National Aeronautics and Space Administration

# NASA Triennial Health Physics Meeting

## Office of the Chief Health and Medical Officer

## April 19 - 21, 2011

**Glennan Conference Room**
**NASA Headquarters**
**Washington DC**

www.nasa.gov

**NASA 2011 Triennial Health Physics Meeting**

In cooperation with the NASA Senior Environmental Health Officer, the Agency Occupational Health Support Office planned and executed The Triennial Health Physics Meeting for the Office of the Chief Health and Medical Officer (OCHMO). The focused meeting designed specifically for the Professional Development and Continuing Education of the NASA Health Physics Community was held in the Glennan Assembly Room at NASA Headquarters in Washington, DC April 19-21, 2011.

This directed training and professional development event focused exclusively on the enhancement of the NASA Radiation Protection Community and included presentations by NASA internal experts as well as several experts from other federal agencies including Environmental Protection Agency (FAA), Department of Homeland Security (DHS), Federal Aviation Administration (FAA), Occupational Safety and Health Administration (OSHA), Department of Defense (DoD), Nuclear Regulatory Commission (NRC), Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA). Continuing education credits were awarded by the American Board Of Health Physics, the Board of Laser Safety, and the American Board of Industrial Hygienists. Twenty-two attendees representing all NASA Centers and Facilities (except JSC, WSTF, MAF, and WFF) participated in the three-day meeting.

In general the agenda was organized to cover the major areas of NASA Health Physics Programs: sources of ionizing radiation, radiofrequency radiation, and lasers. Complementary topical areas were grouped together. Ionizing radiation safety talks were planned for the first day. Nuclear and non-NASA federal agency talks were planned for the second day. Laser safety topics dominated the third day. Specific training was provided on Radio Frequency Safety by the U.S. Army Institute of Public Health (formerly US Army CHPPM) and Mishap & Close-Call Reporting and Investigation by the Acting NASA Mishap Investigation Program Manager. Off site lectures at the National Institutes of Health (NIH) and the National Institute of Standards (NIST) and technology provided NASA health physics professionals insight into the management of Radiation Protection Programs at two other NRC licensed facilities that, like NASA, are also agencies of the Federal Government.

## NASA Triennial Health Physics Meeting

**TUESDAY, APRIL 19**

| | | |
|---|---|---|
| 7:55 | 8:00 | **Welcome**<br>Cathy Angotti, Director, Occupational Health<br>Office of the Chief Health and Medical Officer (NASA Headquarters) |
| 8:00 | 8:20 | **Agency Health Physics Update**<br>Guy Camomilli, Senior Environmental Health Officer<br>Office of the Chief Health and Medical Officer (NASA Headquarters) |
| 8:20 | 8:50 | **Radiation Effects Facility Irradiator Upgrades**<br>Daniel Simpson, Radiation Safety Officer<br>Goddard Space Flight Center (NASA) |
| 8:50 | 9:05 | WITHDRAWN |
| 9:05 | 9:20 | Break |
| 9:20 | 9:35 | **Irradiator Project Lessons Learned**<br>Gloria Mar, Radiation Safety Engineer<br>Jet Propulsion Laboratory (California Institute of Technology) |
| 9:35 | 10:30 | **Health Physics Assessments for X-Ray Scanner Devices**<br>John Cardarelli, PhD, CHP<br>Occupational Safety Program Office<br>U.S. Environmental Protection Agency |
| 10:30 | 11:15 | **Health Physics Evaluations for Medical and Analytical X-Ray Devices**<br>Marcum Martz, CHP, Radiation & Laser Safety Officer<br>Occupational Safety Program Office<br>Jet Propulsion Laboratory (California Institute of Technology) |
| 11:15 | 11:45 | **GRC Cyclotron Decommissioning**<br>Gerald Wood, Radiological Engineer<br>Plum Brook Research Reactor Decommissioning Project (SAIC) |
| 12:00 | 1:00 | Lunch |
| 1:00 | 2:45 | **RF Radiation Safety Training**<br>Brad J. Roberts, Electronics Engineer<br>Radio Frequency Program<br>US Army Institute of Public Health<br>U.S. Department of Defense |
| 2:45 | 4:30 | **Mishap & Close-Call Reporting & Investigation Training**<br>Gerald Schumann<br>Office of Safety & Mission Assurance (NASA Headquarters) |

## NASA Triennial Health Physics Meeting

**WEDNESDAY APRIL 20**

| | | |
|---|---|---|
| 8:00 | 8:30 | **Major Source Launch Contingency Planning**<br>Randall Scott, Radiation Protection Officer<br>Kennedy Space Center (NASA) |
| 8:30 | 9:15 | **Interagency Nuclear Safety Review Process (INSRP)**<br>John Lyver, PhD & Peter Prassinos<br>NASA Office of Safety and Mission Assurance (NASA Headquarters) |
| 9:15 | 10:00 | **Responding to Nuclear Terrorism**<br>Brooke Buddemeier, Certified Health Physicist<br>Global Security Directorate<br>Lawrence Livermore National Laboratory |
| 10:00 | 10:15 | Break |
| 10:15 | 11:00 | **Excellence in Radiation Protection Programs**<br>Donald Cool, PhD, Senior Advisor, Radiation Safety and International Liaison<br>Federal and State Materials and Environmental Management Programs<br>U.S. Nuclear Regulatory Commission |
| 11:00 | 11:30 | **Update on the NRC's Tritium Exit Sign Demand for Information**<br>Angela McIntosh<br>Federal and State Materials and Environmental Management Programs<br>U.S. Nuclear Regulatory Commission |

## NASA Triennial Health Physics Meeting

**THURSDAY APRIL 21**

| | | |
|---|---|---|
| 8:00 | 8:45 | **MOBLAS-7 Lessons Learned**<br>Patrick Hancock , Deputy Division Chief,<br>Occupational Safety & Health Division<br>Goddard Space Flight Center (NASA) |
| 8:45 | 9:30 | **Laser Lessons Learned**<br>Kim Merritt, Radiation & Laser Safety Officer<br>Langley Research Center (Safety & Quality Assurance Alliance) |
| 9:30 | 9:45 | Break |
| 9:45 | 10:30 | **OSHA Radiation Protection Program Activities**<br>Sven Rundman, Senior Industrial Hygienist<br>Office of Health Enforcement<br>Occupational Safety and Health Administration<br>U.S. Department of Labor |
| 10:30 | 11:15 | **Exemptions from FDA Laser Regulations**<br>Patrick Hintz<br>Center for Devices and Radiological Health<br>Food and Drug Administration<br>U.S. Department of Health and Human Services |
| 11:15 | 12:00 | **ANSI Z136.6 Outdoor Laser Safety Updates**<br>Robert Aldrich, Laser Safety Specialist<br>Lead Naval Technical Laboratory for Laser Safety<br>U.S. Department of Defense |
| 12:00 | 12:45 | Lunch |
| 1:00 | 3:00 | **Optical Radiation: An Overview of Biological Effects and Exposure Limits**<br>David Sliney, PhD<br>Consultant |
| 3:00 | 3:15 | Break |
| 3:15 | 4:15 | **Agency Outdoor Laser Coordination**<br>Kelly J. Neubecker, Esq<br>Airspace and Rules<br>Federal Aviation Administration<br>U.S. Department of Transportation |
| 4:15 | 4:30 | **Closing Remarks**<br>Guy Camomillli, Senior Environmental Health Officer<br>Office of the Chief Health and Medical Officer (NASA Headquarters) |

# 2011 Triennial HP Meeting
# Washington DC

Guy Camomilli

April 19, 2011

# 4 NASA HP Meetings
## (Then and Now)

- Annapolis MD – October 2- 5, 2000
- Cocoa Beach FL – June 6-10, 2005
- Cocoa Beach FL – May 12-16, 2008
- Washington DC – April 26-28, 2011
- Improvements

# Annapolis MD – 2000

- 5 Center Presentations
- CHPPM Nonionizing Training
- KSC Support for Cassini
- Technical Tour of GSFC

# Cocoa Beach FL – 2005

- Disney Technical Tour
- NRC Presenter
- SAM 935
- RF Training
- NASA HP Policy
- Pluto New Horizons

# Cocoa Beach FL – 2008

- ABHP Certification Course
- Technical Tour of KSC
- FAA Presentation

# Washington DC - 2011

- Hopes and Expectations
- Meeting Overview
- Credits
- Attendees

# Improvements

- Meetings/ViTS/WebEx
- Qualifications
- Policy
- Professional Community

# Welcome

2011 Triennial HP Meeting

Washington DC

# Summary

**Radiation Effects Facility Irradiator Upgrades**

This presentation described the challenges of working with high activity sources during the project to increase the strength of a center irradiator. Much of the material presented is Sensitive Information and unavailable for distribution to attendees.

Dan Simpson, GSFC Radiation Safety Officer

daniel.s.simpson@nasa.gov

**Irradiator Project Lessons Learned**

This presentation conveyed aspects of a new source installation and the radiation safety challenges experienced at another NASA site.

Gloria Mar, JPL Radiological Safety Engineer

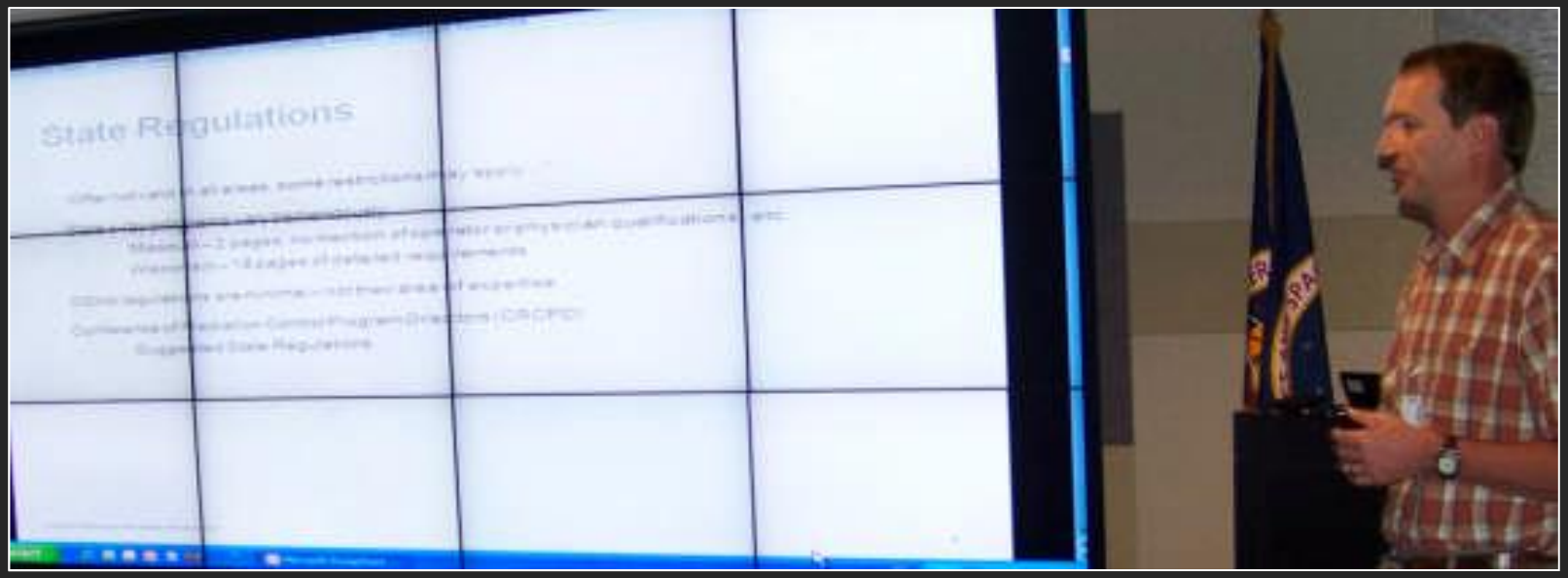
Gloria.d.mar@jpl.nasa.gov

**Health Physics Assessments for X-Ray Scanner Devices**

This talk had high value because of the many types of x-ray devices at NASA Centers. The presenter not only addressed the typical NASA devices, but also discussed assessments and hazards associated with standard airport scanners and the controversial new millimeter wave and backscatter devices presently being deployed in US airports through which NASA employees pass while on travel.

John Cardarelli, PhD, CHP/CIH, U.S. EPA

cardarelli.john@epa.gov

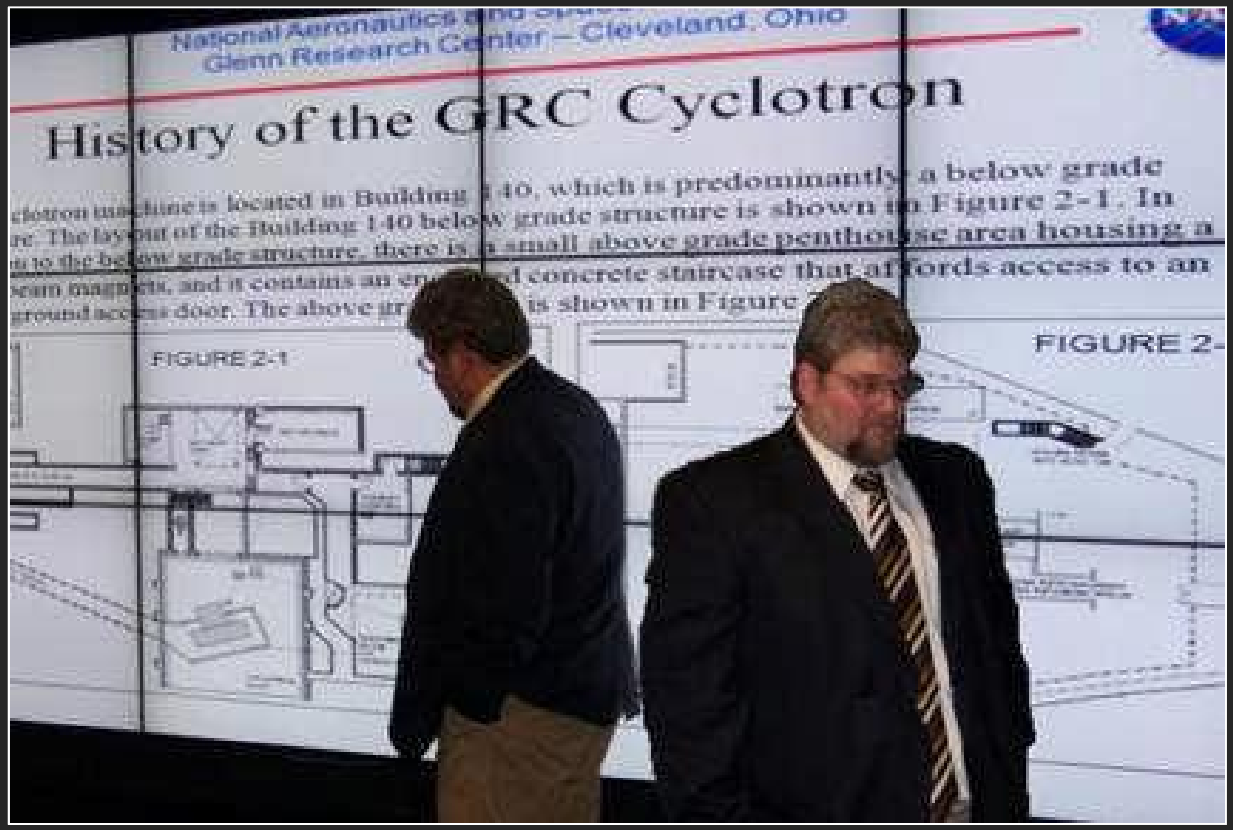



**Health Physics Evaluations for Medical and Analytical X-Ray Devices**

An important component of the medical x-ray QA is the health physics assessment. Marc also addressed to a lesser extent health physics evaluations for analytical x-ray devices at NASA Centers.

Marcum Martz, CHP, RSO/LSO, JPL

**Marcum.martz@jpl.nasa.gov**




**GRC Cyclotron Decommissioning**

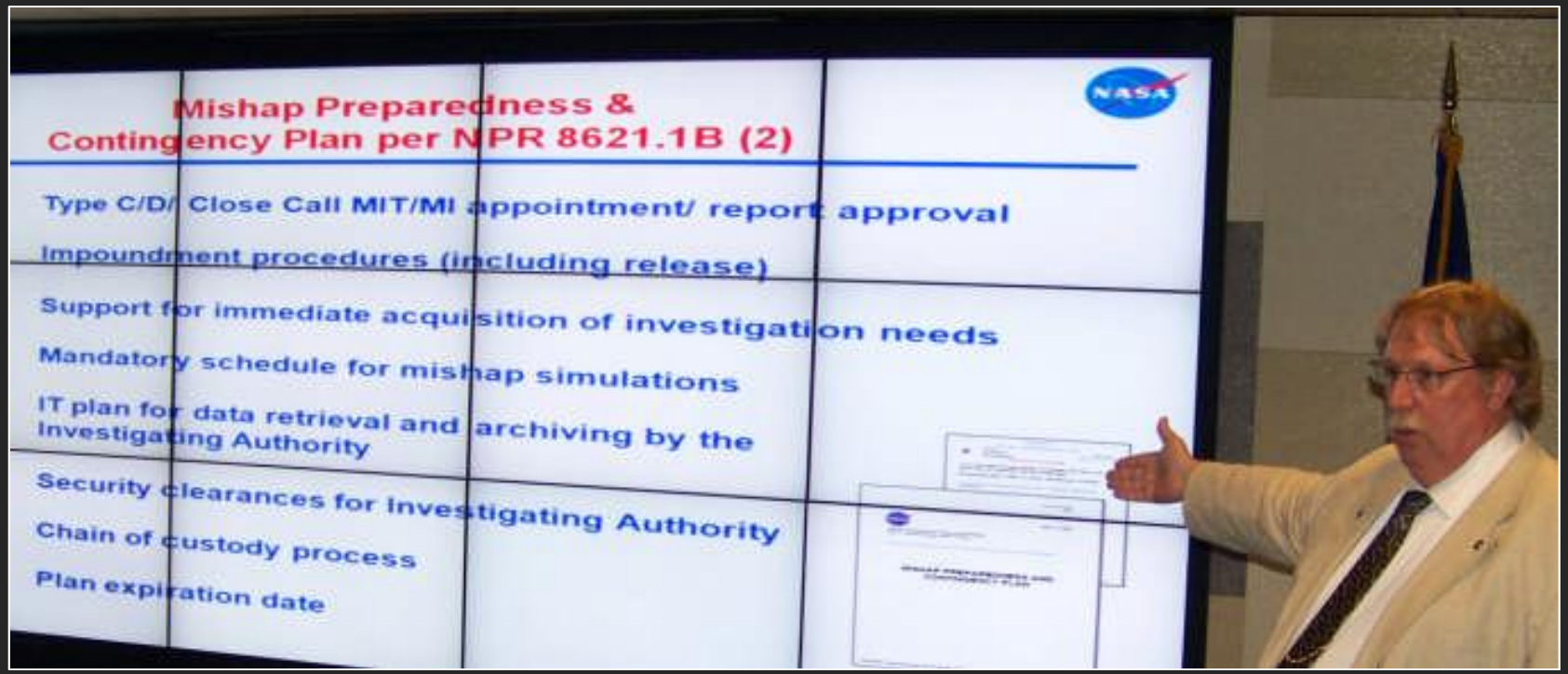
As the GRC reactor facility decommissioning project enters into its final phase prior to license termination the experienced workforce is transitioned to the cyclotron to begin the initial phases of its decommissioning, site characterization.

Gerald Wood, Radiological Engineer - Plum Brook Decommissioning Project
gerald.l.wood@nasa.gov

**RF Safety Training**

Formerly known as CHPPM, the Institute of Public Health Command provided expert training on the IEEE Standards C95.1 and C95.7 which form the bases for NASA radiofrequency safety program requirements.

Brad J. Roberts, Radio Frequency Program, US Army Institute of Public Health
brad.roberts@us.army.mil




**Mishap Overview Training**

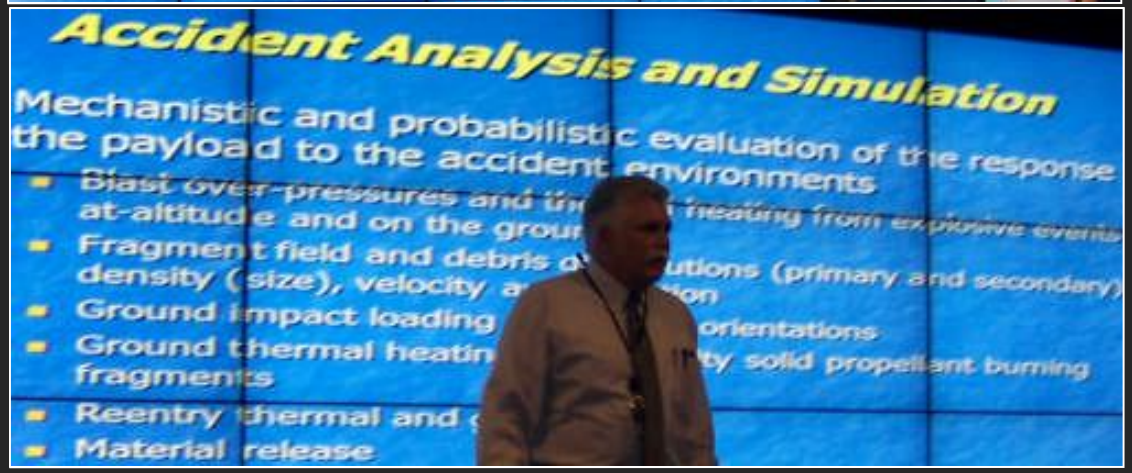
This training was intended to provide attendees with an introduction to the tools needed to respond to mishaps involving radiation sources and complement the two center presentations which deal with circumstances surrounding and corrective actions for actual laser mishaps.

Gerald Schumann, NASA Mishap Program Manager, OSMA
gerald.d.schumann@nasa.gov

**Major Source Launch Contingency Planning**

Beginning the day after Thanksgiving this year the window opens for NASA to launch the Mars Science Laboratory with the Curiosity rover and its Plutonium 238 multi-mission radioisotope thermoelectric generator (MMRTG) aboard an Atlas 5 rocket. This discussion detailed the radiological contingency plans to be implemented should a launch anomaly cause the release of radioactive materials.

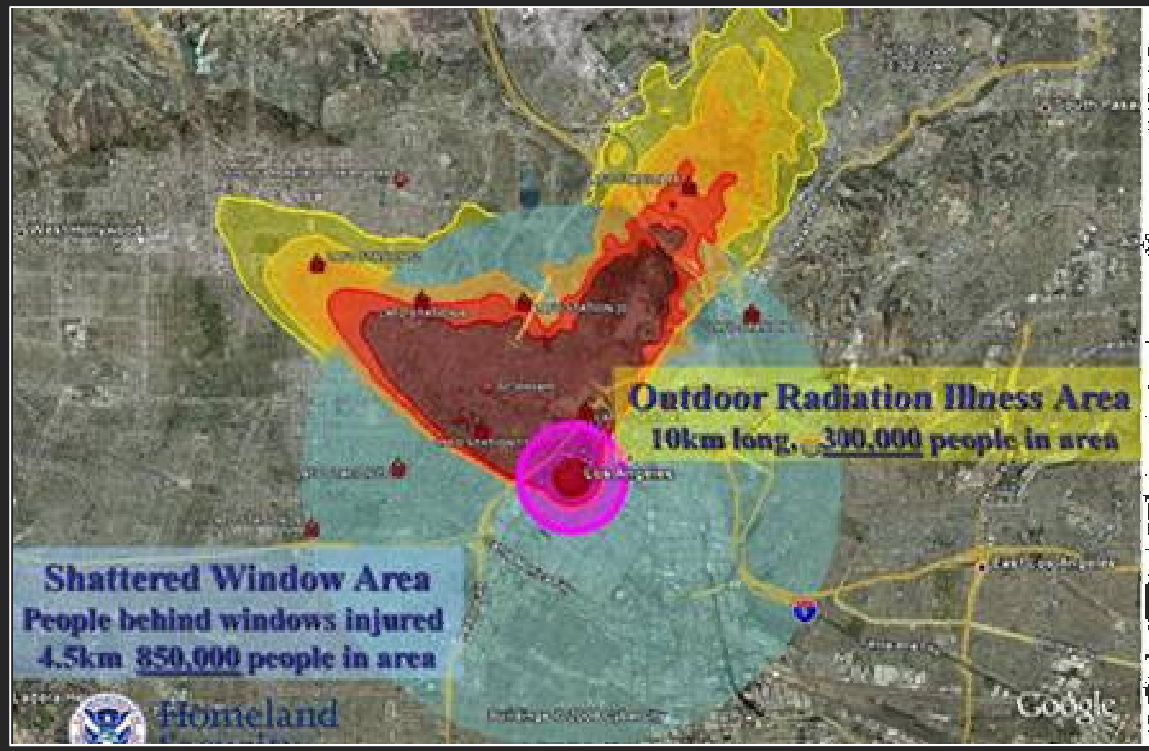
Randall Scott, KSC Radiation Protection Officer
randall.e.scott@nasa.gov

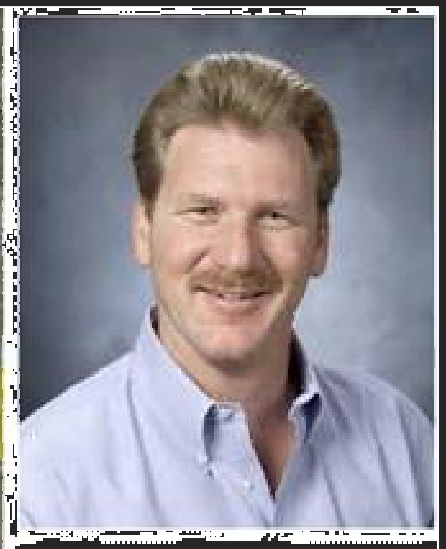



**Interagency Nuclear Safety Review Process (INSRP)**

This two part presentation addressed NASA's decades of experience assessing safety prior to launching major radiological sources into space and provided perspective that complemented the KSC launch accident contingency plans discussed by Randy Scott .

John Lyver, PhD and Peter Prassinos, OSMA
jlyver@nasa.gov and peter.g.prassinos@nasa.gov



**Responding to Nuclear Terrorism**

Since the events of September 11, 2001 the U.S. Government has done extensive research into the effects of a domestic detonation of an improvised nuclear device. This briefing provided detailed information about blast effects, fallout patterns, and structural shielding characteristics to provide NASA radiation protection specialists with a unique professional development opportunity.

Brooke Buddemeier, CHP, Lawrence Livermore National Laboratory
brooke2@llnl.gov

**Excellence in Radiation Protection Programs**

The duel objectives in planning this presentation were to convey important NRC expectations for management of radioactive materials to the NASA RSOs and to strengthen existing relationships with NRC regulators.

Donald Cool, Senior Advisor, NRC
donald.cool@nrc.gov

**Update on the NRC's Tritium Exit Sign Demand for Information**

This tritium exit sign talk had two objectives, to provide follow-up information associated with a significant NASA radioactive material inventory effort of early 2010 and also to strengthen existing relationships with the NRC regulators.

Angela McIntosh, U.S. NRC
angela.mcintosh@nrc.gov

**NIH HP Program**

Classroom lectures and a visit to the radioactive and mixed waste operations facility at the National Institutes of Health campus gave NASA radiation safety professionals insight into another Federal Agency's management of radioactive materials under an NRC license.

