June 3, 2013

Air and Radiation Docket and Information Center
Environmental Protection Agency
Mailcode: 6102T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Docket ID No. EPA-HQ-OAR-2010-1064

To Whom It May Concern:

The American Urological Association (AUA), representing more than 90 percent of the practicing urologists in the United States, welcomes the opportunity to submit comments on Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures. The longstanding mission of the AUA is to promote the highest standards of clinical urological care through education, research, and formulation of healthcare policy. We appreciate your attention to the concerns of America’s urologists and the chance to serve as a resource to the Environmental Protection Agency (EPA). As a profession that relies on imaging, the AUA welcomes this timely opportunity to offer thoughtful input that we hope may be valuable to the EPA.

The AUA realizes that the guidance report is intended for the federal medical community, but notes that the recommendations are also “suitable for use by the broader medical community.” With this understanding, the AUA reviewed the guidance report for relevance to our members. We believe many of the recommendations represent common practice standards in today’s medical community and are most likely used by our members who provide imaging services. However, there were some recommendations that we believe would be too onerous for independent providers or are inappropriate in a report intended for the federal medical community.

The AUA is concerned about comments made in the section concerning physician self-referral (Lines 1255-1298, Pages 20-21). The report acknowledges that this is not particularly applicable in federal facilities; thus the comments are therefore targeting civilian facilities. Since this is the case, the AUA urges the EPA to delete this section from the document. The issue of physician self-referral has been ongoing for
many years, often becoming a target for attack by lawmakers and regulators. This situation is exacerbated by competing specialty groups, who disagree with one specialty’s ability and authority to engage in imaging. In essence this has turned into a “turf war” regarding market share. The arguments opposing self-referral frequently lack supporting evidence. Additionally, they fail to consider what is best for the patient, which should be the driving determinant in healthcare.

In 2011, the AUA conducted an independent analysis on whether self-referral was driving imaging rates. By studying data extracted from the 100 Percent Physician Supplier Summary Procedure Master File from 2003-2009, the AUA’s findings refuted assertions that urology’s self-referral of imaging services is driving imaging utilization. A copy of the AUA’s assessment is attached. We cannot speak for other specialties, but we do note that it is wrong to make general assumptions about physician self-referral like the EPA has.

In addition, the EPA recommendations fail to consider what is best for the patient. Again, while we cannot speak for all specialties, we do know that in office imaging is important in urology. Given the time-sensitive and serious nature of many conditions urologists address, having the physician who initially saw the patient also conduct imaging is often critical to the successful management of patients with a diagnosis of kidney stones, organ obstructions or potential cancers, such as prostate, testicular and bladder cancers. Sending a patient to outside facilities for services would not only delay the care which may be needed but it may pose additional challenges for patients such as taking additional time off from work, traveling to a facility that is inconvenient, or arranging for assistance to attend a medical appointment(s). These challenges are additional steps which may prevent patients from getting imaging and that could be detrimental for the patient. Given the choice, most patients would rather have the imaging by a provider they know and trust during the same office visit. These benefits are difficult to quantify and have not been studied at length. It should also be noted that practices are always willing to provide referrals to those patients who wish to receive imaging elsewhere. So, patients may choose other options if they are concerned about self-referral.

Not only have urologists been concerned about providing care to their patients in the timeliest and most efficient manner, but the AUA has long been concerned about patient-related radiation safety. The link between radiation exposure and secondary cancer is well established and is the reason for urology’s emphasis on non-ionizing radiology tests when appropriate. Additionally, our field has advanced the use of lower energy forms of standard radiology tests such at CT scans. All of the AUA’s guidelines address imaging where relevant, and the AUA extended this to develop specific imaging guidance (Evidence Report for Imaging in the Management of Ureteral Calculous Disease) to accompany a technical assessment (Clinical
Lastly on the subject of self-referral, there are some specific statements in this section which cause the AUA concern.

