

Developing Medical Physics Technical Standards Through the AAPM and ANSI



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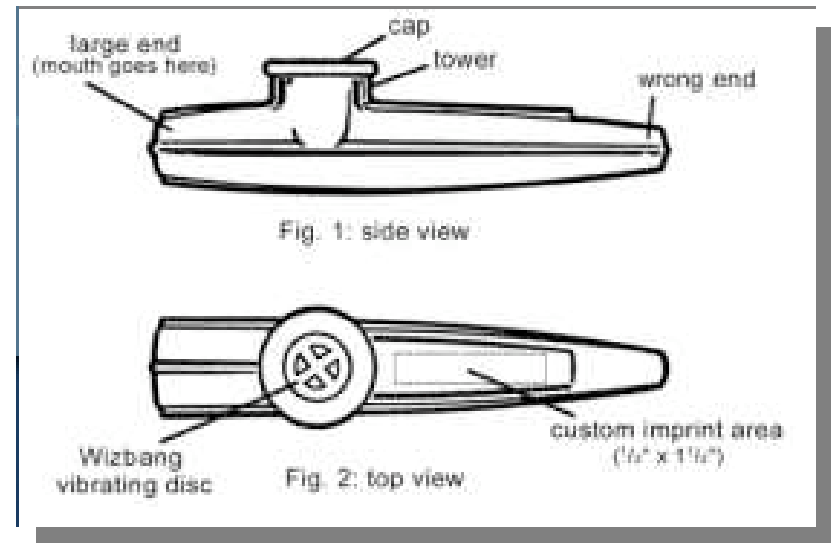
THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

The Problem

- AAPM publishes Task Group reports
 - TG-51, TG-43, TG-40, etc.
- Not standards
 - Not intended to be used for accreditation or regulation
 - Several have been adopted in part into regulation
 - Happens without our control or approval
 - Has caused problems for physicists

The Problem [2]

- ACR and other publish professional standards
 - Often don't address technical issues
 - Not binding
 - Practice guidelines (e.g., for digital radiography) make recommendations, not requirements



TG Reports \Rightarrow Standards?

- Part of TG-40
 - Minimum acceptable QA
- TG-51
 - External beam calibrations
- TG-45/IEC 60976
 - Linear accelerator acceptance testing/QA
- Report 74 from DI TG-12
 - QC procedures for R&F imaging equipment

Example of Canadian Standards

- Stereotactic Radiosurgery
- LDR Prostate Brachytherapy
- CT Simulation
- Brachytherapy
- Major Dosimetry Equipment

SRS QA Tests

Designator	Test	Performance	
		Tolerance	Action
Patient Specific*			
PSL1**	Patient monitoring system	Functional	
PSL2**	Machine interlocks (as appropriate)	Functional	
PSL3	Collision tests	Functional	
PSL4	Imaging parameter check	Appropriate	
PSL5	MU calculation (independent check)	3%	
PSL6**	Couch/Pedestal Locking	Functional	
PSL7**	Cone alignment (if appropriate)	0.5 mm	0.75 mm
PSL8	Field shape check (if appropriate)	0.5 mm	0.75 mm
PSL9	Target coordinate check	0.75 mm	1 mm
PSL10**	Laser check	0.75 mm	1 mm
PSL11	Head Frame motion	1 mm	1 mm
PSL12	Checklist use	Documented	
Quarterly			
QSL1	Isocentre wobble diameter (gantry)	0.5 mm	0.75 mm
QSL2	Isocentre wobble diameter (couch)	0.5 mm	0.75 mm
QSL3	Couch and gantry axis coincidence	0.5 mm	0.75 mm
QSL4	Collimator wobble diameter	0.5 mm	0.75 mm
QSL5	Records	Complete	
Annually			
ASL1	Acceptance functional tests	Functional	
ASL2	Percentage depth dose	2%	2%
ASL3	CT localization performance	1.5 mm	1.5 mm
ASL4	MRI localization performance	2 mm	2 mm
ASL5	Angiography localization performance	1 mm	1 mm
ASL6	Dose profiles (FWHM)	1 mm	1 mm
ASL7	Dose delivery test	2%	5%
ASL8	Output factors	2%	3%
ASL9	Radiation/mechanical isocentre coincidence	0.5 mm	0.5 mm
ASL10	Known target test (CT-based)	1 mm	1.5 mm