Robert Zoon, NIH Director of the Division of Radiation Safety zoonr@ors.od.nih.gov

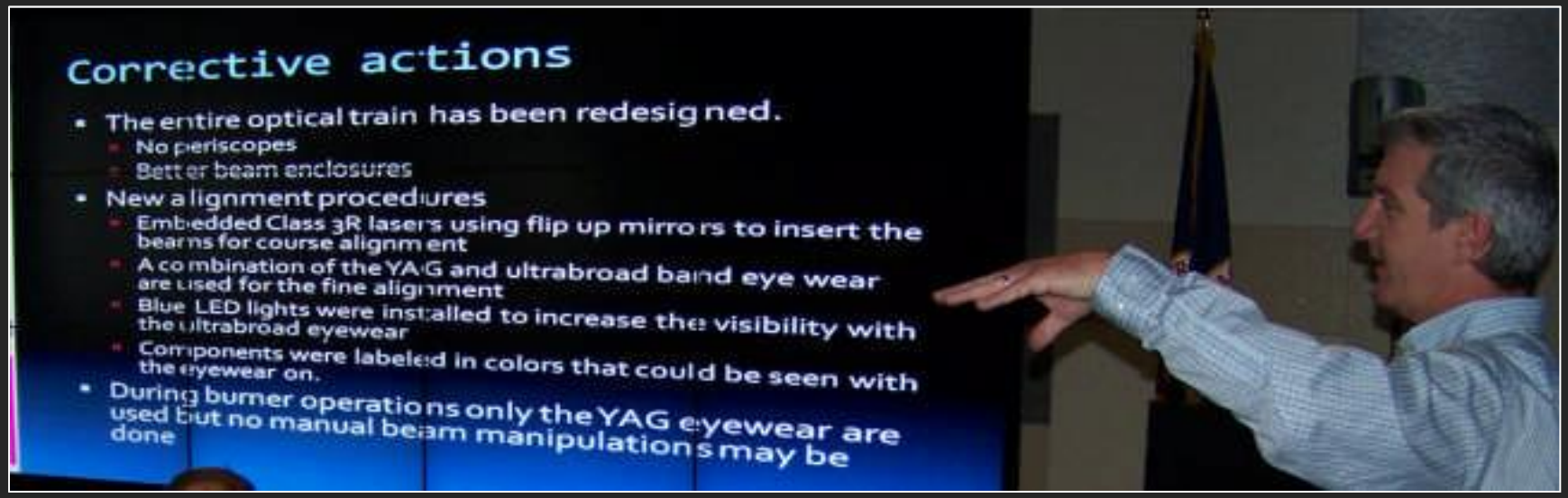
Nancy Newman, NIH RSO newmann@mail.nih.gov

**NIST HP Program**

thomas.obrien@nist.gov Classroom lecture and visits to the Vertical Beam Irradiator, Neutron Source Calibration, and Neutron Source Calibration facilities gave attendees additional insight into a second Federal Agency's management of radioactive materials under an NRC license. The three PhDs that talked about their areas of expertise were: Vertical Beam Irradiator Tour (hosted by Dr Ronnie Minnitti, Neutron Source Calibration Facility Tour (hosted by Dr Scott Dewey), and Neutron Instrument Calibration Facility Tour (hosted by Dr. Alan Thompson). The classroom lecture also complemented presentations from the 2009 Occupational Health Meeting in Cleveland with a discussion of the investigation and root cause of the plutonium spill at the NIST laboratory in Boulder, Colorado. Our host was Thomas O'Brien, CHP, Radiation Safety Officer, NIST

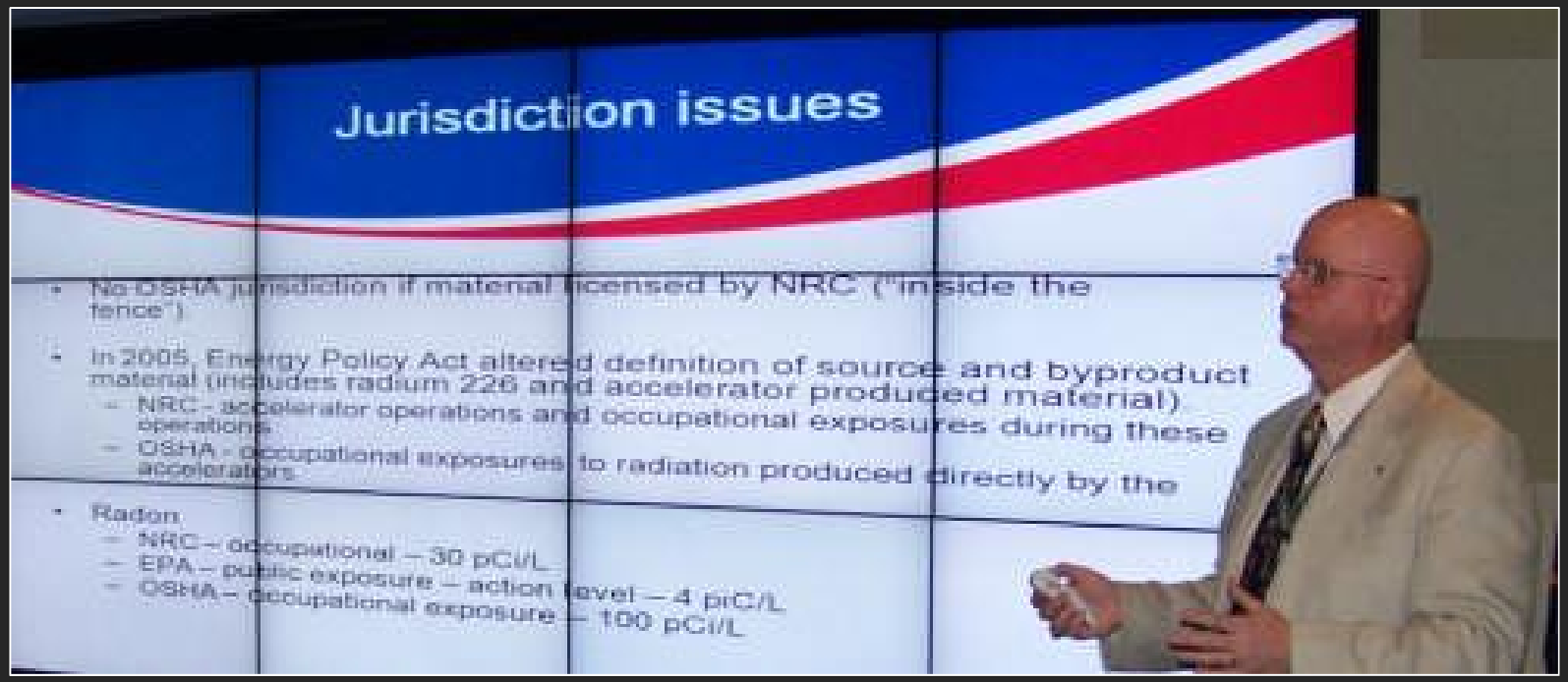
**MOBLAS-7 Lessons Learned**

patrick.a.hancock@nasa.gov The objective of this presentation was to provide NASA radiation safety professionals with an understanding of the circumstances that led to the failure of engineering controls and an unintentional illumination of an aircraft and the corrective action that NASA and FAA officials approved to restart operations. Everyone believes that an accident can't happen at their well-engineered site until it does; especially one with 20 years of safe operating experience. Ted Simmons helped Patrick put this together. This was Patrick's third NASA HP Meeting. Patrick Hancock, GSFC



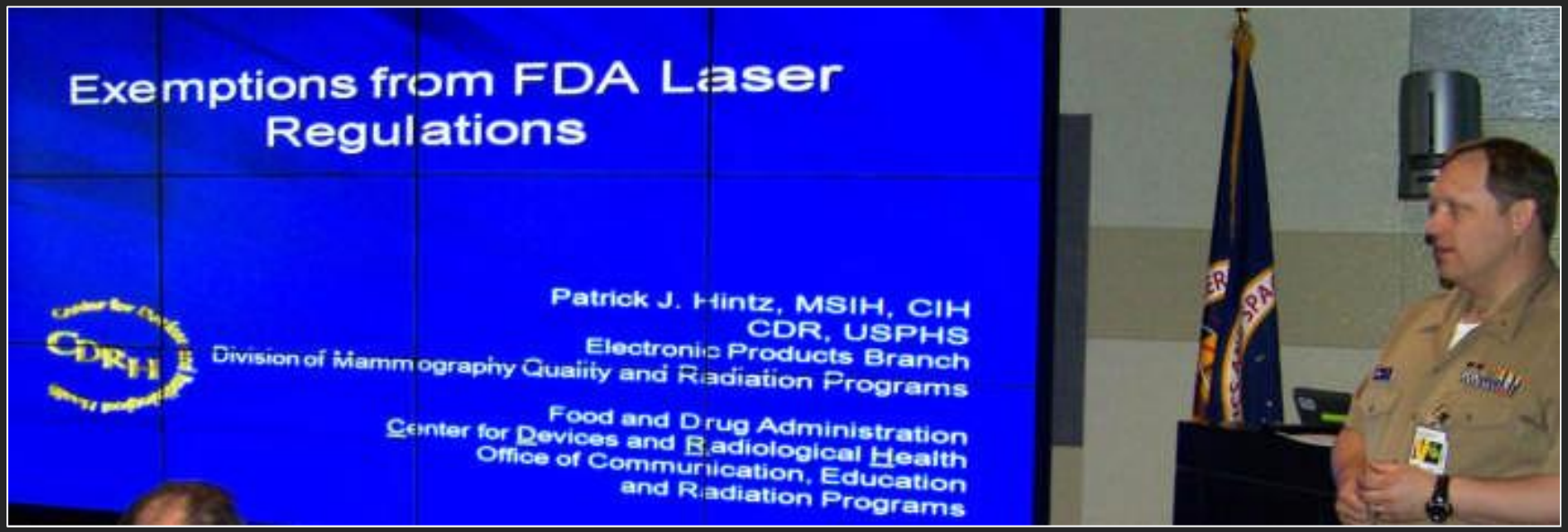

Lessons Learned from Langley Laser Accident

Kim Merritt, Radiation & Laser Safety Officer, Langley Research Center (Safety & Quality Assurance Alliance). This laser accident is significant because it resulted in permanent injury to the researcher. The Center LSO investigated and reports the conditions that led to the accident and provides **recommendations** for other LSOs to prevent a recurrence of this type of accident at other NASA Centers. This presentation was planned to complement the GSFC MOBLAS-7 laser mishap and Mishap Training provided by the NASA Mishap Program Manager.



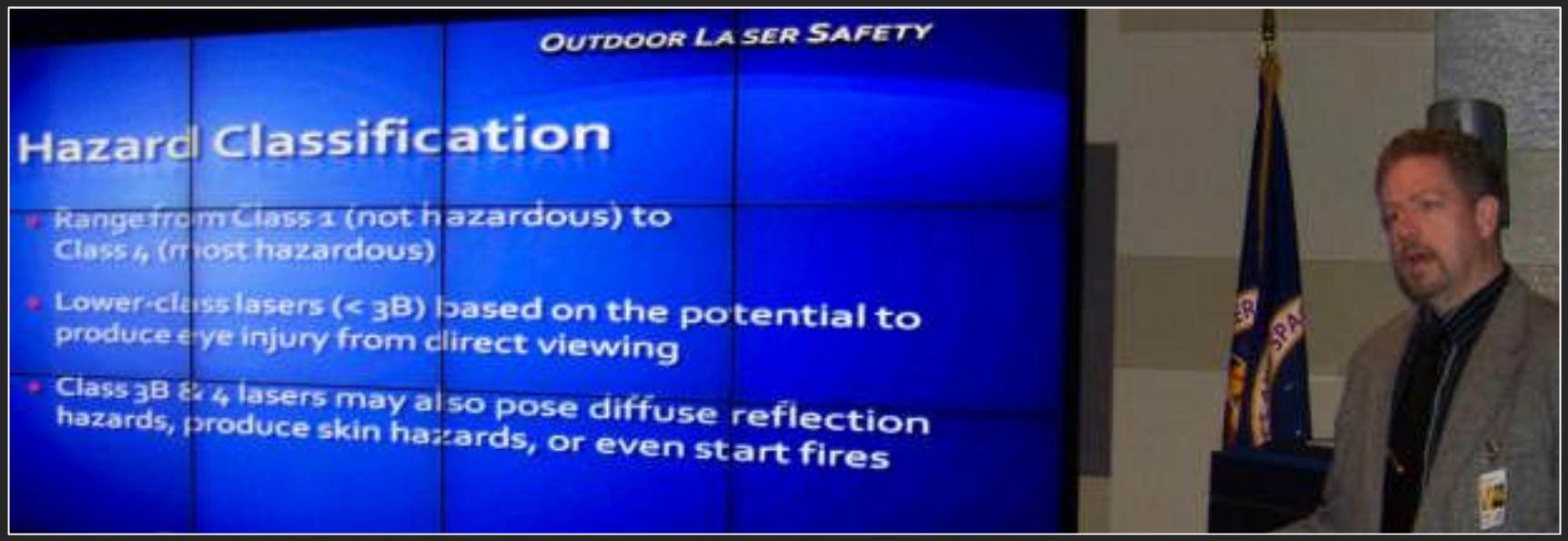

**OSHA Radiation Protection Program Activities**

rundman.sven@dol.gov In addition to NRC regulations, NASA ionizing and non-ionizing radiation source uses are subject to OSHA requirements in Title 29 Code of Federal Regulations Parts 1910.1096, 1910.97, and 1926.54. In recent years OSHA considered updating its rules for ionizing radiation which are based on outdated standards. This presentation provided an update on current activities in OSHA's Radiation Protection Program.



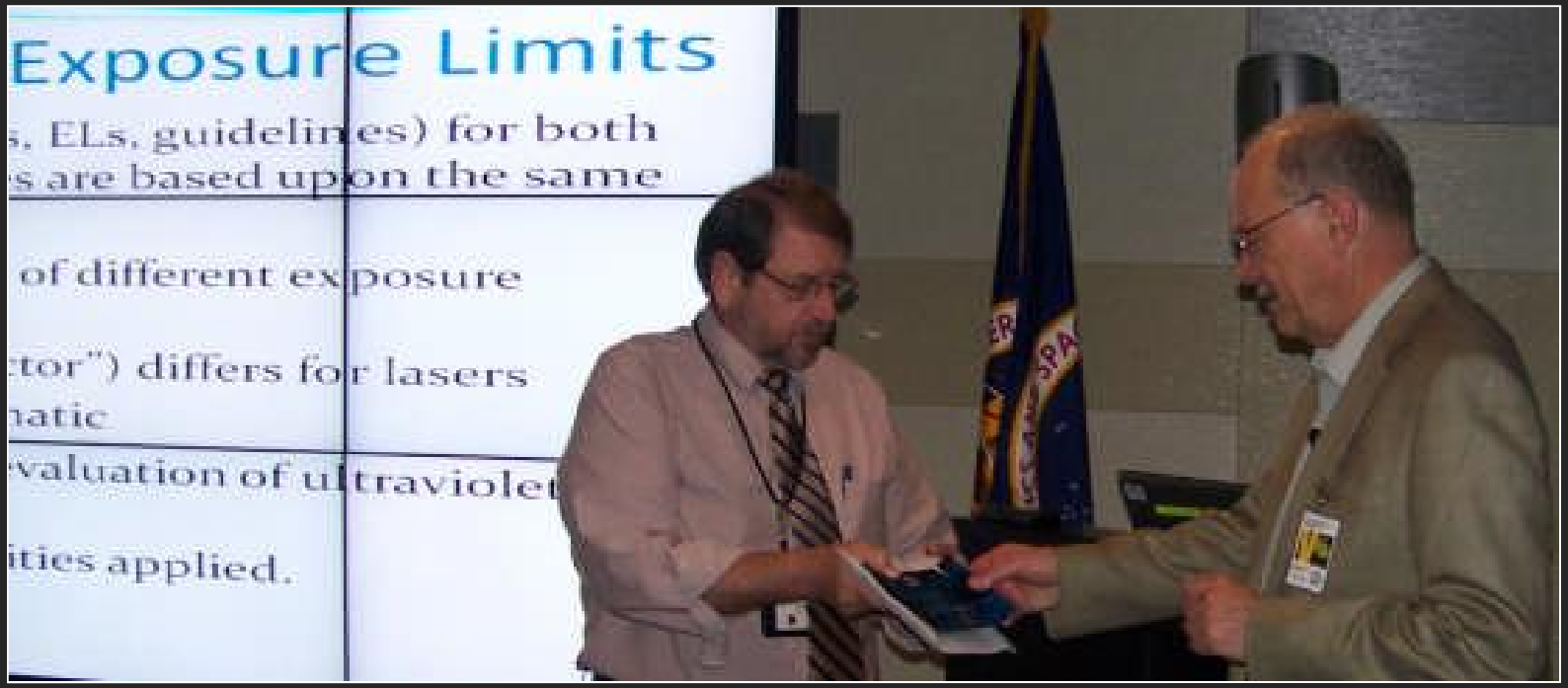

**Exemptions from FDA Laser Regulations**

patrick.hintz@fda.hhs.gov Patrick first approached me about this topic at an SAE G10-T meeting. Unique laser systems designed for NASA science missions and R&D should not be held to the Federal Laser Products requirements. Center LSO's can work with him directly. Patrick Hintz, Center for Devices and Radiological Health, FDA




**ANSI Z136.6 Updates**

robert.c.aldrich@navy.mil Another contact made through the SAE G10-T group. Robert gave great background into the need for and technical bases for the Safe Use of Lasers Outdoors ANSI standard that NASA incorporates as an NPR 1800.1 requirement by reference. Robert Aldrich, Lead Naval Technical Laboratory for Laser Safety, U.S. Navy




**Optical Radiation: Overview of Biological Effects and Exposure Limits**

david.sliney@att.net This is the second time in recent years that Dr. Sliney addressed our group. Previously he talked at the OH Conference Plenary and HP breakout in Lake Tahoe. Despite the existence of safety standards and regulations, accidental eye and skin injuries still occur. Accidents are most frequently attributed to the lack of understanding of hazards and safety procedures. This course summarized optical radiation bioeffects and discussed the exposure limits established by the International Commission on Non-Ionizing Radiation Protection and the similar Threshold Limit Values (TLVs) of the American Conference of Governmental Industrial Hygienists. David Sliney, PhD, Consulting Medical Physicist.

**Agency Outdoor Laser Coordination**

kelly.neubecker@FAA.GOV Proper coordination of outdoor laser use proposals is essential to preventing delays to airborne and ground-based laser science missions. A thorough discourse of the FAA's processing procedures provided attendees the keys to more effectively coordinate with the FAA and OCHMO. Kelly Neubecker, FAA

# Presentations

National Aeronautics and Space Administration
Goddard Space Flight Center

# Radiation Effects Facility Irradiator Upgrades

Dan Simpson
Radiation Safety Officer

Presentation Unavailable

Gloria D. Mar
Jet Propulsion Laboratory
California Institute of Technology

April 19, 2011

# Irradiator Project

## Lessons Learned

- Conduct weekly meetings (initially) months in advance and daily meetings the week before, schedule site visit with irradiator vendor (for core members and support team)
- Coordination between multiple groups and contractors
- Create action item list with name(s) of responsible party
- Open channel of communication
- Constant follow-up on status updates
- Conduct walk-through (facility and transportation route) with contractors at least two months prior to irradiator arrival
- Provide ample time for requesting and reviewing Site Specific Safety Plan (SSSP), Critical Lift Plan, Injury Illness Prevention Plan (IIPP), Travel Plan, and Transportation Plan

# Irradiator Project

## Lessons Learned

- Check utility lines [Re-routed overhead utility lines (A/C and heating lines) inside test cell due to limited overhead space for irradiator]
- Clear area and rope off others for supplies/lift storage/movement, restrict access with guard during irradiator activities
- Update property asset on NASA books
- Special Permit Authorization approval from U.S. NRC and DOT to use GE Model 1500 Container months in advance
- Ensure personnel are T&R'ed and comply with Increased Controls
- Monitor radiation levels continuously during source transfer operations
- Research other activities on-site week of irradiator install e.g. Athlete, shuttle routes, and road closures due to flight hardware

# Irradiator Project

## Lessons Learned

# Irradiator Project

## Sequence of Events

# Irradiator Project

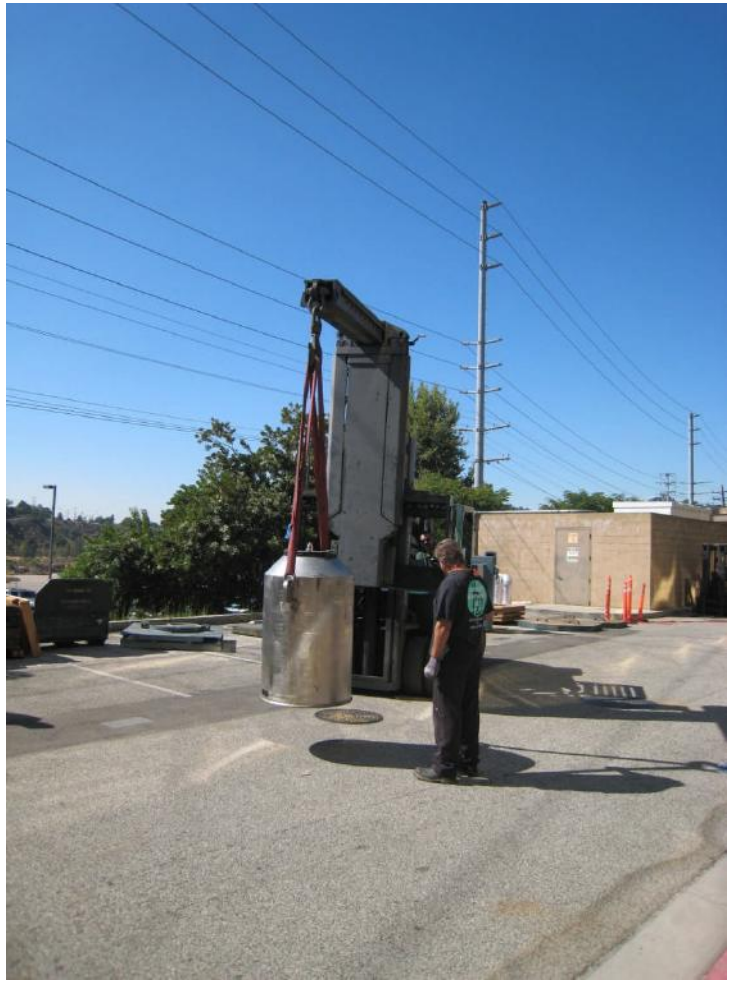
## Source, irradiator shield, tower, pneumatic and control panels arrived at JPL

# Irradiator Project

## Shipping Container from GE – Approval received from U.S. NRC and DOT

# Irradiator Project

## Movement of new source to High Dose Rate Facility



# Irradiator Project

## New source moved from inner shipping container to transfer shield (show video)

# Irradiator Project

## Irradiator set up in Test Cell

# Irradiator Project

## Transfer shield (with source) along with irradiator shell moved to Test Cell

# Irradiator Project

## Operating tower assembly mounted on irradiator and electrical panel/air lines connected

# Decommissioning Old Source

## Source transferred to transfer cask and into GE shipping container

A

B

C

# Irradiator Project

## Old source in shipping container moved to truck bed and relocated off-site

# Radiation Shielding Design, Verification and Quality Assurance Testing for Diagnostic, Cabinet and Analytical X-Ray Machines

Marc Martz, CHP

Gloria Mar, MS

Don Farley, MS, DABMP

# Background – Regulatory Authority

- Atomic Energy Act of 1954 (and subsequent Energy Reorganization Act of 1974)

  Use of reactor byproduct material regulated by **NRC**

  (Also including accelerator-produced isotopes and Ra-226, as of August, 2005)

- Manufacture of radiation-emitting products regulated by **FDA**

- Use of ionizing radiation-emitting products regulated by **state departments of health**

# Outline

- Disclaimer: These slides cover a broad range of topics, and are intended to provide useful resources, not a full discussion of each topic.
- Regulations and Recommendations
- Diagnostic Radiography
    - Shielding Design in a Nutshell
    - Shielding Verification
    - Quality Assurance
- Cabinet and Analytical X-Ray
    - Shielding Surveys and Inspections
    - Open Beam Configurations
    - Backscatter X-Ray

# State Regulations

- “Offer not valid in all areas, some restrictions may apply…”
- State x-ray programs vary tremendously:

  Missouri – 2 pages, no mention of operator or physician qualifications, etc.

  Wisconsin – 18 pages of detailed requirements.
- OSHA regulations are minimal – not their area of expertise
- Conference of Radiation Control Program Directors (CRCPD)

  Suggested State Regulations

# CRCPD Suggested State Regulations

- Part E – Radiation Safety Requirements for Industrial Radiographic Operations [1999 Rationale]
- Part F – Diagnostic X-rays and Imaging Systems in the Healing Arts [2009 Rationale]
- Part H – Radiation Safety Requirements for Non-Medical Radiation Generating Devices [1991 Rationale]
- Part I – Radiation Safety Requirements for Particle Accelerators [1991 Rationale]
- Part X – Medical Therapy [2009 Rationale]

# Not Really Regulations…but…

- Joint Commission for the Accreditation of Health Care Organizations (JCAHO)
- Centers for Medicare and Medicaid Services (CMS)
- National Committee for Quality Assurance (NCQA)
- **Without accreditation, insurance will not pay!**
- Accrediting organizations typically require “industry standards”.

