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## The Changing Regulatory Environment

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2015 AAPM Spring Clinical Meeting




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## Regulators

- Federal Agencies – e.g., NRC, OSHA, FDA, EPA
- State Agencies - Agreements States
- Local Agencies – County, City
- Others – Accrediting bodies?? – e.g., ACR, IAC, RadSite™, The Joint Commission

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## The NRC Commission As of March 7, 2015

				
Chairman: Stephen Burns – Democrat Appointed 11/5/14 Became Chairman 1/1/15 Term ends 6/30/19	Kristine Svinicki – Republican Appointed 3/28/2008, Reappointed 6/29/12; Terms ends 6/30//17	William Ostendorff – Republican First term: 4/1/10 – 6/30/11; Second term: 7/7/11 – 6/30/16	Jeff Baran- Democrat First term: 10/14/14 to 6/30/14 Second Term: 1/2/15- 6/30/18	

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## Agreement States

- Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, provides for a Federal-State regulatory framework for the control of byproduct, source, and small quantities of special nuclear material (hereinafter termed “agreement material”) as identified by Section 274b of the AEA.



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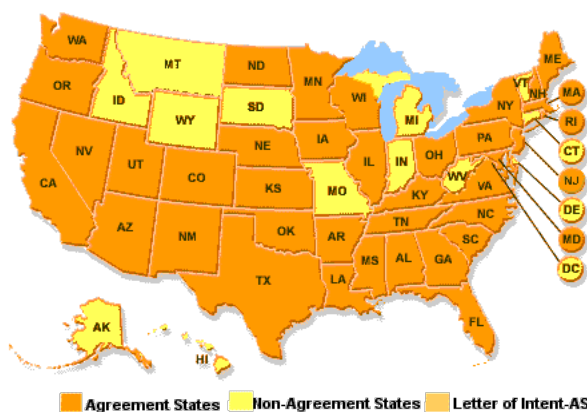
## Agreement States

- Under a signed agreement, **NRC relinquishes** its regulatory authority in certain areas and allows the State Government to assume that regulatory authority, as long as the State program **is adequate to protect public health and safety** and **compatible** with the Commission's program.



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## The 37 Agreement States





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## NRC Policy Statements on Agreement States

- In 2013, NRC published a request for comments on two policy statements related to Agreement States:
  - “Policy Statement on Adequacy and Compatibility of Agreement State Programs” and
  - The “Statement of Principles and Policy for the Agreement State Program”



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## Adequacy and Compatible

- In accordance with Section 274 of the AEA, an Agreement State program should provide for an acceptable level of protection of public health and safety in an Agreement State (**the “adequacy” component**).
- The Agreement State should also ensure that its program serves an overall nationwide interest in radiation protection (**the “compatibility” component**).



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## Purpose of Request for Comment

- Revised to add information on security of radioactive materials and
- Incorporate changes in the NRC's policies and procedures since the last revision in 1997.



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## Five Principles of Good Regulation\*

- Independence,
- Openness,
- Efficiency,
- Clarity, and
- Reliability.

\*Reference: 78 FR 33122, were adopted in 1991 by the Commission.



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**78 FR 33122 – Policy Statement on Adequacy and Compatibility of Agreement State Programs: Statement of Principles and Policy for the Agreement State Program [published June 3, 2013]**

- “The American taxpayer, the rate-paying consumer, and licensees are all entitled to the best possible management and administration of regulatory activities. The highest technical and managerial competence is required and must be a constant agency goal. The NRC must establish means to evaluate and continually upgrade its regulatory capabilities. Regulatory activities should be consistent with the degree of risk reduction they achieve. **Where effective alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay.**” (78 FR 33127)



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**78 FR 33122 - Continued**

- “Once established, **regulation should be perceived to be reliable and not unjustifiably in a state of transition.** Regulatory actions should always be fully consistent with written regulations and should be **promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes.** **Failure to adhere** to these principles of good regulation in the conduct of operations **should be a sufficient reason for a regulatory program to self-initiate program changes that will result in needed improvements.** All involved should welcome expressions of concern that indicate a program may not be operating in accordance with these principles and revise their program to more completely reflect these principles.” (78 FR 33127)



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## Determining Agreement State Adequacy

- A program is adequate if it provides reasonable assurance of protection of public health and safety in regulating the use of agreement material.
- The level of protection afforded by the program elements of the NRC's materials regulatory program is presumed to be adequate.
- Therefore, the overall level of protection of public health and safety provided by a State program should be equivalent to, or greater than, the level provided by the NRC program.