CAPCA Quality Control Standards: Stereotactic Radiosurgery/Radiotherapy, Nov 2005

Dosimetry Equipment QA

Table 1: Quality Control Tests

(a) Reference Dosimetry: Secondary Standard			
Designator	Test	Performance	
		Tolerance	Action
Initial use and following calibration			
ISS1	Extra-cameral signal (stem effect)	0.5%	1.0%
ISS2	Ion collection efficiency	Characterize	
ISS3	Linearity	0.5%	1.0%
ISS4	Leakage	0.1%	0.2%
ISS5	Collection Potential Reproducibility	1.0%	2.0%
At each use			
ESS1	Reproducibility	0.2%	0.5%
Bi-annual (i.e., every two years)			
BSS1	Calibration at standards lab		

CAPCA Quality Control Standards: Major Dosimetry Equipment, Sept 2004

HDR Brachytherapy

- The US does not have a national dosimetry standard for HDR ^{192}Ir
 - Standard developed at UW adopted by ADCLs
- UW procedure could be formalized through an ANSI standard, would then be recognized internationally
 - Would facilitate comparisons, perhaps simplify approval process for new devices

Brachytherapy Seeds

- TG-43
 - Manufacturers could be held to an ANSI standard
 - Would provide data in compliance with TG-43 when applying for FDA approval

100 YEARS OF THE IEC

[ABOUT THE IEC](#)[IEC IN ACTION](#)[CONFORMITY ASSESSMENT](#)[STANDARDS DEVELOPMENT](#)[FOR MEMBERS AND EXPERTS](#)[WEB STORE SEARCH](#)[Version française](#)

WHAT'S RELATED

- 🔒 **Special IEC community rate for *The Economist***
- ▶ IEC technical committee creation: the first half-century
- ▶ Development and growth of IEC technical committees: 1950 to 2006
- ▶ 1906 Preliminary Meeting Report
- ▶ IEC History: 1906-1956
- ▶ IEC Bulletin - 75th anniversary edition
- ▶ IEC SI Zone
- ▶ 1901-2001, Celebrating the Centenary of SI - Giovanni Giorgi's Contribution and the Role of IEC

1906-2006

The electric century

In the beginning...

[Techline](#)[IEC Centenary Challenge](#)[Events](#)[Presidents](#)[General secretaries](#)[Cool stuff](#)

The IEC came into being on 26-27 June 1906 in London, UK, and ever since has been giving the very best global standards to the world's electrotechnical industries. The IEC thanks industry, government, academia, end-users, and everyone else who has been involved from around the world for 100 years of commitment and partnership.



Role of the IEC and Impact of its Standards

- IEC's international standards facilitate world trade by removing technical barriers to trade, leading to new markets and economic growth.
- They also represent the core of the World Trade Organization's Agreement on Technical Barriers to Trade (TBT), whose 100-plus central government members explicitly recognize that international standards play a critical role in improving industrial efficiency and developing world trade.
- Using IEC standards for certification at the national level ensures that a certified product has been manufactured and type-tested to well established international standards. The end user can be sure that the product meets minimum (usually high) quality standards, and need not be concerned with further testing or evaluation of the product.

Adoption of IEC Standards



In Europe:

- ◆ IEC standards selected for “parallel voting” by CENELEC
- ◆ When approved, assigned “EN” number
- ◆ Standards adopted as written and carry the force of law
- ◆ EC members must enforce

Adoption of IEC Standards



In US:

- IEC standards (or sections) incorporated into ANSI standards, FDA regulations, NEMA guidelines, etc.
- IEC standards can be used as written; FDA requires vendor to report compliance

International Electrotechnical Commission
Central Office, Geneva

TC 61

TC 62

Electrical Equipment
in Medicine

TC 63

SC 62 A

Common Aspects

SC 62 B

Diagnostic
Equipment

SC 62 C

Equip for RT, NM,
Dosim.

