August 5, 2010

Nuclear Regulatory Commission
Material Licensing Branch
US Nuclear Regulatory Commissions, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

24-13365-01

ATTN: Toye Simmons
Kevin Null

RE: Notification of Radiation Safety Officer Change

Ms. Simmons:

Analytical Bio-Chemistry Laboratories is making notification to you of the termination of our Interim Radiation Safety Officer, Elaine McCoy, and the naming of Frank White as the Interim Radiation Safety Officer as we complete our search for a new RSO. In the interim capacity, Dr. White will be working for Susan Engelhardt, of Engelhardt & Associates, Inc., a radiation consulting firm. Dr. White has been actively involved in the radiation activities at ABC Laboratories for 2 months, and has been working with the radiation safety functions performed by Ms Hecht and Ms. McCoy during this period.

Dr. White's responsibilities during this interim period are the over sight of the routine, day-to-day radiation safety program and license compliance performed by trained Environmental, Health & Safety Technicians who have been performing these functions under the supervision of Ms. Hecht and Ms. McCoy. In the event of an emergency, Engelhardt & Associates will provide supervision by phone until a consultant arrives at the site.

Attached for your review is the resume for Dr. Frank White.

If you have any questions of need further information, please feel free to contact me at 573-777-6042.

Sincerely,

Scott Ward

G. Scott Ward
SVP & GM Chemical Services
Chairman Radiation Safety Committee, ABC Laboratories, Inc.

573289

CURRICULUM VITAE

NAME:	Franklin (Frank) H. White	
TITLE:	Director, DMPK and Synthesis	
EDUCATION:	Postdoctoral Research Fellow	Colorado State University
	PhD, Organic Chemistry	Indiana University, Bloomington
	BS, Chemistry	Univ. of North Carolina, Chapel Hill

PROFESSIONAL MEMBERSHIP(S):

American Chemical Society
International Isotope Society
-Central US Chapter, President
-Central US Chapter, Secretary
-Board of Representatives to the International Chapter Trustees

SUMMARY OF PERTINENT EXPERIENCE:

<u>ABC Laboratories, Inc</u>

Director, DMPK and Snthesis, June 2010 - present

Plans and directs activities of DMPK and Synthesis Services group supporting research and development for pharmaceutical, chemical industries, animal health or other organizations by performing the following duties personally or through subordinate supervisors. Responsible for overseeing the safe use of carbon-14 radioisotope operations within the synthesis laboratories by appropriately trained personnel. Responsibilities include ensuring proper training in the use of radioisotopes, overseeing the cleaning of contaminated "hot spot" areas within the laboratory, and reviewing weekly wipe test results of the laboratory. Plans, coordinates, and directs client contracted programs for research, product development, and improvement of manufacturing processes. Works with HSE personnel to see that radioactive waste is disposed of properly. Directs technical resources in the form of staff, equipment and facilities to provide company's service to the chemical industries. Coordinates day to day activities of subordinates to achieve expected results both technically and financially according to applicable government regulations, manufacturing processes, or other considerations, and approves modification of standards, specifications, and processes. Responsible for the technical product quality that is produced by the operating group. Responsible for day to day activities of supervising capital and labor resources to achieve client contractual obligations. Reviews research, testing, quality control, and other operational reports to ensure that quality standards, efficiency, and schedules are met. Interprets results of laboratory activities to laboratory personnel, management, and professional and technical societies. Advises management, technical personnel, and representatives of other organizations of activities.

Eli Lilly and Company

Principle Research Scientist ***2004-2010***
Research Scientist ***1998-2004***

Conceptualization, synthetic pathway design, process evaluation, and preparation of radiolabeled (^{14}C and ^{3}H) and stable labeled (^{2}H, ^{15}N, and ^{13}C) molecules for use in product development and registration studies involving humans and laboratory animals. Understanding of species metabolism was required. Helped facilitate the implementation of quality systems for the performance of radiolabeled operations conducted under GLP and cGMP conditions. Served as an early focal point in the team development of project goals and timelines for the preparation of radiolabeled drug product for human single-dose safety studies. Authored and revised SOP's to meet EPA and FDA regulatory requirements. Assisted with gap analysis of internal quality systems. Assisted in the preparation of IND documentation for the cGMP preparation of API and NDP (active pharmaceutical ingredient and new drug product).

Dow AgroSciences

Senior Scientist ***1997-1998***
Senior Research Chemist ***1991-1997***
Research Chemist ***1989-1991***

Conceptualization, synthetic pathway design, process evaluation, and preparation of radiolabeled (^{14}C and ^{3}H) and stable labeled (^{2}H, ^{15}N, and ^{13}C) molecules for use in product development and registration studies involving laboratory animals, and plants. Trained associates in techniques that are used in radiosynthesis laboratories to ensure their safe use of radioisotopes. Helped oversee decommissioning activities of radiolabeled synthesis labs in Midland, MI by performing clearance wipe tests, briefing decommissioning personnel of safety procedures, and answering procedural questions from decommissioning personnel.

Colorado State University; Department of Chemistry

Postdoctoral Research Associate, 1987-1989

Conducted research in synthetic organic chemistry. Research focused on the asymmetric alkylation of indole alkaloids through the use of chiral formamidine directing groups.

Indiana University, Bloomington; Department of Chemistry

Graduate School, 1982-1987

Conducted research in synthetic organic chemistry. Research focused on the synthesis of highly functionalized tetrahydrofuran containing natural products. Methodology for the construction of this molecular framework was investigated.

PUBLICATIONS & PRESENTATIONS:

Tabor DC, White FH, Collier LW, Evans SA, Jr. 1983. Regioselective catalytic transfer hydrogenation of dimethyl bicyclo[2.2.1]hepta-2,5-diene-2,3-dicarboxylate and related compounds over palladium on carbon. J Org Chem 48:1638.

Williams DR, White FH. 1985. Hydroxyl-directed iodoetherifications of allylic alcohols. synthesis of (±)-citreoviral. Tetrahedron Lett 26: 2529.

Williams DR, Phillips JG, White FH, Huffman JC. 1986. Studies of stereochemical control using □-lithiosulfinyl carbanions. Tetrahedron 42: 3003.

Williams DR, White FH. 1986. Studies of tetrasubstituted tetrahydrofurans. Tetrahedron Lett 27: 2195.

White FH. 1987. Synthesis of tetrasubstituted tetrahydrofurans. The total synthesis of (±)-citreoviral and (±)-citreoviridin. Indiana University, Bloomington (IN): PhD Thesis.

Williams DR, White, FH. 1987. Total synthesis of (±)-citreoviridin. J Org Chem 52: 5067.

Meyers AI, Miller DB, White FH. 1988. Chiral and achiral formamidines in synthesis. The first asymmetric route to (-)-yohimbone and an efficient total synthesis of (±)-yohimbone. J Amer Chem Soc 110: 4778.

Woodburn KB, Batzer FR, White FH, Schultz MR. 1993. The aqueous photolysis of trichlopyr. Environ Toxicol Chem 12: 43.

White FH, Clodfelter,DK. 2004. Synthesis of LY335979-[piperazine-14C]. Dean DC, Filer CN, McCarthy, KE, editors. Synthesis and Applications of Isotopically Labeled Compounds, Volume 8. John Wiley and Sons, 385.

White FH, Kowalenko P. 2004. Synthesis of a stable labeled metabolite of LY582563. Dean DC, Filer CN, McCarthy, KE, editors. Synthesis and Applications of Isotopically Labeled Compounds, Volume 8. John Wiley and Sons, 389.

Davis RA, Wheeler WJ, White FH. 2004. Synthesis of labeled LY504132, a selective estrogen receptor modulator. Dean DC, Filer CN, McCarthy, KE, editors. Synthesis and Applications of Isotopically Labeled Compounds, Volume 8. John Wiley and Sons, 393.