# Industry Standards

- National Council on Radiation Protection and Measurements (NCRP)

  Shielding, radiation protection

- American Association of Physicists in Medicine (AAPM)

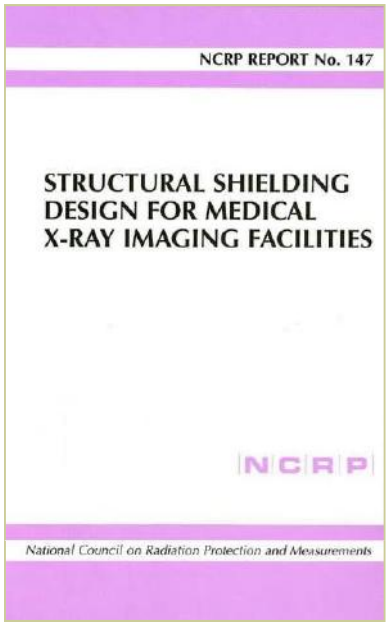
  Performance standards, measurement protocols

- American College of Radiology (ACR)

  As yet, no accreditation for radiography

- American National Standards Institute (ANSI)

  Detailed component analysis



# Shielding Design – NCRP 147

- Check your state regulations – who can legally perform shielding design calculations?
- Checklist of things you need:
  - Scale drawing of facility
  - Any special equipment features
  - Anticipated patient load
    - pts/week
    - exam types
    - beam directions
  - Image size(s)

# Assumptions

- Occupancy of surrounding areas

  NCRP 147, Table 4.1

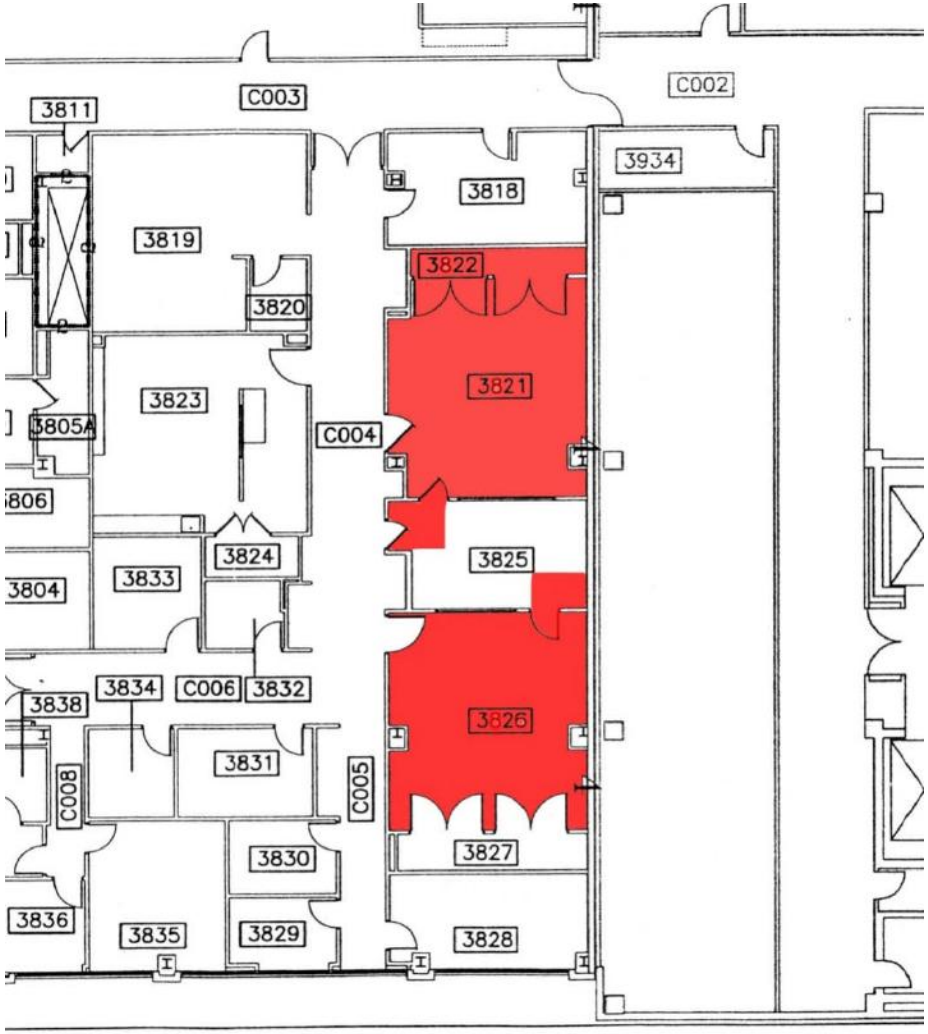
- Scattered radiation dose

  NCRP 147, Table 4.7

  Image size

  Exam type

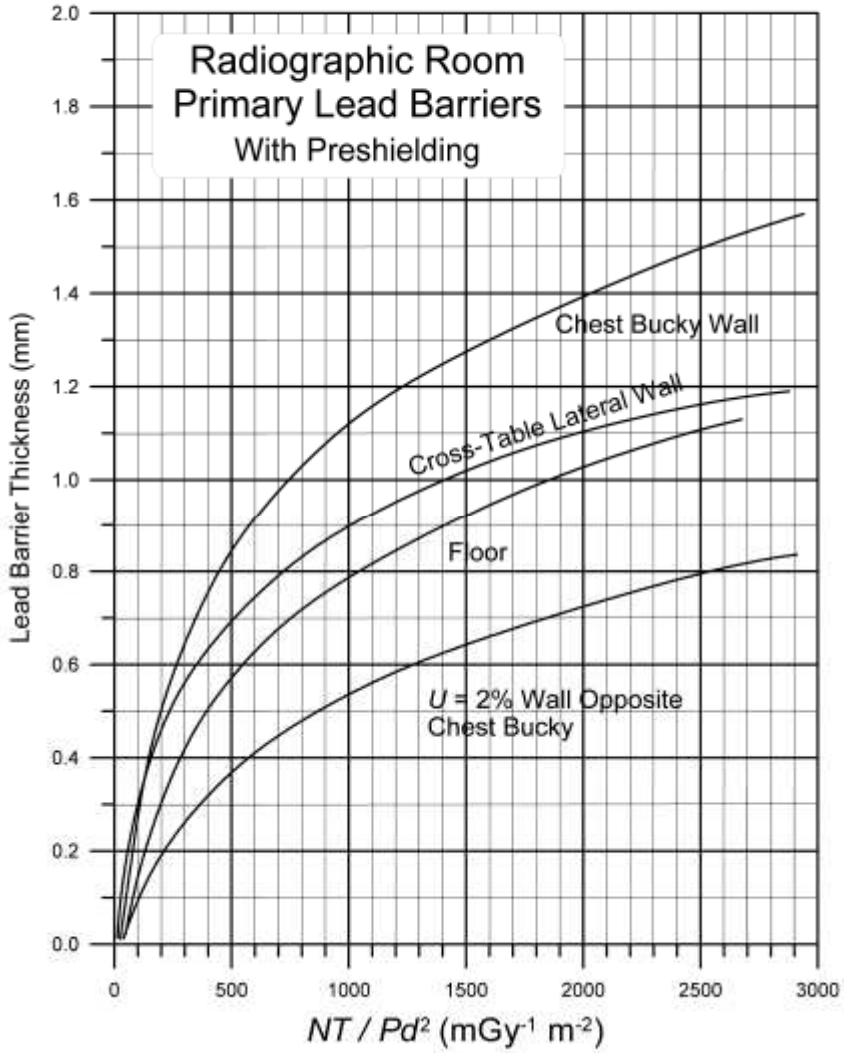
  mGy/patient



# Lead Thickness

- **Two methods:**
- Plot dose on graph, find thickness
- Calculate based on fit equations (not as bad as it looks!)

$$x = \frac{1}{\alpha\gamma}\ln\left(\frac{B^{-\gamma} + \frac{\beta}{\alpha}}{1 + \frac{\beta}{\alpha}}\right)$$



**Shielding Worksheet, Emergency Dept Rm 1329**

**Patients/week** **100**

| Barrier | **N wall** | **N door** | **E wall** | **E wall** | **E window** | **S wall** | **W wall** | **floor** | **ceiling** |
|---|---|---|---|---|---|---|---|---|---|
| Area | corridor | corridor | corridor | control | control | EMS lounge | locker/office | ground | roof |
| Restricted/Unrestricted | U | U | U | R | R | U | U | U | U |
| Occupancy (T)[2] | 0.2 | 0.2 | 0.2 | 1 | 1 | 1 | 1 | 0 | 0.025 |
| Distance (ft) | 8.00 | 9.00 | 14.00 | 13.00 | 13.00 | 6.00 | 4.00 | 4.00 | 14.00 |
| Distance (m) | 2.44 | 2.74 | 4.27 | 3.96 | 3.96 | 1.83 | 1.22 | 1.22 | 4.27 |
| Primary Use Factor (U)[1] | 0 | 0 | 0.02 | 0.02 | 0.02 | 1 | 0.09 | 0.89 | 0 |
| Primary Radiographic workload (mGy/pt @ 1m)[3] | | | 5.2 | 5.2 | 5.2 | | 5.2 | 5.2 | |
| Secondary radiographic (mGy/pt @ 1m)[3] | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 |
| Primary Chest workload (mGy/pt @ 1m)[3] | | | | | | 2.3 | | | |
| Total (mGy/wk @ 1m) | 250 | 250 | 260.4 | 260.4 | 260.4 | 480 | 296.8 | 712.8 | 250 |
| Total (mGy/wk @ barrier) | 8.41 | 6.64 | 2.86 | 16.58 | 16.58 | 143.45 | 199.57 | 0.00 | 0.34 |
| Design Goal (mSv/wk) | 0.02 | 0.02 | 0.02 | 0.1 | 0.1 | 0.02 | 0.02 | 0.02 | 0.02 |
| Required Transmission Factor | 2.38E-03 | 3.01E-03 | 7.00E-03 | 6.03E-03 | 6.03E-03 | 1.39E-04 | 1.00E-04 | #DIV/0! | 5.83E-02 |
| Preshielding[4] (mm Pb) | 0.30 | 0.00 | 0.30 | 0.30 | 0.30 | 0.85 | 0.30 | 0.85 | |
| Preshielding Factor[5] | 1.00E+00 | 1.00E+00 | 6.00E-01 | 6.00E-01 | 6.00E-01 | 1.50E-02 | 6.00E-01 | 1.50E-02 | 1.00E+00 |
| mGy/week preshielded | 8.41 | 6.64 | 1.72 | 9.95 | 9.95 | 2.15 | 119.74 | 0.00 | 0.34 |
| Standard Barrier | 31 mm drywall | 51 mm wood door | 31 mm drywall | 31 mm drywall | 3/8" glass | 31 mm drywall | 31 mm drywall | 100 mm concrete | 125 mm concrete |
| Transmission factor[6] | 2.30E-01 | 7.00E-01 | 2.30E-01 | 2.30E-01 | 3.00E-01 | 2.30E-01 | 2.30E-01 | 7.00E-03 | 5.00E-03 |
| mGy/week standard barrier | 1.93 | 4.65 | 0.39 | 2.29 | 2.98 | 0.49 | 27.54 | 0.00 | 0.00 |
| Additional attuenation factor | 1.0E-02 | 4.3E-03 | 5.1E-02 | 4.4E-02 | 3.4E-02 | 4.0E-02 | 7.3E-04 | #DIV/0! | 1.2E+01 |
| **Required (mm Pb) to be added[7]** | **0.75** | **1.02** | **0.31** | **0.3** | **0.35** | **0.35** | **1.47** | **0** | **0** |
| **Recommended Lead Sheeting (lbs/ft$^2$)** | **2** | **2.5** | **1** | **1** | **1** | **1** | **4** | **NONE** | **NONE** |
| **Recommended Lead Sheeting (inches)** | **1/32** | **5/128** | **1/64** | **1/64** | **1/64** | **1/64** | **1/16** | **NONE** | **NONE** |

Notes:

[1] NCRP #147, Table 4.4, assumed to be 1 for all secondary radiation

[2] NCRP #147, Table 4.1

[3] NCRP #147, Table 4.5, 4.7

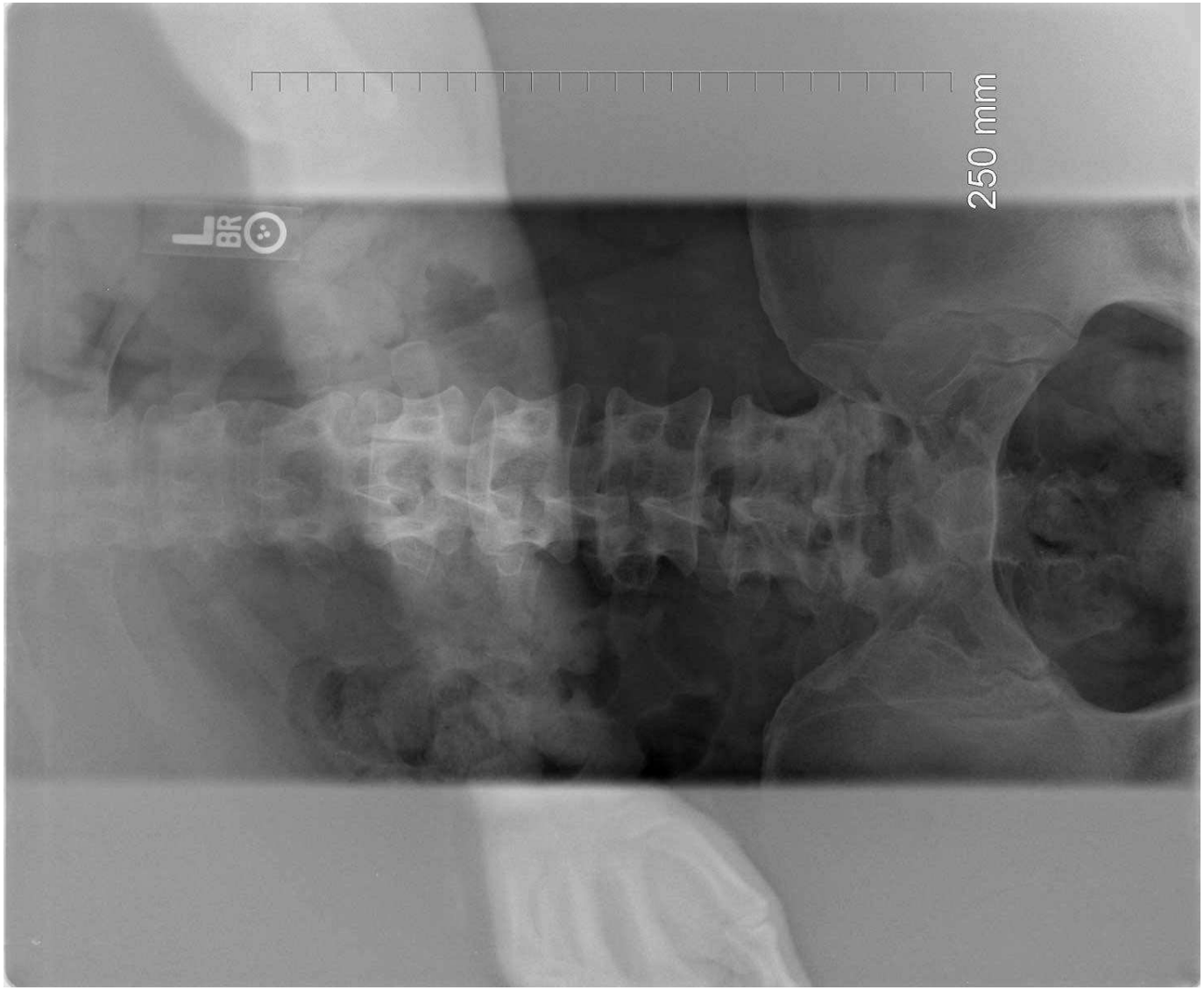
[4] NCRP #147, Table 4.6

[5] NCRP #147, Appendix B, Figure B.2

[6] NCRP #147, Appendix B,C; Figure B.2 - C.7

[7] NCRP #147, Appendix B,C; Table B.1, C.1

# Sure, you're shielded, but…



# Shielding Verification

- Again, check your state regulations:
  - Approval prior to use? (mostly a therapy requirement)
  - Qualified physicist
  - Is it required at all?
- NRCP 147, Chapter 6
- Practical advice:
  - Max conditions
  - Water phantom
  - Ion chamber with micro-R sensitivity
  - Voids check with GM

# Quality Assurance – Diagnostic Radiography

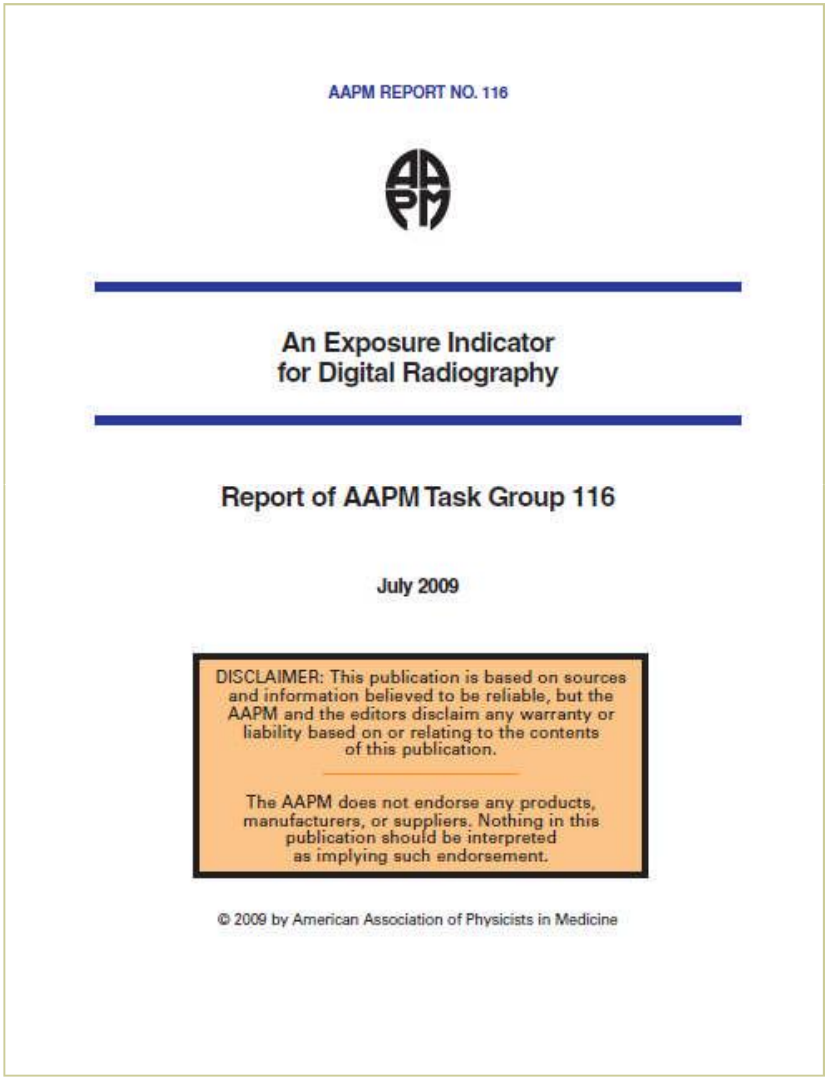
- "Industry Standard"

  CRCPD and States require annual performance testing of fluoroscopy and therapy, but not radiography

  Old School Approach – wait until the images get so bad the radiologist can't read them anymore!

# Radiography QA

- QA is the Medical Physicist's domain – don't try this at home!
- AAPM constantly updates their recommendations – keep up with the latest
- Radiology is a moving target:
  - Plane film
  - DR
  - CR
  - Flat panel



AAPM REPORT NO. 116

An Exposure Indicator for Digital Radiography

Report of AAPM Task Group 116

July 2009

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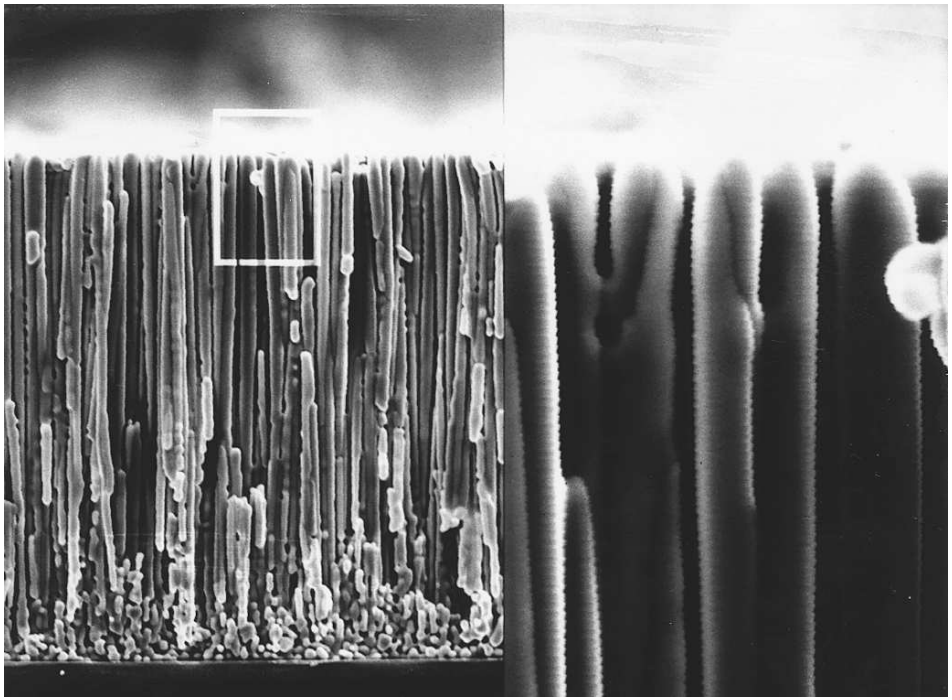
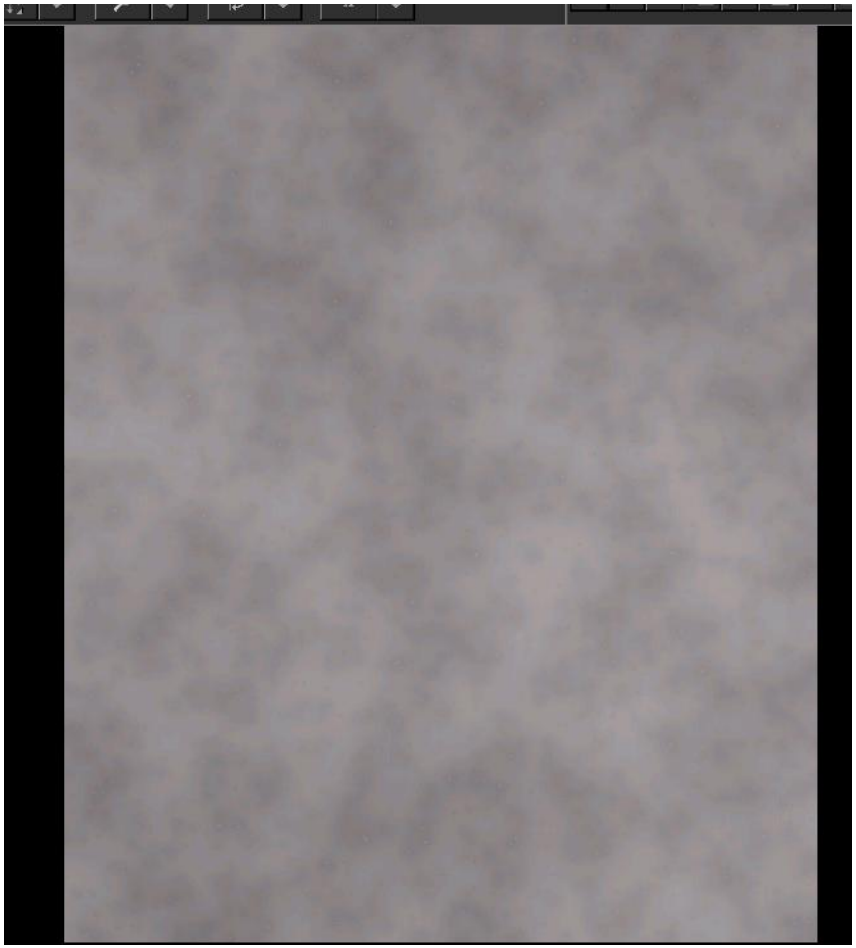
# Why do QA?

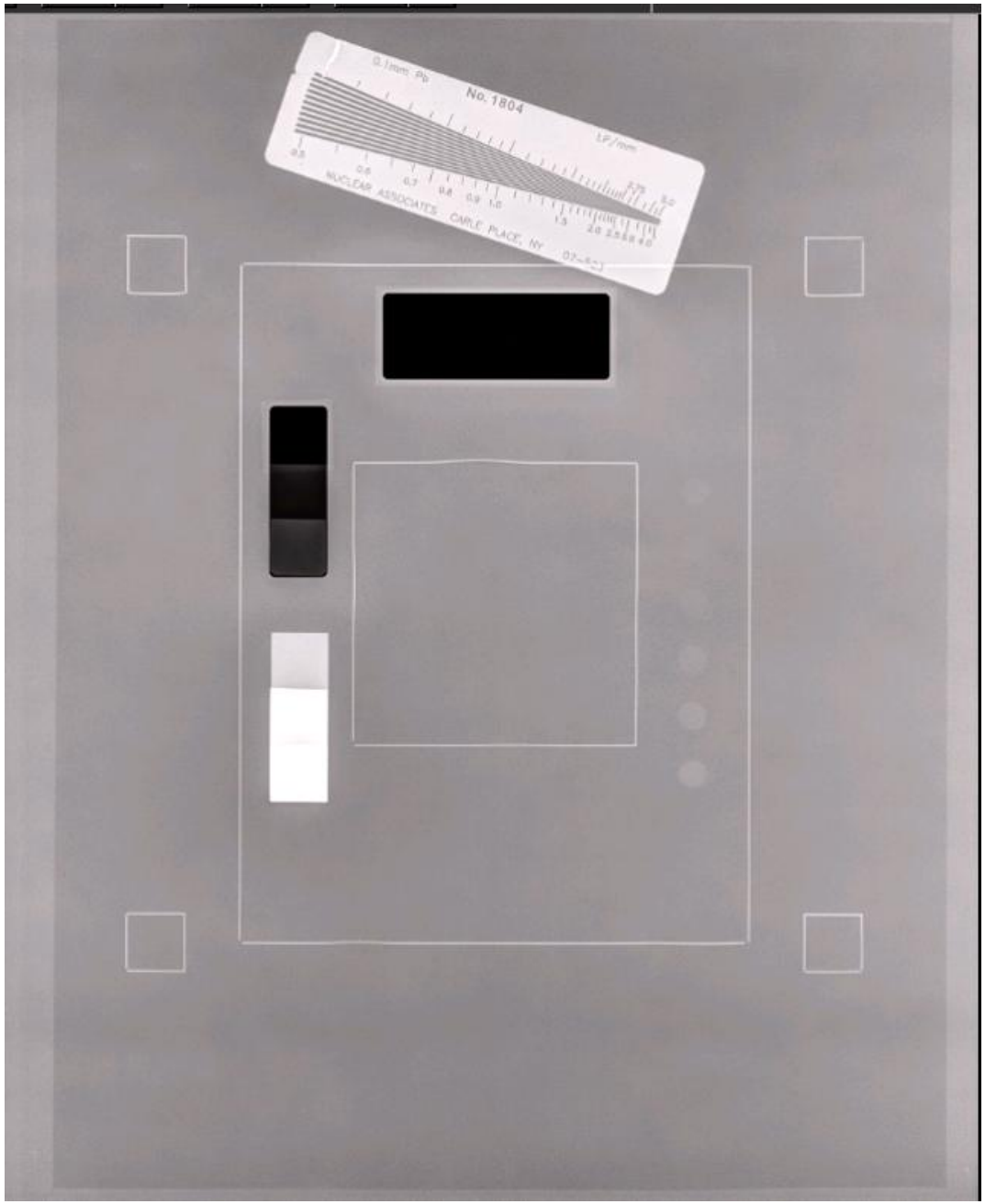


Cesium iodide crystals from a CR imager

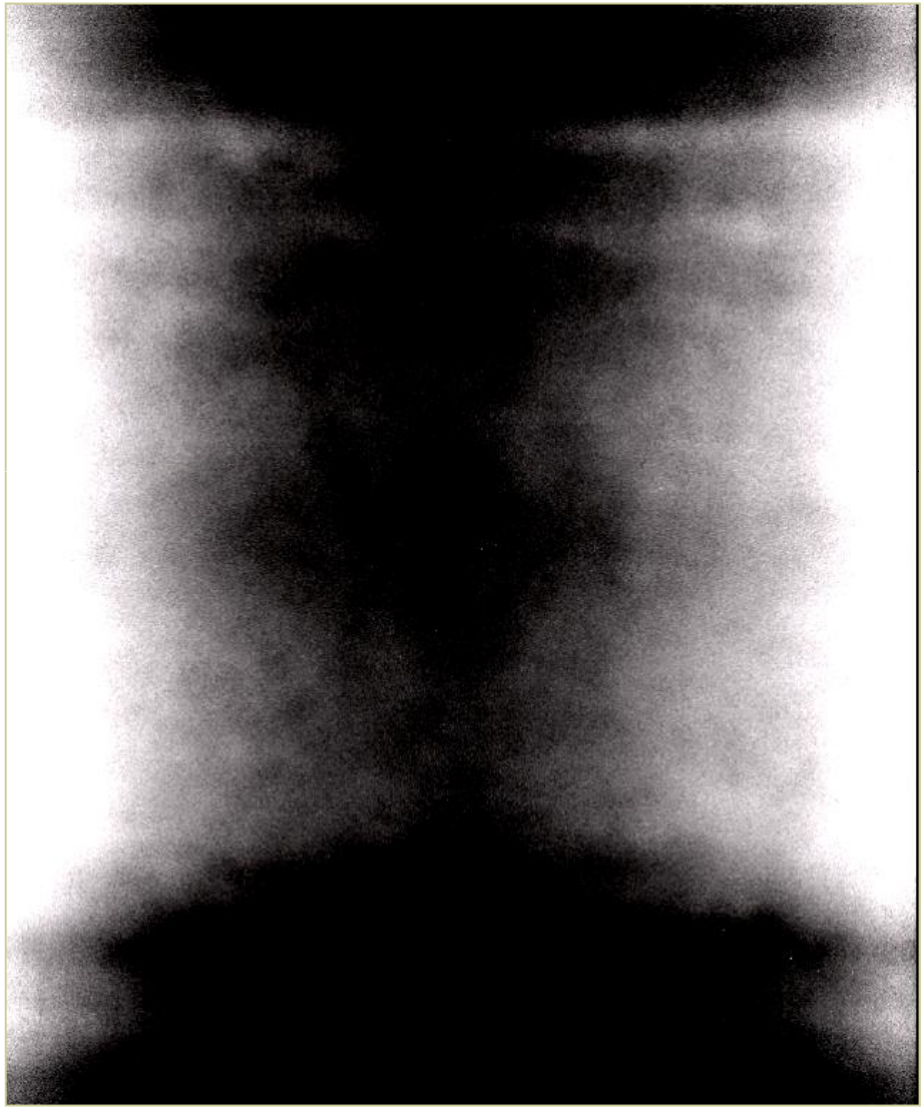


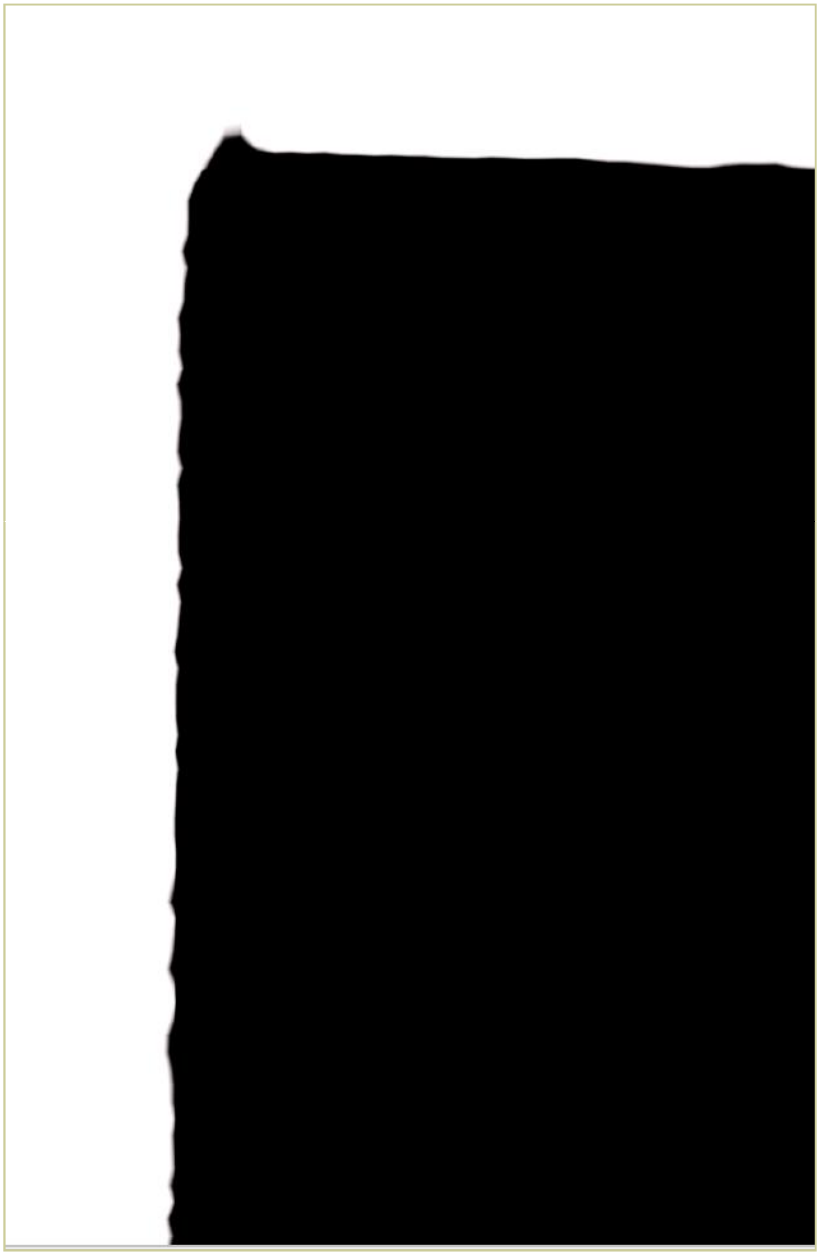
# You get the picture!