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## What Is A Compatible Program?

- It should consist of those program elements necessary to meet a larger nationwide interest in promoting an orderly pattern of regulation of radiation protection.
- It is generally limited to areas of regulation involving **radiation protection standards** and activities with **significant transboundary implications**.



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## Agreement State Compatibility

- An Agreement State radiation control program is compatible with the Commission's regulatory program when its program does not create:
  - conflicts,
  - duplications,
  - gaps, or
  - other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.



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## Compatibility A – Basic Radiation Protection Standards

- Meaning dose limits, concentration and release limits related to radiation protection in Part 20, that are generally applicable, and the dose limits in 10 CFR §61.41.3.
- Also includes:
  - limited number of definitions, signs, labels, and scientific terms that are necessary for a common understanding of radiation protection principles among licensees, regulatory agencies, and members of the public.





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## Compatibility A

- Such State standards **should be essentially identical to those of the Commission**, unless Federal statutes provide the State authority to adopt different standards.
- Basic radiation protection standards **do not include** constraints or other limits below the level associated with “adequate protection” that take into account permissible balancing considerations such as economic cost and other factors.



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## Compatibility B – Program Elements with Significant Transboundary Implications

- The Commission will limit this category to a small number of program elements that have significant transboundary implications.
  - For example:
    - transportation regulations and
    - sealed source and device registration certificates
- Agreement State program elements **should be essentially identical** to those of the Commission.



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## Compatibility C – Other Commission Program Elements

- State programs should include other NRC program elements that are important for an Agreement State to have in order to avoid conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.
- They should embody the essential objectives of the corresponding Commission program elements.



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## Compatibility C – Other Commission Program Elements

- Agreement **State program elements maybe more restrictive than Commission program elements**; however, they **should not be so restrictive as to prohibit a licensed activity**.



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## **Compatibility D - Program Elements Not Required for Compatibility**

- An Agreement State has the flexibility to adopt and implement program elements within the State's jurisdiction that are not addressed by the NRC, or program elements not required for compatibility.



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## **Health & Safety Compatibility Criteria**

- An “adequate” program should include those program elements not required for compatibility but necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. These program elements make up the category Health and Safety.



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## **Compatibility D - Program Elements Should**

- Be compatible with those of the Commission;
- Not preclude, or effectively preclude, a practice in the national interest without an adequate public health and safety or environmental basis related to radiation protection; and
- Not preclude, or effectively preclude, the ability of the Commission to evaluate the effectiveness of the NRC and Agreement State programs for agreement material with respect to protection of public health and safety.



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## **Next Steps Towards Revising Radiation Protection Regulations 10 CFR Part 20 Advanced Notice of Proposed Rule**



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### Background

- ICRP Recommendations announced December, 2007
- Initial NRC Staff Recommendations – SECY-08-0197, December 2008
- NRC Staff Recommendations for direction – SECY-12-0064, April 2012
- Commission direction SRM-SECY-12-0064, December 17, 2012
  - The Commission approved in part, and disapproved in part, the staff's recommendation
- NRC Staff prepared an Advance Notice of Proposed Rulemaking



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### 10 CFR Part 20

- The Advanced Notice of Proposed Rulemaking (ANPR) was issued July 25, 2014 in the Federal Register Notice ([79 FR 43284](#)).
- Comments were originally due November 24, 2014.
- **The comment period was extended to March 24, 2015.**



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## Overall Comments

- AAPM commends NRC for consulting with public stakeholders on the impact of any proposed changes to 10 CFR Part 20, *Standards for Protection Against Radiation*.
- This is particularly true for medical stakeholders because our services and personnel are subject to additional oversight/regulations, standards, and decisions above and beyond the radiation safety aspects of patient care.
- NRC should only revise its regulations and/or guidance if the existing regulations do not adequately protect public health and safety and a technical basis can be developed supporting the need to change.



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## Overarching Issues Posed by NRC

- Cumulative effects of regulation
- Regulatory impact
- State implementation



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## Overarching Issue Not Posed by NRC

- We need consistency across all federal and state agencies.
- Existing problems and discrepancies will only be perpetuated if only NRC changes its regulations.