White FH, McKendry LH. 1998. Synthesis of carbon-14 Labeled DE-570. A comparison of three differentially labeled triazolopyrimidine syntheses. 11th Central US Regional Meeting of the International Isotope Society.

Wheeler WJ, White FH, Kennington JW, O'Bannon DD, Mattiuz EL, Stoddard EA and Clodfelter DK. 2003. The synthesis of isotopically labeled 3-(1-methyl-1*H*-indol-3-yl)-4-[1-[1-(2-pyridinylmethyl)-4-piperidinyl]-1*H*-indol-3-yl]-1*H*-pyrrole-2,5-dione (LY317615) and its primary phase I metabolites. 16th Annual Meeting of the Central US IIS, St. Louis, MO, September 18-19, 2003.

White FH, Barbuch RJ, Brown CJ, Chaudhary AK, Clodfelter DK, Czeskis BA, Ehlhardt WJ, Maple SR, Vandenbranden M, Wrighton S. 2003. Metabolite identification and the synthesis of carbon-14 labeled multidrug resistance modulator LY335979. 16th Annual Meeting of the Central US IIS, St. Louis, MO, September 18-19, 2003.

Analytical Bio-Chemistry Laboratories, Inc.

August 5, 2010

Nuclear Regulatory Commission
Material Licensing Branch
US Nuclear Regulatory Commissions, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

ATTN: Kevin Null
Patricia Pelke

RE: 90 Day Path Forward – Stemming from Confernce Call between ABC and the NRC on 8/2/2010

Mr. Null and Ms. Pelke

90 Day Path Forward

- ABC's highest and number one priority is making sure that we are meeting all of our NRC license requirements and the safety of our employees.
- ABC's second priority is the decommissioning of the sanitary lagoon and removal of Building D from our license. ABC will not proceed forward with any decommissioning activities until a RSO is in place and has had sufficient time to review current procedures and evaluate our decommissioning plans.
- Effective immediately, Frank White will be named Interim RSO for ABC. Mr. White is a full time employee of ABC who works on site. Mr. White will be responsible for managing the day to day adherence to our NRC license and will be assisted by and supervise our two Safety Technicians. Mr. White will work under the guidance of Englehardt and Associates who is our regulatory radiation safety consultant. An amendment letter will be forth coming along with Mr. White's resume for your review and approval.
- Starting August 16th, Bradly Keck will serve as our RSO. Mr. Keck will also have the assistance of Englehardt and Associates for guidance as well if needed. An amendment letter and qualifications will also be submitted prior to August 16th for your review and approval. Mr. Keck is an independent consultant and will not be an ABC employee, but will serve as the RSO until futher notice. Mr. Keck will be on site at ABC in this capacity. ABC is in the process of hiring a long term RSO and anticipates having this individual hired within 2 months.
- Once a long term RSO is hired, ABC will request an amendment change naming that person as full time RSO at that time.
- In addition, ABC assures the NRC that no new Users or Uses will be named or allowed during RSO transition until a RSO is in place. Qualified but unauthorized users will be allowed to work only under direct supervision of a current named User during the RSO transition.

Attachments for your review:

1) Qualification/Training Records for Daniel Reeder/David Cozad – Environmental Health and Safety Technicians for ABC
2) Radiation Safety Training Materials provided and given by Engelhardt & Associates in July, 2010

If you have any questions of need further information, please feel free to contact me at 573-777-6042.

Sincerely,

Troy DeVault
VP Corporate Services

TRAINING FOR ISOTOPE USERS

Engelhardt and Associates

CHANGES

- NRC has eliminated the annual dosimetry report distribution requirement
  - Still can get them at any time by requesting them
  - Would still get them if the dose was >100 mrem
- General licenses are being eliminated
- Consideration of a lower dose limit
- NCRP 160
- Accidents from 2009
- Audit

REGULATIONS

- Food and Drug Administration - n/a for our site
  - Any machine produced radiation
- Agreement State/NRC
  - Currently Missouri is still an NRC state
  - Byproduct material
  - Accelerator/Cyclotron produced material
  - Naturally occurring material
- States - n/a for our site
  - X-rays

REGULATIONS

- Post notices-right to know Form, license, regulations, operating procedures, n.o.v.
- Inform individuals working in or frequenting a restricted area
- Advise each worker of exposures
- NRC inspections-allowed, requested, consultations
- Report problems/violations
- Taught in regs,rules, sops, eps, health physics

REGULATIONS-(CONTINUED)

- Written radiation protection programs
- Occupational dose limits
- Dose limits for member of the public
- Surveys and monitoring
- Provisions for exposure control
- Storage and control of RAM
- Waste disposal
- Records, Reports

COMPANY REGULATIONS

- Licenses
  - Actual company specific regulations
  - Inspections will start here
  - Changes must be submitted
  - Types of licenses
    - General
    - Specific
    - Broadscope
- Radiation Safety Program

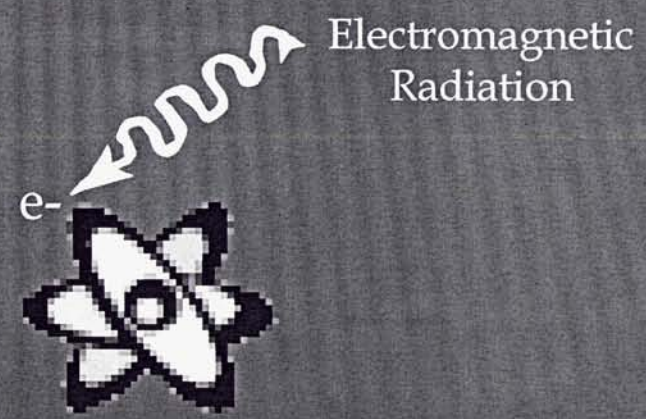
RADIOACTIVE DECAY

- Nuclei that have excess energy (unstable mass/charge ratio) are radioactive and emit particles and energy to remove the excess.

IONIZATION

- The process of stripping electrons from their orbits
  - Interaction with ionizing radiation can cause this (e.g. collision, charge attract/repel)
  - Chemical changes can occur possibly resulting in cellular damage
  - Neutral atoms can become ions (unbalanced charge) after ionization