SC 62 D

Non-Radiological

WG-1

Equip for RT

WG-2

Equip for NM

WG-3

Equip for
Dosimetry

Role of Working Group

Electrotechnology. A natural passion.



- Develop Standards
 - Safety Standards
 - safety and "essential performance"
 - Technical Reports
 - Performance Standards
 - Performance Guidelines

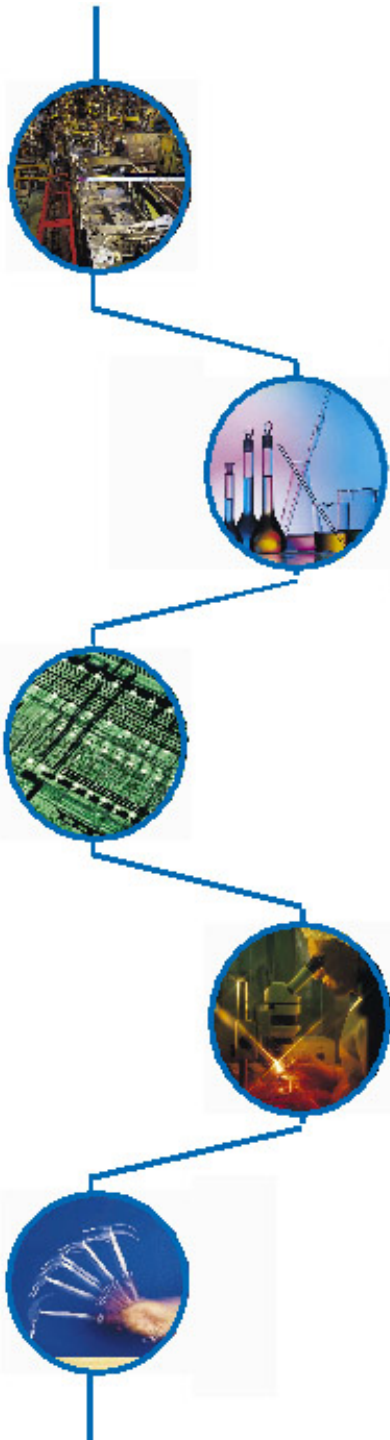


Publications from WG-1

- Equipment for Radiation Therapy
 - Linear Accelerators
 - Cobalt Units (including Gammaknife)
 - Orthovoltage Treatment Units
 - Simulators
 - Brachytherapy Remote Afterloaders
 - Treatment Planning Systems

Electrotechnology. A natural passion.





American National Standards Process Summary

Source: psa@ansi.org

May 14, 2007

MISSION

To enhance the global competitiveness of U.S. business and the American quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and ensuring their integrity.



ANSI IS...

- Only accreditor of U.S. Standards Developers
- Only body that approves standards as American National Standards (ANS)
- Represents the US Internationally at ISO (International Organization for Standardization)
- Represents the US Internationally through its US National Committee at the IEC (International Electrotechnical Commission)

AAPM has
members on TAGs
to USNC



ANS GOVERNANCE BODIES

- Executive Standards Council (ExSC)
 - Accredits American National Standards Developers
 - Accredits US Technical Advisory Groups (TAGs) to ISO
 - Oversees Accredited Standards Developer Audit Program
 - Maintains most ANSI procedures and policies
 - Hears appeals and considers complaints

- Board of Standards Review (BSR)
 - Approves American National Standards
 - Hears appeals and considers withdrawal requests

- ANSI Appeals Board (AB)



STANDARDS DEVELOPER ACCREDITATION

- Only ANSI-Accredited Standards Developers may submit their standards through the American National Standard approval process
- ANSI-accreditation signifies that the standards developer is committed to an open, fair and time-tested consensus process that benefits stakeholders and the American public
- ANSI-Accredited Standards Developers are accredited to the requirements contained in the *ANSI Essential Requirements: Due process requirements for American National Standards*