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## Commission Directive on Regulatory Basis

- In developing the regulatory/technical basis, NRC should demonstrate evidence of a problem with the existing regulation or scientific concern.



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## Administrative Control Levels (ACLs)

- NRC has indicated that it is considering to “Require licensees to establish one or more administrative control levels (ACL) as part of their radiation protection program and to establish specific procedures for individual protection.”
- What is meant by an ACL?
- How will these be interpreted/enforced by the regulatory authorities?
- Is this simply another term for Dose Constraint in ICRP Report 103?
- Will these become “de facto” limits?
- Are these simply a way to get around the Commission directive to leave the annual limit as is?



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## “Require licensees be provided with record of all other concurrent sources of occupational exposure”

- At what frequency?
- How will this be enforced?
- Are there privacy issues associated with this?
- What if another employer refuses to release the information?
- What level of compatibility will this be for Agreement States?
- Assume that this also includes occupational exposure from non-material sources of exposure. If only non-material exposure from other employer, why should that information be released?
- How would this apply to consultants or non-employees?







## Dose to the Lens of the Eye

- Proposal is to reduce the dose to the lens of the eye from (150 mSv (15 rem)) for the lens of the eye 50 mSv (5 rem) LDE
  - Most likely to be impacted are interventional radiologists and cardiologists.
  - If the dose is lowered, will this have a negative impact on practice of medicine decisions?
  - Would it result in procedures having to be time limited or restrict those that can perform the procedure?



## Six Issue Papers for Consideration

- [Issue Paper 1: Update 10 CFR Part 20 to Align with International Commission on Radiological Protection Publication 103 Methodology and Terminology.](#)
- [Issue Paper 2: Occupational Dose Limit for the Lens of the Eye.](#)
- [Issue Paper 3: Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker.](#)
- [Issue Paper 4: Individual Protection - ALARA Planning.](#)
- [Issue Paper 5: Metrication - Units of Radiation Exposure and Dose.](#)
- [Issue Paper 6: Reporting of Occupational Exposure.](#)



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### ACMUI\* Subcommittee Comments on Part 20

- Issue Paper 1 – **Supports** updating Part 20 to align with the ICRP report 103 methodology and terminology.
- Issue Paper 2 – **Supports** the change of the occupational dose limit for the lens of the eye to 50 mSv (5 rem).
- Issue Paper 3 – **Does Not Support** change of the dose limit for the embryo/fetus of a declared pregnant worker from 5 mSv (500 rem).

\*The Advisory Committee on the Medical uses of Isotopes



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### ACMUI Subcommittee Comments on Part 20

- Issue Paper 4 – **Does Not Support** revising or adding regulatory requirements regarding a licensee's ALARA program.
- Issue Paper 5 – **Supports** the change to use SI units in radiation protection regulations, but recognizes the need by some licensees to have a reasonable period of time to transition from the use of conventional units.
- Issue Paper 6 - **Does Not Support** expansion of additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR §20.2206(a).



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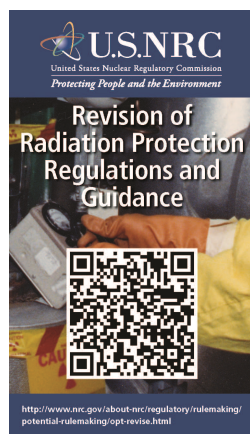
## ACMUI Subcommittee Comments on Cumulative Effects of Regulation

- ACMUI **recommends** NRC use a similar implementation plan as that used for the last significant change of Part 20 in 1991\* where licensees could choose to implement the regulatory change anytime within a given timeframe.
- ACMUI **recommends** a time frame of at least **3 years** to allow implementation of procedure, training, hardware, and software changes needed to comply with the new regulations.

\*56FR23360, May 21, 1991.



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<http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html>



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## ***XR-29 “Standard Attributes on CT Equipment Related to Dose Optimization and Management” – or “MITA Smart Dose CT”***



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### **MITA XR-29**

- In early 2013, MITA combined two standards DICOM Structured Dose Reporting and Dose Check with two product features (reference protocols and automatic exposure control) into a new standard: *XR-29 “Standard Attributes on CT Equipment Related to Dose Optimization and Management”* – or “MITA Smart Dose CT”.



