

#### REGULATIONS AND STANDARDS

MODULE 5



## History

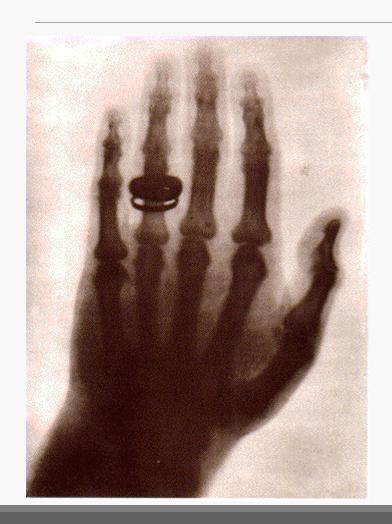
X-rays were first discovered in 1895 by **Wilhelm Conrad Röntgen** (1845-1923), who was a Professor at Wuerzburg University in Germany.

He observed them on November 8, 1895, while experimenting with cathode rays in his laboratory.

He initially called them "X-rays" due to their unknown nature.



# The First X-Ray

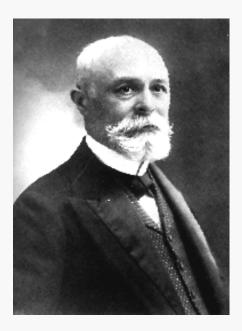


On 22 December 1895, Mr. Roentgen made the first x-ray photograph (his wife's hand).

# History (Cont.)

- On 1 January 1896, Roentgen announced his discovery to the world.
- •14 February 1896, four days after news of the discovery reached the U.S, x-rays were used to guide surgery in New York.
- In early 1896, the Italian military began using x-rays to diagnose and treat wounded soldiers

### At the same time ...



In February 1896, Henri Becquerel discovered radioactivity.

## Recognizing the Hazards

- Jan 1896: The first radiation burns were reported.
- •Nov 1896: Elihu Thompson intentionally exposed his little finger to radiation over a period of a few days and then cautioned against over exposure "... or there may be cause for regret when too late."
- Becquerel and Pierre Curie both suffered abdominal burns from carrying vials of radium in their vest pockets.

### **Dose Limits**

- •1977: ICRP (International Commission on Radiological Protection) recommends 5 rem/yr including internal exposures
- •1990: ICRP recommends 2 rem/yr averaged over 5 years with no single year exceeding 5 rem.
- •1994: NRC (Nuclear Regulatory Commission) adopts 1977 recommendations.

## What Needs to be Regulated?

- Byproduct Material
- Source Material
- Special Nuclear Material
- Naturally occurring and Accelerator produced Radioactive Material (NARM)
- ➢ Ionizing Radiation Producing Devices

## **Byproduct Material**

"..Radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material." - NRC

### Source Material

"Material containing either the element **thorium** or the element **uranium**; provided that the uranium is not enriched in the isotope uranium-235 above that found in nature.

Both natural **uranium** and **depleted uranium** are considered source material. Source material can also be a combination of thorium, depleted uranium, and natural uranium and the material can be in any physical or chemical form.

Ores that contain uranium, thorium, or any combination thereof, at one-twentieth of one percent (0.05 percent) or more by weight are source material." - NRC

## Special Nuclear Material

"Special nuclear material" (SNM) is defined by Title I of the <u>Atomic Energy Act of 1954</u> as **plutonium**, **uranium-233**, or **uranium enriched in the isotopes uranium-233** or **uranium-235**, but does not include source material." - NRC

#### **NARM**

Naturally occurring or Acceleratorproduced Radioactive Material, such as radium, and not classified as source material.