BENEFITS OF ACCREDITATION AND ANS APPROVAL

- Hallmarks of the ANS Process
 - Openness, due process, consensus by a balance of materially-affected interests, consideration of views and objections
 - Transparency of the process
 - Fundamental fairness - Ensures level playing field
- Minimizes some legal risks by requiring procedural safeguards (re: antitrust, product liability/negligence, etc.)
- Government acceptability (e.g. National Technology Transfer & Advancement Act of 1995)
- Accreditation is a prerequisite for the National Adoption of an ISO or IEC standard as an ANS



ANSI ACCREDITATION REQUIREMENTS

- A standards developer's written procedures for the development and approval of proposed American National Standards must meet ANSI due process and consensus requirements
 1. Openness
 2. Balance and Lack of Dominance
 - Discrete interest category definitions
 3. Public comment opportunity
 4. Consideration of Views and Objections



ORGANIZATIONAL MEMBER

Organizational Member

A not-for-profit scientific, technical, professional, labor, consumer, trade or other association or organization that is involved in standards, certification or related activities.

- [Click here](#) to access an Organizational Member application.
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american national standards institute

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organization name

name of president or CEO

corporate website address

brief description of organization

primary representative name

title

street address

city

state/province

postal code

country

phone

fax

e-mail (required)

secondary representative name

[fee schedule]

ANSI membership is based upon a calendar-year billing cycle. An interested party may join ANSI at any time and pay a prorated fee that is calculated on a quarterly basis. Future billing cycles will begin on January 1 of each subsequent year.

annual membership fee in \$ (see schedule on reverse)

[payment information]

a check, made out to ANSI, is enclosed

please charge fee to the credit card indicated below

Visa (13 or 16 digits)

MasterCard (16 digits)

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charge card number

month | year

expiration date

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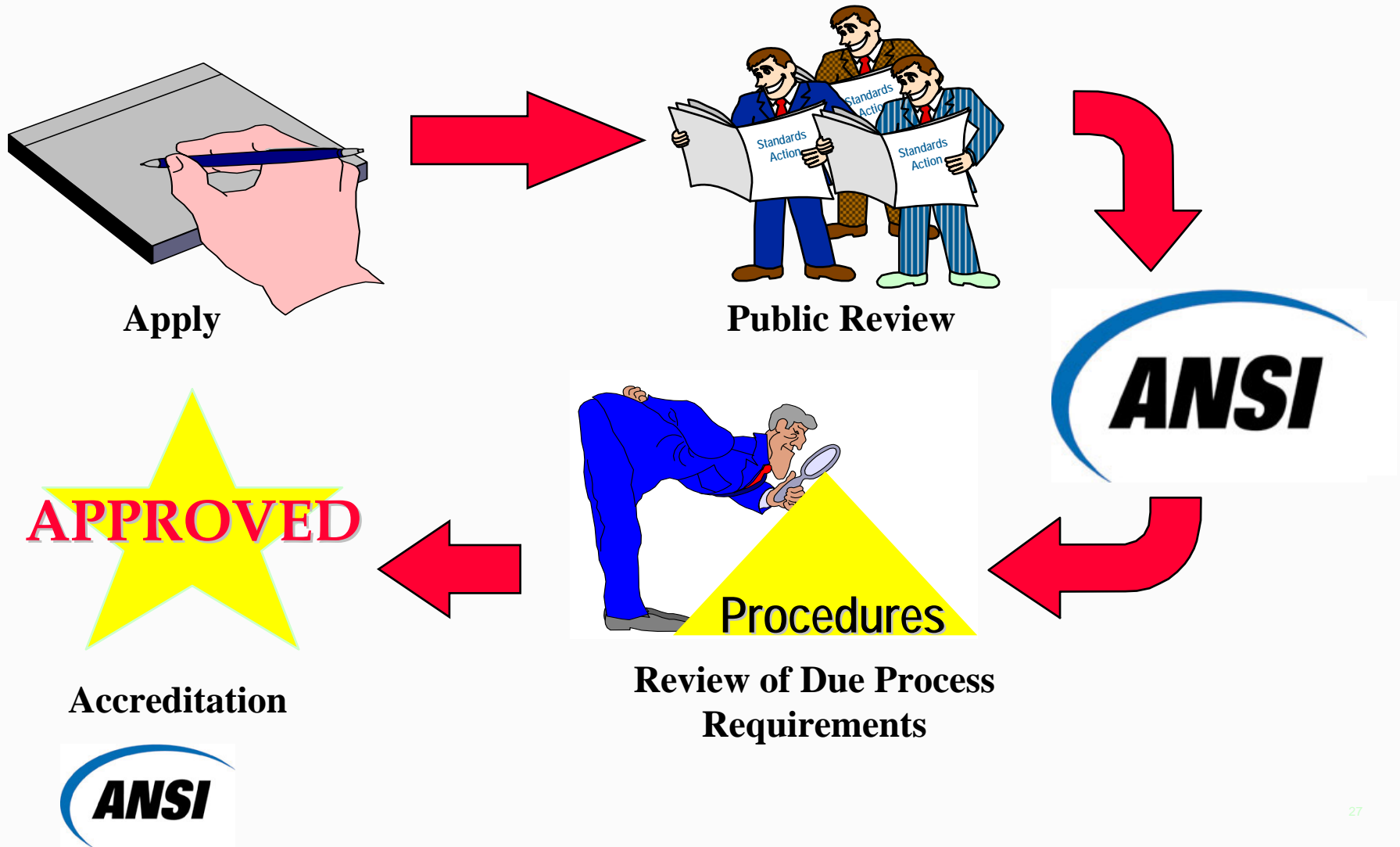


