Non-Coherent Light Sources

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Overview

- What is a non-coherent light source?
- Light Emitting Diodes (LEDs)
  - How FDA regulates these products
  - FDA's concerns
- UVC Lamps
  - How FDA regulates these products
  - FDA's concerns
- Questions for TEPRSSC

Non-Coherent Light Sources

- Electronic products that emit light, commonly known as a ‘lamps’.
- “Non-coherent” means that the amplitude and phase of the emitted light waves fluctuate randomly in space and time.
  - Light-Emitting Diodes (LEDs)
  - UVC lamps

How FDA Regulates These Products

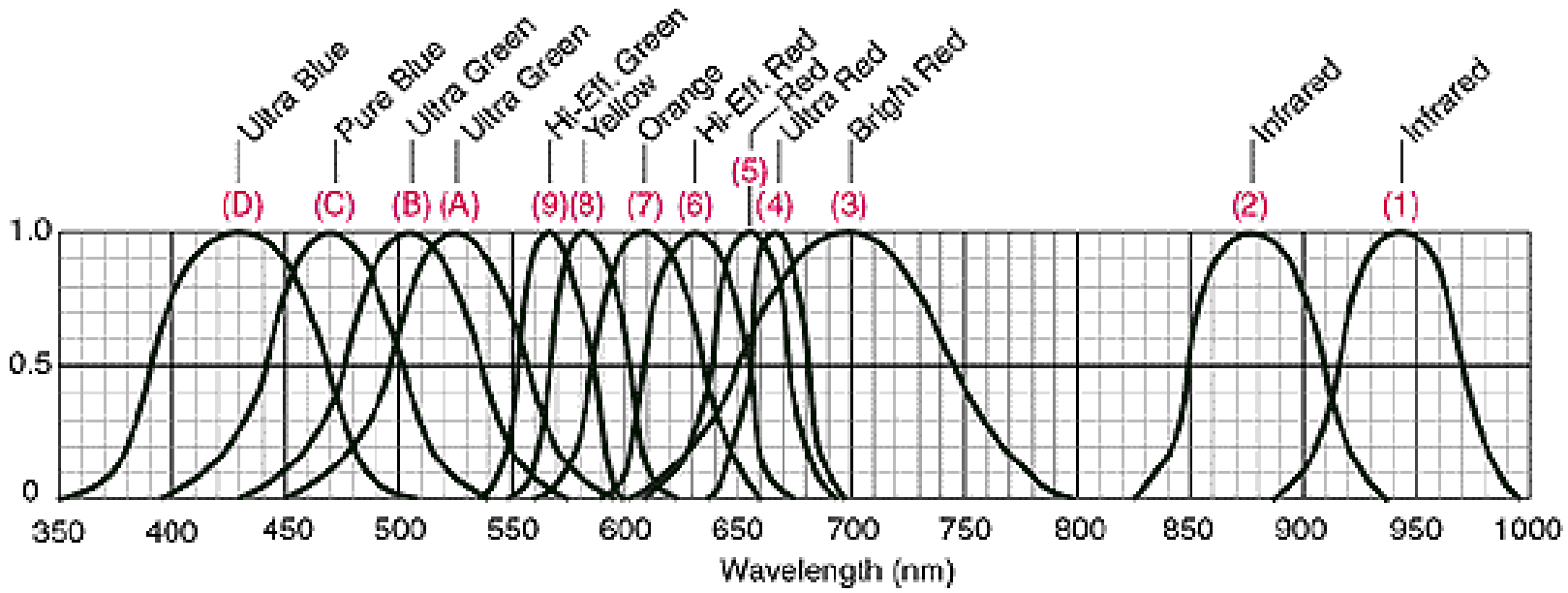
- 1979 - FDA developed Performance Standards for two types of non-coherent light sources (lamps) that emit UV:
  - Sunlamp Products (amended in 1985)
  - High-intensity Mercury Vapor Lamps
- Since that time, FDA has not developed any new Performance Standards for lamps
  - Sunlamp performance standard scheduled to be amended in 2016

What is a LED

- Light-emitting diode = semiconductor diode that emits light when electrical current is applied
- Bandgap determines wavelength of emitted light
- Not a “laser”

