



June 4, 2012

Architectural and Transportation Barriers Compliance Board  
Office of Technical and Informational Services  
1331 F Street, NW, suite 1000  
Washington, DC 20004-1111

**Re: Docket No. ATBCB 2012-0003; Accessibility Standards for Medical Diagnostic Equipment**

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to comment on the Proposed Accessibility Standards for Medical Diagnostic Equipment. As an organization with a long commitment to quality and safety in medical imaging, and as vigorous advocates of access to imaging services, we recognize the importance of ensuring appropriate access to diagnostic equipment for all patients. To this end, we welcome the opportunity to work with the Access Board as you develop accessibility standards and to serve as a resource to the Board and to any agencies contemplating regulations or policies that might conform to such standards.

As an introductory point, we want to acknowledge the tremendous amount of work the Board has undertaken in developing its draft standards. The questions included by the Board in their request for comments reflect an awareness of the multitude of variables that go into the design of diagnostic medical equipment and a recognition of the complexity of the Board's task. While we appreciate the Board's willingness to engage stakeholders in its processes, we are concerned that the process of closed Board deliberations followed by opportunities for stakeholder comment is not an ideal method for eliciting the technical expertise of stakeholders on such a complex subject with interrelated features. Accordingly, we respectfully request that to the extent possible, the board rely on already-developed usability standards specific to medical diagnostic equipment, while recognizing the limitations of accessibility standards developed outside the context of medical equipment. Also, we would encourage open back-and-forth dialogue similar to the process used in a negotiated rulemaking or consensus standard development process. Finally, as adoption of the Board's standards are contemplated, we encourage close coordination among the various stakeholders (such as manufacturers, physicians, medical physicists, technologists, medical suite architects, hospital administrators, and regulatory agencies such as the Food and Drug Administration and the Occupational Safety and Health Administration) to avoid conflicting standards and requirements that could jeopardize the industry and ultimately patient's access to imaging.

### **Importance of Diagnostic Imaging**

Although the work of the Board presumes the importance of medical imaging, it is worth noting that medical imaging is a critical component of medical care. Advances in medical imaging have improved disease screening and diagnosis for a range of acute and chronic conditions, allowing many diseases to be identified early when they can more readily be treated. Medical imaging can improve health care outcomes, reduce the use of more invasive or unnecessary procedures, diminish patient recovery times, and save significant resources within the health care system.

### **Regulatory and Standardization Considerations Specific to Diagnostic Imaging Devices**

Medical imaging devices, and the clinical imaging suites in which they are housed, are highly complex and subject to a plethora of national and international standards and regulations. Although we recognize the statutory deadline the Board faces, we strongly urge that any accessibility standards the board adopts fully accounts for the structural, functional, fiscal, and regulatory constraints that contribute to the design characteristics of the equipment.

As the Board heard in oral testimony during each of the public meetings, significant effort has been undertaken and great strides have been made in meeting the accessibility needs of the full range of patients who rely on diagnostic imaging equipment. In response to feedback from clinicians, technologists, and patients, much of the equipment used in medical imaging today has been designed with patient accessibility in mind and include features such as wheel chair accommodation, positioning support features, patient transfer and positioning devices, and visual, audio and tactile cueing among others.

When considering how best to accommodate the needs of the full gamut of patients that rely on diagnostic imaging, it is important to recognize the diversity of the patients we serve, and the clinical environment in which we serve them. In most cases, imaging equipment must accommodate patients of all ages and sizes from very small children to extremely large adults. Likewise, there is great variability in patients' need for assistance, even among individuals who would not be considered to have a disability. This is especially true in light of the variety of situations in which patients are imaged including sedated, unconscious and seriously ill patients; critical care, emergency room and trauma cases; patients experiencing extreme acute or chronic pain, and patients with temporary or permanent disabling conditions.

Overlaying the need to ensure accessibility for the full range of patients who require imaging, and the variety of situations in which imaging is done, are a myriad of similarly-critical priorities, standards and regulatory requirements that equipment manufacturers must meet. Additional (sometimes competing) priorities include the safety and effectiveness of the device; the ability of the operator/technologist to use and access the device and assist the patient; ergonomic, health and safety considerations of the operator/technologist; and, most importantly, the ability of the equipment to produce diagnostic quality images, to name a few. Standards that manufacturers must meet include requirements for structural strength; material choice; radiation safety for the patient, operator, and the public; electrical safety; positional accuracy requirements; usability and human factors standards; and risk mitigation, among others.

### **Independent Access to Diagnostic Imaging Equipment**

Although we understand that the Board was tasked with the development of standards that would allow “independent entry to, use of, and exit from the equipment by individuals with disabilities to the maximum extent possible”, we note that medical imaging equipment is not intended to be used independently by patients regardless of whether the patient has a disability. For every diagnostic imaging procedure, a trained technologist assists the patient in safely accessing the equipment and helps to place and position the patient to ensure a diagnostic quality image. While maximizing patient comfort is always a key consideration, safety and the ability to achieve a diagnostic quality image for all patients must not be sacrificed.

As the Board weighs the competing priorities that manufacturers must balance, and as implementing bodies contemplate enforcement of the Board standards, we urge recognition of the fact that independent access is not the equivalent of “full and equal access” to health care services and facilities. We also note that based on the diversity of patient needs, there is no single standard that will be ideal for every patient. Board guidance should allow for alternative means of meeting the goal of accessibility to the extent possible. Furthermore, there may be physical limitations imposed by the underlying nature of the technology; for example, open MRI machines may accommodate patients with a wide range of body habitus and weight, but that particular technology does not allow for the highest quality images required in many diagnostic situations compared to other magnet configurations and field strengths.

### **Incremental Cost Considerations**

An important part of accessibility to certain patient care services is ensuring the economic feasibility of accommodating, upgrading/purchasing, and maintaining equipment that meets the specified standards. ACR applauds the Board’s efforts to determine the incremental costs of various aspects of the proposed standards. ACR encourages the Board to carefully consider such information submitted by manufacturers with the appreciation that all costs are invariably passed down to facilities and patients in need of these medical devices. Concern over costs can also be a major factor in the selection of medical equipment by providers of imaging services, and can be a consideration as to whether or not providers choose to offer modalities for which the cost of providing the service cannot be recouped.

We note that most facilities that provide imaging services offer multiple imaging modalities and thus would incur a cumulative cost far greater than the costs of acquiring any single piece of imaging equipment. Moreover, in many cases, the medical facilities that house the imaging devices would need to undergo substantial renovation to accommodate different design configurations. The cost of such updates would undoubtedly be substantial, particularly to update rooms that have been built around specific equipment and those requiring costly shielding to address radiation protection issues.

To minimize the cost burdens, we strongly encourage the grandfathering of equipment currently in use to allow it to be used for its full life cycle. As noted during Board testimony, this is particularly important to ensure that those facilities that have already expended significant resources in an effort to maximize user-accessibility are not unduly disadvantaged for having done so.

Thank you in advance for your consideration of these comments. Please contact Gloria Romanelli, Esq., ACR Senior Director of Government Relations, at [gromanelli@acr.org](mailto:gromanelli@acr.org) or 202-223-1670; or Michael

Peters, ACR Director of Legislative and Regulatory Affairs, at [mpeters@acr.org](mailto:mpeters@acr.org) or 202-223-1670, if you have questions about this submission or if we can otherwise be of assistance.

Sincerely,

A handwritten signature in black ink that reads "Paul H. Ellenbogen, M.D." The signature is written in a cursive style with a large initial 'P' and 'E'.

Paul H. Ellenbogen, MD, FACR  
Chair, Board of Chancellors  
American College of Radiology