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## Four Key Features of XR-29

- Digital Imaging and Communications in Medicine-Structured Reporting (DICOM SR)
- Pediatric and adult reference protocols that are "pre-loaded" in CT scan equipment to serve as a baseline for clinical testing.
- CT scan "dose check" technology that alerts radiologists and radiology technicians when a radiation dose exceeds established thresholds.
- Automatic exposure control



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## Rationale Behind XR-29

- Patients deserve access to the safest equipment available.
- Regulators and others in the imaging community should encourage imaging departments to install and use these technologies.
- Some previously-installed CT equipment in use today does not meet the MITA Smart Dose CT standard.
- Most machines are already upgraded or can be upgraded to comply with MITA Smart Dose CT.
- Approximately 35% of older CT scanners do not have the capacity to be upgraded to meet the XR-29 standard therefore, will not be compliant with this safety standard.



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## ***Protecting Access to Medicare Act of 2014***

- Signed into law on April 1, 2014.
- Section 218(a) includes a new policy that reduces some Medicare payments in order to encourage health care providers to use diagnostic medical imaging technologies that promote patient safety and public health by optimizing the radiation dose used during a computed tomography (CT) scan.



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## ***Protecting Access to Medicare Act of 2014***

- Beginning in 2016, Medicare will pay less (5% in 2016 and 15% thereafter) for certain diagnostic CT scans performed on CT equipment that does not meet the MITA Smart Dose CT standard.
- Billing codes impacted:
  - Identified as of January 1, 2014, by HCPCS (Healthcare Common Procedure Coding System) codes 70450-70498, 71250-71275, 72191-72194, 73200-73206, 73700-73706, 74150-74178, 74261-74263, and 75571-75574.
  - The reduction would also apply to any succeeding codes.



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## What's Next or Demonstrating Compliance with XR-29

- MITA member companies are working to ensure customers can confirm their equipment compliance status well in advance.
- The CT manufacturers have committed to provide their customers with a certificate proving compliance upon request no later than July 1, 2015.
- Additionally, all new CT equipment **will be delivered with the XR-29 compliance certificate after July 1, 2015.**



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## How To Tell if Your CT Scanner is XR-29 Compliant

- Each vendor is developing or has developed an implementation system which works for their customer's needs.
- Short answer - check with your manufacturer to learn how they intend to provide you with evidence of XR-29 compliance.



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## Checking to See if Your Scanner is XR29 Compliant

- The following manufacturers currently have information available online:
  - [General Electric](#)
  - [Hitachi](#)
  - [Siemens](#)
  - [Toshiba](#)



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## [GE Healthcare](#)

### Is your CT system MITA Smart Dose Compliant?

The National Electrical Manufacturers Association's Medical Imaging & Technology Alliance (MITA) continues its dose reduction effort with the approval of MITA Smart Dose, a standard that offers healthcare providers an additional tool to optimize and manage dose in CT scanning.

Several attributes of CT equipment help physicians and technologists optimize and manage dose. The MITA Smart Dose standard, also known as NEMA XR 29-2013, bundles four of these important features to ensure that compliant equipment produces high-quality diagnostic images while supporting patient safety. They are:

- DICOM Dose Structured Reporting, which enables recording of post-exam dose information in a standardized electronic format. This information can be included in the patient record, promoting the establishment of diagnostic reference levels, as well as facility dose management and quality assurance.
- Pediatric and adult reference protocols, a set of pre-loaded protocols on a CT system that serve as a baseline for a variety of clinical tasks.
- CT Dose Check, which incorporates two features - dose notifications and dose alerts - that can alert operators and physicians when dose exceeds established thresholds.
- Automatic Exposure Control (AEC), which automatically adjusts the amount of radiation used, based on the size, shape and composition of the patient, in order to achieve a specified level of image quality.

On April 1, 2014, the President signed into law the Protecting Access to Medicare Act of 2014. Beginning in 2016, Medicare will pay less for certain diagnostic CT scans performed on CT equipment that does not meet the MITA Smart Dose CT standard. To find out if your GE Healthcare system meets the MITA Smart Dose CT standard, please access the "Check your system ID" application below. For general questions or to request more information, please [contact us](#).

[Check your system ID for compliance](#)





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**Hitachi**

### MITA Smart Dose Standard (XR-29) Information for Hitachi CT Systems:

Hitachi Medical Systems America, Inc. (HMSA) is a corporate supporter of the M ITA Smart Dose Standard (XR-29).