# QA Testing

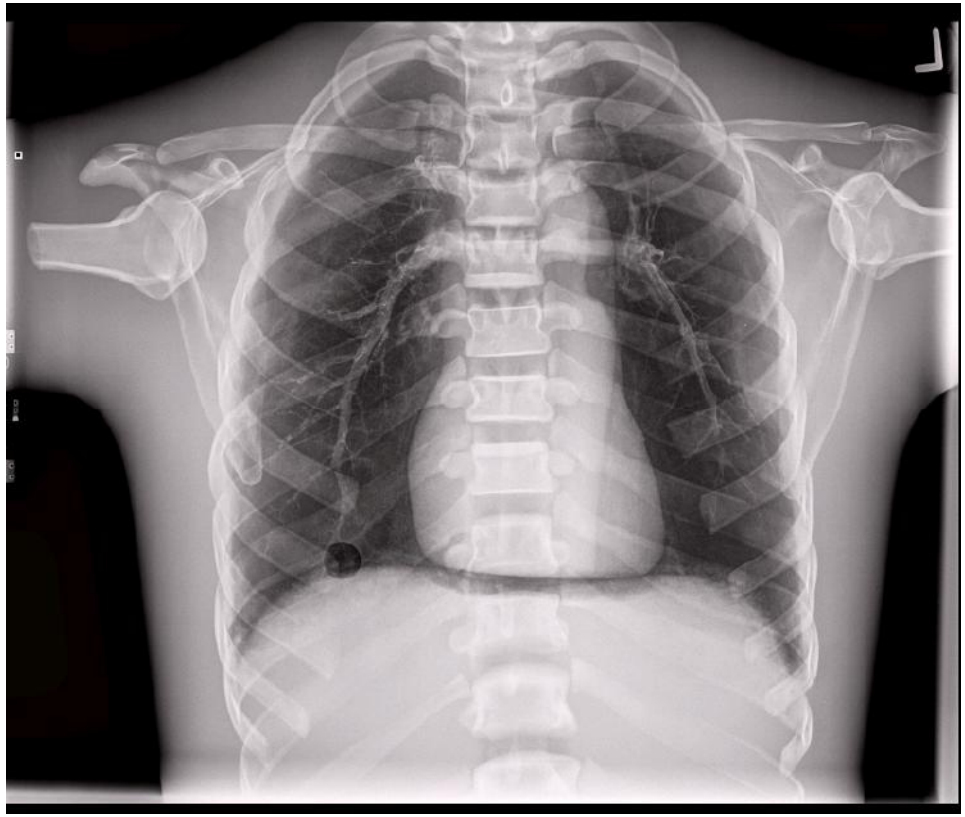


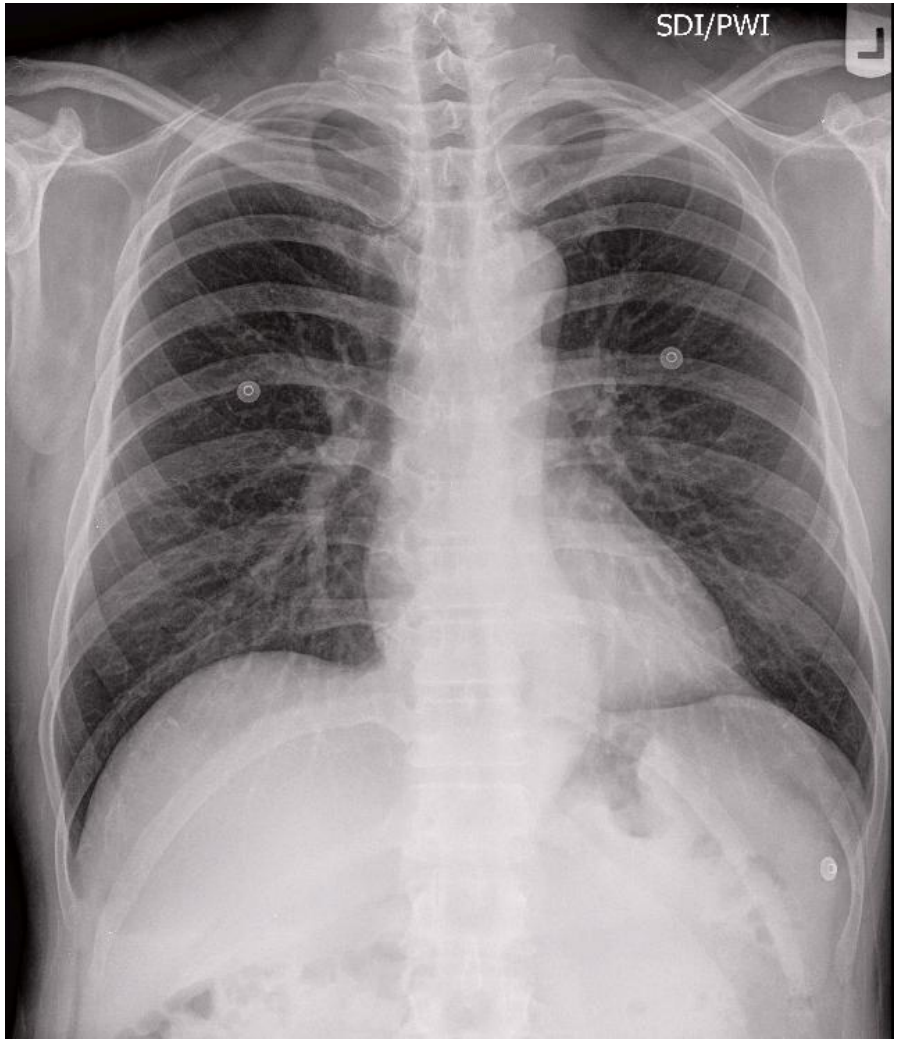
# QA Testing





# Keep it Real





# Cabinet X-Ray

- “Cabinet X-Ray” as used in state regulations mean a unit certified to comply with 21 CFR 1020.40
- Some states have regulations, some don’t…CRCPD does not recognize cabinet units
- Typical requirement is for annual testing

# Annual Radiation Survey

- Limit: 0.5 mrem/hr at any surface “averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure”
- Check interlocks for functionality, verify lights working properly

# Good Reasons to do Annual Surveys

- User modification
- Heavy utilization
- Outputs can be high
- Accidents

# Quirks

# Analytical X-Ray

- Can be scary!
  - Energy low: 5-25 keV
  - Intensity very high – “bright” sources
  - 2 Gy dose in a matter of seconds
- Can be certified as cabinet units…or NOT

LYTRON RC

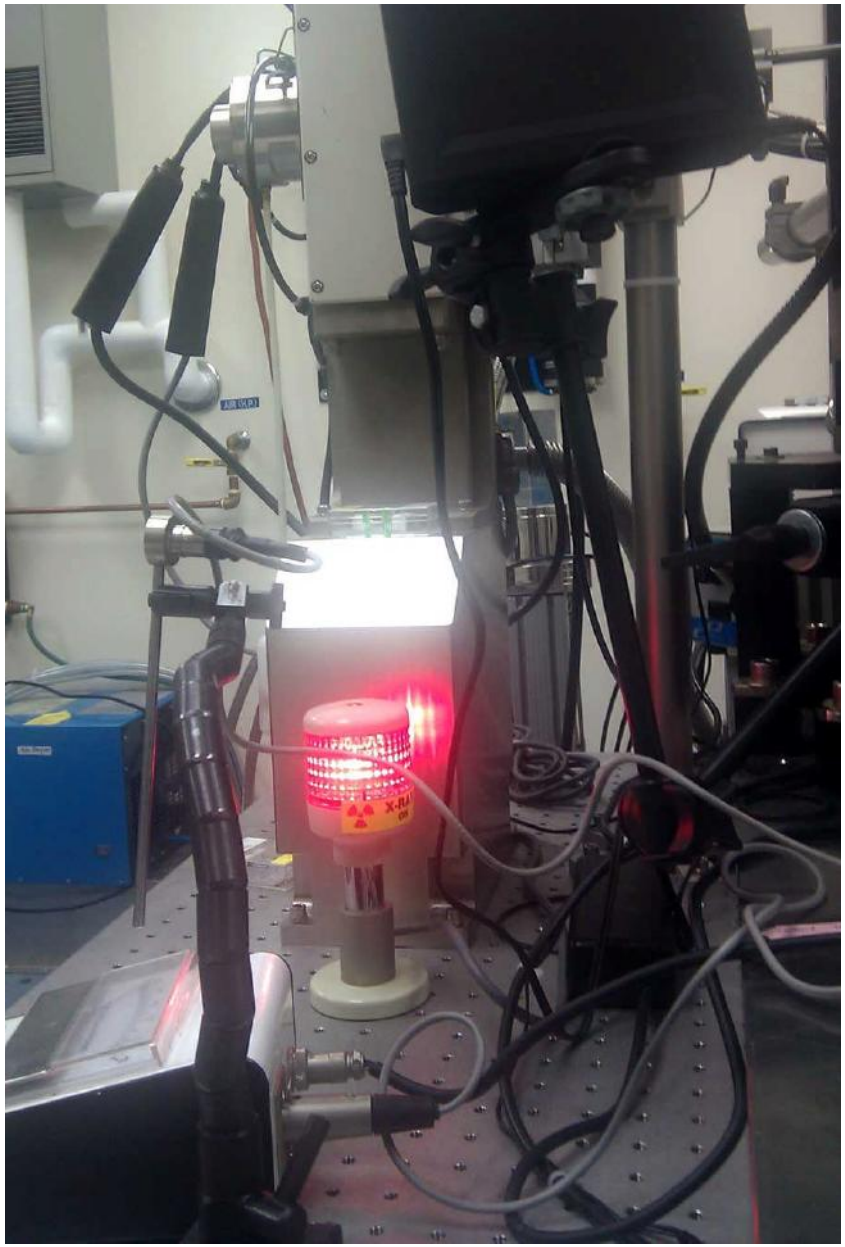
# Suggested Testing

- Radiation survey
- Check interlocks, lights
- Verify dosimetry

Wisconsin regulations:Finger or wrist dosimetry devices shall be provided to and used by any of the following individuals:

1. An analytical x−ray equipment worker using a system having an open−beam configuration and not equipped with a safety device.

2. Personnel maintaining analytical x−ray equipment if the maintenance procedures require the presence of a primary x−ray beam when any local component in the analytical x−ray system is disassembled or removed**. Reported dose values may not be used for the purpose of determining compliance with s. DHS 157.22 unless the dose values are evaluated by a medical physicist.**



# Backscatter X-Ray

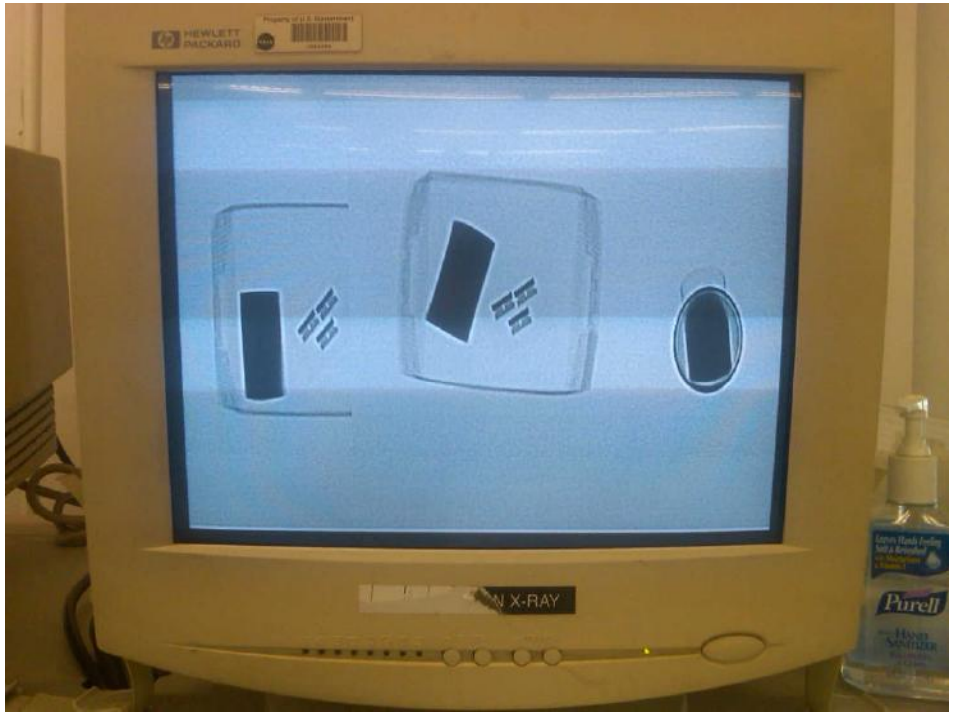
# Inspection

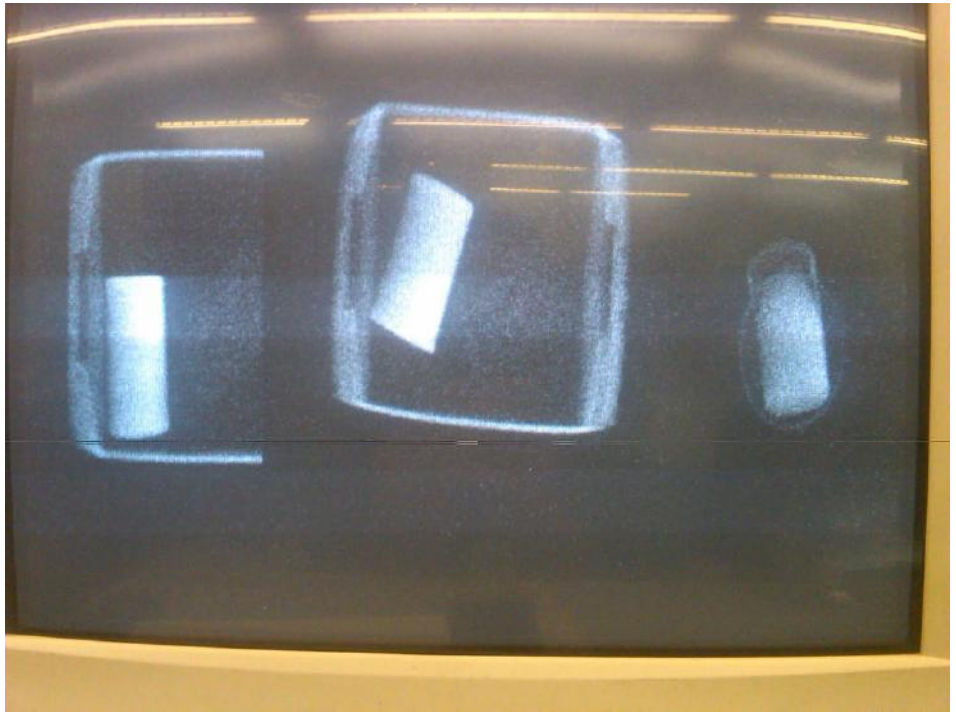
- Package Inspection

  Don’t fit in a neat regulatory category

- Radiation survey
- Warning light function check
- Performance – Get the spec manual off the internet

  Test various objects – wire, plastics, liquids, etc.


HEWLETT PACKARD
N X-RAY
Purell



# Useful References

- http://www.fda.gov/Radiation-EmittingProducts/default.htm
- http://www.crcpd.org/ssrcr.aspx
- http://www.ncrponline.org/
- http://www.aapm.org/pubs/reports/RPT_74.PDF
- http://www.acr.org/accreditation.aspx
- http://www.mcw.edu/amrso/file_share.htm

NASA

# Health Physics Assessments for Scanning Devices used in Homeland Security

John Cardarelli II, PhD, CHP, CIH, PE

Triennial NASA Health Physics Training

Washington, D.C.

April 19, 2011

# Outline

- **X-rays vs. Gamma rays**
- **Regulations, Guidance, & Standards**
- **Instrumentation and dosimetry**
- **X-ray Technologies**
  - Cabinet X-ray systems - *TSA Study*
  - Explosive Detection Systems - *TSA Study*
  - Backscatter Imaging - *ANSI Standard*
  - Transmission Imaging - *ANSI Standard*
- **Gamma ray Technologies**
  - Vehicle and Cargo Inspection Systems
- **Recent Literature Findings**

# X-ray vs. Gamma rays

in Homeland Security applications

## X-rays

Artificial Radiation Source

Originate from orbital electrons

Generally lower than 500 keV

Less penetrating

FDA regulates manufacturers

EPA establishes federal policy

OSHA regulates worker safety

States regulate use of electronic sources of radiation

Agency specific radiation safety procedures

## Gamma rays

Natural Radiation Source

Originate from within nucleus

Generally higher than 500 keV

More penetrating

NRC / States regulate manufacturers and worker safety

Agency specific radiation safety procedures

# Regulations, Guidance, & Standards

- 1987 Presidential Directive for Fed. Employees
- OSHA radiation standards (out-dated)
- FAA Regulations
- NCRP and ICRP recommendations
- State Regulations (pre- and post-creation of TSA)
- Occupational vs. Public Dose Limits?
- FDA Regulations
- ISCORS (guidance document)
- ANSI Standards (N43.17, 2009)

**Developed consensus standards for Homeland Security applications**

# FDA Regulations

- http://www.fda.gov/cdrh/comp/eprc.html
- Law: Federal Food, Drug, and Cosmetic Act Subchapter C - Electronic Product Radiation Control
- Regulations: Title 21 CFR 1000 – 1005, 1010, and 1020.40
- Cabinet X-Ray FAQ: http://www.fda.gov/cdrh/comp/cabinetxrayfaq.html

# Survey Instruments

- **Field Testing Instruments**
  - Specific Protocol
    - ✓ "Stoms" meter to ID areas of highest leakage
    - ✓ Ionization Chamber to conduct leakage measurements
- **FDA Regulations**
  - Leakage limit based on Television Standard (1959)
  - 0.5 mR/hr @ 5 cm from surface

# “Stoms” Meter

**Eight GM detectors used to survey wide surface areas for radiation**

# Field Testing Challenges

- **FDA Regs specify instrumentation**

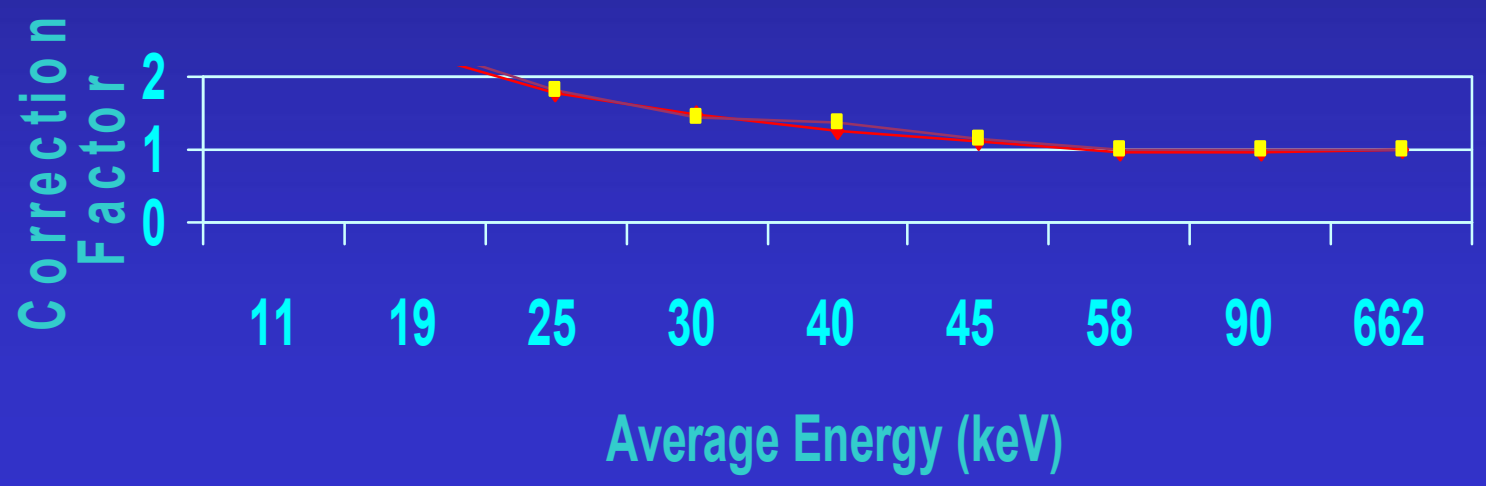
- 10 $cm^2$ detector surface area
- Victoreen 440 RF/D
  - ✓ Meets FDA requirements
  - ✓ Slow response and does not integrate
  - ✓ May not accurately measure leakage from the EDS equipment

- Fluke biomedical 451P
  - ✓ Does not meet FDA requirements (chamber size)
  - ✓ Quicker response times & integrates
  - ✓ Most people are using this
  - ✓ May not accurately measure leakage from the EDS equipment

# Field Testing Challenges

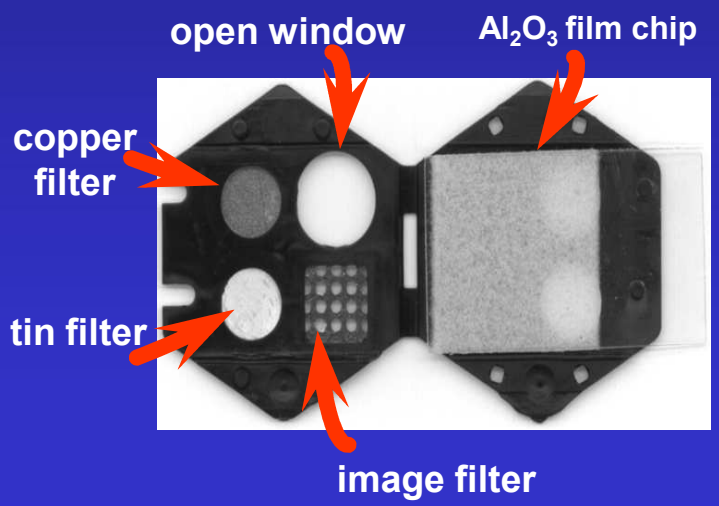
## special calibration needed for Fluke 451P

- **Calibration Issues**
  - Cs-137 (662 keV)
  - EDS Machines (180 keV max; 60 keV avg)
  - Average “leakage” energy unknown
  - Should correction factor be applied?



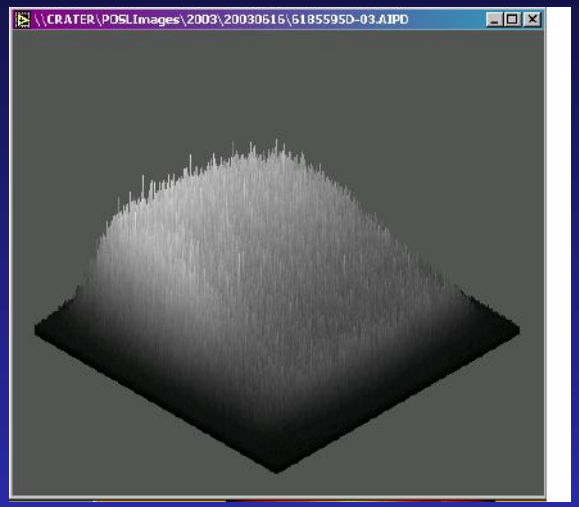
# Dosimetry Challenges

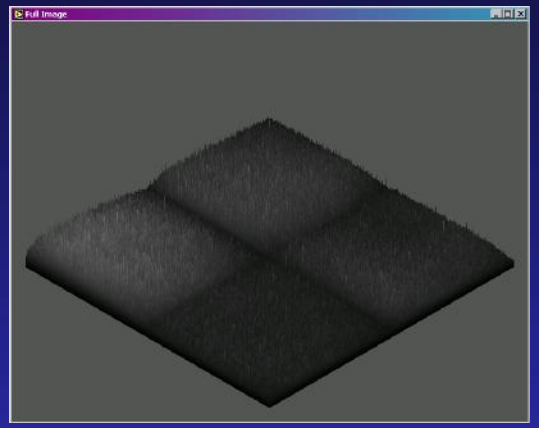
- **Dynamic Environment**
  - Evolving airport policies
  - Workforce
    - ✓ Various work schedules, assignments
    - ✓ Part-time vs. Full-time
  - Historical Practices
  - Training
  - Technology
  - Whole body & Wrist

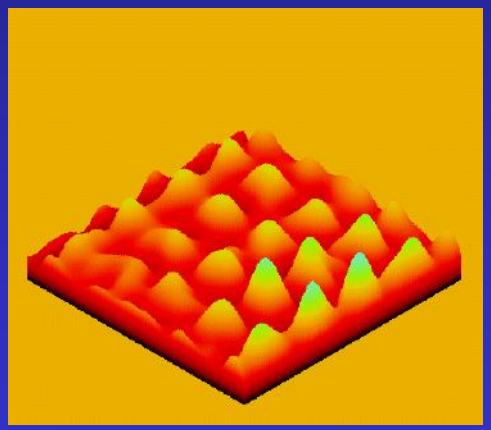


# OSL Image

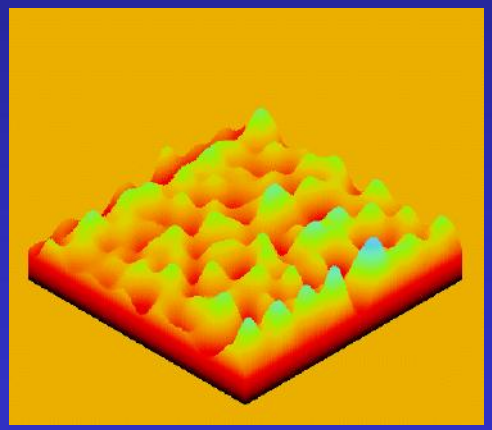
**InVision CTX 9000; L3 6000; FAA Tech. Center Test**