ACCREDITATION FEES

- \$3,000 Initial Application Fee
- Annual National Assessment Fee – sliding scale in 2007 from \$1,655 for 0-3 ANS
- Includes cost of periodic procedural audit
 - (5 year cycle)



ACCREDITATION PROCESS



MAINTENANCE OF ACCREDITATION

- Procedural audit typically once every 5 years
- Submission of periodic compliance forms when ANSI's procedural requirements change
- Submission of procedural revisions for approval (reaccreditation process: similar to steps in the accreditation process)
- Payment of ANSI Membership/Maintenance of Accreditation Dues



ACCREDITED STANDARDS DEVELOPERS

- Currently there are about 200 ASDs
- Developing standards in virtually all industry sectors
 - *A few examples: medical devices, telecommunications, records management, fire protection, welding, earth-moving machinery, information technology and interoperability, air-conditioning and refrigeration, electrical safety, sunglasses, bicycle helmets, boilers and pressure vessels, metalworking skills assessment, welding skills certification, nuclear equipment operator certification, certification of hazardous waste incinerator operators, etc.*



THE AMERICAN NATIONAL STANDARD DESIGNATION

SIGNIFIES THAT STANDARDS...

- Are developed using fair, open process that ensures a level playing field
- Meet the needs of materially affected interests
- Are voluntary – compliance is not required unless adopted by regulation or statute



ANS APPROVAL PROCESS

- Stage 1: PINS form to ANSI
 - Announcement of project initiation
 - PINS deliberation if claim of conflict or duplication is raised
- Stage 2: Approval of draft
 - Consensus body approves text of draft standard
 - Must meet numerical requirements for consensus as described in developer's accredited procedures (e.g. approval by a majority of consensus body and 2/3 of those voting, etc.)
- Stage 3: Public Review
 - BSR-8 form initiates announcement in *Standards Action*. Developer may also announce in industry publications, etc. (multiple public reviews are possible)



ANS APPROVAL PROCESS

- Stage 4: Comment resolution
 - Public and consensus body member comments

- Stage 5: Recirculation (if applicable)
 - Unresolved negative comments from consensus body members and public review commenters as well as any substantive changes to the text, must be recirculated to the entire consensus body to allow them to vote, reaffirm a vote or change a vote

