MRI, to determine prostate volume and resultant calculated absorbed dose. Ultrasound cannot be used for post-treatment dosimetry because it cannot detect the placement of the seeds, therefore CT must be used. Use of CT has its own difficulties because it routinely shows the prostate as being larger than it actually is, making an accurate calculation of dose difficult. However, CT is the only method to show where the seeds have been implanted, which is most important when calculating post-implant dosimetry.

Further, a dose-based definition poses problems because there can be changes in the treatment volume (e.g., the prostate gland) and the relative position of the radioactive sources within the treatment site. The final calculated dose is thereby affected because of the time interval between the initial or preplan volume study and the end of the implant. Another compounding factor is that seeds reduce in strength as time goes by, so while this might technically meet the regulatory criteria of an overdose at day 1,clinically, it is a desired implant that does not pose any risk to the patient and is a perfectly acceptable implant at day 30.

Instead of a rule based on absorbed dose, ASTRO recommends using a target-based definition (>20 percent of source strength implanted outside the planning target volume) to define medical events for regulatory purposes. This is because the total source strength implanted within and around the prostate is under control of the authorized user, but the subsequent prostate volume and the resultant dose to the prostate is not. The actual dose and the dosimetric parameters will vary considerably depending upon when and how the images were obtained, how the prostate was contoured, the amount of radioactivity implanted, and the amount of swelling or edema.

We believe a target-based criterion, (>20 percent of source strength implanted outside the planning target volume) will correctly identify as medical events cases in which a large number of sources have been improperly implanted outside the treatment site, but be less likely to generate spurious medical events than a dose-based definition.

Conclusion

ASTRO believes that a target-based definition is a necessary change to ensure that those implants that could potentially cause serious patient harm are categorized as medical events, and not those that are medically acceptable. We appreciate the NRC's deliberations on this issue and look forward to working with the Commission to revise this definition so that patients have access to safe, medically appropriate procedures.

ASTRO

TARGETING CANCER CARE

Statement of
Dr. Bradley Prestidge
Medical Director, Radiation Oncology
Memorial Hermann Southwest Hospital
On Behalf of the American Society for Radiation Oncology (ASTRO)
At the Nuclear Regulatory Commission Medical Rulemaking Workshop, Houston, TX
August 11, 2011

Thank you for the opportunity to make this statement on behalf of the American Society for Radiation Oncology. I am Dr. Bradley Prestidge, Medical Director for Radiation Oncology at Memorial Hermann Southwest Hospital. I directed the largest prostate seed implant program in Texas and the south central US and have performed more than 5,000 brachytherapy procedures. With more than 23 years of experience in brachytherapy, I have particular expertise in permanent implant prostate brachytherapy dosimetric analysis and defining implant quality.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO's statement at the workshop held in June in New York provided more detail on our position that a target-based definition for medical events is preferable to one based solely on dose. I will first give a brief overview of our position, and then will focus the rest of my time on some additional topics that arose during the discussion in New York.

ASTRO believes that the current definition of a medical event for permanent implant brachytherapy – one that relies on estimates of absorbed dose – is particularly problematic and requires practitioners to report events that are medically acceptable. In prostate brachytherapy, there are very few serious complications, so there is very little data to guide us, and the quality of the data is very weak. Under Part 35 section 35.3045 it is deemed to be a medical event if "the total dose delivered differs from the prescribed dose by 20 percent or more." ASTRO believes that such a rule is not appropriate for permanent implant brachytherapy. If the NRC definition is rigidly applied, many medically acceptable and appropriate implants will be deemed medical events, creating unnecessary patient apprehension about physician quality. Further, we are concerned the dose-based measure encumbers regulatory bodies (such as the NRC) and the licensees with clinically irrelevant and costly investigations. Hence, a dose-based definition of medical event is not suitable for permanent implant brachytherapy.

Instead of a rule based on estimates of absorbed dose, ASTRO recommends using a target-based definition (>20 percent of source strength implanted outside the planning target volume) to define medical events for regulatory purposes. We believe a target-based criterion for medical events will correctly identify cases in which a large number of sources have been improperly implanted outside the treatment site, but is less likely to generate spurious medical events. In addition, our recommendation accounts for the reality that the total source strength implanted within and around the prostate is under control of the authorized user, but the subsequent prostate volume and the resultant dose to the prostate is not. The actual dose and the dosimetric parameters will vary considerably depending upon when and how the post-implant images were obtained, how the prostate was contoured, the amount of radioactivity implanted, and the amount of swelling or edema.