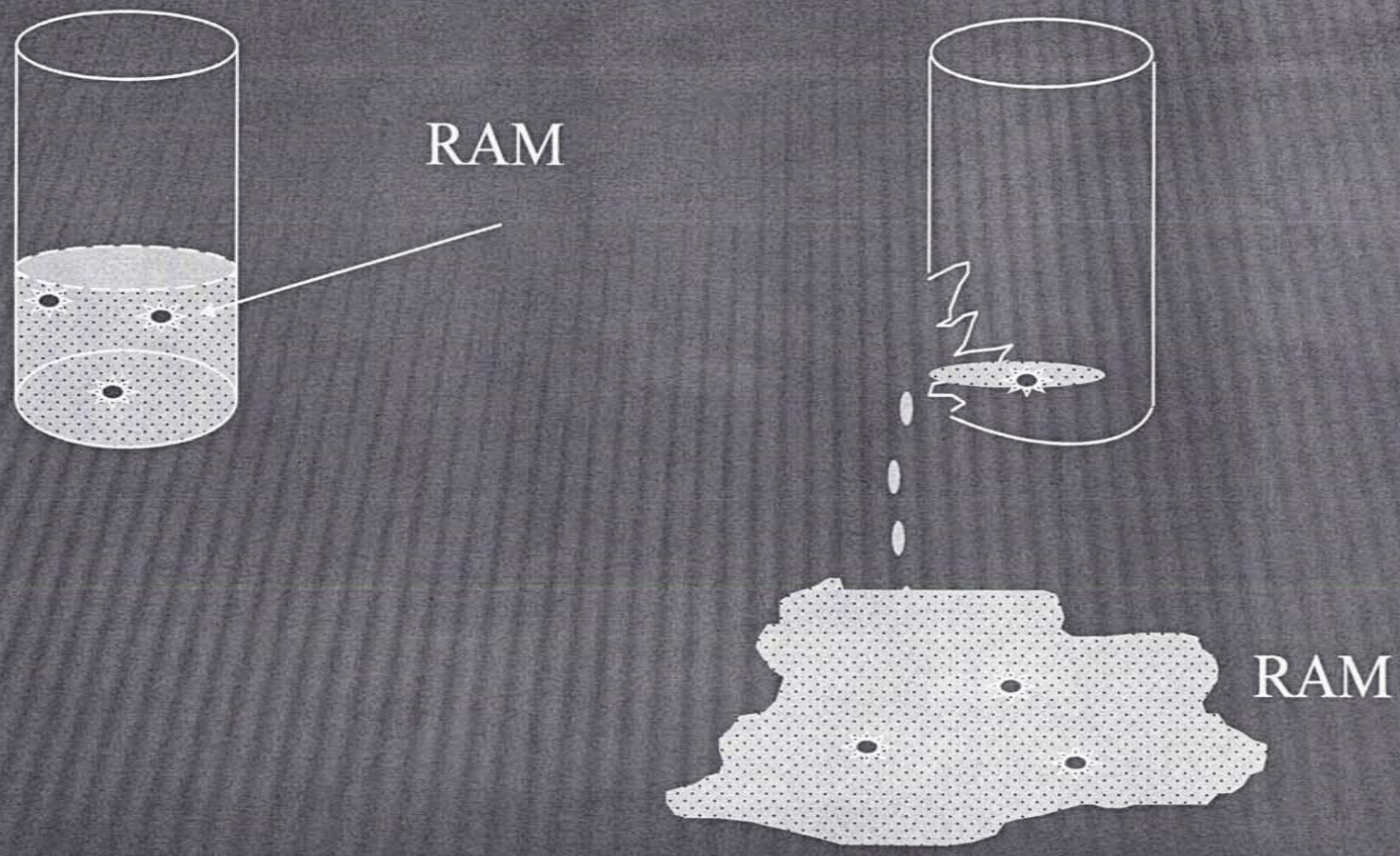
Charge attraction



Collision

Show Example

IRRADIATION VS. CONTAMINATION

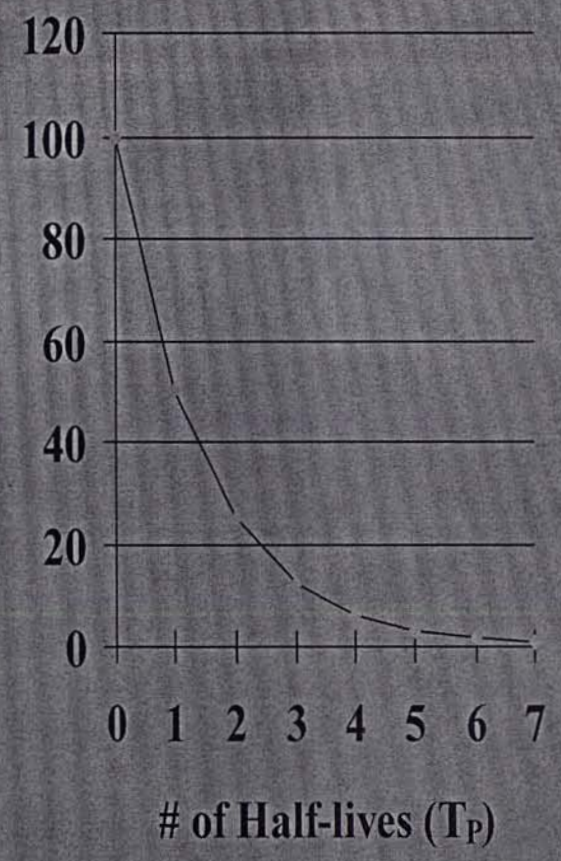


irradiation

contamination

HALF-LIFE (T_P)

- Half-life (T_P) - time required for one-half of the radioactive atoms to undergo decay
  - Decay decreases radioactivity
    - $1\ T_P = 1/2$ (50% remains)
    - $2\ T_P = (1/2)^2$ (25% remains)
    - $7\ T_P = (1/2)^7$ (<1% remains)
    - $10\ T_P = (1/2)^{10}$ (< 0.1% remains)
  - T_P is specific to each radionuclide
    - ^{14}C = 5,730 yr
    - ^{3}H = 12.3 yr
    - ^{125}I = 60 d



ALPHA (α)

Alpha (α)

unstable atom

- Large, heavy particle
  - Helium nucleus ($2p^{+}2n^{o}$)
- Low speed
- Non penetrating
- Range: Short (mm in air)
- Shielding: Paper will stop
- Biological hazard:
  - External - none
  - Internal - high LET

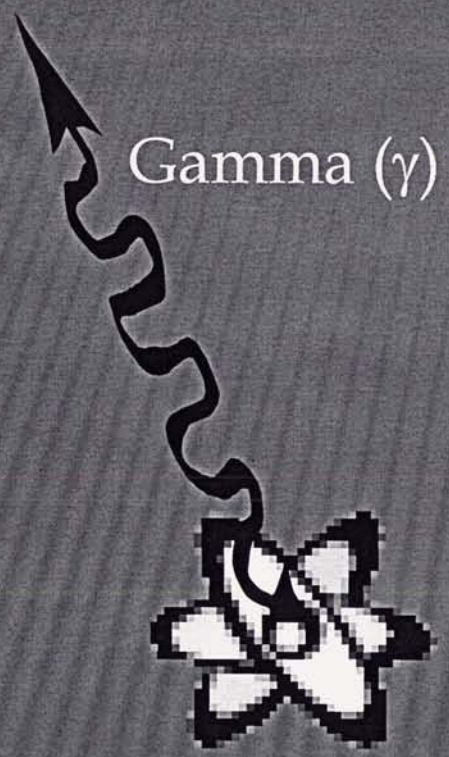
BETA (B)

Beta (β)

unstable atom

- Small, light particle (electron) emitted from nucleus → e- or e+
- High speed
- Can penetrate outer layers of skin: burns
- Range: cm to meter range in air
- Shielding:
  - low E - none
  - high E - plastics/metal
- Biological hazard:
  - External - none at low E
  - Internal - low LET

GAMMA (γ) OR X-RAY (X)



- Electromagnetic, photon
  - No mass or charge
- Penetrating radiation
- Range: Large (several meters in air)
- Shielding: Lead, other metals
- Biological Hazards: external and internal

NEUTRON (N)

Neutron (n)

unstable atom

- Medium size
- High speed
- Penetrating radiation
- Shielding – high hyrdogen content
  - Paraffin, H_2O
- Activation

LOW ENERGY BETA EMITTERS

- Very difficult to detect (LSC)
- Hydrogen-3
  - Decays by 18.6 keV beta particle
  - 12.3 year half life
- Used in exit signs

MEDIUM ENERGY BETA EMITTERS

- Difficult to detect (LSC or GMs)
- Carbon-14
  - 157 keV
  - 5730 year half life
- Sulphur-35 (not currently in use)
  - 167 keV
  - 87.2 day half life

INDIUM-111

- Isomeric Transition from parent
  - 7.7 minute half life
  - 537 keV gamma ray
- Electron capture
  - 2.81 day half life
  - 171 and 245 keV x-rays