- Stage 6: Appeals at developer level



ANS APPROVAL PROCESS

- Stage 7: Submittal to ANSI for approval
 - Submittal of final standard for approval with evidence of consensus (BSR-9 form)

- Stage 8: Notification
 - Notification of final approval/disapproval

- Stage 9: Appeal at ANSI
 - Hearing is scheduled if appeal is filed

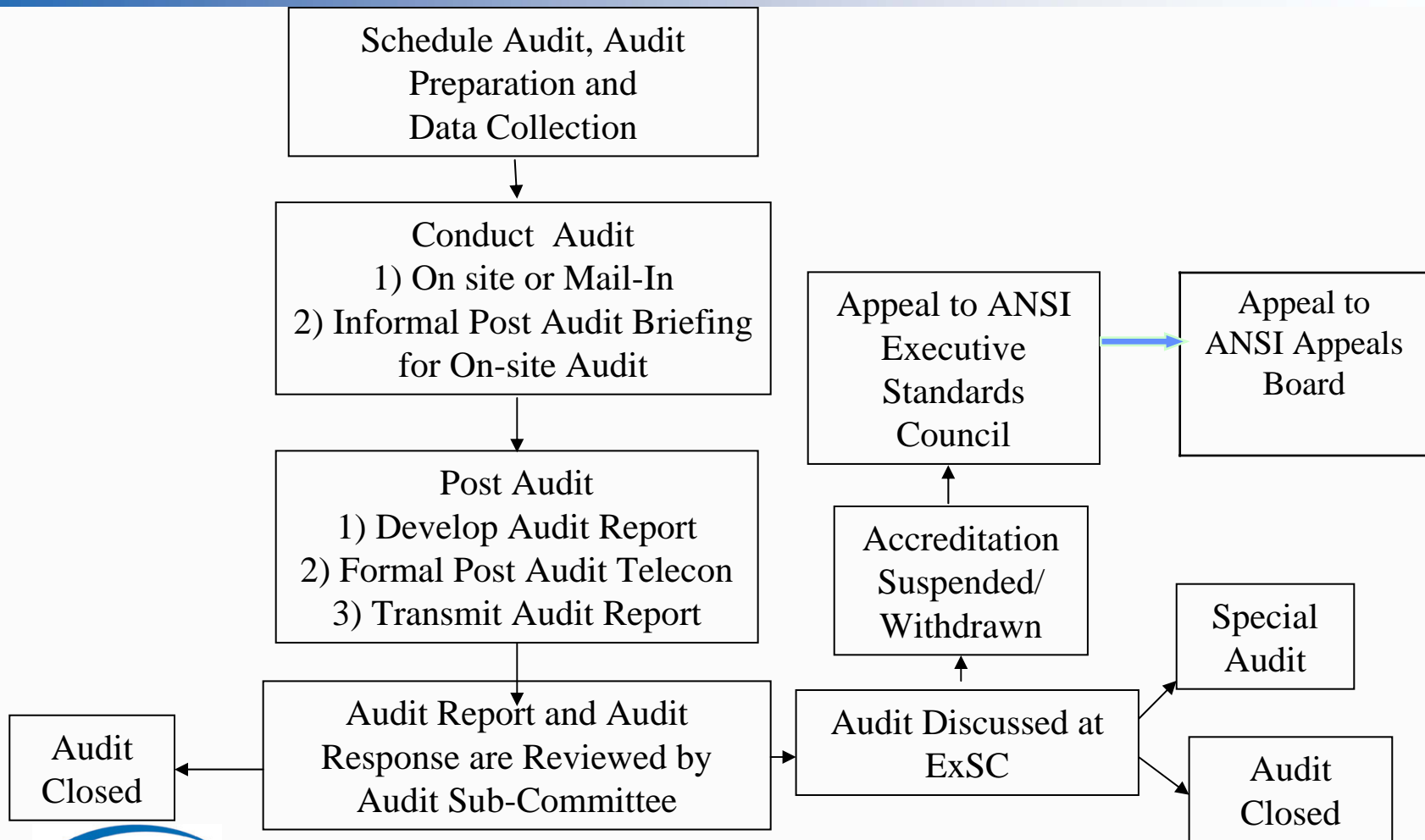


APPEALS

- Informal resolutions encouraged
- Appeals to a developer: in accordance with accredited procedures
- Appeals to ANSI:
 - Board of Standards Review (BSR) – ANS
 - Executive Standards Council (ExSC) – accreditation and procedural compliance issues
 - Appeals Board – final level after the BSR or ExSC appeal concludes



