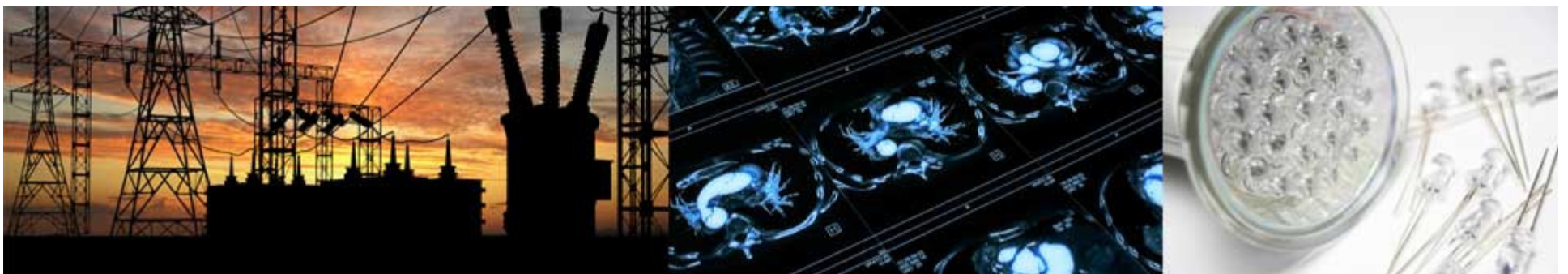


ICEA INTRO TO ANSI PROCESS

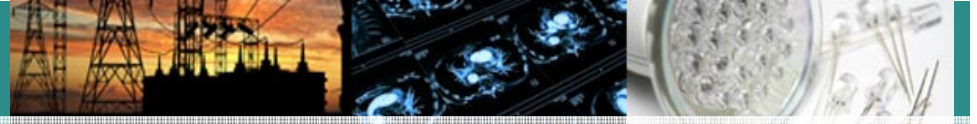


The Association of Electrical and Medical Imaging Equipment Manufacturers



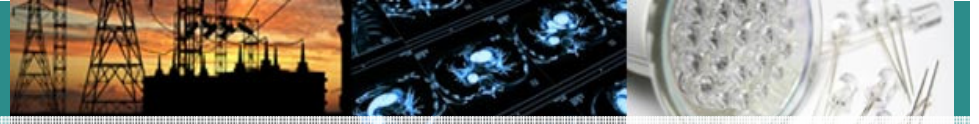


The Association of Electrical and
Medical Imaging Equipment Manufacturers



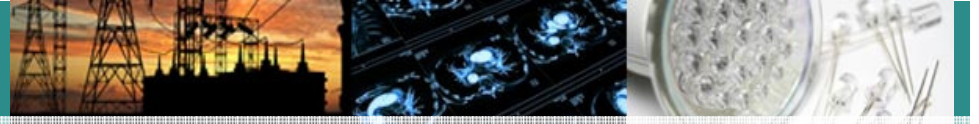
Training Objectives

- Overview of the ANSI Essential Requirements
- Understanding of process for development and approval of ANSI standards



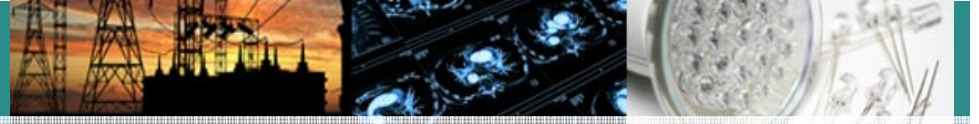
What is ANSI?