#### Examples of NARM Radiation:

#### 1. Naturally Occurring Radioactive Materials (NORM)

These are radioactive elements found naturally in the environment, including:

Isotope	Туре	Where Found
Uranium-238 (U-238)	Alpha emitter	Soil, rock, water
Thorium-232 (Th-232)	Alpha emitter	Soil, rare earth minerals
Radium-226 (Ra-226)	Alpha/gamma	Decay product of uranium
Radon-222 (Rn-222)	Alpha emitter	Gas from soil/rock; accumulates indoors
Potassium-40 (K-40)	Beta/gamma	Found in food (bananas, potatoes), body
Carbon-14 (C-14)	Beta emitter	Organic materials; used in radiocarbon dating

#### 2. Accelerator-Produced Radioactive Materials (ARM)

Created in cyclotrons or particle accelerators, not reactors.

Isotope	Туре	Use
Fluorine-18 (F-18)	Positron emitter	PET imaging (e.g., FDG)
Thallium-201 (TI-201)	Gamma emitter	Myocardial perfusion imaging
lodine-123 (I-123)	Gamma emitter	Thyroid imaging
Carbon-11 (C-11)	Positron emitter	Brain imaging in research
Nitrogen-13 (N-13)	Positron emitter	Cardiac PET studies
Oxygen-15 (O-15)	Positron emitter	Blood flow studies

## Hierarchy of Standards

Federal Laws and Regulations.

State Laws and Regulations

Accreditation Standards.

National and International Consensus Standards and Guidance.

# Who Regulates What in Oklahoma?

NRC: Special Nuclear (more than 200 grams)

State: Source, Byproduct, Special Nuclear (less than 200

grams) NARM and Radiation Producing Devices

**OSHA**: Everything (sort of)

**EPA**: Disposal and Environmental Releases

**DOT**: Transportation

**FDA**: Radiation Producing Devices (Performance)

# OK Environmental Code OAC 252:410

Oklahoma Department of Environmental Quality is the proponent.

The OKDEQ issues specific licenses, for the receipt, possession, distribution, use, transportation, transfer, and disposal of radioactive material.

### OAC 252:410 (CONT.)

OAC 252:410: occupational dose limits, radiation dose limits for individual members of the public, surveys and monitoring, control of exposures from external sources in restricted areas, respiratory protection, storage and control, waste disposal, records, reports, and enforcement.

### Title 10 CFR

- A. Nuclear Regulatory Commission (NRC) is the proponent.
- B. Governs the use of special nuclear material in excess of 200 grams.

#### Title 21 CFR

a. Public Health Service, Center for Devices
and Radiological Health is the proponent.

b. Governs standards and programs for cold cathode discharge tubes, x-ray inspections at airports, industrial x-ray equipment, laser products, ultrasound devices, mercury vapor lamps and sun lamps.

#### Title 29 CFR

Occupational Safety and Health Administration (OSHA) is the proponent.

Governs the use of all ionizing radiation to include alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high speed protons, and other atomic particles.

Part 1910.1096, Ionizing Radiation, includes requirements for dose limits, instructions to employees, posting requirements, and reports of overexposure.

Memorandum of understanding with Nuclear Regulatory Commission.

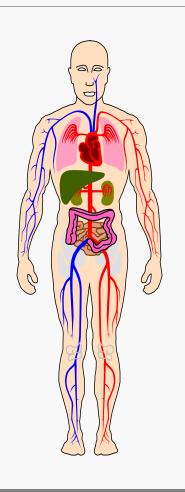
### Title 49 CFR

Transportation of Radioactive Materials.

Regulated, determine methodology with RSO before offsite transportation.

Radioactive Waste is transported off-site by licensed contractors.

# RADIATION PROTECTION GOALS



LIMIT PROBABILITY OF RADIATION BIOEFFECTS.

DEVELOP ACCEPTABLE RISK WITH DERIVED BENEFITS.

PROTECT HUMANKIND AND ITS ENVIRONMENT.