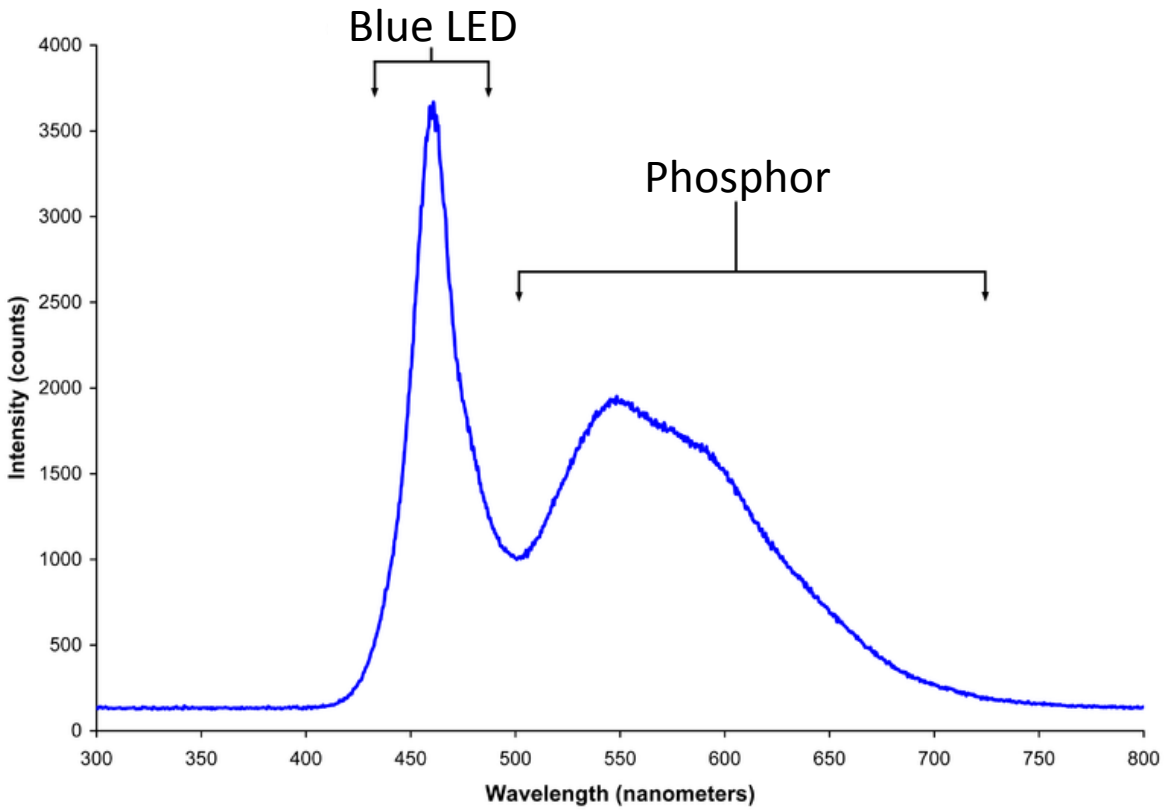
What is a LED

Available in many wavelengths across the optical radiation spectrum (240 – 950 nm)



White LEDs for Lighting

'White' LEDs are possible due to a combination of a blue LED and a phosphor.



White LED Applications

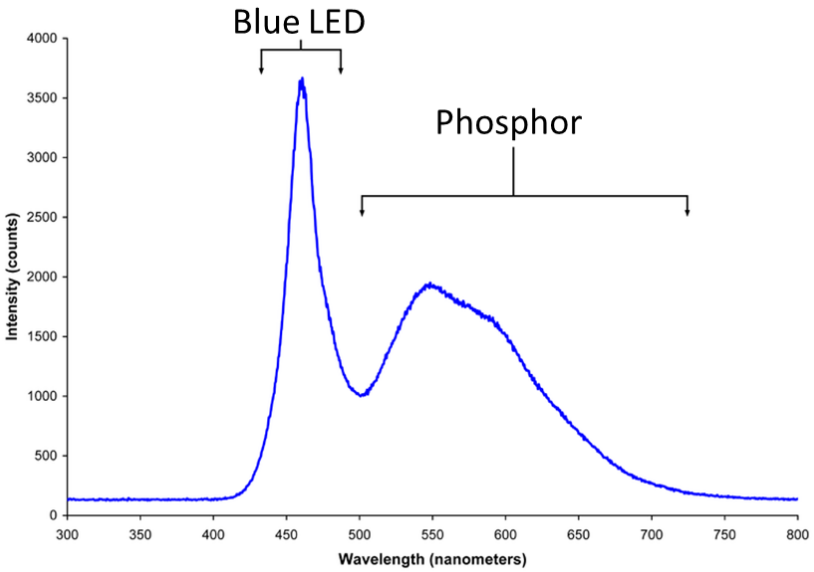
- General illumination at home or work
- Tablets and E-readers
- Outdoor lighting

Safety Concerns

- ANSI/IEC 62471- Photobiological Safety of Lamps and Lamp Systems
  - Classification - 4 Risk Groups (RGs) based on potential acute hazard:
    - RG 0 (or Exempt) – no risk for up to 10,000 s
    - RG 1 (low risk) – no risk under normal conditions of use (up to 100 s)
    - RG 2 (moderate risk) – no risk due to aversion response to bright light sources (up to 0.25 s)
    - RG 3 (high risk) – potential risk even from momentary exposure