Static Exposure



Dynamic Exposure

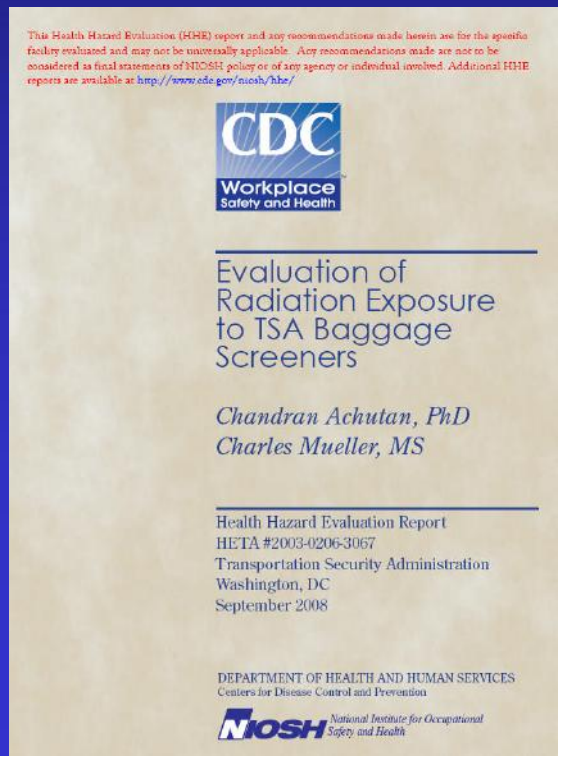
# TSA Study Objectives

## NIOSH HETA #20030206

1. Assess the work practices, procedures, and training provided to TSA employees who operate machines that generate X-rays; (Phase I)

2. Characterize the radiation exposure among employees who operate these machines; (Phase I and II) and

3. Determine if TSA employees who operate these machines are exposed at sufficient levels to require/warrant routine monitoring with radiation dosimeters. (Phase II)



This Health Hazard Evaluation (HHE) report and any recommendations made herein are for the specific facility evaluated and may not be universally applicable. Any recommendations made are not to be considered as final statements of NIOSH policy or of any agency or individual involved. Additional HHE reports are available at http://www.cdc.gov/niosh/hhe/

CDC Workplace Safety and Health

Evaluation of Radiation Exposure to TSA Baggage Screeners

*Chandran Achutan, PhD*
*Charles Mueller, MS*

Health Hazard Evaluation Report
HETA #2003-0206-3067
Transportation Security Administration
Washington, DC
September 2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

NIOSH National Institute for Occupational Safety and Health

# 12 Selected Airports

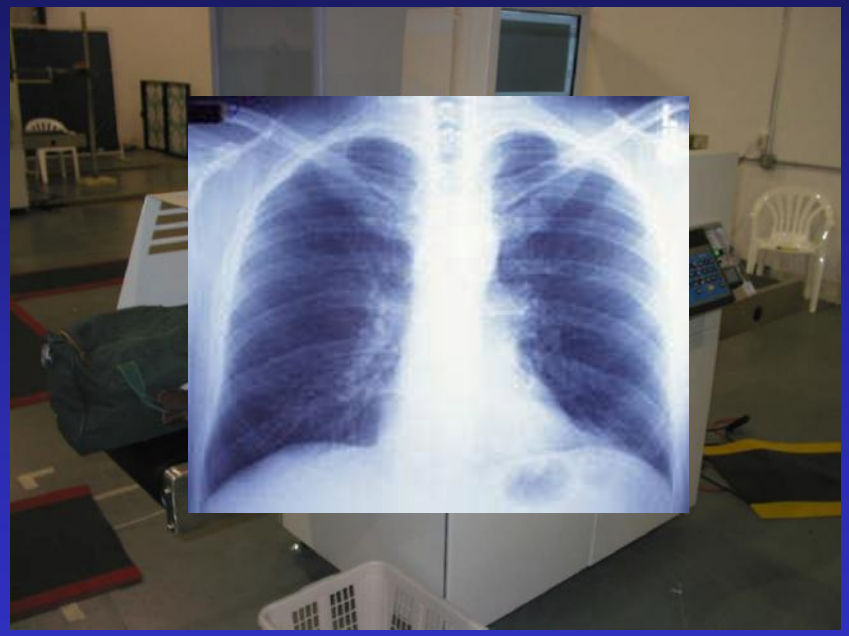
1. Baggage and Passenger Volume
2. EDS Machine Type
3. Time of Year
4. # Screeners operating equipment
5. Work Practices
6. Airport Type (orig. vs. connecting)
7. Prior employee complaints
8. Geographic Location

Field Measurements
Dosimetry and Field Measurements

# TRX Equipment

## "Threat Image Projection - Ready X-ray"

- **TIP Ready X-ray**
  - ***Passenger baggage*** (carry-on)
  - 1974 – present
  - 3 Manufacturers
    - ✓ Heimann
    - ✓ Rapidscan
    - ✓ PerkinElmer

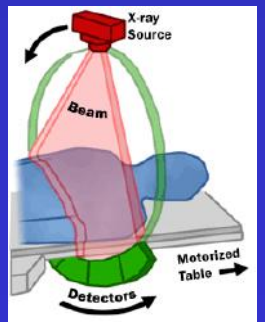


- **Medical Analogy: Standard Chest X-ray**

# EDS Equipment

- **Explosive Detection Systems (EDS)**
  - ***Checked Baggage***
  - X-ray and CT Scanning capabilities
  - 1995 – present
  - 2 Manufacturers
    - ✓ InVision (GE)
    - ✓ L3

- **Medical Analogy: CT Scan**



# Field Investigations

- Interacted with workers
- Spot Measurements
- Record Reviews
- Data collection
- Noted non-radiation concerns and safety hazards

# Initial Findings and Results

- **Non-radiation concerns raised by employees or management**
  - Ergonomics
  - Noise (NIOSH HHE)
  - Jet exhaust / Tug exhaust (NIOSH HHE)
  - Diesel
  - Asbestos
  - Carbon monoxide
  - Heat Stress
  - Indoor air quality (dust) (NIOSH HHE)
  - Bloodborne pathogens (NIOSH HHE)

# Initial Findings and Results

- **Safety Hazards Observed**
  - Conveyor belt systems (In-line)
    - ✓ moving parts / guarding
    - ✓ Low head-space
    - ✓ Access to EDS
  - Slip, Trip, Fall Hazards

# Initial Findings and Results

- **FAQs**
  - Why are we not wearing dosimeters?
  - Residual radiation?
  - Is it safe for pregnant workers?
  - What are the health effects?

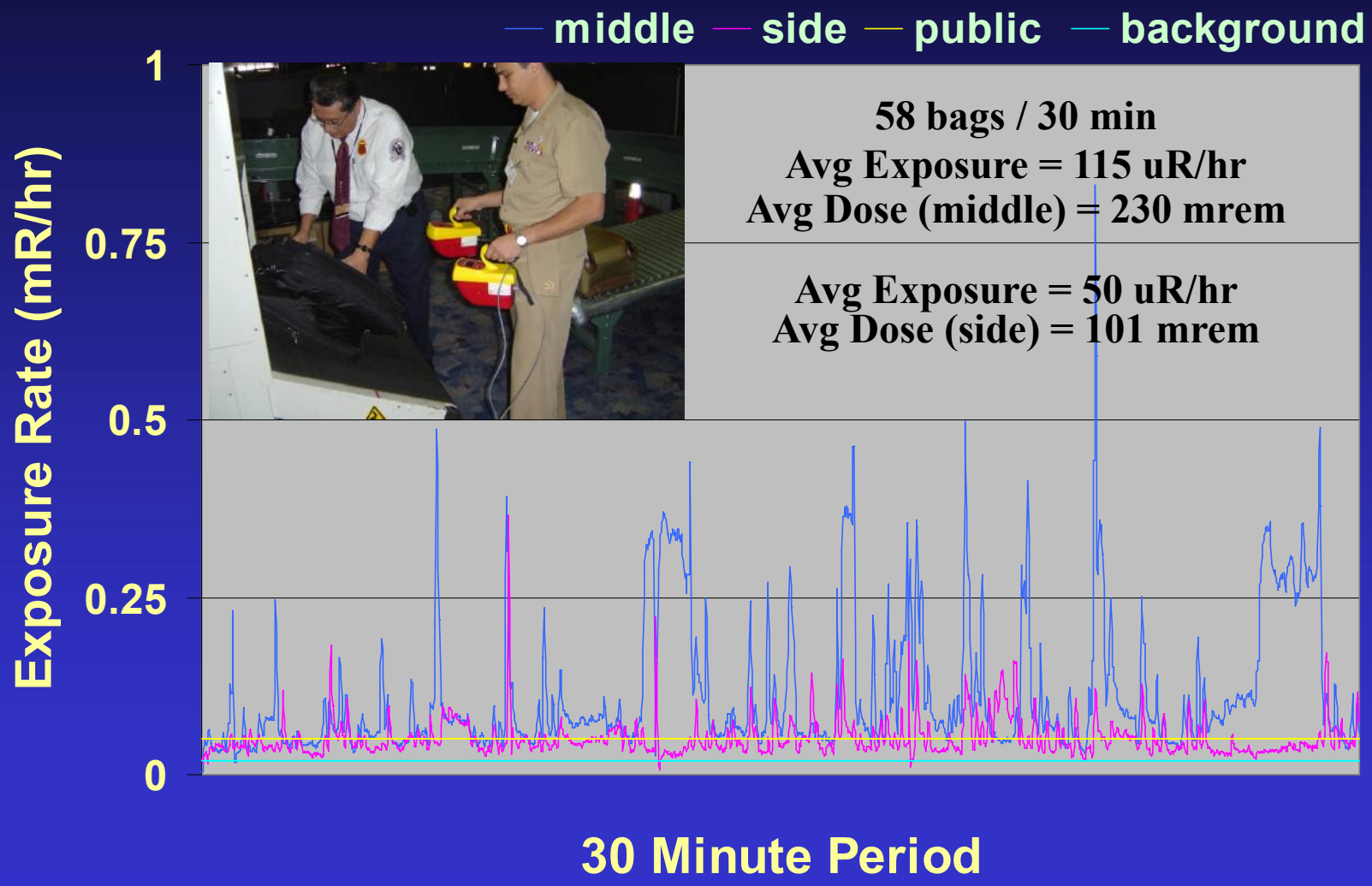
# Initial Findings and Results

- **FAQs**
  - How much radiation is inside the machines?
  - How much radiation is too much to receive?
  - Is radiation stored in the body?
  - How do we know if these machines are FDA compliant?

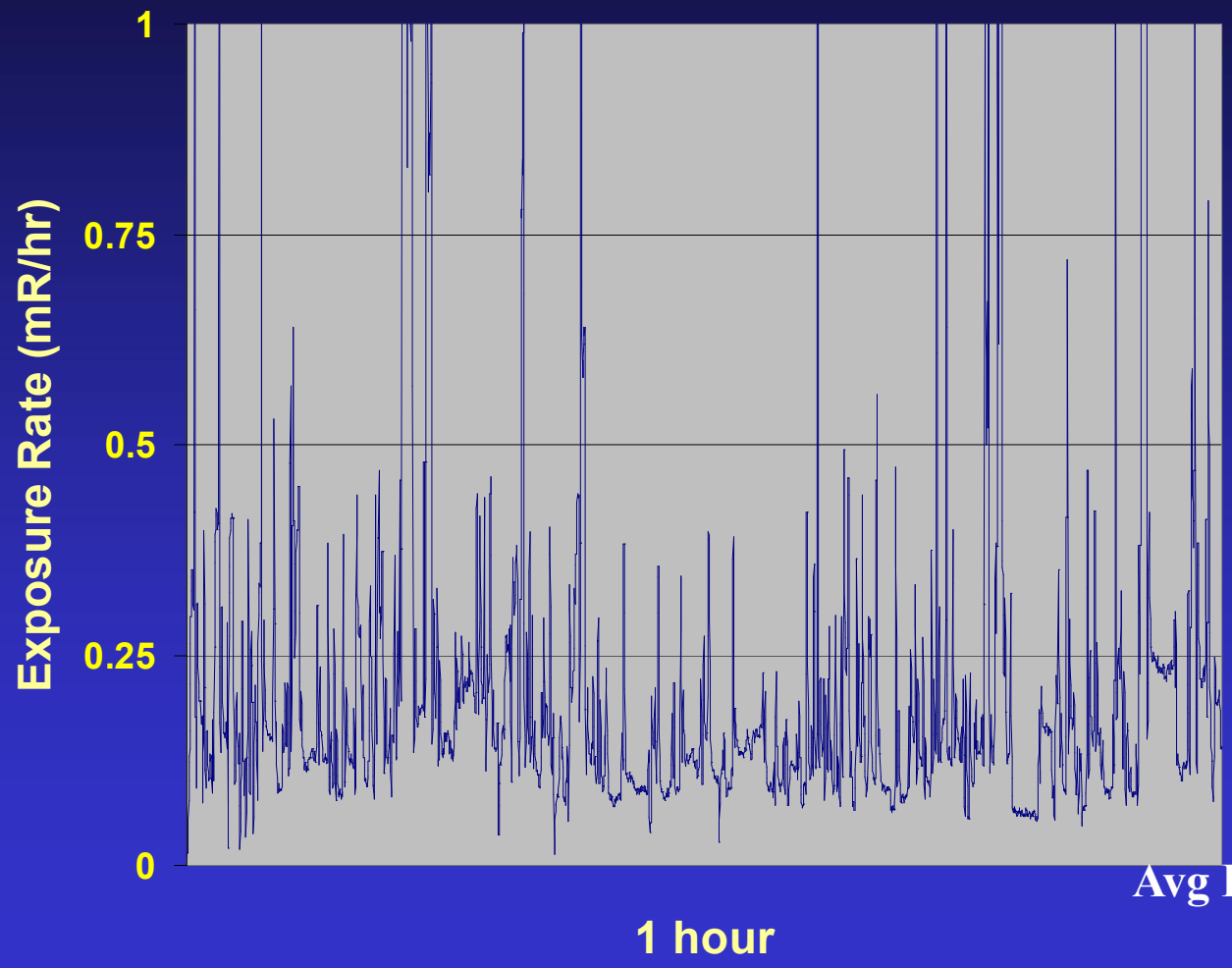
# Initial Findings and Results

| Machine | Exposure Rate mR/hr Inside lead curtains | |
|---|---|---|
| | Entrance | Exit |
| L3 | 2 to 5 | 2 to 5 |
| CTX 2500 | 3 to 50 | 3 to 50 |
| CTX 5500 | 2 to 5 | 3 to 50 |
| TRX | up to 3 | up to 3 |

# What a difference 1 foot makes!



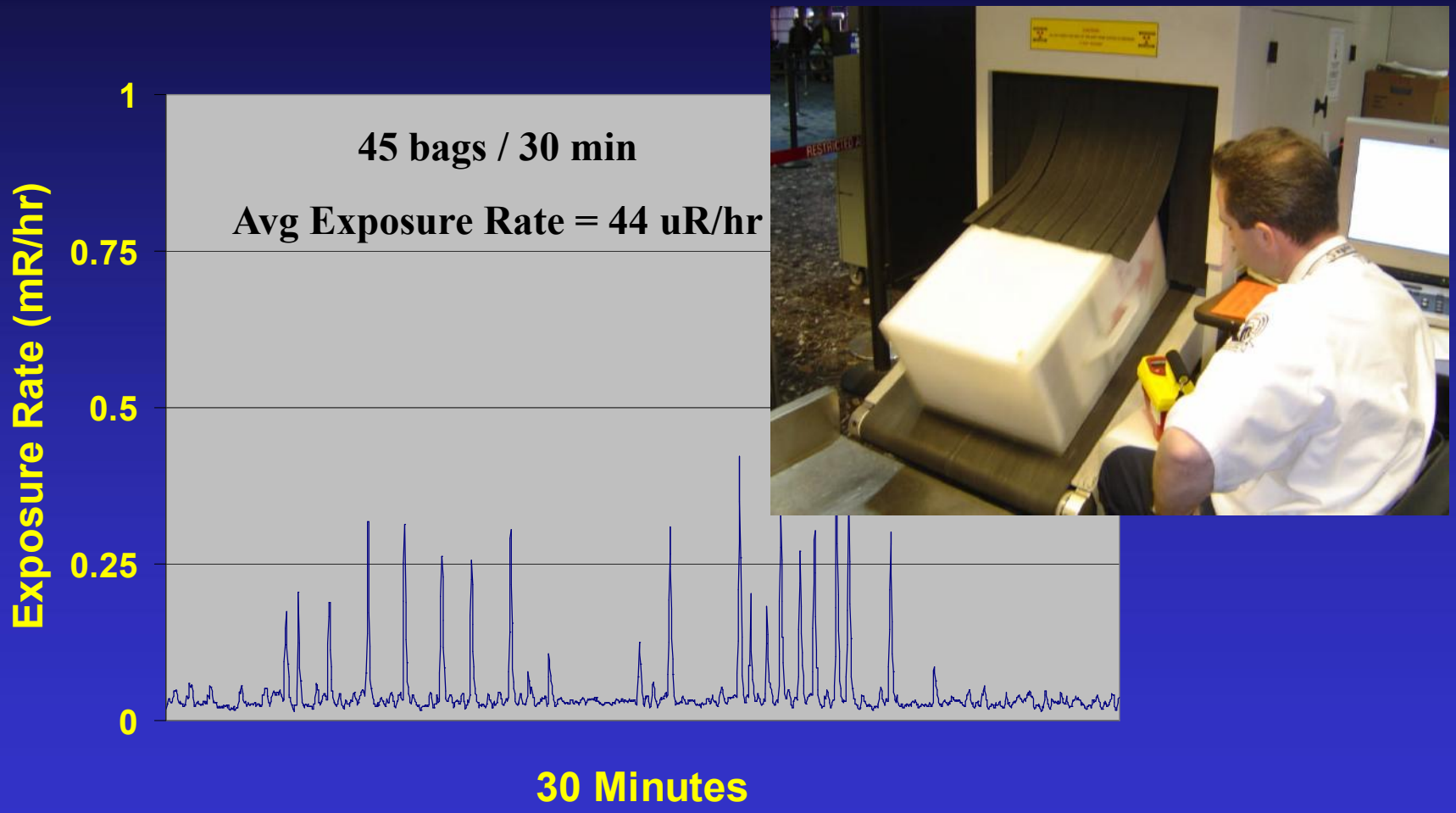
# FDA Leakage Test



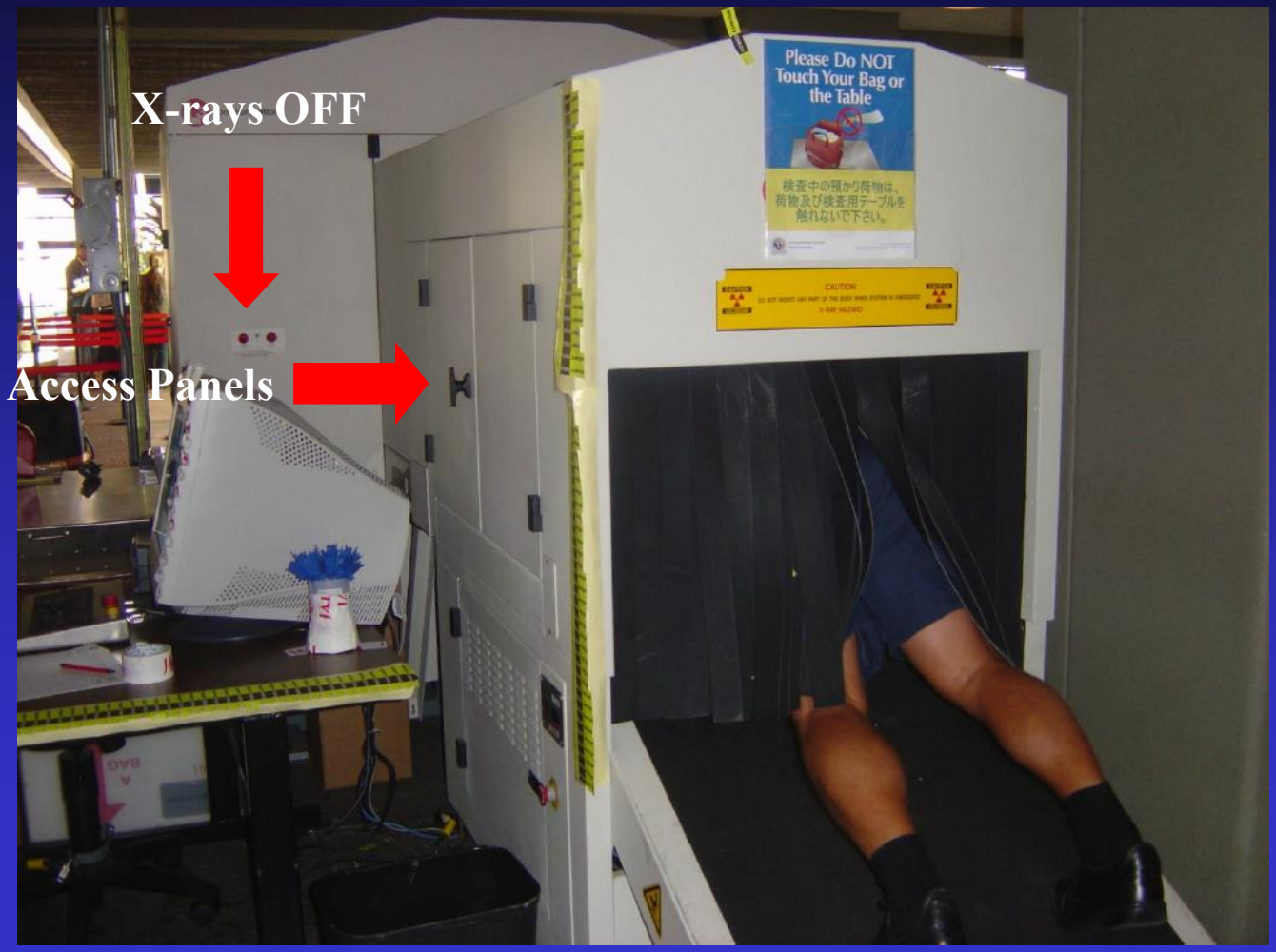
112 bags / 60 min

Avg Exposure Rate = 222 uR/hr

# L3 Operator Exit Location



# Clearing a bag jam



# Clearing a bag jam

•Log-out Tag-Out Issues

# Clearing a bag jam

• Confined Space Concern

# Curling Curtains

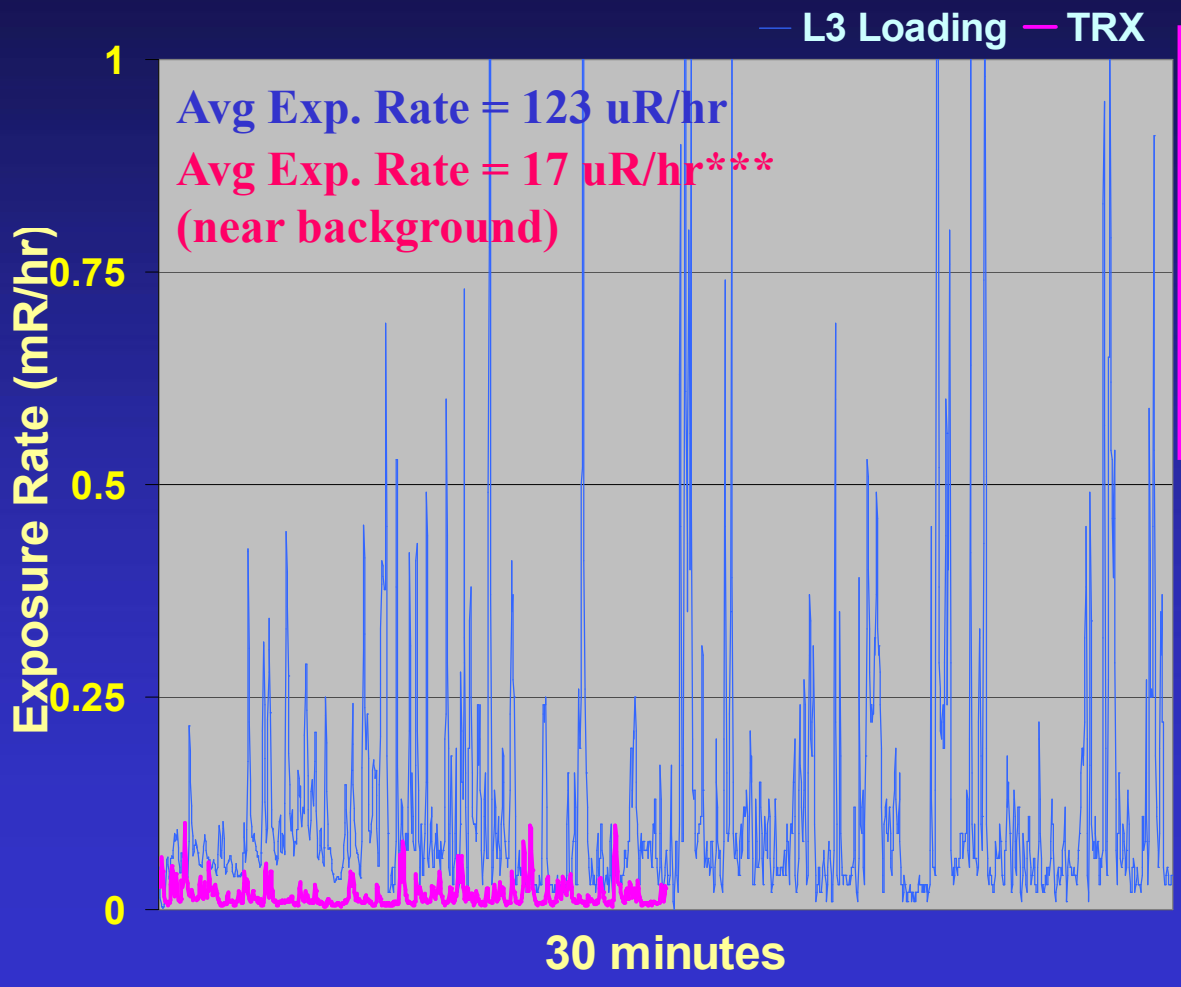
# Displaced Curtains

# Poor Work Practices

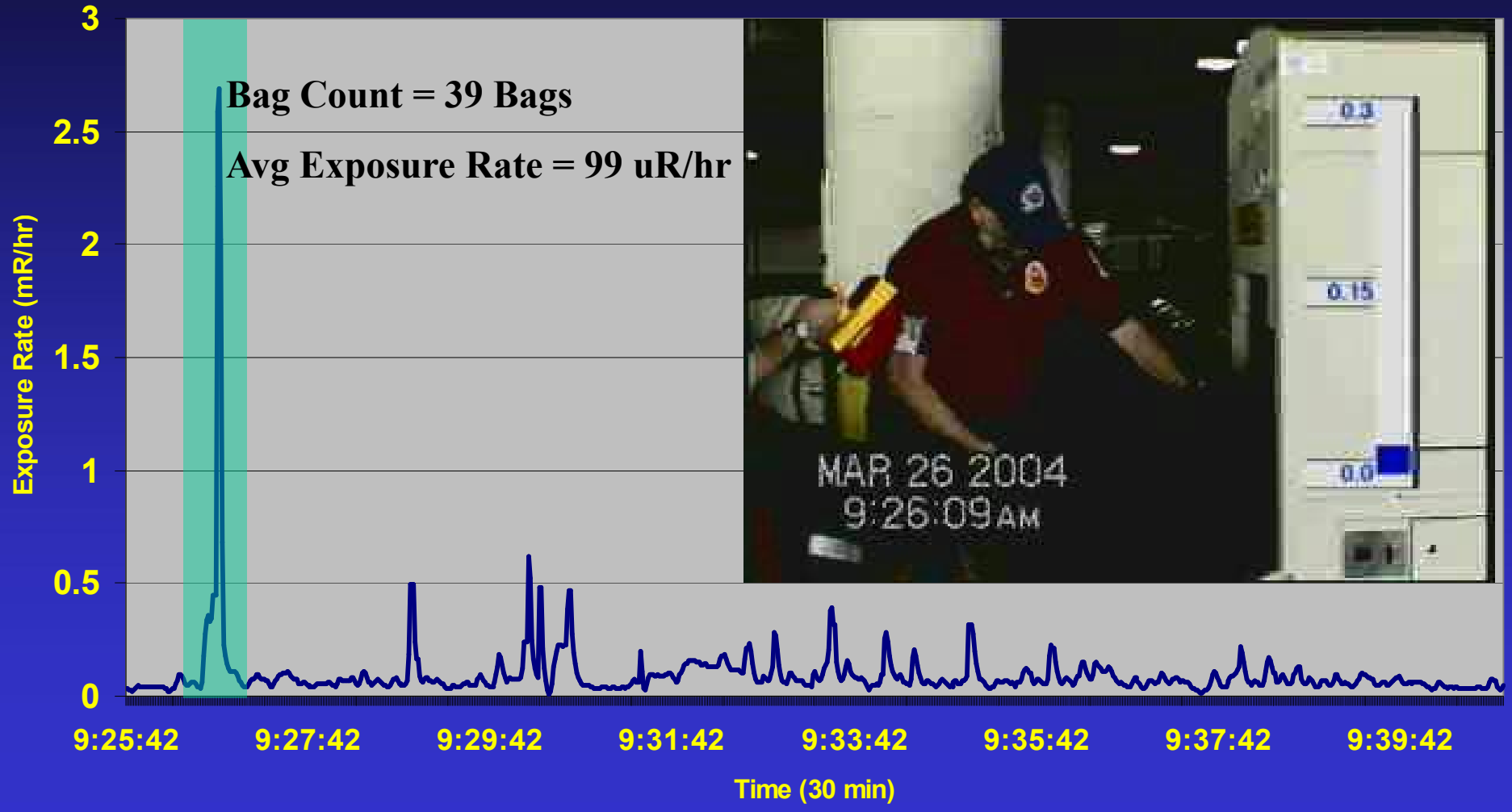
CAUTION

# EDS vs. TRX Dose Potentials

## (L3 Loading vs. TRX exit)



# Exposure during loading



# Reasons to recommend shut-down

- **No. of EDS shut down: CTX-12; L3-6**

| reason | resolution |
|---|---|
| • 3 – gaps between gantry and entry tunnel; | bolted together |
| • 1 – bypassed interlock system; | training |
| • 2 – damaged interior curtains; | maintenance |
| • 12 – HOTSPOT on CTX-5500 | modify curtain |

# Recommendations

- **Radiation Training**
- **Emphasize MAINTENANCE**
  - Keep radiation leaks “as low as reasonably achievable” ALARA
- **Post Radiation Survey Results**
  - Improves awareness
  - Encourages communication
  - Empowers the workforce

# Recommendations

- **Access Panel Keys**
  - Encourage use but limit abuse
- **"Push-Sticks"**
  - solid material (prevent "funnel effect")
  - non-metallic (reduces scatter)
- **Prevent blockage of emergency shut-off switches (TRX and EDS)**
- **Prevent unauthorized access to the gantry.**
- **Involve State Radiation Safety Programs**

# Recommendations (L3 EDS)

- **Re-engineer Entrance and Exit Tunnels**
  - Ergonomics
  - Greatest radiation exposure potential (stand-alones)
- **Bolt tunnels to gantry**
- **Improve conveyor belts**
- **Improve safety interlock system**

# Recommendations (InVision EDS)

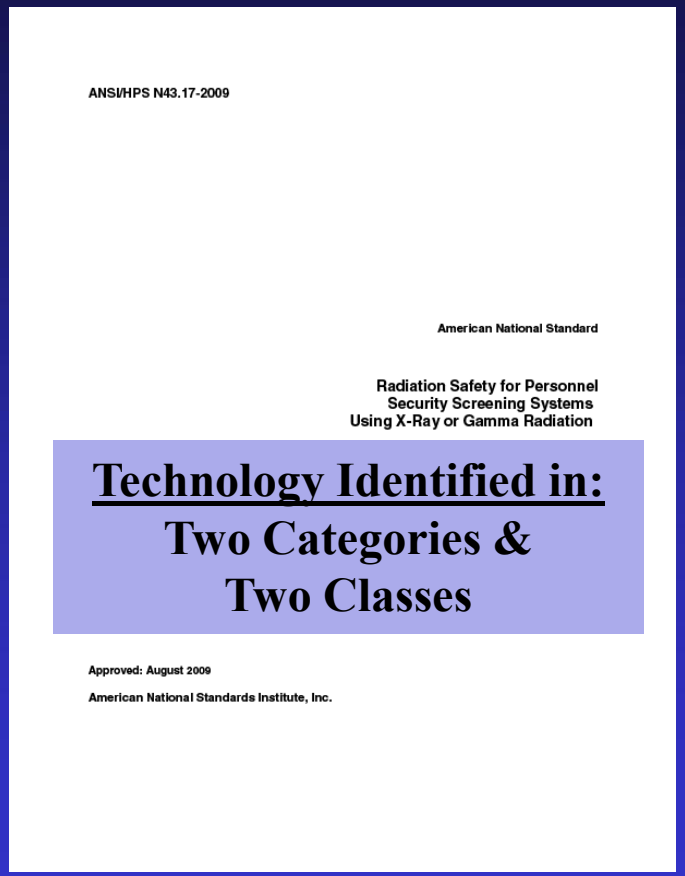
- **Be aware of "Hot Spot"**
  - About 8 inches from curtain
  - >1,500 uR / hr
  - Not a direct hazard to TSA workers, but it is correctable.

