



# The Role of Regulators in Protecting and Promoting Public Health in Radiology

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# Regulator's Role

- Promote and protect the health of the public by ensuring the *safety* and *effectiveness* of radiology devices



# Safety

The benefits of the device, when used properly, should outweigh any probable risks



# Effectiveness

The device, when used properly,  
should provide clinically significant  
benefits

# Bonn Call for Action

- Regulators have a major role in achieving three of the 10 aims:
- *Strengthen radiation protection for patients and health workers*
- *Attain maximum benefit with minimum risk to patients*
- *Enhance the safety and quality of radiological procedures*

# Approach to Regulation

- Classify and regulate based on potential harm to patient and user
- Ensure compliance with relevant standards
- Ensure that instructions for use are adequate
- Ensure that hazards (including radiation hazards) are mitigated to the extent possible

# Regulatory Activities

- Pre-market
- Post-market
- Compliance

# Other Responsibilities

- Work with industry and professional organizations to develop standards for device safety and performance
- Outreach to stakeholders
- Conduct research to quantify benefit (e.g., image quality) and risk (e.g., dose) in order to improve evaluation of safety and effectiveness





# Other Responsibilities

- Establish personnel qualifications and ensure compliance
- Facility accreditation
- Quality assurance programs



# Thank You