- American National Standards Institute
- Private, non-profit organization
- Administers and coordinates the U.S. voluntary standardization system
- Headquarters, Washington, D.C.
- ANSI doesn't write standards
- ANSI is not associated with the Federal government



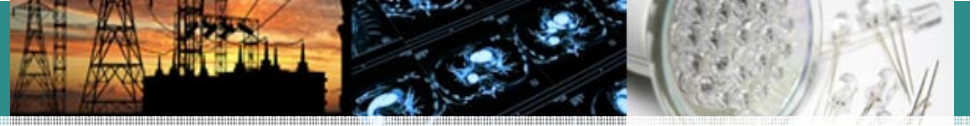
Why Seek ANSI Approval?

- Nationally recognized and acknowledged
- Evidence of due process and openness
- Consensus of materially affected and interested parties
- May allow for easier access into IEC



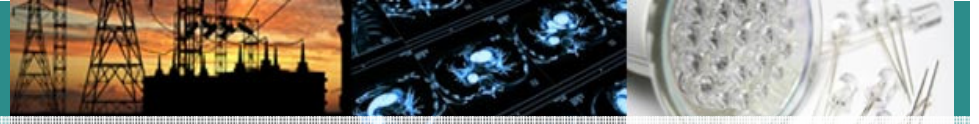
ANSI Essential Requirements

- Guiding document for ANSI procedures
- Principles
 - Openness
 - Transparency
 - Balanced representation
 - Due Process



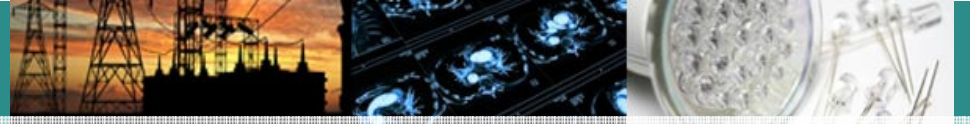
Openness

- Open to all persons affected by activity in question
- No undue financial barriers to participation
- No technical or organizational membership requirements.



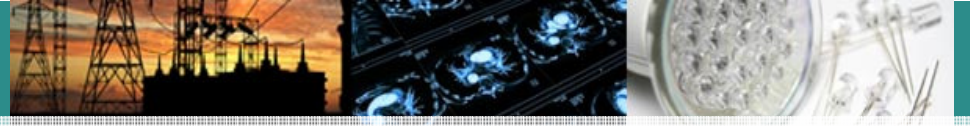
Lack of Dominance

- Not dominated by any single interest category, individual or organization
- ANSI defines dominance as position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to exclusion of fair and equitable consideration of other viewpoints



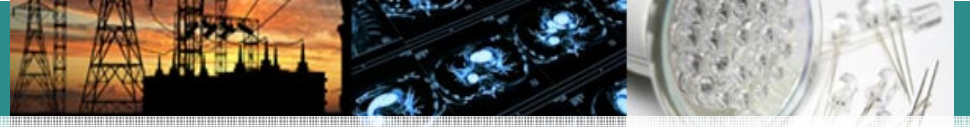
Balance of Interests

- Standards development process should have a balance of interests
- Participants from diverse interest categories shall be sought with objective of achieving balance
 - Safety – no single interest category constitutes more than 1/3 of the membership
 - Product – no single interest category constitutes a majority of the membership



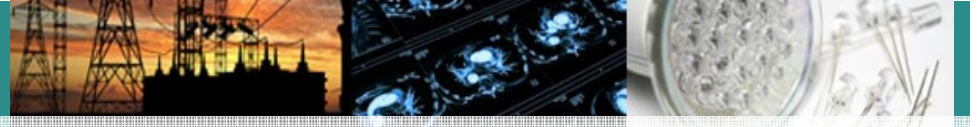
Interest Categories

- Shall be defined and such definitions shall be available upon request
 - Producer
 - User
 - General Interest
 - Others – Government, utility, etc