Safety Concerns

- Blue light hazard
  - Blue light is hazardous to the retina, especially due to reduced pupillary constriction compared to white light
  - Peak of hazard is @ 440 nm
  - High luminance or hot spots due to small source size
- Glare from increased scatter (due to shorter wavelengths)
  - Afterimages
- Circadian rhythm disruption
  - Fatigue
  - Sub-optimal performance
  - Effects on long-term health



Safety Concerns

Uncertainty regarding chronic effects of low doses on eye damage, e.g. Age-related macular degeneration (AMD)

- Sunlight exposure has been shown to be a risk factor for AMD
- No studies with appropriate animal models
- Hunter JJ *et al*, 2012 found subthreshold retinal damage at doses < published thresholds
- Military personnel in desert for several months have retinal lesions similar to solar retinitis

2010 ANSES Study

White LEDs

- Most types were < RG 1
- Some RG 2 (moderate risk, similar to high pressure metal halide lamps)
- Safe exposure times
  - 10 – 30 s for white LEDs
  - Few seconds for blue LEDs

2010 ANSES Study

Recommendations

- Manufacturers should classify and label their LEDs by RG
  - Update IEC 62471 to provide more guidance on evaluating LEDs
- Limit LEDs for general public to RG1
- Provide distance at which product is RG0
- LED systems > RG1 be installed only by professionals
- Lighting systems design—only indirect light to reduce glare

American Medical Association (AMA)

2016 Report on effects of LED lighting

- Strong economic incentive to overhaul existing street lighting and convert to LED lighting
- Early LED designs emitted excessive blue light, which contributes to disability glare/visual impairment
- 1st generation outdoor LED lamps (still being installed) have a “Correlated Color Temperature” (CCT) index of 4000 K
- Current outdoor lighting (typically sodium lamps) has a CCT of 2100 K
- Daylight is ~ 6500 K
- Newer LEDs are ~ 3000K, which is slightly warmer in tone and has less impact on humans and wildlife

AMA

2016 Report on effects of LED lighting

- Glare:
  - Outdoor LED lighting can lead to worse glare than conventional high pressure sodium (HPS) lighting
  - LED glare can be minimized by proper design and CCT control
  - Proper shielding can minimize discomfort and disability glare
- Circadian disruption:
  - White LEDs estimated as > 5 times more effective in influencing circadian physiology vs. a HPS lamp
  - Brighter residential nighttime lighting is associated with reduced sleeping times, lower sleep quality, impaired daytime functioning and obesity
  - High CCT LEDs could impact the long-term health of exposed populations

AMA

2016 Report on effects of LED lighting

Recommendations:

- Supports proper conversion from current HPS lighting to LEDs to reduce energy consumption
- Encourages use of < 3000 K CCT lighting for outdoor installations
- Encourages use of proper shielding of LEDs to reduce glare
- Encourages use of dimming in off-peak times

UVC Lamps

- Lamps emitting optical radiation in the 100 to 280 nm range
- Peak emission from low pressure, mercury-based lamps at 253.7 nm
- UV LEDs are also available, e.g., at 214 nm or 247-280 nm

Common Uses for UVC lamps

- Air disinfection
- Water disinfection
- Food processing hygiene
- Laboratory hygiene
- Medical device sterilization
- Consumer use for home sterilization
  - Air
  - Surfaces
  - Often no mention of skin or eye hazards

Bioeffects of UVC

UVC lamps - Germicidal lamps due to their ability to kill bacteria and other microorganisms

- Can cause skin sunburn (erythema)
- Can cause sunburn of cornea (photokeratitis)
- DNA damage – may lead to long-term effects, e.g., skin cancer
- UVC lamps also produce ozone, which is irritating to the respiratory system

Safety Concerns

- UVC lamps are widely available in consumer products, with no mandatory requirements for testing or warning labels/instructions
- UVC lamps have identical socket designs to other lamps:
  - UVC lamps are sold separately
  - UVA lamps in insect traps or nail curing devices
  - General illumination lamps
  - There are reports of incorrect replacement and resultant injuries

FDA Regulation

- No current FDA Performance Standards/requirements for testing or labeling of UVC lamps
- Precedent: current FDA Performance Standard for Sunlamp Products contains a requirement regarding socket designs

Questions for TEPRSSC

- Does TEPRSSC have any comments or concerns about the ANSES/AMA proposals?

Questions for TEPRSSC

- Does TEPRSSC have any comments about the best way to deal with potential hazards of UVC lamps, including the risk of incorrect installation?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