# Recommendations (InVision EDS)

- Increase distance of exit electric eye

# Human Screening Technologies ANSI N43.17, 2009

- "This standard does not address the evaluation of the societal benefit of security screening." (p.1)
- "This standard recognizes the potential for a net security benefit to society and presupposes appropriate justification of each screening practice." (p. 4)
- "…the standard takes into consideration the minimization of the dose as balanced against the security benefit to society." (N43.17, 2002, p. iii)


ANSI/HPS N43.17-2009

American National Standard

Radiation Safety for Personnel
Security Screening Systems
Using X-Ray or Gamma Radiation

**Technology Identified in:**
**Two Categories &**
**Two Classes**

Approved: August 2009

American National Standards Institute, Inc.

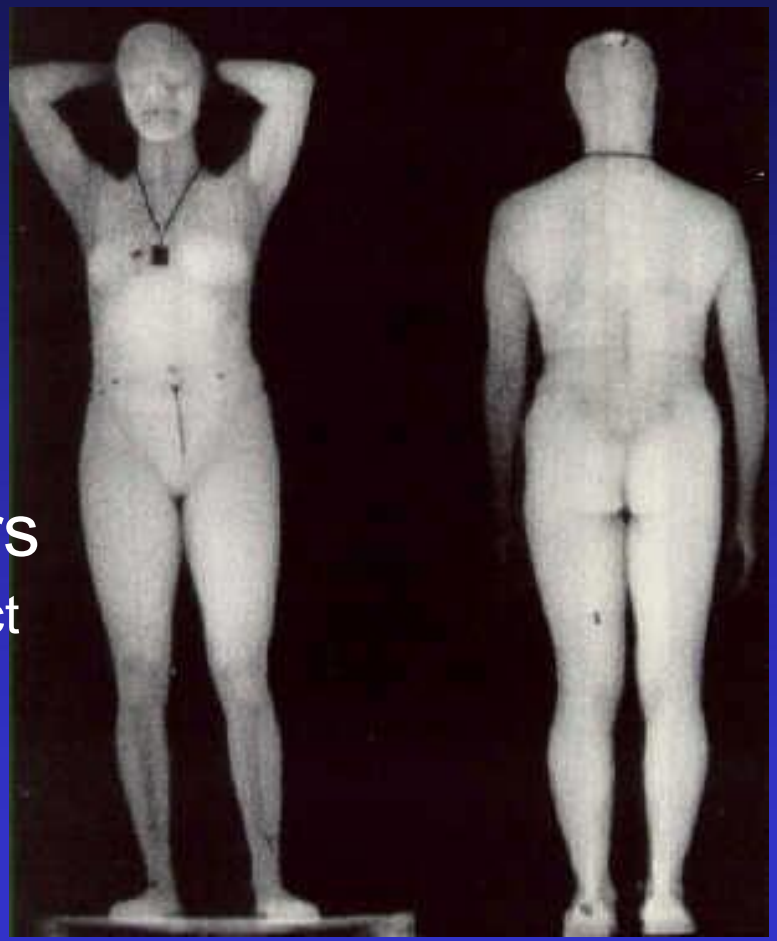
# Category I – General Use

ANSI N42.17

Backscatter Technology

- Class A: Full Body Scanner
  - 0.25μSv (25 μrem) effective dose per *screening*
  - 250 μSv (25 mrem) per year

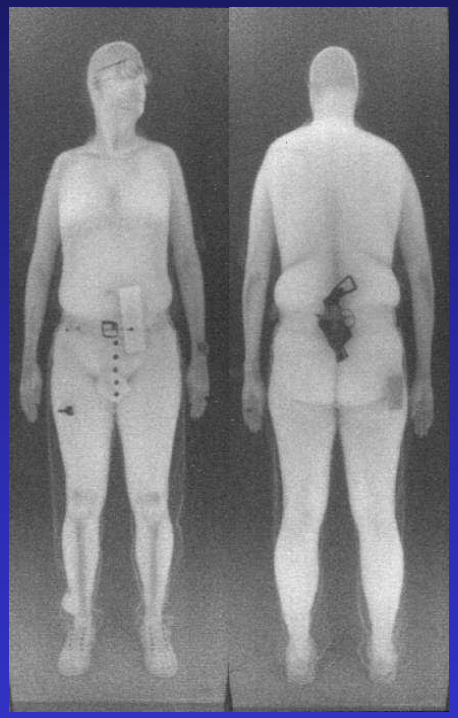
- Class B: partial body scanners
  - Ambient Dose Equivalent Area Product
  - ADAP < 0.03μSv $m^2$ per *scan*
  - *Ceiling* N = 75 μSv $m^2$ / ADAP



# Backscatter X-Ray
## (Secure 1000)

Manufactured by Rapiscan Products Inc.

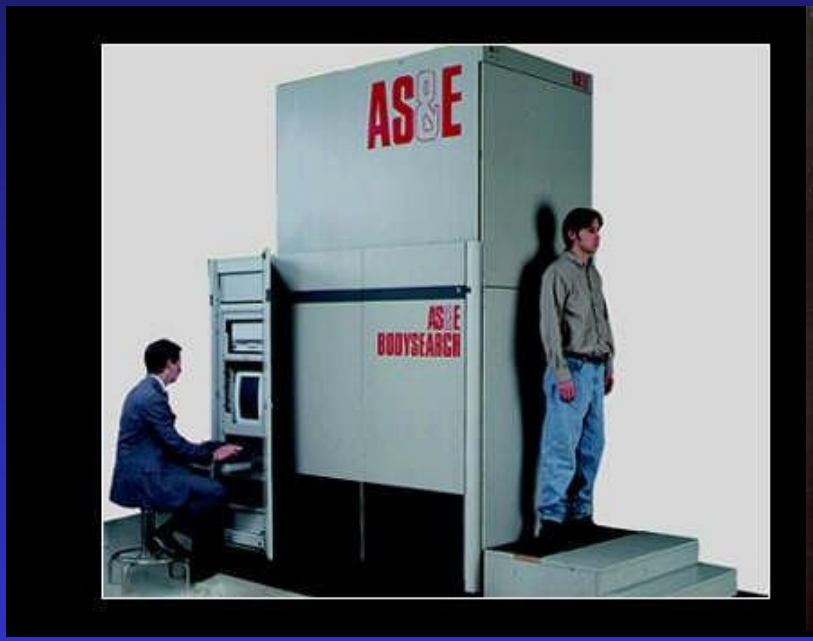
Detectors

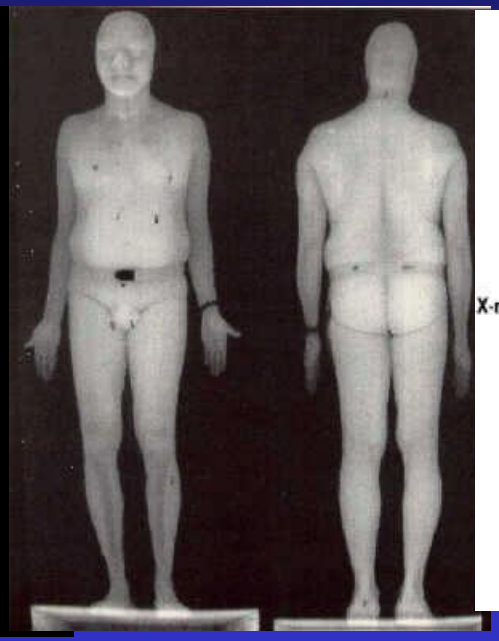


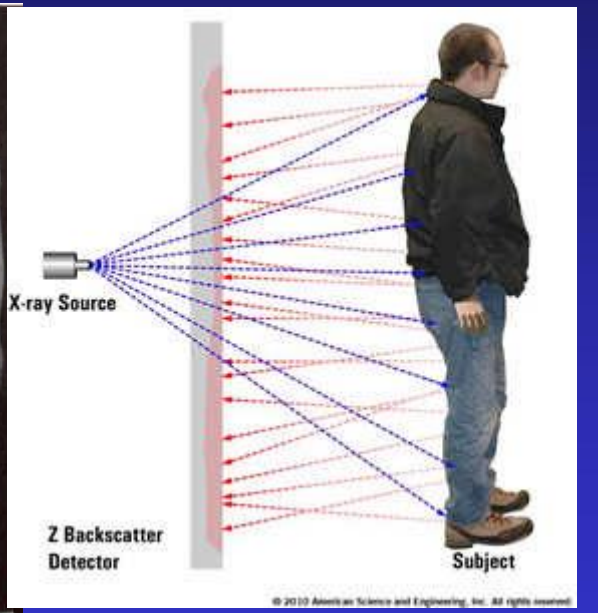
Effective Dose: Less than 0.25 μSv (25 μrem) per screening

# Backscatter X-Ray
## (Bodysearch)

Manufactured by American Science and Engineering, Inc.





# Transmission X-ray

**ANSI N42.17**

Category 2 – Limited Use

- Replaces strip search

- Class A: Full Body Scanner
  - 10μSv (1 mrem) effective dose per *screening*
  - 250 μSv (25 mrem) per year

- Class B: partial body scanners
  - Ambient Dose Equivalent Area Product
  - ADAP < 3 μSv $m^2$ per *scan*
  - *Ceiling* N = 75 μSv $m^2$ / ADAP

# Transmission X-Ray
## (Conpass Body Scanner)

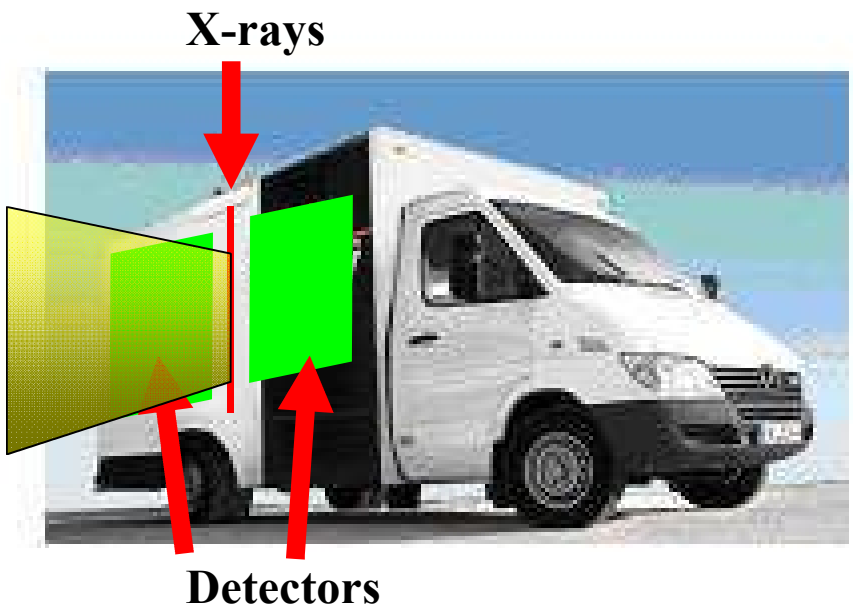
**Manufactured by MMC International**

# Transmission X-rays Specifications

(Conpass Body Scanner)

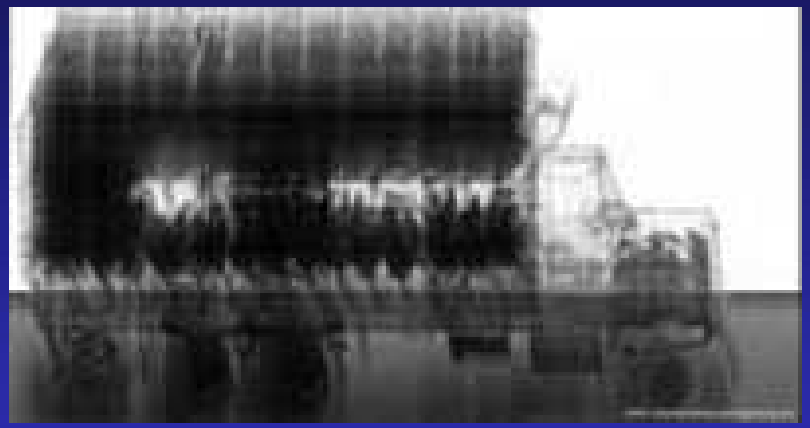
- Scanning Time: 10 Seconds
- Dose to a Subject: 5 µSv (0.5 mrem) per Inspection
- Dose to Operator < 5 µSv (0.5 mrem) per hour
- 100x More Dose to Subject than Backscatter imaging

# Backscatter Cargo, Vehicle, Inspection Systems




Backscatter X-ray System for Cargo, Locating threats in parked vehicles, and Possibly Screening of Pedestrians

# Backscatter vs. Transmission X-ray Technology



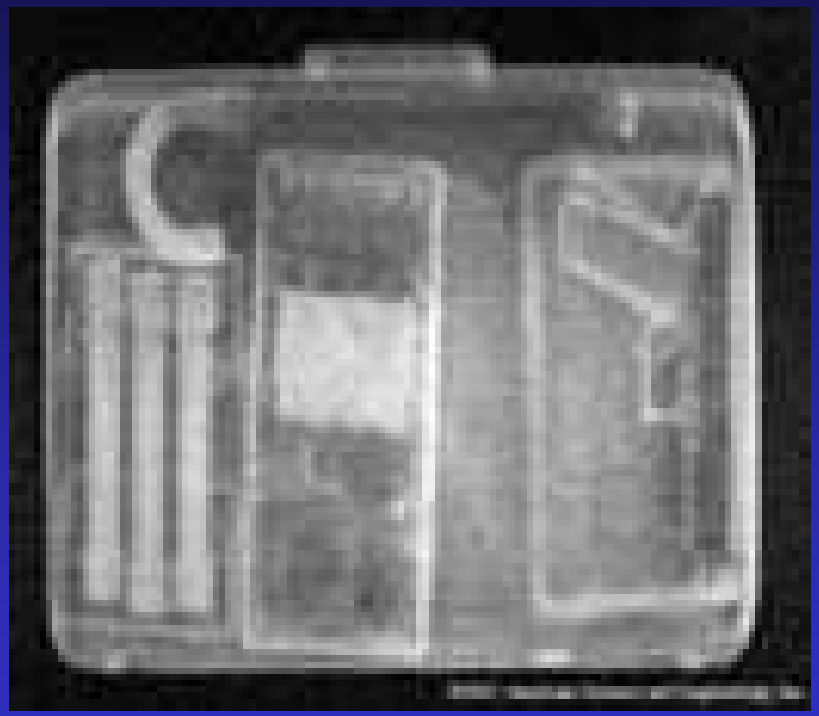
**Backscatter Image**

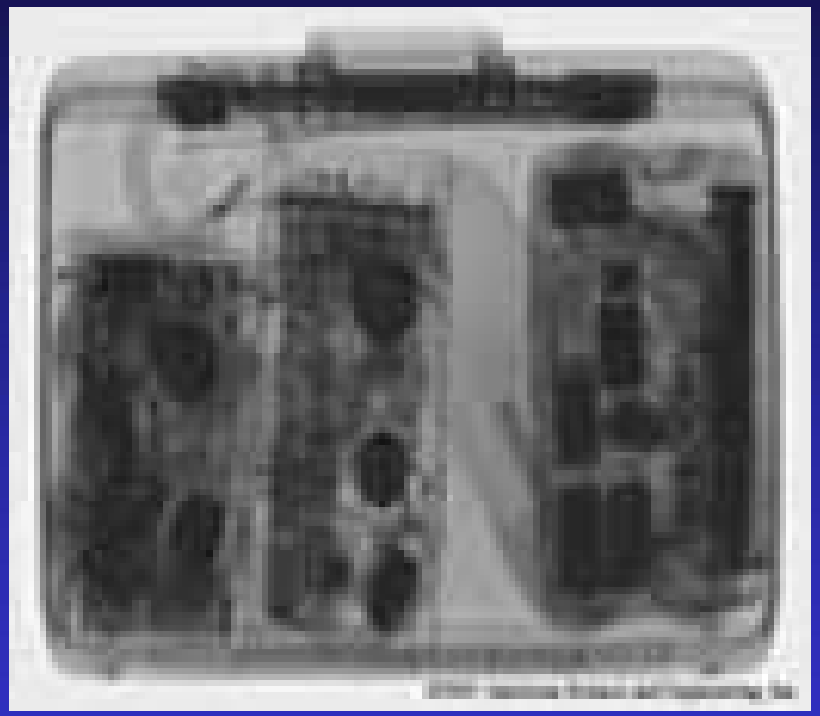
**Highlights Lighter elements**

**Transmission Image**

**Highlights Heavier elements**

# Backscatter vs. Transmission X-ray Technology





# Mfr's Proposed Uses

- Airline Passenger Control
- Diamond Mines → OSHA ?
- Prisons → OSHA ?
- Public Offices → OSHA ?
- Banks → OSHA ?
- Etc.

NOTE:

Occupational radiation exposures to the operators and workers in certain industries.

Screenings of members of the public may be optional, but workers may feel compelled to comply to x-ray screening to keep their jobs.

# Affected Federal Departments

- **Department of Homeland Security**
  - Customs and Border Protection
  - Transportation Security
- **Department of Defense**
- **Department of Justice**
- **Department of State**
- **Department of Treasury**
  - Secret Service
- **Department of Energy**
- **NASA**

# VACIS Demonstration
## (fixed and mobile setup)

# Driver Dose Potentials

## *Dose Estimator for a worker who drives cargo through a Co-60 VACIS System*

*Directions: Insert assumption values in red. The rest of this spreadsheet is password protected.*

***Modality: Stationary Setup***

| *KEY FACTORS THAT AFFECT DOSE* | Assumptions | COMMENTS |
|---|---|---|
| **Exposure Rate (microR / hr) measured at the driver's location** | *190* | This value (190) represents the highest measurement obtained during a study in Orange County, CA. You may insert a higher number but it may not reflect reality. I would not recommend going any higher than 250 micro R per hour. |
| **Length of Scan (seconds)** | *10* | This assumes the driver always remains at the same location during the scan, which we know is not true because he/she drives the cargo pass the scanner thereby reducing the time spent near the source, increasing the distance and shielding from the source. The typical range is from 5 to 20 seconds. Ten seconds was the approximate length during the study in California. *No matter what value is used, this assumption will tend to OVERESTIMATE the drivers actual dose.* |
| **Number of scans per day that a driver can complete** | *50* | This assumes the same driver conducts the driving. |
| **Number of days per year a driver works** | *365* | A very conservative assumption |
| Estimated ANNUAL DOSE (mrem) | **9.6** | This should be compared to the *dose constraint* " per year from any single source of radiation. |
| DOSE LIMITS | | |
| Dose Limits to Workers "Radiation Workers" | 5,000 | mrem per year |
| ***Dose Limits to Members of General Public*** | 100 | mrem per year from ALL sources |
| | 25 | mrem per year to any single so |

# Cargo and Rail VACIS

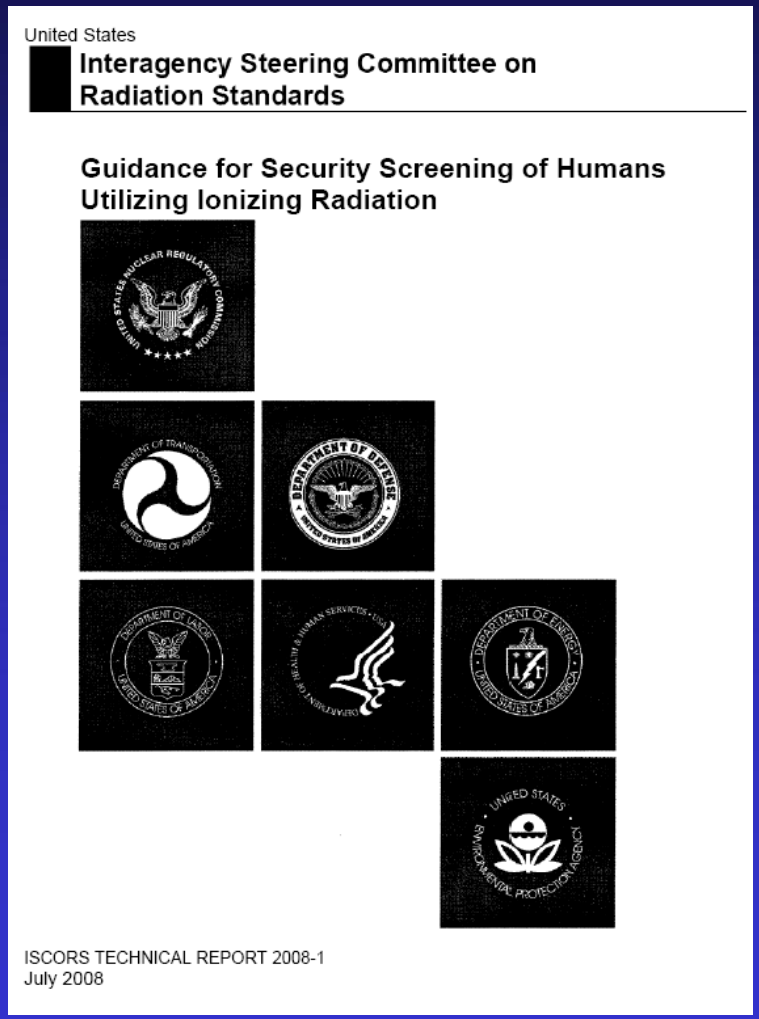
Cargo

Rail

# ISCORS

## Interagency Steering Committee on Radiation Standards

- **Agencies should document**
  - Security needs, magnitude of threat and risk of not implementing the screening technology
  - Optional technologies considered
  - Risks (radiation, safety, etc.) vs. reduced security threat
  - Confirm availability of funding to implement a comprehensive program
  - Commitment for periodic reassessment


United States
Interagency Steering Committee on Radiation Standards

Guidance for Security Screening of Humans Utilizing Ionizing Radiation

ISCORS TECHNICAL REPORT 2008-1
July 2008

http://www.iscors.org/doc/GSSHUIR_July_2008.pdf

# Recent Literature

- **Airport Full-Body Screening: What is the Risk?**
  - TSA deployed 486 scanners in 78 airports
  - 1,000 scanners to be deployed by 2012
  - Scan < 1% dose from cosmic exposures
  - No significant threat of radiation from scans

**Mehta, P. and Smith-Bindman, R. *Archives of Internal Medicine*, March 28, 2011**

# Future of Ionizing Radiation

- **Dr. Cardella Predicted**
  - Increased uses of IR
  - Micro-trend: improved X-ray Tubes
  - Mega-trend: non-radiologist operators
  - Mandated polices (formal training)
  - Internet Generation

# Summary

- **Regulations**
- **Instrumentation**
- **Homeland Security Technologies**
  - X-ray technologies
  - Gamma-ray technologies
- **New "Security-based" workforce that is exposed to radiation**
- **Research showing no significant risks.**

# Worker Concerns About Security X-Ray Equipment

- **Not Classified as Radiation Workers**
  - Some receive little or no radiation training
  - Most are not monitored with dosimetry
  - May receive "occupational exposures"

- **Worker concerns about exposure**
  - EDS Systems in Airports (N= 40,000+)
    - ✓ Federally owned equipment, states lost jurisdiction
    - ✓ OSHA regulates federal workers
  - Vehicle and Cargo Inspection Systems (VACIS) at Ports and Border Crossings (union and federal employees) (N= 10,000+)

# State Survey

**December 2002**

Does your state inspect industrial application radiation machines at airports or other points of entry into the US?

**23 States responses:**

- **15 – Yes; 2 to 5 year inspection frequency**
- **1 – Yes, no specific frequency**
- **1 - Yes, annually!**
- **1 - Yes, until TSA took over**
- **1 – Yes, but inspections conducted by FDA**
- **1 – Yes, continue to register and inspect until TSA decision**
- **1 – No, do not register or inspect**
- **2 – No**

# State Survey

**December 2002**

Does your state regulate or inspect federally-owned/operated x-ray machines located at federal facilities, airports or other points of entry in the US?

**23 States responses:**

- **16 - No**
  - **upon request, some medical mobile units**
- **1 –Yes: working with TSA to register and inspect**
- **1 – FDA does all federal inspections**
- **5 – no response**

# State Survey

**December 2002**

Have you or would you respond to a federal worker and state resident who complains of exposure violations within a federal agency and no mechanism for change?