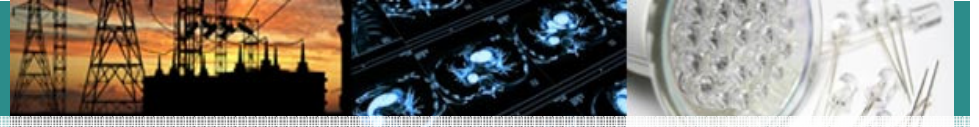
Written Procedures

- Required for any process used to develop ANSI standards
- Shall govern the methods used for standards development and shall be available to any interested person
- A copy of Committee procedures shall be filed with ANSI



Due Process

- Evidence of due process
 - Any person with direct and material interest has right to participate
 - Allows for equity and fair play



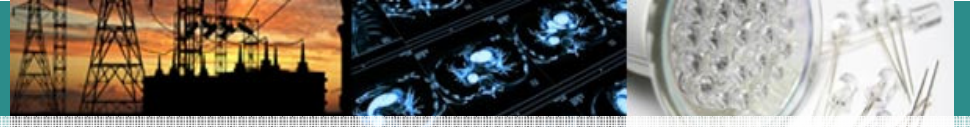
Appeals Procedures

- Persons who have directly and materially affected interests and who have been or will be adversely affected by **any procedural action or inaction** by a standards developer with regard to the development of a proposed ANS or the revision, reaffirmation, or withdrawal of an existing ANS, have the right to appeal.



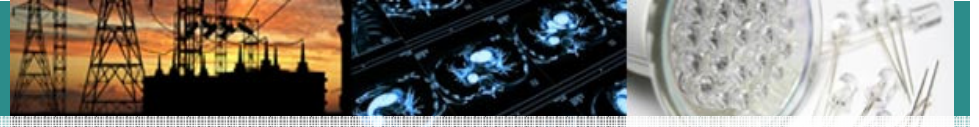
Appeals Procedures

- Shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of substantive and procedural complaints regarding any action or inaction
- ANSI does not resolve appeals



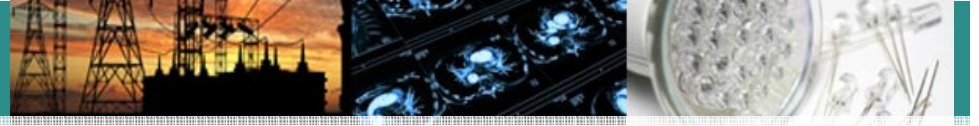
Record Retention

- Periodic maintenance – one complete standards cycle or until standard revised
- Withdrawal – at least 5 years following the date of withdrawal
- Continuous maintenance – minimum of 5 years.



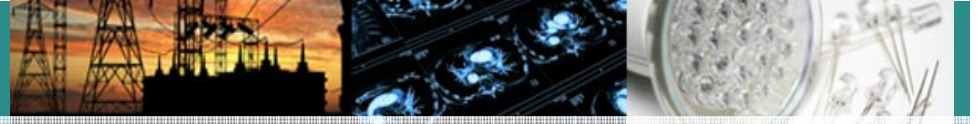
Patents in ANSI Standards

- ANSI patent policy recently revised.
- Acceptable if technical reasons justify this approach.
- License made available without compensation to applicants, or
- License made available to applicants under reasonable terms and conditions.
- Patent policy required in procedures



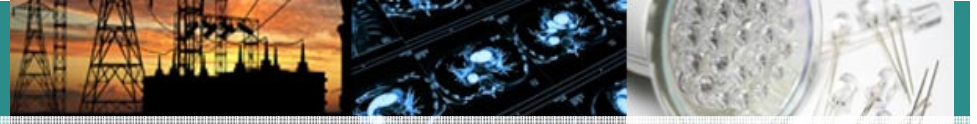
Patents in ANSI Standards

- Record of patent holder's statement shall be placed and retained in ANSI files.
- Standard shall include a notice that calls attention to possibility that use of invention covered by patent rights may be required.
- ANSI not responsible for identifying patents for which license may be required or for conducting inquiries into legal validity or scope of patents.