NICKEL-63

- Decay

  Beta Particle 66.9 keV

- Half life = 100 years

- Used in Gas Chromatographs

COMMONLY USED RADIONUCLIDES

Nuclide	Primary Decay Products	Maximum Energy (MeV)	Half-Life	Lowest ALI (mCi)	External Hazard
H-3	β	0.019	12.3 y	80	No
C-14	β	0.156	5730 y	2	No
S-35	β	0.167	87 d	2	No
In-111	ε, x-rays	0.245	2.81 d	4	No
Ni-63 (sealed)	β	0.066	95 y	0.8	No

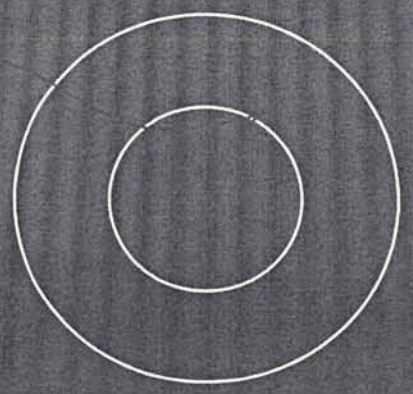
- Annual Limit on Intake (ALI) - amount of radioactivity that if taken internally will result in a dose to reference man equal to the annual limit

CURIE (CI)

- Amount of radioactivity
- Physical quantity
- 3.7×10^{10} dps/2.22×10^{12} dpm
- Expressed as Curies/gram or ml typically

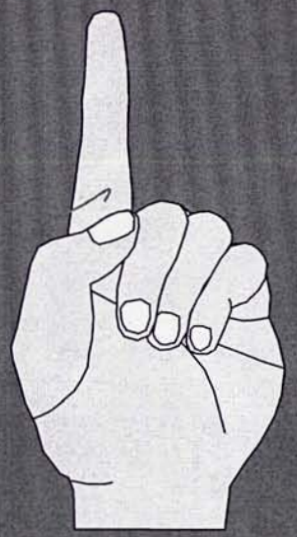
EXPOSURE AND DOSE MEASUREMENTS

- rad (Radiation Absorbed Dose)
  - A measure of the energy transferred to the medium
  - 1 rad is 62.4E6 MeV/g of the medium



EXPOSURE AND DOSE MEASUREMENTS

- Rem (Roentgen Equivalent Man)
  - Measurement of biological damage in human tissue



COMPARISON OF DOSE UNITS

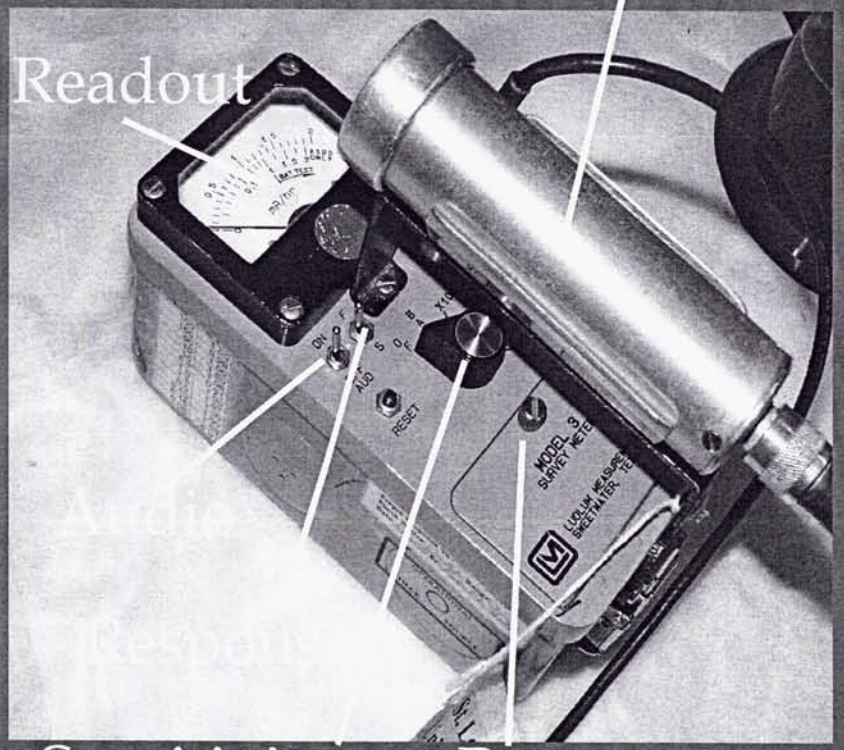
- For x-rays and gammas:
  1 Roentgen=1 rad=1 rem
- Some particles produce greater effect for the same amount of energy
- Due to linear energy transfer (LET) which measures the relative biological effectiveness

MEASURING DOSES

- Active devices
  - Alarming area monitors
  - Geiger counters
  - Ionization chambers
  - Direct reading dosimeters
- Passive devices
  - Film badges
  - TLDs
  - LSCs

CHOICE DEPENDS ON WHAT'S BEING MEASURED

- Dose - Personnel dosimeter
- Exposure - Geiger counter ➔
- Radioactivity (contamination)
  - Direct method - scan a surface for removable or fixed activity (analyze directly)
    - Geiger counter
  - Indirect method - wipe test a surface for removable activity and count wipe (analyze remotely)
    - Liquid scintillation counter
    - Gamma counter



USE OF BADGES/DOSIMETERS

- Finger dosimeters should be worn on the hand most likely to receive a dose, facing the appropriate direction
- Badges should be worn between the waist and neck, on the torso

DECLARED PREGNANT WORKER

- Declaration must be in writing
- Have the right to declare, not to declare, and to undeclare
- Dose limits are 500 mrem over the term of pregnancy, uniform over months
- Special fetal monitor
- Keep records seperate

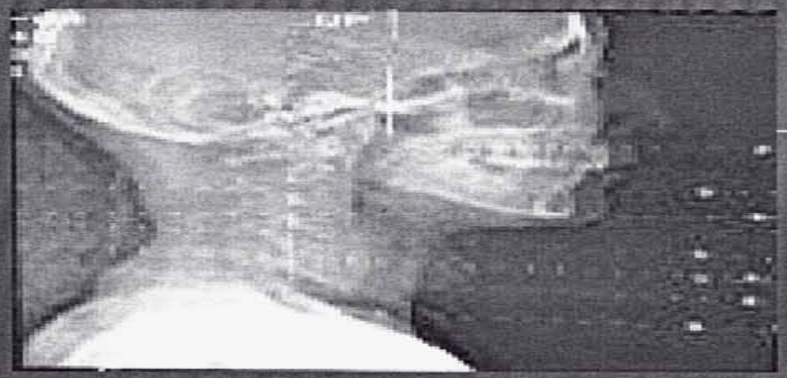
LIMITS ON DOSES-ALARA

- Badged radiation workers
  - Total body-5000 mrem/year
  - Eye dose-15000 mrem/year
  - Skin, extremity, organs-50000 mrem/year
- Unbadged radiation workers
  500 mrem/year
- General public
  100 mrem/year

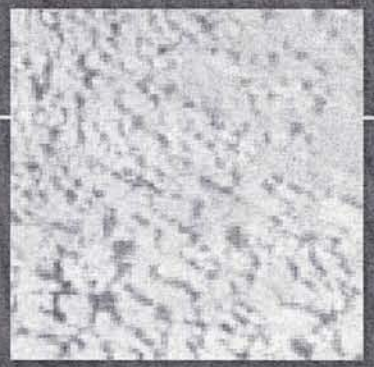
AREA RESTRICTIONS

- Restricted areas
  - High radiation areas
    > 100 mrem/hour
  - Radiation areas
    > 5 mrem/hour
- Unrestricted areas
  - 2 mrem/hour
- Caution Radioactive Material signs