In 2013 MITA/NEMA published the "Smart Dose" Patient Safety Standard (XR-29), that describes the minimum recommended dose management features that CT's in the US should include.



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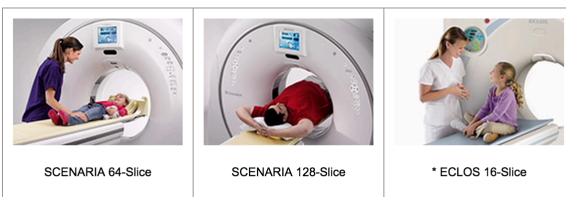
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As a responsible CT Industry Stakeholder; HMSA actively supports efforts to reduce CT patient radiation exposure in accordance with ALARA Practices and to continually develop a full range of dose reduction features for incorporation in our CT equipment models. As a part of our corporate commitment to improving dose safety HMSA supports the initiatives of Image Gently®, Image Wisely®, is a member of the AAPM Protocol Optimization Working Group and a Supporter of MITA's Smart initiatives, including CT Smart Dose.


**Hitachi**

The following Hitachi CT models are already in compliance with the MITA Smart Dose Standard (XR-29):


- All Scenaria 64-slice Systems
- All Scenaria 128-slice Systems
- All ECLOS 16-slice Systems operating at software level V2.11 or higher\*.



\* ECLOS software version V2.11 is pre-installed with all new deliveries and a free software upgrade offered to all earlier ECLOS deliveries that are covered by HMSA warranty or full Service Agreement.

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### XR-29 Compliance




Signed into law on April 1, 2014, the Protecting Access to Medicare Act (H.R. 4302) prevented a 24% cut to physician payments and established a new Computed Tomography (CT) Dose Differential Payment Policy. This policy requires Medicare providers to meet the NEMA XR-29 Smart Dose Standard for dose optimization on CT exams. Effective January 1, 2016, freestanding imaging centers and hospital outpatient providers who accept Medicare patients and do not meet this standard will be subjected to a 5% reimbursement cut for CT scans on non-compliant equipment. In 2017 and beyond, Medicare providers using non-compliant CT equipment will experience a 15% reimbursement reduction. This differential payment based on safety is somewhat unique in the U.S., which generally reimburses independent of equipment type.

**Siemens Position**

The NEMA Smart Dose Standard is the next step in a longstanding effort by Siemens Healthcare and the industry to reduce and optimize dose to improve patient safety. As such, Siemens Healthcare fully supports the NEMA Smart Dose Standard and the CT Dose Differential Payment Policy, which establishes a dose optimization standard and provides an incentive for providers to meet that standard.

All new Siemens Healthcare CT systems are fully compliant with the Smart Dose Standard. And, we are committed to helping existing customers successfully meet these standards before 2016 and thus avoid cuts in Medicare reimbursement. The following new Siemens SOMATOM CT scanners have demonstrated compliance with the NEMA XR 29 Smart Dose Standard: Force, Definition Flash, Definition Edge, Definition AS and AS+, Perspective, and Emotion.

## Siemens

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Check to see if your system complies with XR-29.

First Name

Last Name

Title

Organization

Email

Follow-Up Phone Number

Address

City

State

Zip Code

Functional Location#

Functional Location# should be formatted as follows: 400-XXXXXX

Additional System Functional Location#

## Siemens



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Understanding your business is our business. In the face of XR-29 Dose Standard, Toshiba has the CT system solutions that fit your needs.

✓ **XR-29 Compliant**  
At the forefront of dose management and new standards, all Toshiba CT systems delivered since 2011 already meet the XR-29 standards


✓ **XR-29 Upgradable**  
95% of Toshiba's CT install base is fully XR-29 upgradable, these systems can be brought to compliance in just days—not weeks

✓ **XR-29 Savings**  
Downtime for a new installation is costly; upgrading your system is a fast solution that eliminates the concern—and at a fraction of the cost of system replacement

Downloads

- XR-29 Compliance—Take it off your To-Do List
- Toshiba Partners with Houston Healthcare to Optimize Dose Management—Case Study
- NEMA Standard XR-29-2013—New Guidelines for Dose Management

Request your XR-29 Compliance Certificate [Request Certificate »](#)



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## Non-compliant with XR-29

- CT scanners that do not meet XR-29 **do not have to be removed from service.**
- If you choose to use a non-compliant scanner, you will simply be reimbursed at a lower rate.
- However, we are waiting to see what requirements will be imposed by the Accreditation Bodies and Centers for Medicare & Medicaid Services.