**23 States responses:**

- **9 – OSHA**
  - **6 – OSHA;**
  - **1 – OSHA and FDA;**
  - **1 – OSHA and TSA;**
  - **1 – OSHA or NRC**
- **3 - FDA**
- **4 – Federal Agency**
- **1 – Public Health Authority**
- **1 – TSA**
- **1 – Employee or Union Representative**
- **1 – Federal Court**
- **3 – no response**

# State Survey

**December 2002**

What has been your state's experience in enforcing or attempting to enforce state regulatory radiation machine authority with a federal agency?

**23 States responses:**

- **11 – None**
- **1 – Poor (serious violations)**
- **1 – OSHA referred back to State**
- **1 – Good (when inspection conducted upon their request)**
- **1 –provided technical input**
- **3 – no response**
- **5 - Ask Federal facilities (EPA, Air Force, FBI, Fed. Highway Admin) to register but compliance is optional**

# State Survey

**December 2002**

Are you aware that OSHA Regulations, 29 CFR 1910.1096 have not incorporated current 10 CFR Part 20 requirements particularly worker exposure limits nor mention protection required for a declared pregnant woman?

**23 States responses:**

- **5 – No**
- **13 – Yes**
- **1 – Does not directly affect the State**
- **4 – No response**

# Radiation Workers?

**10 CFR 20.1003 Definitions.**

- ***Member of the public*** **means any individual except when that individual is receiving an occupational dose.**

- ***Occupational dose*** **means the dose received by an individual in the course of employment in which the individual's assigned *duties involve exposure to radiation* or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public.**

# Radiation Workers?

10 CFR 835 DOE Definitions.

- **Member of the public** means an individual who is not a general employee. An individual is not a ``member of the public'' during any period in which the individual receives an occupational dose.

- **Occupational dose** means an individual's ionizing *radiation dose (external and internal) as a result of that individual's work assignment*. Occupational dose does not include doses received as a medical patient or doses resulting from background radiation or participation as a subject in medical research programs.

# Radiation Workers?

**FAA Radiation Safety Plan.**

- **The existing OSHA regulation for ionizing radiation, 29 CFR 1910.1096, is also outdated. For example, it does not specifically address protection of pregnant workers. Current ACGIH 1998 safety standards for ionizing radiation are adopted, including new ionizing radiation terminology, exposure units (dose and dose-rate), and exposure safety guidelines (Table 1, *ibid.*), as relevant to FAA workplace environments. However, OSHA's safety program elements for ionizing radiation (e.g., labeling, personal monitoring triggered by a certain radiation level, reporting, and recordkeeping) shall be preserved, as well as the ACGIH-endorsed ALARA (as low as reasonably achievable) principle to keep radiation exposure levels below the recommended guidelines in the workplace.**

- ***Commercial products* and unintentional sources of workplace radiation (such as office computers and video display terminal (VDT) units, cellular and satellite telephones, microwave ovens, and *personnel security screening systems*) are not included in the RSP. These are covered by other applicable public safety and health radiation emissions standards and regulations of the Federal Communication Commission (FCC) and the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH). However, radiation safety for FAA users of such devices shall be assured by requiring manufacturer data and proof of compliance with applicable safety standards (see paragraph 1410(d)(3)).**
  - (3) Ensure that manufacturers and suppliers of FAA-purchased equipment containing radiation sources provide appropriate radiation source identification, emissions data, and potential hazard warning labels that demonstrate compliance with RSP standards and guidelines.

# Radiation Workers?

OSHA Definitions.

- ***Restricted area*** **means any area access to which is controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.**

- **TSA Screeners do not work in "restricted areas" per the definition above.**

# What do the Numbers Mean?

**(above background radiation Levels; ~20 uR/hr or 360 mrem/yr)**

- **50** uR/hr leads to 100 mrem (1 mSv), which is the public dose limit
- **50** mrem / month – PREGNACY DOSE LIMIT
- **500** uR/hr is FDA leakage limit at 5cm from the surface of the cabinet X-ray unit
- **5,000** mrem is the occupational dose limit to the whole body (50 mSv)
- **50,000** mrem is the occupational dose limit to the hands / feet (500 mSv)
- **2,000** mrem is the ICRP recommended annual dose limit (2 mSv)

# Interpreting Dose

| Exposure Rate (uR / hr) | 2000 hours/year or 160 hours/month | Dose | Comment |
|---|---|---|---|
| 50 | | 100 mrem/ yr | Public Dose |
| 313 | | 50 mrem/mth | Pregnancy Dose Limit |
| 500 | | - na - | FDA Leakage Limit |
| 2,500 | | 5,000 mrem/yr | Whole Body Dose |
| 1,000 | | 2,000 mrem/yr | ICRP Dose |

# Questions

# Decommissioning the Glenn Research Center Cyclotron

Gerald Wood, SAIC

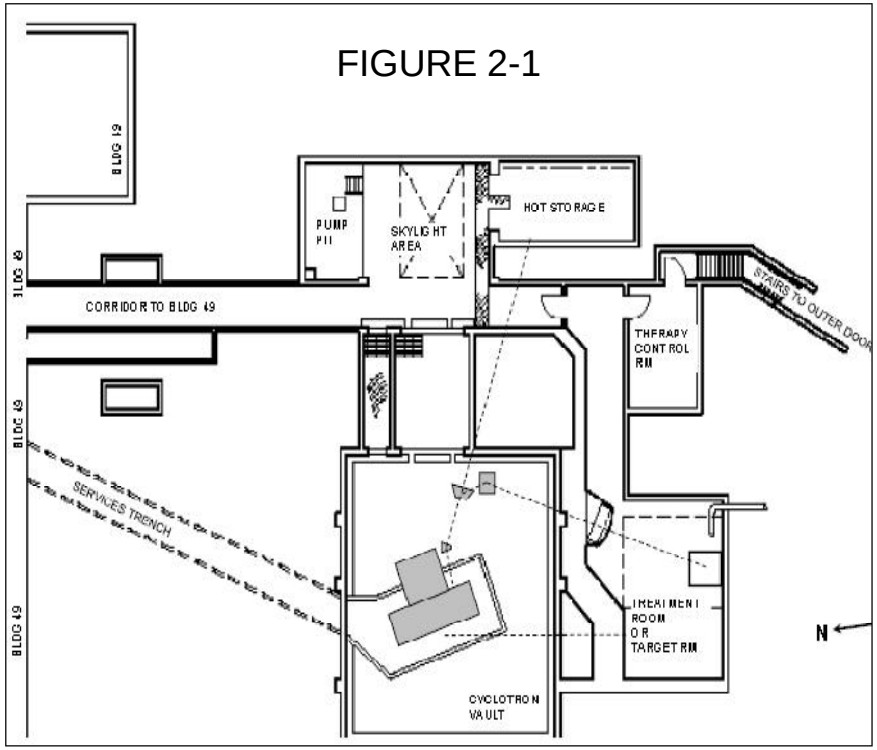
Plum Brook Station
Sandusky, Ohio

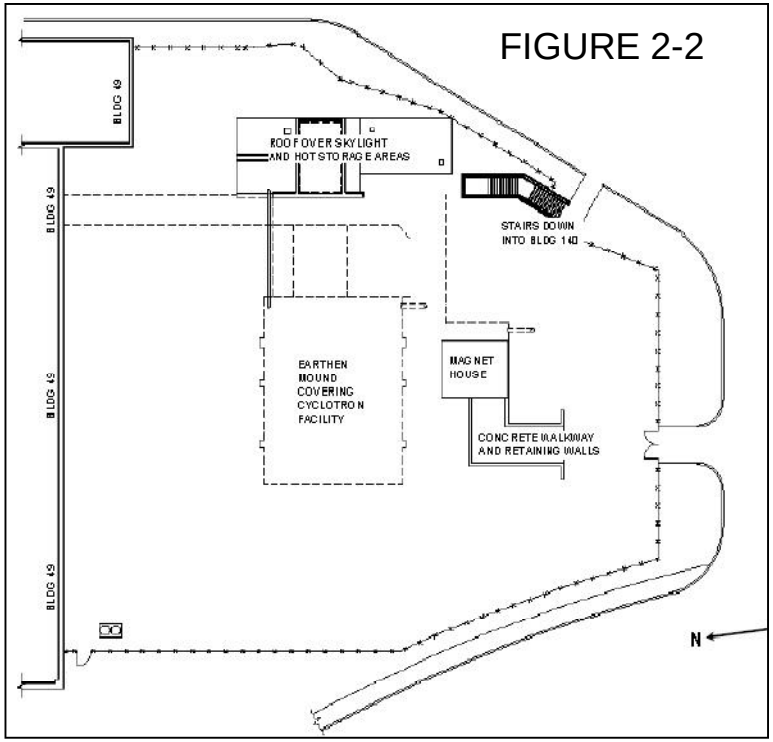
# History of the GRC Cyclotron

The property is a 69-inch cyclotron type particle accelerator at the NASA Glenn Research Center at Lewis Field. The facility is located in Building 140 which interconnects at the basement level with Building 49. The two buildings lay between Wolcott Road and the north-western edge of the Cleveland Hopkins International Airport boundary fence near the South-Eastern boundary of the NASA property.

# History of the GRC Cyclotron

- The cyclotron machine is located in Building 140, which is predominantly a below grade structure. The layout of the Building 140 below grade structure is shown in Figure 2-1. In addition to the below grade structure, there is a small above grade penthouse area housing a set of beam magnets, and it contains an enclosed concrete staircase that affords access to an above ground access door. The above grade area is shown in Figure 2-2.



# History of the GRC Cyclotron

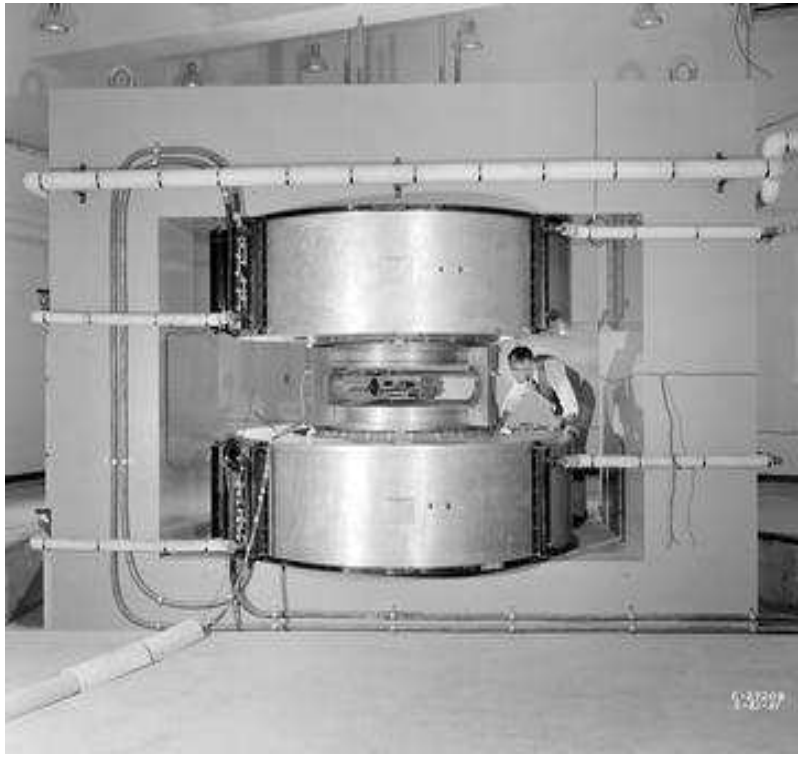
- The NASA Glenn Research Center facilities have their origin in 1941 when construction began on the National Advisory Committee for Aeronautics (NACA) Aircraft Engine Research Laboratory near Cleveland, Ohio. Construction was on a 351 acre site of land acquired from the City of Cleveland at the South West boundary of the city. In May of 1942, research began at the facility. The facility was designed to focus on research and development of aircraft engines and would eventually play a major role in the advances in aircraft propulsion during World War II. In 1947, the facility was renamed the Flight Propulsion Research Laboratory. The following year it was renamed the Lewis Flight Propulsion Laboratory in honor of George W. Lewis under whose leadership the early site had been developed and managed. In 1958, President Eisenhower announced the formation of a new space agency, the National Aeronautics and Space Administration (NASA), formed around the organization of NACA, and renamed the facility the NASA Lewis Research Center. In 1998 the facility was renamed NASA John H. Glenn Research Center at Lewis Field.

# History of the GRC Cyclotron

In the late 1940's, General Electric began construction of the cyclotron facility under a 'turn-key' agreement with NACA. In 1955, after about seven years of construction, the 60-inch cyclotron became operational and was turned over to NACA for performance of materials research. It was used in performing material irradiation studies.

# History of the GRC Cyclotron

- In 1955, after about seven years of construction, the 60-inch cyclotron became operational and was turned over to NACA for performance of materials research. It was used in performing material irradiation studies.

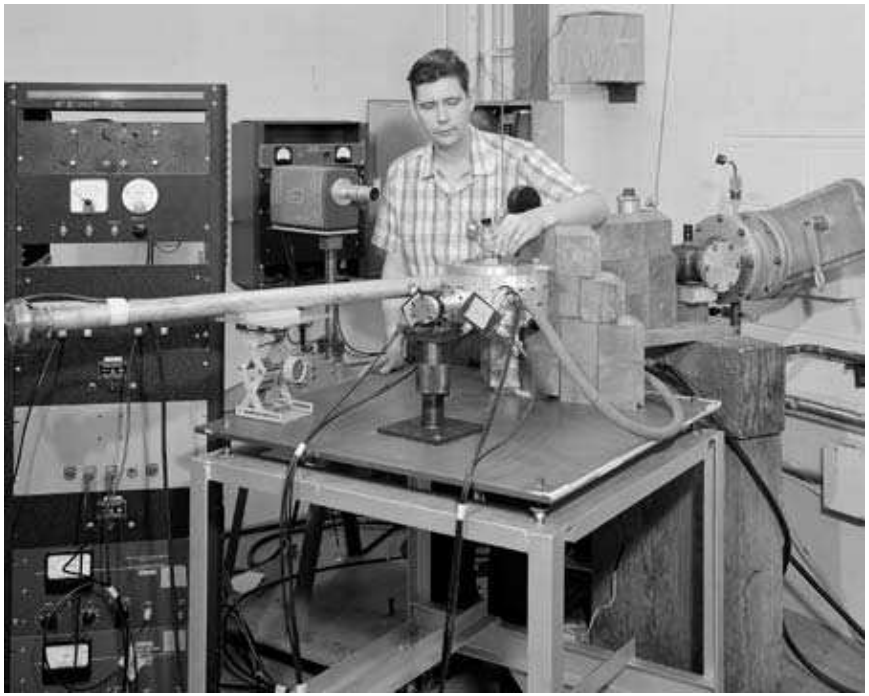


# History of the GRC Cyclotron

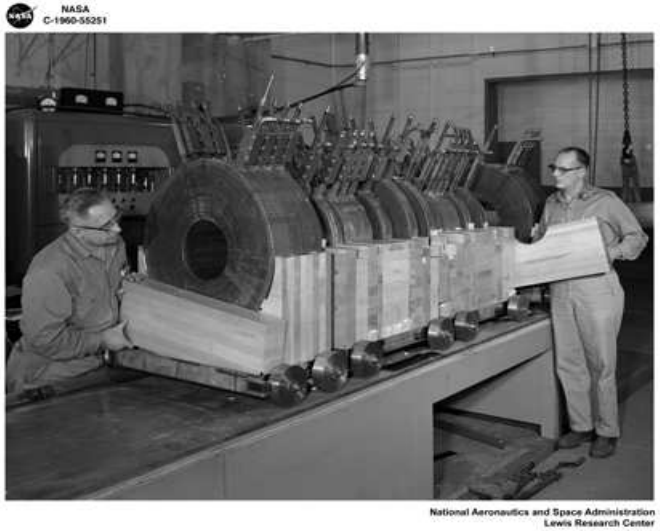
- The system was a charged particle accelerator capable of accelerating alpha particles (He-4 nuclei), protons, and deuterons to energies of 40 MeV, 20 MeV, and 20 MeV respectively.

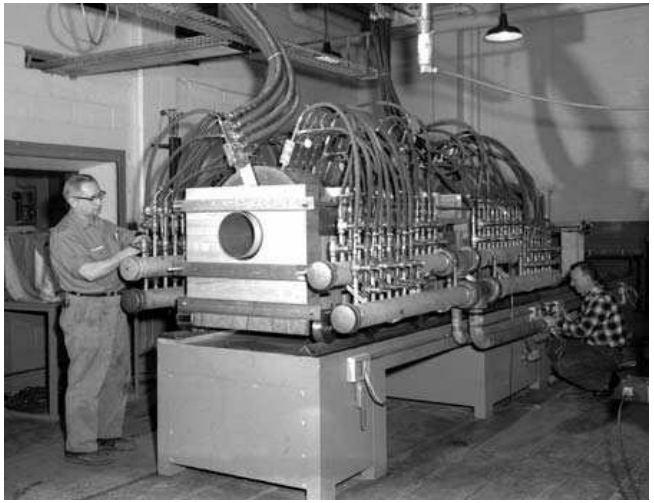
# History of the GRC Cyclotron

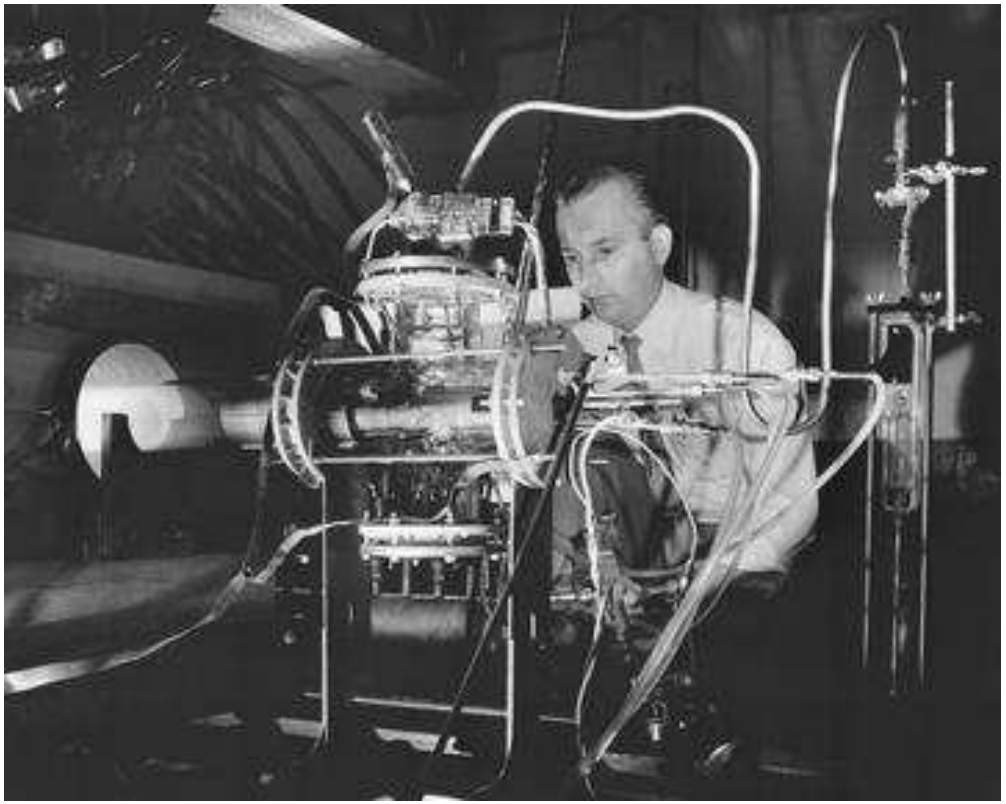
- The system operated extensively until 1970 when it was shutdown to perform a significant upgrade to the machine.

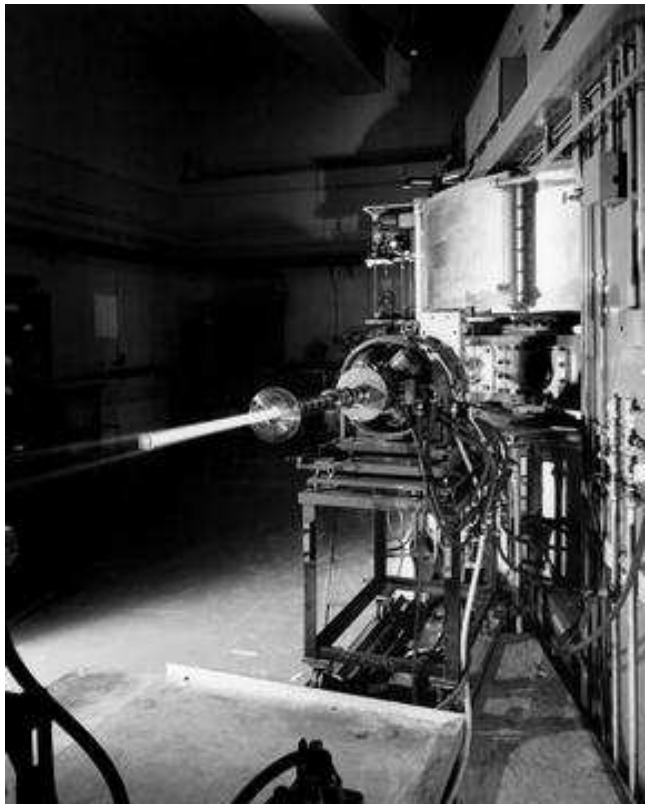


# History of the GRC Cyclotron







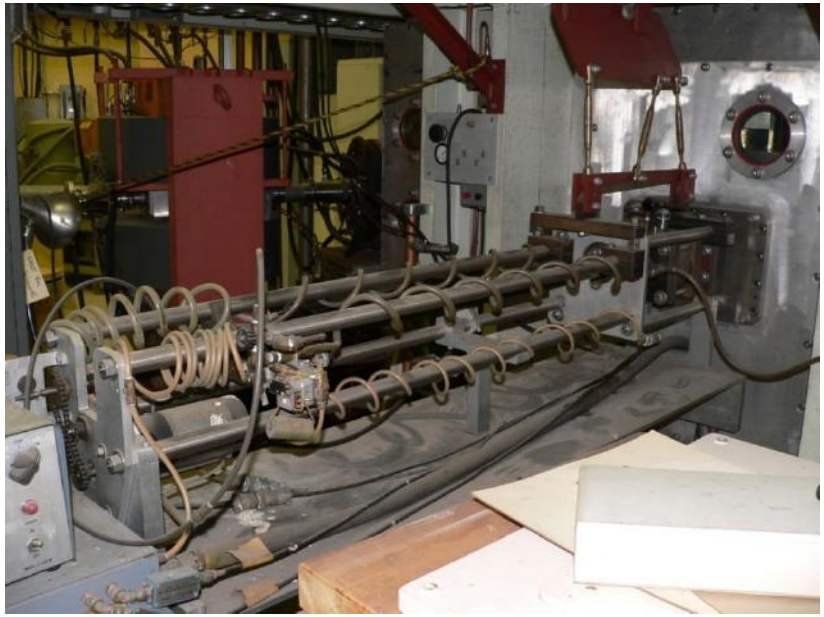


# History of the GRC Cyclotron

- Dismantlement of the old cyclotron equipment was performed from October of 1970 until July of 1971 when installation of the modified equipment began. Work continued on the upgrade installation until January of 1973 when startup testing began. The modified system was a 69-inch cyclotron with the capability of variable energy.

# History of the GRC Cyclotron

- It was a more versatile system capable of accelerating protons to energies of 10 to 55 MeV, alpha particles to energies of 24 to 58 MeV, deuterons to energies of 7 to 29 MeV, and He-3 nuclei to energies of 15 to 65 MeV. In addition, the system could produce collimated neutron beams by bombardment of beryllium target materials. The modified machine had a much higher efficiency, meaning that less particle impingement would occur inside the machine, resulting in less radioactive activation of the materials of construction.



# History of the GRC Cyclotron

- In 1975, a cooperative program between NASA and the Cleveland Clinic Foundation was implemented in which the cyclotron would be operated by NASA technicians to provide neutron radiation therapy to oncology patients under the care of Cleveland Clinic Foundation medical staff.

# History of the GRC Cyclotron

- Additional particle beam control systems were installed to allow generation of collimated neutron beams in a patient treatment center. The center was part of a national research program that included Fermi Laboratory, Naval Research Lab, Texas A&M, and the University of Washington. The NASA system was the first to include both horizontal and vertical neutron beam capabilities.

# History of the GRC Cyclotron

- Building remodeling was done to provide for a patient receiving area. The experimental treatment program lasted until late 1990 when the program was terminated after treating about 1200 patients.
- There was documentation in the records that would indicate that the cyclotron was also engaged in the production of radioisotopes prepared for medical administration to human patients in hospitals in the area.
- Operator log entries for the period 1975 through 1990 indicate that the majority of the cyclotron run time was devoted to the Cleveland Clinic Foundation treatment studies. However, irradiation experiments also continued at the cyclotron for other NASA irradiation studies and support of university programs.

# History of the GRC Cyclotron

- The system continued to operate as a research tool until it was permanently shut down in December 1990.

- The cyclotron is currently licensed under paragraph 9.A. of NRC License 34-00507-16.

# Decommissioning of the GRC Cyclotron

- In 1991, NASA implemented a plan that would perform decontamination and release of the cyclotron facility. The plan included decontamination of laboratories and rooms in Building 49, decontamination of adjacent rooms in Building 140 and converting them to use by the Health Physics Staff, and closure of the cyclotron itself for decay-in-storage. In 1994, NASA planned a major renovation to Building 49 to establish the Comparative Technology Research Center.

# Initial Decommissioning Efforts

- Radioactive contaminants identified during surveys included **Cs-137, Co-60, Ra-226, Na-22, Mn-54, Ag-110, Th-232, and U-238**.
- It is also expected that the concrete walls of the facility may contain the activation products **Eu-152 and Eu-154.**
- During operation, radiation from the cyclotron vault was shielded by a 'water wall' and water filled door. Both were drained during the decontamination project. Analysis of water samples from the two tanks found no radioactive contamination.
- Oil contaminated with **Zn-65**, an activation product of irradiated copper, was packaged in drums and allowed to decay. After a period of decay of about six years, it was disposed of as waste oil.
- Nearly all of the loose radioactive material in the facility was packaged and shipped for disposal as radioactive waste.
- When the project completed in late 1994, Building 140 was left secured to allow further decay of the cyclotron and the beam equipment.

# Subsequent Decommissioning Efforts

- In 2010 NASA began additional efforts to complete the decommissioning of the Cyclotron Facility, as an NRC licensed facility the cyclotron bibliography of decommissioning controlling documents includes the following benchmark publications:
  - United States Nuclear Regulatory Commission Inspection Manual, Inspection Procedure 84750
  - NUREG-1727, "NMSS Decommissioning Standard Review Plan," September 15, 2000
  - NUREG-1757, "Consolidated NMSS Decommissioning Guidance", September 2003
  - NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM), Revision 1 (June 2001)
  - Title 10 Code of Federal Regulations, Part 20, Subpart E, "Radiological Criteria for License Termination"
  - Title 10 Code of Federal Regulations, Part 20.1402, "Radiological Criteria for Unrestricted Use"
  - Title 10 Code of Federal Regulations, Part 61.55, "Waste Classification"
  - EPA/SW-846, Test Methods for Evaluating Solid Waste, Volume 1A: Laboratory Manual Physical/Chemical Methods, 1986 updated 1992

# On-Going Decommissioning Efforts

- Approval of and implementation of a Characterization Plan was initiated in early 2010 and continues at this time.
- The specific goals of this characterization are;
  - Determine the nature and extent of radiological and industrial contaminants
  - Provide radiological data to support classification of the facility (MARSSIM impacted Class 1, 2, or 3 or non-impacted)
  - Provide data to support evaluation of remedial alternatives and technologies
  - Support development of the Decommissioning Plan and Final Status Survey Plan (FSSP)
  - Provide input to pathway analysis/dose or risk assessment models for determining site-specific derived concentration guideline levels (DCGLs)
  - Provide input for estimating health and safety and environmental impacts as a result of decommissioning activities
  - Provide data for preparing project schedules, cost estimates, and waste estimates
  - Provide data to support development of waste stream profiles to meet disposal facility waste acceptance criteria
  - Provide data needed to complete FSS Design Packages

# On-Going Decommissioning Efforts

- Preliminary results of the characterization effort display the following trends;
  - Only minor surface contamination clean-up will be required in systems and structures outside the cyclotron vault room.
  - Isolated areas of loose surface alpha activity exist which are restricted to the radioisotope production and preparation areas.
  - Cyclotron machine DEE's, metal support structures plus the associated control and beam management components and systems show activation and contamination throughout the cyclotron vault room and in the concrete structure of the vault room.