RADIATION SOURCES AND BACKGROUND



TERRESTRIAL RADIATION



- Varies greatly with location
  - Uranium, thorium, radium
- Ground — 28 mrem/yr
  - Granite, minerals, soils, water
- Radon — 200 mrem/yr
- Total — 228 mrem/yr
- Examples:
  - Ramsar, Iran (26 rem/yr)
    - ~2 mrem/hr @ waist level
  - Brazil (7 rem/yr)

COSMIC RADIATION

- Exposure changes with elevation
- Average: ~30 mrem/yr

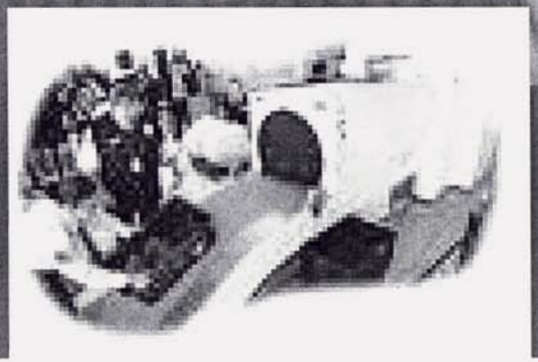
- Sources of exposure
  - + protons, neutrons, betas, gammas, x-rays, etc.
  - + Cosmogenic radionuclides

INTERNAL SOURCES

- Our body tissues 39 mrem/yr
  - Carbon-14
  - Potassium-40
  - Radium-226
- Diet
  - Water
  - Food
    - Brazil nuts
    - No Salt
    - Whiskey
    - Milk
    - Salad Oil

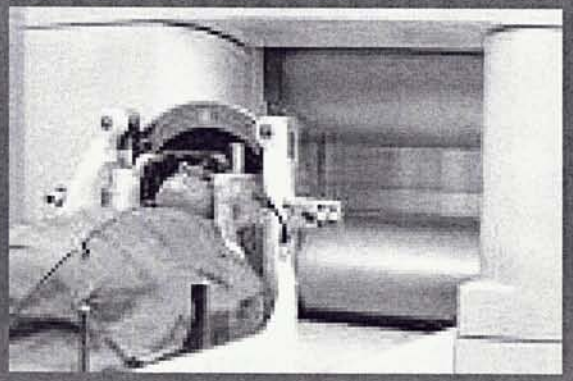
CONSUMER PRODUCTS

- US Average 11 mrem/yr
- Products include:
  - + Orange fiesta ware
  - + Ceramics
  - + Porcelains
  - + Luminous dials
  - + Smoke Detectors
  - + Lantern Mantles



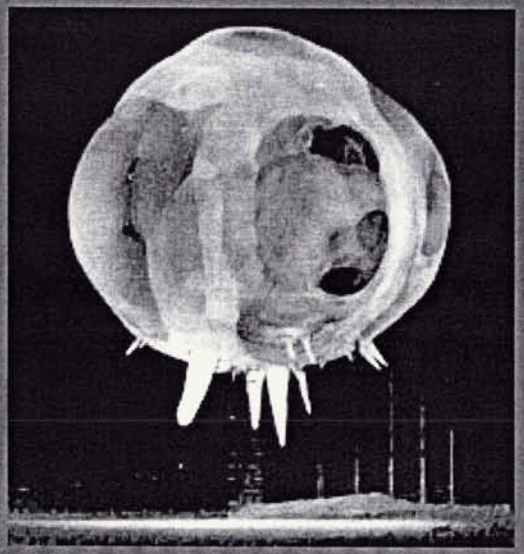
MEDICAL EXPOSURES

- Doses vary tremendously based on type of treatment
  US Average: 300 mrem/yr
- Examples:
  - Chest x-ray (~20 mrem)
  - Dental x-ray (hundreds of mrem)
  - Cardiac perfusion (1200-3300 mrem)
  - CAT Scan (50-5000 mrem)
  - Cardiac Catherization (~10 rem)
  - Radiotherapy (~200 rem each)

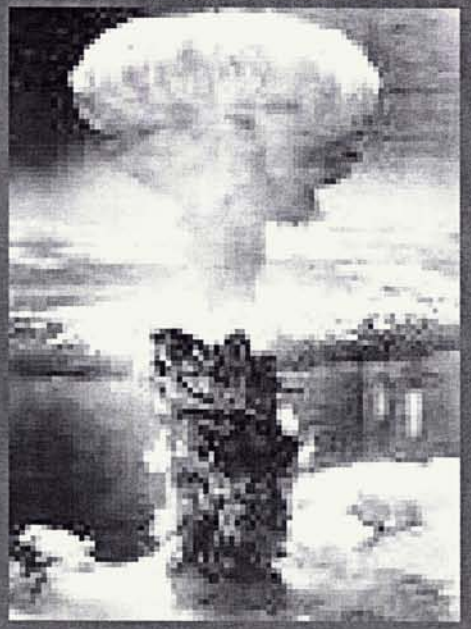


WEAPONS

- Dose depends on many factors
  - Size of bomb
  - Type of bomb
  - Location
  - Weather
  - Time