- **They (self-referral examinations) are frequently performed by equipment operators lacking adequate training and having supervision by health professionals with inadequate radiologic experience** (Lines 1275-1277, Page 21). Urology residency education requires extensive training in the diagnostic imaging tests used in patient care. Plus, the AUA has sought to provide our members with additional training, which some states and/or insurance companies require. Because of this, the AUA joined with the American Institute of Ultrasound in Medicine (AIUM) to develop a practice guideline for the performance of an ultrasound examination in urology. This guideline assists practitioners and provides direction in the areas of kidney, bladder, prostate, scrotal, and penile ultrasound. The guideline also addresses key issues relating to documentation, quality control and improvement, safety, infection control, and patient education. The AUA and AIUM also created *Training Guidelines for the Performance of Ultrasound Examinations in the Practice of Urology*. These guidelines both served as a roadmap for the development of practice accreditation for urologic ultrasound through the AIUM.

- **Thus, the conduct of self-referral x-ray examinations should be permitted only by a physician whose qualifications to supervise, perform, and interpret diagnostic radiologic procedures have been demonstrated to the appropriate authorities** (Lines 1286-1288, Page 21). As we previously stated, urologists have the appropriate training and can demonstrate their qualifications to supervise, perform and interpret diagnostic radiologic procedures based on standards set by organizations such as AIUM and the Intersocietal Accreditation Commission. Therefore the EPA should remove such statements from the document.

- **Self-referral practices in contract civilian facilities can lead to overutilization due to economic incentives for the referring physician and should be prohibited** (Lines 1296-1297, page 21). As we stated earlier, there is little evidence to support the common misconception of overutilization due to self-referral. In fact, the AUA’s analysis refutes this. Therefore, we again recommend that this statement be removed from paper.

- **Some examinations performed by non-radiologists may occur because of the convenience of having the x-ray unit and the patient in the same location, or, in the case of civilian contract services, need to justify the equipment purchased or maintenance costs** (Lines 1277-1280, Page 21). The AUA finds this statement, especially the end, highly offensive. It is strictly an editorial
comment without merit or evidence, and it must be removed from a
document providing recommendations for federal facilities.

Moving on, the EPA hopes that the medical community at-large will adapt the
recommendations made in this document, and for the most part, this should not be a
challenge for providers. However, the AUA suggests that you reconsider the
following few statements which, we believe, would be very difficult for smaller,
independent providers to achieve.

- **Facilities should establish a formal mechanism whereby Radiological Medical
  Practitioners are available to consult with Referring Medical Practitioners
  regarding the optimal diagnostic imaging method to answer the clinical
  question while minimizing ionizing radiation dose to the patient** (Line 3249,
  Page 71). Previously the document recommended that a mechanism for
  consultation with Radiological Medical Practitioners should be made
  available, which is reasonable, and this is the standard that should be
  followed.

- **Facilities should use reference levels as a quality improvement tool by
  collecting and assessing radiation dose data. Each facility should also submit its
  radiation dose data to a national registry, if and when such a registry is
  available** (Line 3260, Page 71). Many providers are not familiar with or have
  the technology to participate in a registry, and reporting could be
  burdensome depending on the program’s requirements. If the EPA is truly
  interested in obtaining this data, the registry should strictly be voluntary.
  Those that are interested could provide the information, and the EPA would
  then gain the data they deem valuable without taxing those who could not
  participate. One way to increase reporting to this registry may be to tie it to
  another reporting program such as Center for Medicare and Medicaid
  Services’ (CMS) Physician Quality Reporting System (PQRS). If providers
  could report radiation dose data to the EPA’s registry and simultaneously
  participate in the PQRS program successfully, participation would likely be
  substantial.

In summary, the AUA once again applauds the EPA for its recommendations, the
majority of which we believe our members who provide imaging services are
already adhering to, and appreciates the opportunity to submit comments on this
important topic. For the most part, the recommendations are applicable to any
healthcare provider who offers imaging. It is likely that many practices that offer
such services already follow to these recommendations or others very similar.
There were a few general recommendations (previously noted) that would be
burdensome to practices, and thus we suggest the EPA edit these. Again, we
strongly urge the EPA to remove the section on physician self-referral. Such
comments are inappropriate in recommendations geared toward federal facilities,
and they further promulgate arguments in what is essentially a “turf war” between medical specialties. The federal government should not play a role in this dispute. This recommendation is an abuse by the EPA of its authority since the recommendation would limit a physician’s ability to provide timely and often critical patient services.

If you need further information or have questions about our comments, please contact Jennifer Bertsch, AUA Manager, Quality, at jbertsch@auanet.org or 410-689-4043.

Sincerely,

J. Quentin Clemens
Chair, Quality Improvement and Patient Safety Committee
Chair, Data Workgroup