# RADIATION PROTECTION OBJECTIVES

PREVENTION OF NON-STOCHASTIC DISEASE

SEVERITY VARIES WITH MAGNITUDE OF DOSE

HEALTH EFFECTS HAVE A THRESHOLD DOSE

EXAMPLES: CATARACTS, IMPAIRMENT OF FERTILITY

# RADIATION PROTECTION OBJECTIVES (cont.)

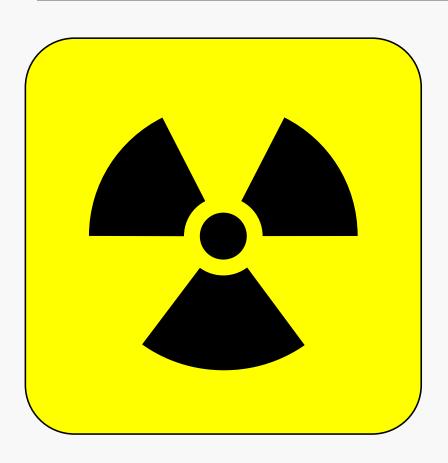
LIMIT RISK OF STOCHASTIC HEALTH EFFECTS (i.e. cancers, mutations)

SEVERITY INDEPENDENT OF DOSE (BOTH SOMATIC AND GENETIC)

EXAMPLES: LEUKEMIA, MALGNANT TUMORS



# RADIATION PROTECTION PHILOSOPHY



BENEFITS SHOULD BE GREATER THAN RISKS INVOLVED.

•KEEP RADIATION DOSES AS LOW AS REASONABLY ACHIEVABLE (ALARA).

#### RADIATION RISK, IN PERSPECTIVE

#### RADIOGENIC HEALTH EFFECTS HAVE NOT BEEN OBSERVED BELOW DOSES OF 10 REM.

#### What the science says:

- Epidemiological studies (e.g., atomic bomb survivors, medical workers, nuclear industry):
- At doses below 10 rem (100 mSv), the signal (effect) is hard to distinguish from background noise (cancer and illness already occur naturally).
- Large uncertainties exist at low doses, and no clear causal link to increased cancer risk has been statistically proven at these levels.
- Regulatory approach:
- Despite lack of observed effects at <10 rem, agencies like the ICRP, NCRP, EPA, and U.S. NRC use the Linear No-Threshold (LNT) model:
  - Any dose, no matter how small, is **assumed** to carry some **increased risk** of cancer or genetic damage.
  - This is a conservative, precautionary approach for radiation protection.

#### RADIATION RISK PERSPECTIVE

A limitation of Quantitative Risk Assessments (QRAs) in radiation protection is that they are most-reliably used for doses at or above 5 rem per year, or a lifetime dose of 10 rem above natural background.

Limitation Overview		
Issue	Explanation	
Statistical Uncertainty	At doses below ~10 rem (100 mSv), the <b>signal (radiation-induced cancers)</b> is <b>too small</b> to distinguish from natural background cancer rates.	
Epidemiological Sensitivity	Studies need <b>very large populations</b> and <b>long follow-up times</b> to detect small increases in risk — which becomes impractical and unreliable below 5–10 rem.	
Confounding Variables	Lifestyle, environment, genetics, and random variation all interfere with attributing risk to radiation at low doses.	
Extrapolation Errors	QRAs often <b>extrapolate from high-dose data</b> (e.g., >50 rem) to low-dose ranges using models like the <b>LNT model</b> , which may not reflect actual biology at low doses.	
Biological Repair Mechanisms	At low doses, the body may <b>repair damage effectively</b> , meaning actual risk could be lower than predicted by linear models.	

#### RADIATION RISK PERSPECTIVE

Below **5 rem per year**, radiation risk assessment shifts from **quantitative** to **qualitative** approaches — and this is where **ALARA** becomes central in managing exposure.

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At radiation doses below 5 rem (50 mSv) per year:

- Health risks are too small to be directly observed.
- Quantitative risk estimates (like cancer probability) become highly uncertain and model-dependent.
- Therefore, regulators and health physicists do not rely on numerical risk estimates.
- Instead, they use qualitative judgment, principles, and best practices.

# Notice to Employees

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It is a <u>requirement</u> of the Oklahoma Department of Environmental Quality that Notice to Employees from DEQ form # 410-3 be <u>posted</u>.

It informs employees of their rights and where they can report concerns & where they can examine the license and the regulations.