US Average today	<1 mrem/yr
Nagasaki	~200,000 rad



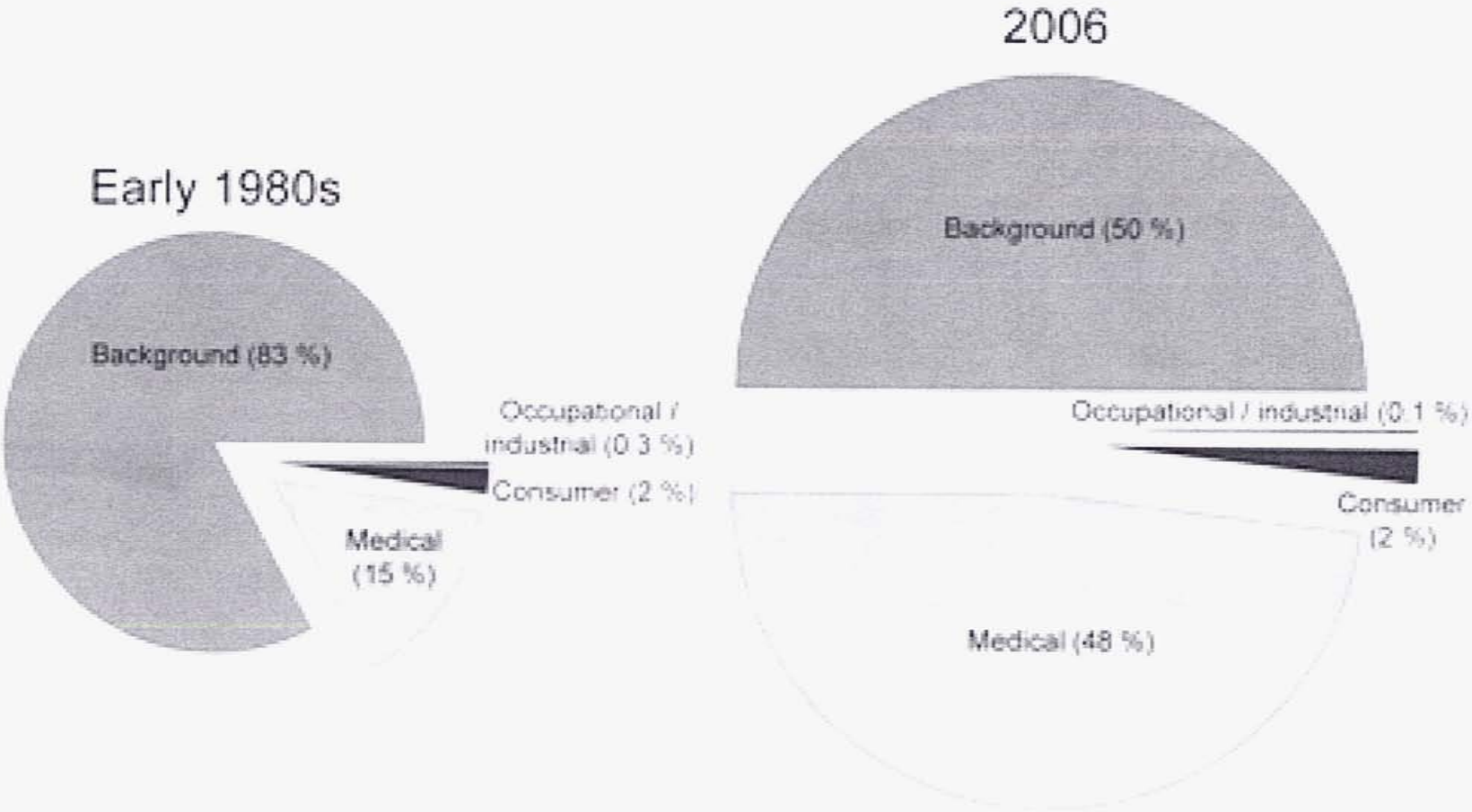
- Dirty Bombs

AVERAGE US POPULATION DOSES

- Natural Background ~ 295 mrem/yr
  - From body tissues, terrestrial and cosmic
- Man-made Sources ~ 312 mrem/yr
  - From products, medical and fallout
- Total ~ 600 mrem/yr

Note: statistics taken from NCRP Report #93 and #160

NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*



	Early 1980s	2006
Collective effective dose (person-Sv)	835,000	1,870,000
Effective dose per individual in the U.S. population (mSv)	3.6	6.2

BACKGROUND SUMMARY

- Doses are quite varied
- Medical can be quite high
- Tobacco is the wild card:
  Pack/day for a year 2-8 rem
- Statistics
  - Chance of dying of cancer ~20%
  - Chance of getting cancer 38-46%
  - 1000 mrem will increase chance of dying of cancer by 0.04%

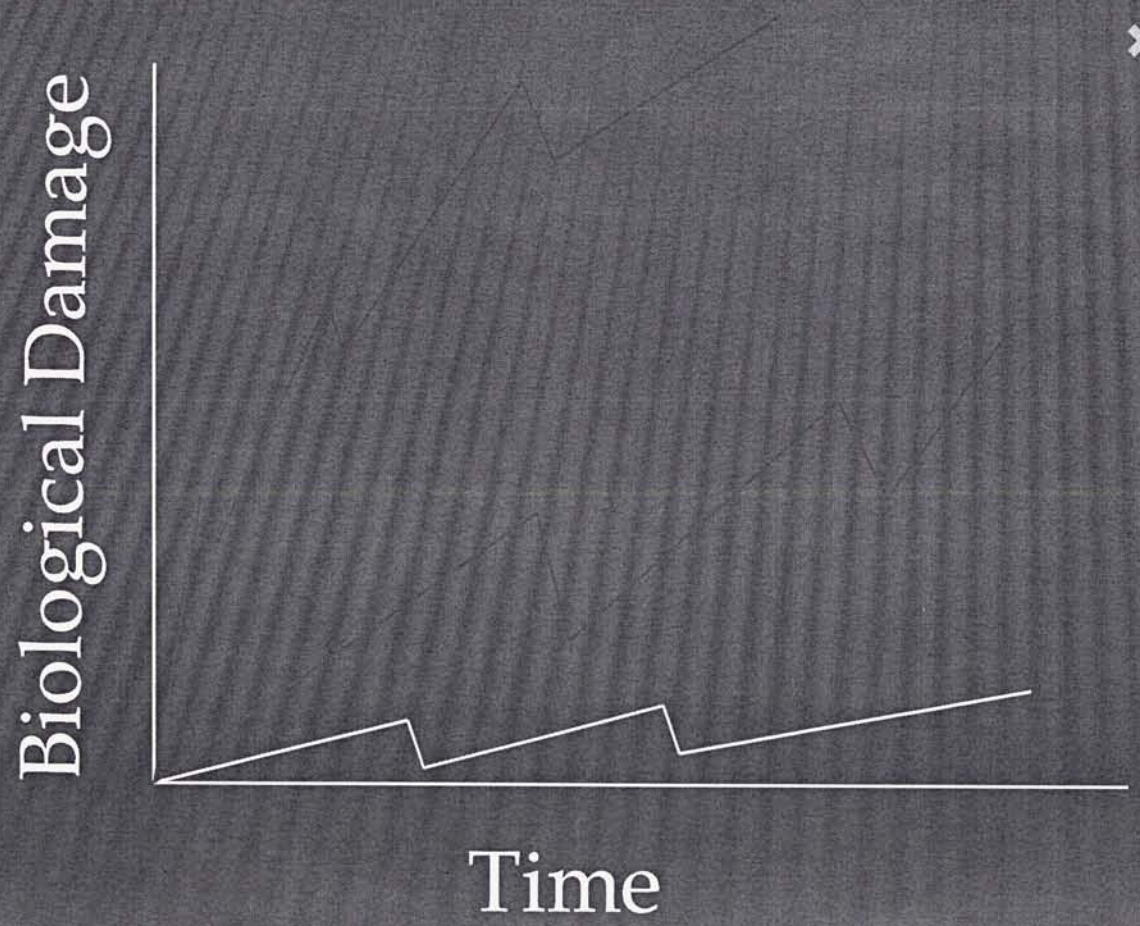
RADIATION BIOLOGY

- Free radicals
  - Unpaired/odd number of electrons
  - Estimated damage: G value
- Law of Bergonie and Tribondeau
- Acute versus chronic
- Threshold/Hormesis

RADIOSENSITIVITY OF CELLS

- The damage to cells depends on three factors:
  - Reproductive activity-as this increases, radiosensitivity increases
  - Mitotic activity-as the length increases, radiosensitivity increases
  - Differentiation-as this increases, radiosensitivity decreases

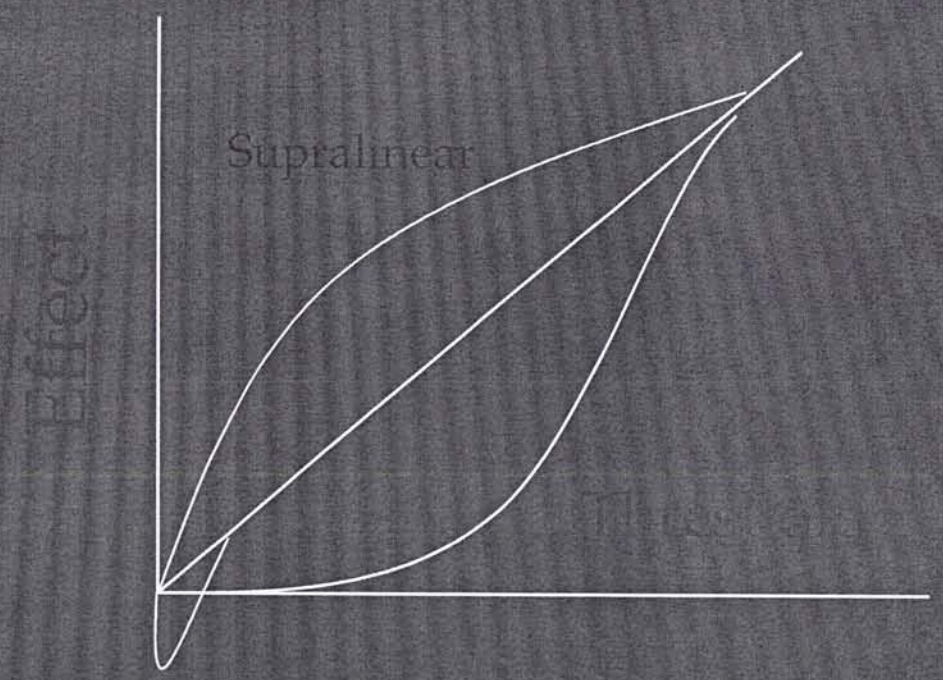
ACUTE/CHRONIC EXPOSURES



- Chronic exposures are less harmful as the cells have more time to repair

RADIATION EFFECTS AT LOW DOSES

- Linear--Assumes any exposure has some effect
- Threshold--Assumes that low doses have no effect
- Others
  - Hormesis
  - Supralinear