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One issue raised during the New York workshop that we'd also like to address involves defining the treatment site. Because prostate tumors are found in the periphery of the gland, ASTRO believes that the physician must be permitted to define the treatment site in the written directive, and that treatment site must be allowed to include an area just outside of the prostate gland itself. Under the current definition, it is not considered a medical event if a physician is overly cautious and implants the seeds far away from the periphery, and thus far away from the tumors being treated. While not a medical event, this would be to the detriment of the patient since the tumor may not be properly treated. This is an example of why we must rely on physicians to define the treatment site, and why it is so important that the seeds reach the intended, physician-determined target.

In addition to the physician determining the target in the written directive, the physician must be allowed the flexibility to update the written directive up until the time the patient leaves the care of the physician (or authorized user). Permanent implant brachytherapy for prostate cancer is a dynamic procedure impacted by changes in prostate size and shape as well as the imaging modalities used. Some flexibility must be allowed during the procedure to make changes, just as flexibility is allowed during traditional surgical procedures.

ASTRO acknowledges there are highly unlikely, yet potential scenarios where a target-based criterion would not adequately identify a medical event, such as when all or most of the sources are implanted in one area of the target volume leaving either a substantial portion of the treatment site uncovered, or a substantial portion of the treatment site "over-covered". Under these circumstances some of the target will be over-dosed and other areas under-dosed, or damage could be caused to otherwise healthy structures. To address these rare events, ASTRO recommends that after the implant is completed, the authorized user be required to affirm in writing on the written directive that the distribution of the sources within the treatment site was as intended per the pre-implant written directive and physics dosimetry plan. Should a medical event occur, it would be found when the post-implant dosimetry images were compared to the written directive and the physics dosimetry plan. We understand concerns that a physician might revise the written directive in an attempt to cover-up a medical event. However, we believe that such a physician would be unlikely to self-report a medical event to the NRC and would be identified and investigated through traditional regulation of medical practice by the state medical licensing board, with appropriate notification to the NRC.

In the Federal Register notice announcing these workshops, the NRC asked what an appropriate time frame should be required for post-implant dosimetry. ASTRO believes that requirements for post-implant dosimetry should be left to the judgment of medical specialty societies, institutions and individual providers. In addition, each institution has a distinct patient population and must be allowed to practice according to their specific needs and capabilities. Should post-implant dosimetry become a regulatory requirement, there will always be outliers with medically acceptable reasons (co-morbidities, geography, inability to travel, etc.) and it would be unfair to label those situations as medical events.

We also would like to respond to an issue that arose at the workshop in New York, when an NRC representative stated an interest in examining events that would be considered "near misses" so that the potential for serious patient harm can be avoided. While we greatly appreciate the intent to ensure patient safety by preventing errors via the examination of "near misses," we are concerned that by requiring the reporting of near misses, the NRC may be straying from its authority and into an area of medicine outside of its expertise. ASTRO believes that addressing system breakdowns to prevent patient harm is critical, but is the responsibility of hospitals, clinics, professional societies, and health care quality improvement experts. We do not believe the NRC has the resources or expertise to use such information to improve medical practice, nor does the agency have the legal confidentiality protections to ensure that reported information is not used inappropriately, such as in spurious medical liability cases.

ASTRO, as part of its Target Safely patient safety initiative, is exploring working with a federally-designated Patient Safety Organization (PSO) that would collect reports of errors and near misses and recommend system changes to prevent future errors. The information submitted to these organizations is protected and confidential under the Patient Safety and Quality Improvement Act of 2005. Under such a system, the NRC and other regulatory bodies would have access to deidentified, aggregate data. ASTRO believes that this type of patient safety activity is best handled in the context of the PSOs.

Conclusion

ASTRO believes that a target-based definition is essential to ensure that those implants that could potentially cause serious patient harm are categorized as medical events, while not capturing medically acceptable implants. We appreciate the NRC's deliberations on this issue and look forward to working with the Commission to revise this definition so that patients have access to safe, medically appropriate procedures.

Joosten, Sandy

From: Cindy Tomlinson [cindyt@astro.org]
Sent: Wednesday, November 30, 2011 10:38 AM
To: Leon S. Malmud (malmudls@tuhs.temple.edu)
Cc: CHAIRMAN Resource; Bruce Thomadsen; James Welsh; Fuller, Michael; Cockerham, Ashley; Bradford, Anna
Subject: Letter from ASTRO regarding definition of Medical Event
Attachments: FINAL ACMUI letter on ME 11 30 11.pdf; ACMUI letter on ME -- Attachments 11.28.11.pdf

Dr. Malmud,

Please find attached a letter from the American Society for Radiation Oncology (ASTRO) regarding the definition of medical event.

Should you have any questions, please do not hesitate to contact me.

Best,

Cindy Tomlinson
Manager of Regulatory Affairs
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