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## Ethics Committee Update



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## Ethics Committee

- A Committee of the Professional Council
- Rule 3.7.2: The Committee on Ethics shall advise the Professional Council and, through it, the Board of Directors, on matters relating to the ethical practice of medical physics.
- Current Chair Jeff Limmer



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## Activities of the Ethics Committee

- Develops guidance pertaining to the ethical practice of medical physics.
- Prepares and maintain procedures for resolving ethical problems.
- Educates the medical physics community on the ethical principles of professional practice.
- Investigates formal complaints of alleged unethical actions by weighing the evidence to assess compliance and based on the review conclusions, recommends sanctions to the Board.



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## Role of the Ethics Committee

- However, the vast majority of the Ethics Committee's work is to provide confidential advice and sometimes mediation on issues brought forward to the Ethics Committee.
- Most activity of the Ethics Committee does not result in formal sanctions.



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## The Code of Ethics

- Rule 4.0.2: All applicants for membership and affiliation must attest that they will abide by the AAPM Code of Ethics.
- AAPM Board of Directors approved the Code of Ethics as Professional Policy 24 – November 26, 2012
  - <http://www.aapm.org/org/policies/details.asp?type=PP&id=265>
- The Code is intentionally short on prescription, meant as guidance rather than “law”.



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## The Code of Ethics

- Structured in 3 main parts
  - Statement of principle
  - Specific guidance for various situations
    - Research Ethics
    - Education Ethics
    - Business/Government Ethics
  - Formal complaint process –
    - Provides a detailed pathway with a neutral, objective and confidential process to follow for receiving and taking action on any potential or alleged violation of AAPM ethical policy.



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## The Code of Ethics - Principles

- The following Principles of the American Association of Physicists in Medicine (AAPM) are core values intended to aid all members and affiliates to act in an ethically professional manner. The Principles are not a set of laws, but standards of ethical conduct. The Principles provide a framework for members and affiliates to conduct themselves with respect to patients, colleagues, and the public. Corporate affiliates shall abide by these same ethical principles, where applicable.



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## Review and Revision of the Code

- Professional Policies all have “sunset” dates and must be reviewed and renewed on a schedule.
- The Code of Ethics is due for sunset in 2017.
- Task Group 109 has been reconstituted to conduct a careful review of the existing Code and perhaps recommend revisions.
- Your input is invited.
  - A survey is being prepared and will be distributed to all AAPM members late March/early April.



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## Code of Ethics Review

- The purpose of this review is to determine if:
  - Changes to the current Code of Ethics are necessary,
  - There are additional topics that should be included,
  - Changes have occurred in the practice environment that should be included in the Code of Ethics, or
  - There were omissions in the current Code of Ethics that should be included and addressed now.



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## Task Group 109 Contact Information

- If you have comments or concerns that Task Group 109 should consider as they review the current Code of Ethics, please contact:
  - **Christina Skourou, Chair of TG-109**
    - **Email:** [Christina.Skourou@slh.ie](mailto:Christina.Skourou@slh.ie)





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## Future Considerations

- We all need to engage in meaningful discussions with regulators and legislators on patient care, and the safe and effective use of radioactive materials in medicine.



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## Opportunities

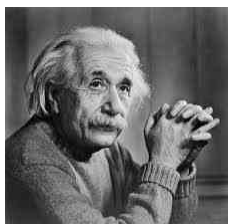
- Let's consider the next ANPR, proposed rule, request for information as an invitation to meet and discuss issues with the regulator as opportunities to improve patient safety through working together to identify issues, solutions that are adequate, inspectable and allow the licensee to be compliant.
- Let's initiate a collaborative effort to develop rules that meet radiation safety issues in medical use of materials.
- Only with this, can we ensure that radioactive materials can be used in diagnosing and treating disease and ensuring quality patient care for all.



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***“Concern for man and his fate must always form the chief interest of all technical endeavors. Never forget this in the midst of your diagrams and equations.”***



**Albert Einstein**



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**Thank you!**



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