WHOLE BODY DEEP DOSE EFFECTS

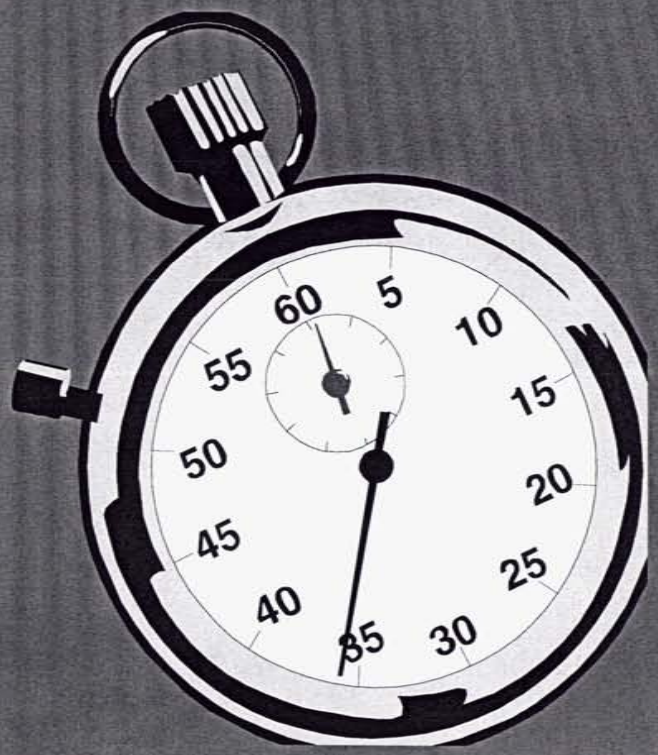
- 0-5 rem — No detectable effects
- 5-50 rem — Slight blood changes
- 50-100 rem — Blood changes, nausea, fatigue
- 100-200 rem — Above plus vomiting
- 200-450 rem — Hair loss, severe blood changes, some deaths in 2-6 weeks
- 450-700 rem — Lethal dose to 50% in 1 month
- 700-1000rem — Probable death within 1 month
- 5000 rem — Incapacitated, death in 1 week

LATENT (LONG TERM) EFFECTS

- Latent effects may result from doses that are within NRC dose limits
  - cancer-leukemia, thyroid, skin, bone, etc.
  - genetic effects-DNA mutations, chromosomal aberrations
  - cataracts
  - life shortening from increased rate of physiological aging

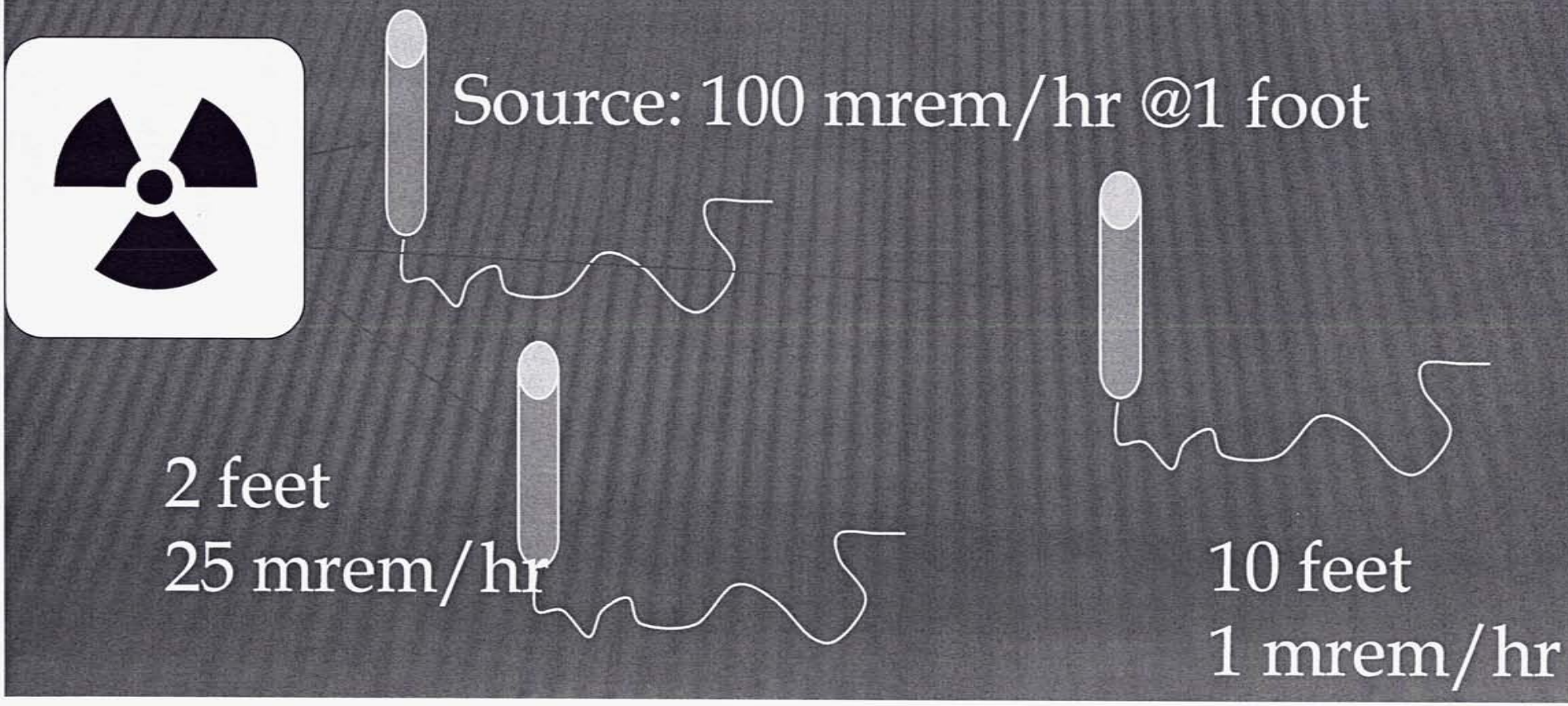
PROTECTION METHODS-TIME

- Dose rate x Time = Dose
- Minimizing time in radiation areas minimizes the dose



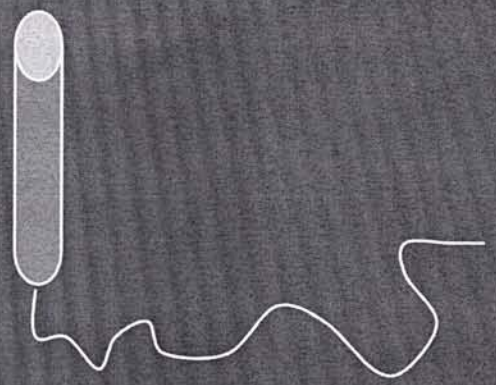
PROTECTION METHODS-DISTANCE

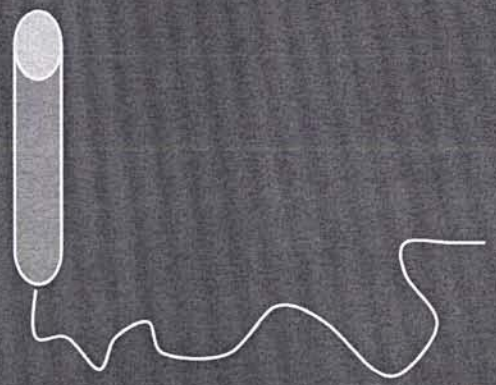
- Inverse square law



PROTECTION METHODS-SHIELDING

100 mrem/hr





One half value layer of material ($x_{1/2}$)