Audit Process – Summary Flow



ANSI'S STANDARDS ACTION

- www.ansi.org/standardsaction
- Available freely to the public
- Published every week
- Includes national and international activity
- Announces: PINS (project initiation notices); public review periods for American National Standards: accreditations and standards; and final approval decisions.
- Announces meetings, all actions re: ANS; any proposed revisions to ANSI procedural requirements, etc.



CONTACTS:

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INFORMATION SOURCES

- www.ansi.org
 - Public Library
 - *Standards Action*
 - *Electronic Standards Store (ESS)*
- www.NSSN.org
- E-mail: psa@ansi.org



STANDARDS DEVELOPED BY HPS

Number	Title	Date	Bytes	Pages
N13 Standards				
 N13.6-1999	Practice for Occupational Radiation Exposure Records Systems	5/6/99	119,594	28
 N13.11-2001	Personnel Dosimetry Performance – Criteria for Testing	7/31/01	380,060	45
 N13.12-1999	Surface and Volume Radioactivity Standards for Clearance	8/31/99	269,891	65
 N13.30-1996	Performance Criteria for Radiobioassay	May 96	498,255	109
 N13.35-1999	Specifications for the Bottle Manikin Absorption Phantom	9/21/99	210,282	22
 N13.36-2001	Ionizing Radiation Safety Training for Workers	10/30/01	190,680	24
 N13.39-2001	Design of Internal Dosimetry Programs	5/24/01	679,430	74
 N13.41-1996	Criteria for Performing Multiple Dosimetry	Dec 96	179,583	21
 N13.49-2001	Performance and Documentation of Radiological Surveys	8/6/01	471,998	36
 N13.52-1999	Personnel Neutron Dosimeters (Neutron Energies Less Than 20 MeV)	10/26/99	69,420	24

STANDARDS DEVELOPED BY HPS [2]

N43 Standards

	N43.2-2001	Radiation Safety for X-ray Diffraction and Fluorescence Analysis Equipment	7/31/01	295,761	25
	N43.4-2005	Classification of Radioactive Self-Luminous Light Sources	Sep 05	71,799	17
	N43.5-2005	Radiological Safety Standard for the Design of Radiographic and Radioscopic Non-Medical X-Ray Equipment Below 1 MeV	Sep 05	69,000	20
	N43.8-2001	Classification of Industrial Ionizing Radiation Gauging Devices	Mar 01	342,664	32
	N43.10-2001	Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Dry Source Storage Gamma Irradiators (Category II)	Jan 01	324,848	38
	N43.15-2001	Safe Design and Use of Self-Contained Wet Source Storage Gamma Irradiators (Category III)	Mar 01	293,812	32
	N43.17-2002	Radiation Safety For Personnel Security Screening Systems Using X-rays	4/3/02	523,664	30

ANSI N44 COMMITTEE

- Houses radiological equipment standards
- Committee has been inactive for many years
- AAPM could become secretariat
- N44 committee is logical home for medical physics-related standards



BENEFITS OF BEING AN ANSI STANDARDS DEVELOPER

- Produce standards that can be adopted by regulators
- Helps to standardize review and approval process
- Standards will have national & international recognition
- Mechanism to adopt international standards
- Facilitates participation in US National Committee of the IEC and US TAGs



BENEFITS TO AAPM MEMBERS

- Clarify consensus on minimum criteria
- Enable regulators to adopt uniform requirements
- Insurance companies could adopt uniform requirements
- Patients and public would have assurance of uniform minimum standards





*Thank you
for your
attention*