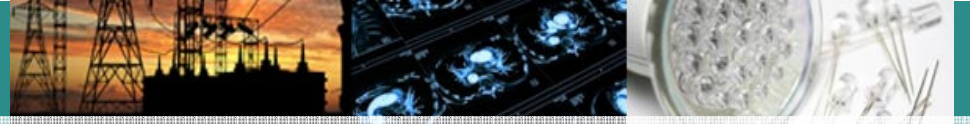
Commercial Terms and Conditions

- Shall not be included in an American National Standard
- Not acceptable to include proper names or trademarks of specific companies or organizations, acceptable manufacturer lists, service provider lists, or similar material in text of standard or in annex or equivalent



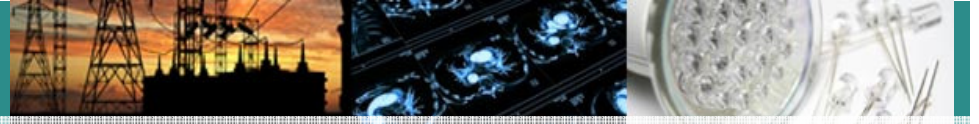
Commercial Terms and Conditions

- Where sole source exists for essential equipment, materials or services necessary to determine compliance with standard, permissible to supply name and address of source in footnote or informative annex as long as words “or the equivalent” are added to the reference.



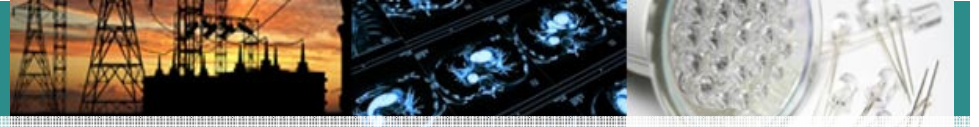
Consideration of Standards Proposals

- Prompt consideration shall be given to all proposals
 - developing new American National standards
 - revising existing American National standards
 - withdrawing existing American National Standards.



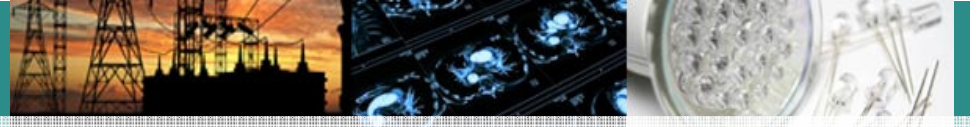
Accredited Standards Committee

- Standing committee established with balanced interests
- Charter to develop and maintain ANSI standards under its scope
- Operating procedures approved
- Ballot body for approval of ANS
- May have subcommittee, WGs, etc.



ANSI Process

- Decision to work on a standard
- Submit **PINs** to ANSI
- Develop draft standard
- Submit **BSR8** to ANSI for public review
- Ballot draft standard to balanced body
- Compile results and report to ballot body

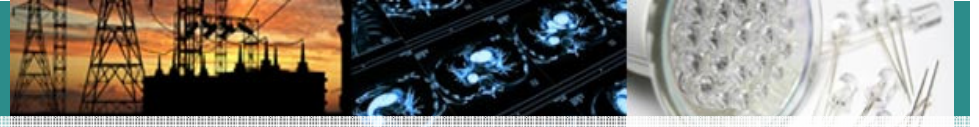


ANSI Process

- Address negative votes and comments
- Circulate negatives votes, comments and responses to ballot body and inform members of right to change their votes
- Change draft standard accordingly
- Compile final results of ballot
- Prepare and submit BSR9
- ANSI approval received from BSR