50 mrem/hr

MINIMIZE INTERNAL EXPOSURE (ALARA)

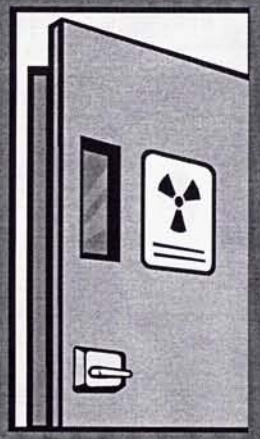
- The "Four I's" of personal contamination:

Inhalation Ingestion Injection Infection

- Identify potential routes of exposure, target organs, etc.
  - check MSDS and follow precautions
  - utilize engineering controls,then PPE as a last resort
- Prevent or minimize contamination

MINIMIZE INTERNAL EXPOSURE (ALARA)

- Contamination Control Measures
  - Restrict access (post room/area)
  - Good housekeeping
    - use secondary containment to minimize leakage
  - Utilize protective devices
    - Change gloves frequently
  - Wash hands regularly
  - Conduct regular surveys



MATERIAL CONTROL/INVENTORY

- Control of material-user responsibility
- Inventory of material
  - Must check every six months
  - Adjust for waste/receipt etc.
- Most important item during regulatory inspections
  - All materials must be secured from unauthorized access
  - Store in a locked area or in a locked freezer/refrigerator
  - Areas must be labeled

LABELING OF RADIOACTIVE MATERIALS

- Quantities in excess of Appendix C must be labeled
- Rooms containing in excess of 10x Appendix C must be labeled
- Appendix C (microcuries):

Hydrogen-3	1000
C-14, S-35, P-33, Ni-63, In-111	100
P-32	10
I-125, I-131	1

SURVEYING

- Use of instrument
- Where to survey
- Documentation of survey
- Frequency
  - License specification
  - After each use

SURVEY INSTRUMENTATION

- Geiger counter/meter
  - check calibration (annual)
  - check batteries (turn off when done)
  - take background reading
  - check with known source
  - check wires
- Wipe tests
  - Instrument for measurement (geiger, LSC)
  - Instrument information (LSC-energies, bkg, calibration)

WASTE DISPOSAL

- Control
- Minimize waste as much as possible
  - Examples: rinsing, trays, diapers
  - Disposal options are limited
  - Options currently open are closing, and others becoming more expensive
- Methods of disposal

EMERGENCIES AND ACCIDENTS

- Have a plan for various scenarios
- Train everyone involved
  - company response personnel, emergency response personnel, lab users
- Have materials ready-emergency kit

POSSIBLE SCENARIOS

- Contamination
- Personnel Contamination
  - External
  - Internal
- Personnel Exposures

DECONTAMINATION

- More that one person available
  - Cleaner, Surveyor, person to get supplies
- Locate all contamination and secure the area...consider the improbable
- Clean from one area to another
- Make sure you do not spread further
- Clean all that you can, contain what you can not

EXTERNAL CONTAMINATION

- Estimate amount on skin
- Decontaminate skin
  - Use warm water
  - Do not use abrasive materials
  - Avoid damaging the skin
  - Avoid eyes and mouth
- Question the individual
- Determine need for medical attention

INTERNAL CONTAMINATION

- Types
  - Ingestion
  - Inhalation
  - Injection
  - Absorption
- Ensure that material is contained
- Bioassay
- Determine need for medical attention

DOCUMENTATION OF INCIDENT

- Why document it?
- Information to include:
  - Extent of problem
  - Exact circumstances
  - Actions taken
  - Action to prevent recurrence
  - Dose estimates for all individuals
- Determine if it is reportable

R&D REPORTABLE EVENTS FOR 2009

- 250 microcurie P-32 package delivered to lab, lab says they never received it, never found
- 1 mCi of P-32 was delivered to lab, lab reported a week later that there was nothing in package
- 100 mCi of I-125 dose was spilled
- Lost 5 mCi of Cr-51 (container left with empty H-3 containers next to waste can)
- 3.7 mCi of I-125 mis-administered to cat (most on floor)

R&D REPORTABLE EVENTS FOR 2009

- Pinhole leak in Am-241 alpha source
  - Found 320 nCi, lost 526 nCi
- Two LSC Cs-137 sources found to be leaking
  - Manufacturer stated 8 year working life
- Drum received contaminated with Cm-244
- Loss of 24 mCi of H-3 due to improper inventory (inventory included 1000 containers)
- 55 mCi of C-14 released during incineration over 15 year period

OTHER REPORTS

- Electron Capture Detectors
  - Several were lost
  - More leaking sources
- Several other check/small sources were lost
  - Including many static eliminators
- Ra-226 smoke detectors put in dumpster
- Many instances with damaged/lost tritium exit signs (>100)
- Sr-90 check source found in mail at DFW
- Irradiator found leaking during source swap out

Certificate of Completion

awarded to

Daniel Reeder

for participation in

Radiation Safety Training – Las Vegas
February 2-4, 2010

ENGELHARDT & ASSOCIATES, INC.
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ABC LABORATORIES, INC

INTRODUCTORY TRAINING

Name: Daniel Reeder

	Instruction	Instruction By Initial/Date	Qualification Approved by Initial/Date	Comments
Safety Seminars	Emergency Response	JBA 29 Jan 08	SCH 15 May 08	
	Glassware and Cylinder Handling			
	Fire Safety Equipment	JBA 29 Jan 08	SCH 15 May 08	
	Electrical Safety	JDW 1 Feb 08	SCH 15 May 08	
	Hazard Communication	JBA 29 Jan 08	SCH 15 May 08	
Introduction to GXP				
Overview of Q7A				
Overview of 21CFR211				
Correct method of amending raw data entries				
Importance of proper identification of sample entries				
Importance of accurate record keeping				
Training Records	TF 28 Jan 08	SCH 15 May 08		
Good Documentation Practices	TF 28 Jan 08	SCH 15 May 08		
Safety Training	JBA 29 Jan 08	SCH 15 May 08		
Rad Safety Orientation	SCH 28 Jan 08	SCH 15 May 08		
Bloodborne Pathogens	JBA 31 Jan 08	SCH 15 May 08		
Intro to GLP	KDL 11 Feb 08	SCH 15 May 08		
Intro. to CGMP's at ABC Labs Power Point Presentation	[illegible] 08 Feb 08	SCH 15 May 08		
CPR First Aid American Heart	[illegible] 24 May 09	SCH 11 Dec 09		
DOT Hazardous Material Update	Kristie Cook Absher 28 Apr 10	TW 04 AUG 10		
Training for Isotope Users	Josh Walkowicz 6 July 10	TW 04 AUG 10		

Form PM-GN 3.000

ABC LABORATORIES, INC.

RECORD OF CONTINUING TRAINING

Name: David Cozad

YEAR 2010

Training Documentation

Training	Instruction By Initials/Date	Approved Initials/Date	Comments
GLP Refresher (Bi-annually)			
GMP Refresher (Annually)			
Radiation Safety* (Annually)			
DEA Training*			
Blood-borne Pathogen (Annually)			
Training for Isotope users.	JW 06 July 2010	TWB 04 AUG 10	

YEAR _____

Training Documentation

Training	Instruction By Initials/Date	Approved Initials/Date	Comments
GLP Refresher (Bi-annually)			
GMP Refresher (Annually)			
Radiation Safety* (Annually)			
DEA Training*			
Blood-borne Pathogen (Annually)			

**Optional depending upon position*

Additional Comments:

Form PM-GN 10.003