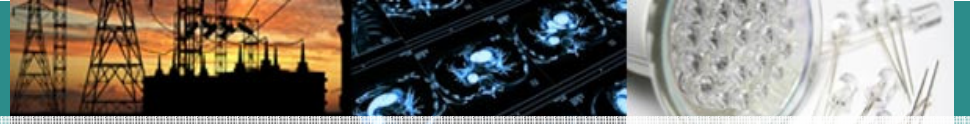


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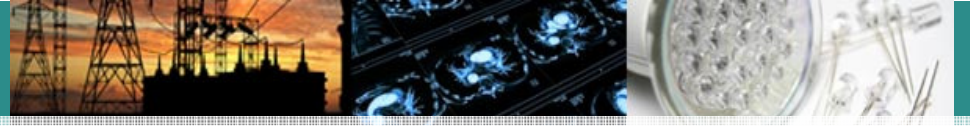
E-MAIL PINS TO ANSI

- Include Announcement of Intent to Canvass (canvass method only)
- Announced in ANSI Standards Actions
- 30-day Announcement



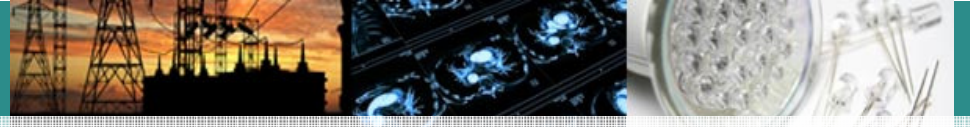
E-MAIL BSR 8 TO ANSI

- BSR 8 Form Requests Announcement for Public Review in ANSI Standards Actions
 - 30-day review if text can be entered in its entirety in Standards Action
 - **45-day review if text can be emailed within 1 day**
 - 60-day review if not specified, or if neither of the above two apply
- May Be Done Concurrently or Before Ballot Issued



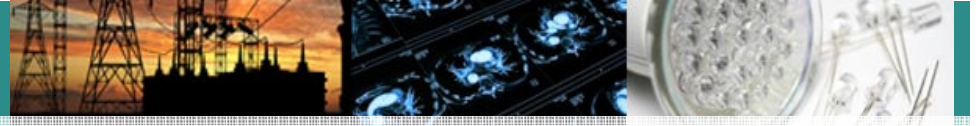
E-MAIL BALLOT

- Generally a 6-week voting period
- Members may vote Affirmative, Affirmative with comment, Negative with comment, or Abstain (with reason)
- Follow-up with non-respondents 2 weeks before close of voting period



Determination of Consensus

- Affirmative votes from at least 50% of the total consensus body, and
- Affirmative votes from at least $\frac{2}{3}$ of those who actually submitted votes, excluding abstentions

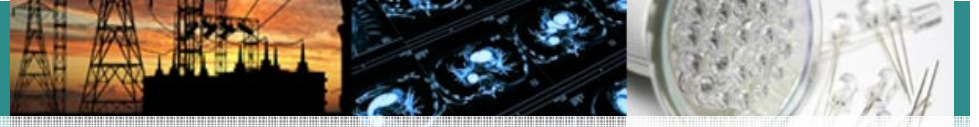


COMPILE RESULTS OF BALLOT

- Comments Received?
- Section Must Attempt to Resolve Comments.
- Notify Individuals who Commented. Must Notify Them of the Right to Appeal.
- Does Section Response Resolve Negative Votes or Comments?
- If Not, Must Notify All on the Canvass List – Give an Opportunity to Change Votes, Based on Comment and Response.
- Issue Final Results to All Those on Canvass List – Majority for Approval



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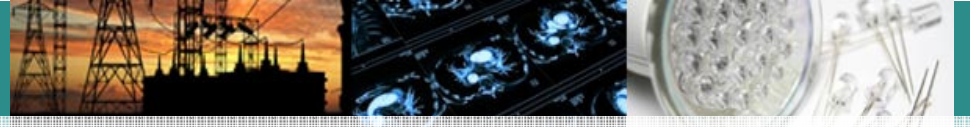


BSR 9 TO ANSI

- BSR 9 is Formal Request for Approval



The Association of Electrical and
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Resources

- ANSI Procedures –
 - www.ansi.org/
 - Click on Domestic Standards Activities, Domestic Programs

The end

Questions