# On-Going Decommissioning Efforts

- Further efforts remaining;
  - Complete characterization field efforts, sampling for hard to detect nuclides and Characterization Report
  - Develop Decommissioning Plan
  - Develop Final Status Survey Plan
  - Acquire Radiological and Mixed Waste Contracts
  - Procure and Implement Decommissioning Contracts
  - Perform Final Status Surveys
  - Develop and submit Final status Survey Reports
- Final Licensed Activity is;
  - Terminate the NRC License

# On-Going Decommissioning Efforts

- Determining the nature and extent of radiological and industrial contaminants
  - Radiological assessment includes characterizing
    - the extent of surface deposited contamination
    - the depth of irradiation in facility structures, systems and components
    - the deposition of activity throughout fluid systems
    - and the distribution of nuclides in these assessments

# On-Going Decommissioning Efforts

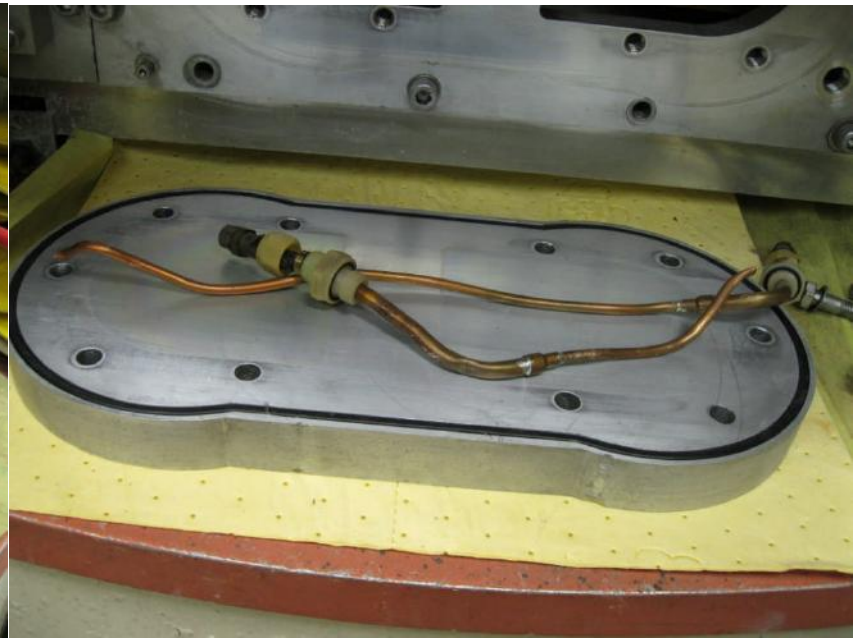
- Surface deposited contamination

# On-Going Decommissioning Efforts

- Determining depth of irradiation in facility structures, systems and components

# On-Going Decommissioning Efforts

- Determining depth of irradiation in facility structures, systems and components



# On-Going Decommissioning Efforts

- Determining deposition of activity throughout fluid systems

# On-Going Decommissioning Efforts

- Preliminary results of the characterization effort display the following trends;
  - Only minor surface contamination clean-up will be required in systems and structures outside the cyclotron vault room.
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# On-Going Decommissioning Efforts

- Further efforts remaining;
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  - Develop Final Status Survey Plan
  - Acquire Radiological and Mixed Waste Contracts
  - Procure and Implement Decommissioning Contracts
  - Perform Final Status Surveys
  - Develop and submit Final Status Survey Reports
- Final Licensed Activity is;
  - Remove the facility from the list of BPM on the license

# On-Going Decommissioning Efforts

- Significant Trends to Date for Characterization Report Development
  - Predominant nuclides in volumetric concrete sampling have been Eu-152 & Co-60
    - Eu-152 consistently found in concrete cores ranging from 3.4 pCi/gm to 2.0 pCi/gm from the structural surface to 6” of depth at that elevation corresponding to the DEE assemblies
    - Co-60 noted in rebar at various depths ranging from 1.3 pCi/gm to 0.2 pCi/gm
  - The predominant nuclide in metal sampling has been Co-60 at levels as high as 160+pCi/gm for irradiated materials in close proximity to the DEE assemblies
  - These levels preclude a “simple” decommissioning as described in NUREG 1757 Volume 2, and indicate a Decommissioning Group 4 as the minimum level of complexity for the GRC Cyclotron, precluding the use of NRC generic screening values for DCGL development

# RF Radiation Safety

## NASA Triennial Health Physics Meeting

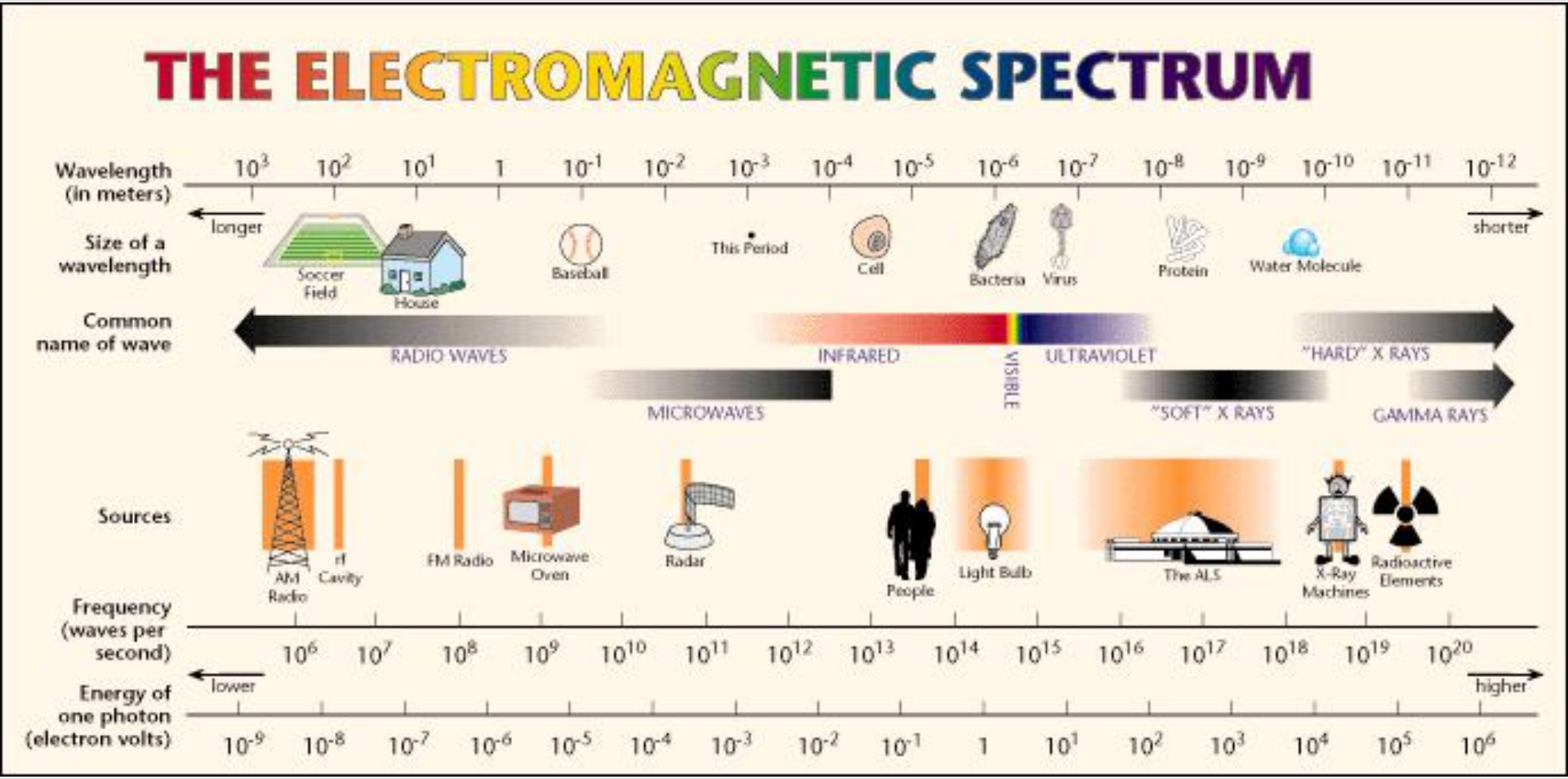
Brad Roberts
Radio Frequency Program

19 April 2011

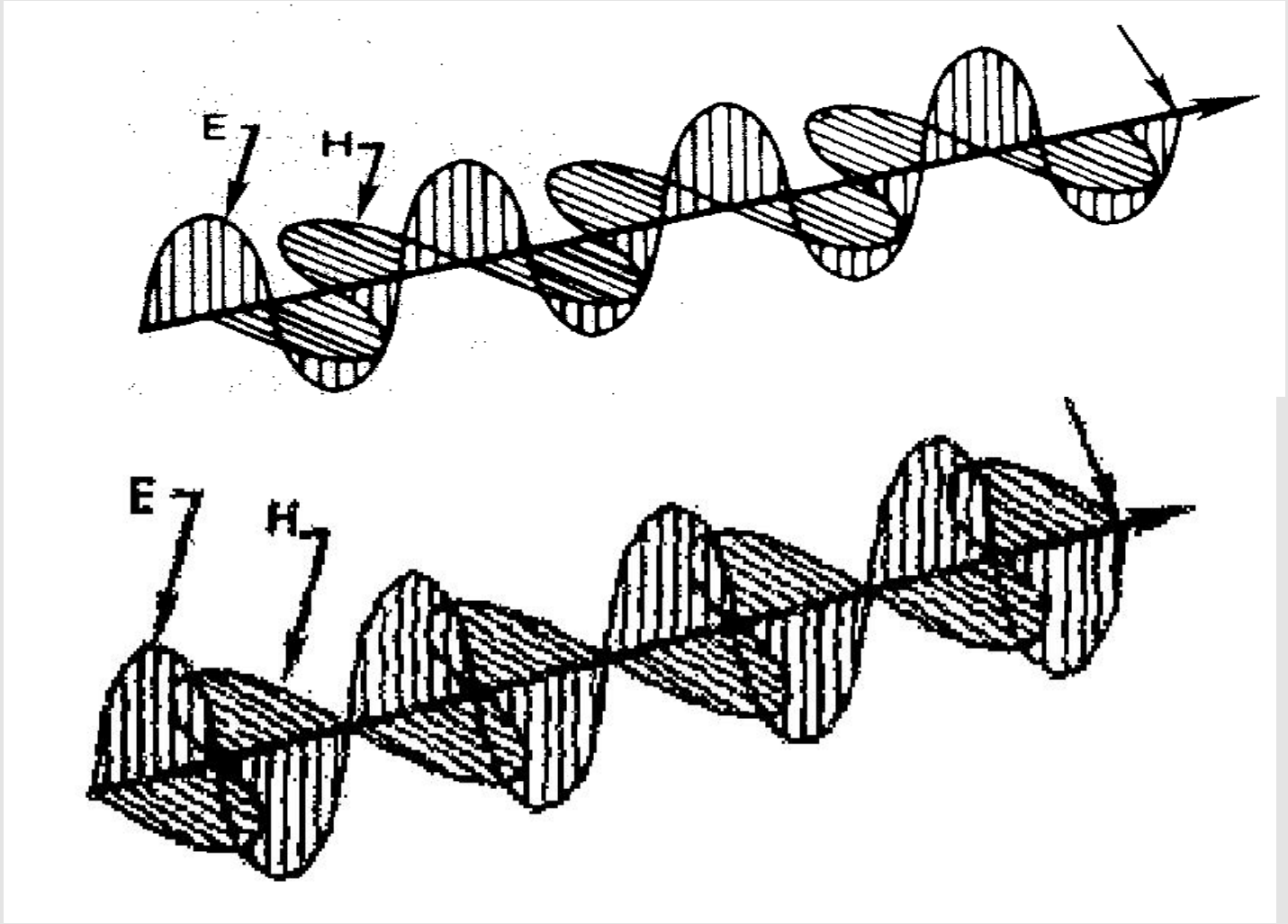
# This Presentation Will Include the Following Topics:

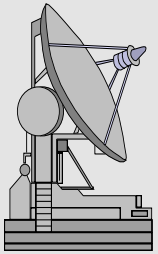
1. Basic Introduction
2. Antennas/Transmission Lines
3. Bioeffects of RF Radiation
4. Standards
5. Instrumentation
6. Radiation Safety Program
7. Wireless Issues
8. Risk Communication

# Introduction to Radio Frequency Radiaiton


THE ELECTROMAGNETIC SPECTRUM
Wavelength (in meters)
$10^3$ $10^2$ $10^1$ 1 $10^{-1}$ $10^{-2}$ $10^{-3}$ $10^{-4}$ $10^{-5}$ $10^{-6}$ $10^{-7}$ $10^{-8}$ $10^{-9}$ $10^{-10}$ $10^{-11}$ $10^{-12}$
longer
shorter
Size of a wavelength
Soccer Field
House
Baseball
This Period
Cell
Bacteria
Virus
Protein
Water Molecule
Common name of wave
RADIO WAVES
INFRARED
VISIBLE
ULTRAVIOLET
"HARD" X RAYS
MICROWAVES
"SOFT" X RAYS
GAMMA RAYS
Sources
AM Radio
rf Cavity
FM Radio
Microwave Oven
Radar
People
Light Bulb
The ALS
X-Ray Machines
Radioactive Elements
Frequency (waves per second)
$10^6$ $10^7$ $10^8$ $10^9$ $10^{10}$ $10^{11}$ $10^{12}$ $10^{13}$ $10^{14}$ $10^{15}$ $10^{16}$ $10^{17}$ $10^{18}$ $10^{19}$ $10^{20}$
lower
higher
Energy of one photon (electron volts)
$10^{-9}$ $10^{-8}$ $10^{-7}$ $10^{-6}$ $10^{-5}$ $10^{-4}$ $10^{-3}$ $10^{-2}$ $10^{-1}$ 1 $10^1$ $10^2$ $10^3$ $10^4$ $10^5$ $10^6$

# Electromagnetic Field





# NONIONIZING RADIATION

Any Electromagnetic Radiation ***NOT*** Capable of Producing Ions Directly or Indirectly.

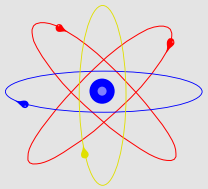
*Radio frequency radiation <u>cannot cause</u> ionization because the associated photon <u>energy is insufficient</u>.

# Nonionizing Radiation

- Generates thermal energy which is absorbed by the body
- When heat is dissipated, thermal effects on the body are reversed
- Effects are not cumulative
- Extreme exposure may produce cataracts, burns or erythema

# Electromagnetic Spectrum

## Compare the Difference



Ionizing

- Produces Ions
- Higher Frequency
- Shorter Wavelength
- Higher Photon Energy (eV)
- Does damage to DNA molecular structure. Effects are cumulative.

Nonionizing

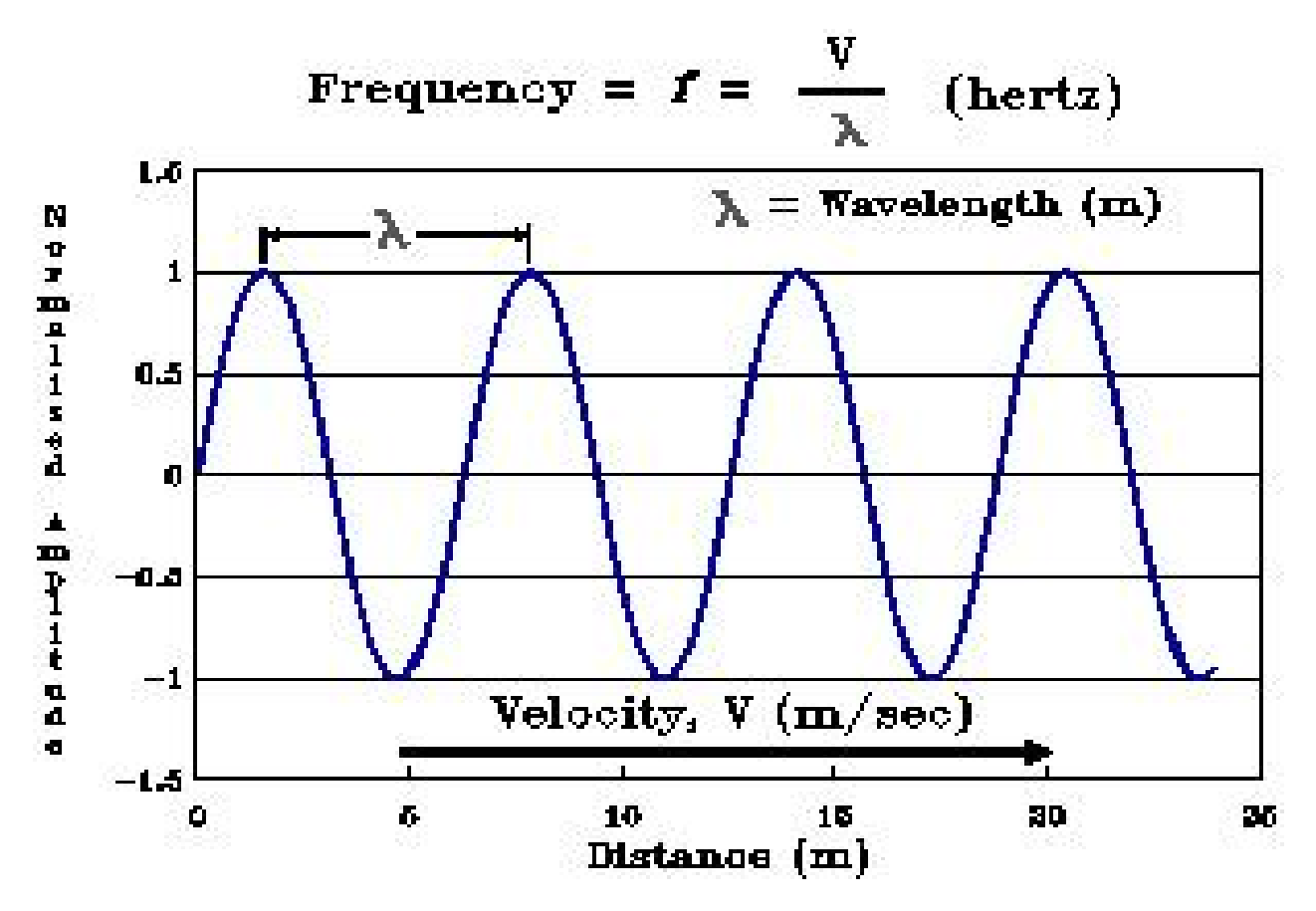
- Cannot Produce Ions
- Lower Frequency
- Longer Wavelength
- Lower Photon Energy (eV)
- Does not damage DNA.

# RF Radiation Frequency Range

3 Kilohertz (kHz) to
300 Gigahertz (GHz)

Wavelength = 100,000 m (62 miles) to
.001 m or 1 mm

# Relationship Between Wavelength and Frequency



# Frequency/Wavelength Units

- Frequency in **Hertz (Hz)**: cycles per second
  - GHz: **Giga**hertz = 1,000,000,000 ( $10^{9}$ ) Hz
  - MHz: **Mega**hertz = 1,000,000 ( $10^{6}$ ) Hz
  - kHz: **kilo**hertz = 1,000 ( $10^{3}$ ) Hz
- Wavelength in **meters (m)**
  - mm: **milli**meter = 0.001 ($10^{-3}$) m
  - cm: **centi**meter = 0.01 ($10^{-2}$) m
  - km: **kilo**meter = 1,000 ($10^{3}$) m

# Frequency Band Designations

| Frequency Range | Designation | Abbreviation |
|---|---|---|
| 3 Hz to 30 Hz | Extremely Low Frequency | ELF |
| 30 Hz to 300 Hz | Super Low Frequency | SLF |
| 300 Hz to 3000 Hz | Ultra Low Frequency | ULF |
| 3 kHz to 30 kHz | Very Low Frequency | VLF |
| 30 kHz to 300 kHz | Low Frequency | LF |
| 300 kHz to 3000 kHz | Medium Frequency | MF |
| 3 MHz to 30 MHz | High Frequency | HF |
| 30 MHz to 300 MHz | Very High Frequency | VHF |
| 300 MHz to 3000 MHz | Ultra High Frequency | UHF |
| 3 GHz to 30 GHz | Super High Frequency | SHF |
| 30 GHz to 300 GHz | Extremely High Frequency | EHF |

# TYPES OF RF SOURCES

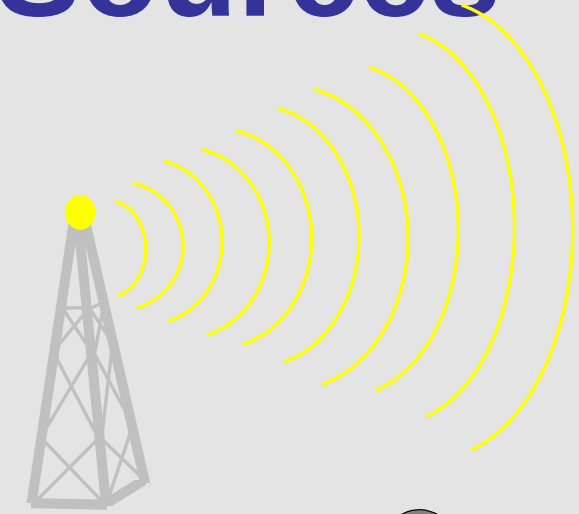
- Radar Systems
- Vehicular Radio Set
- Satellite Communications (SATCOM) Systems
- RF Diathermy Sets, MRI's
- Industrial Heaters/Sealers

- Electronics Countermeasures Equipment (Jammers)
- Backpack, Handheld Radios, Cell Phones
- Avionics Equipment
- Millimeter Wave Radars
- Any Other Sources Which Emit RF

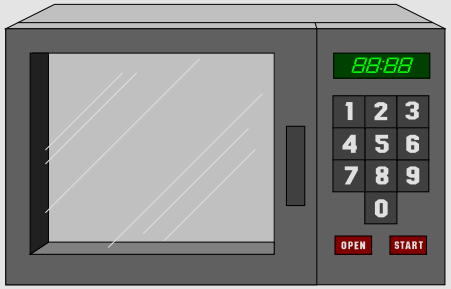
# Nonionizing Sources

**Intentional**

- Radars
- Radio Transmitters
- Cell phones
- Radar Guns
- CB Radios

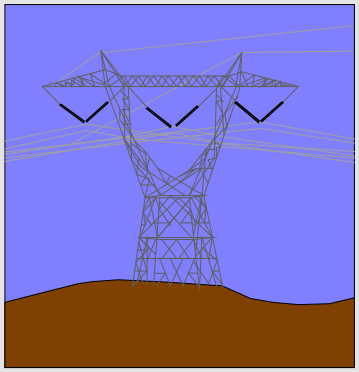


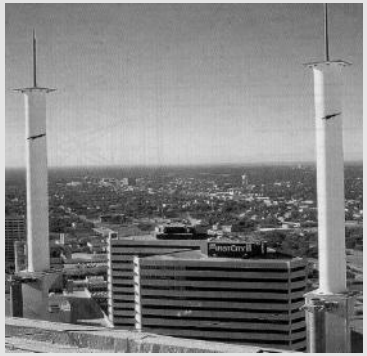
## Nonionizing Sources




Nonintentional

- Microwave Ovens
- Headsets
- Electric Power Lines
- Garage Door Opener
- Computers





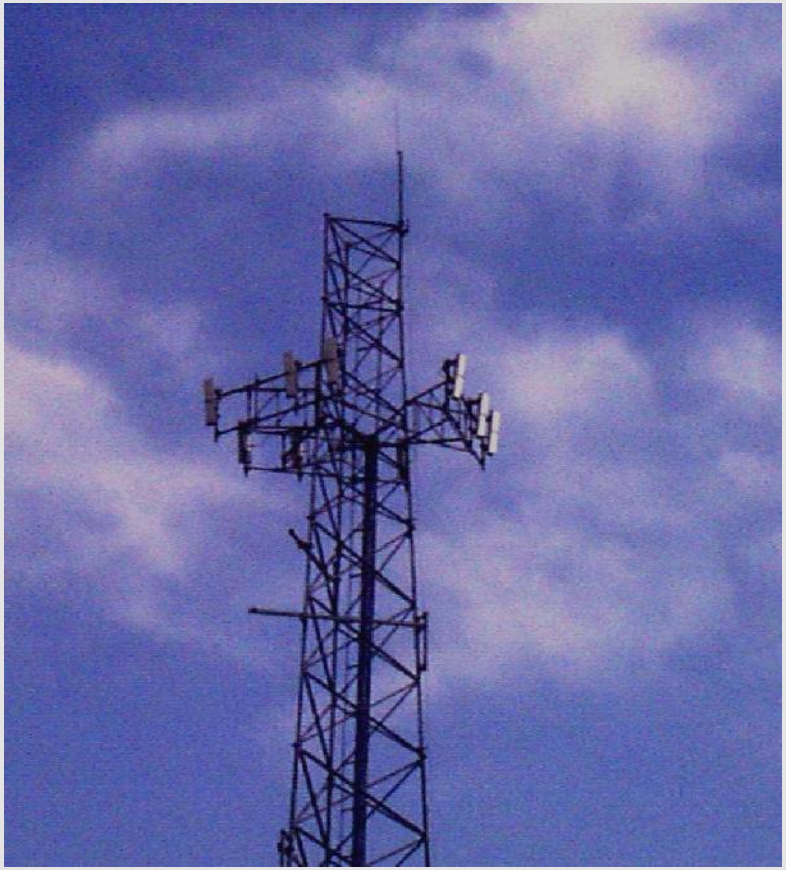
# AN/FSC-78 SATCOM

# Air Search Surface Radar

SPS-49 antenna on frigate JACK WILLIAMS (FFG 24). (Giorgio Arra)

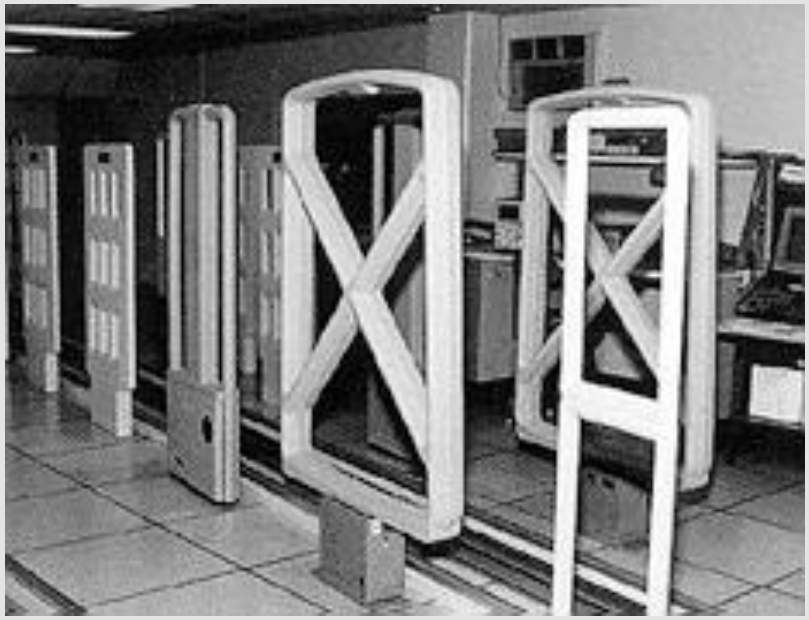
# Cellular Phone Towers

- Transmit at ~900 MHz and 1.8 GHz.
- Several arrays that constitute 360 degree coverage.
- Output power varies but generally about 100 W per transmitter.



# Electrical Scanner Systems

Magnetic tags are installed in merchandise to help reduce theft.

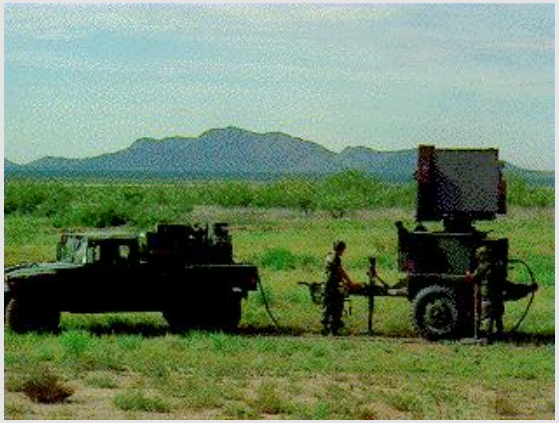


# Antennas and Antenna Patterns

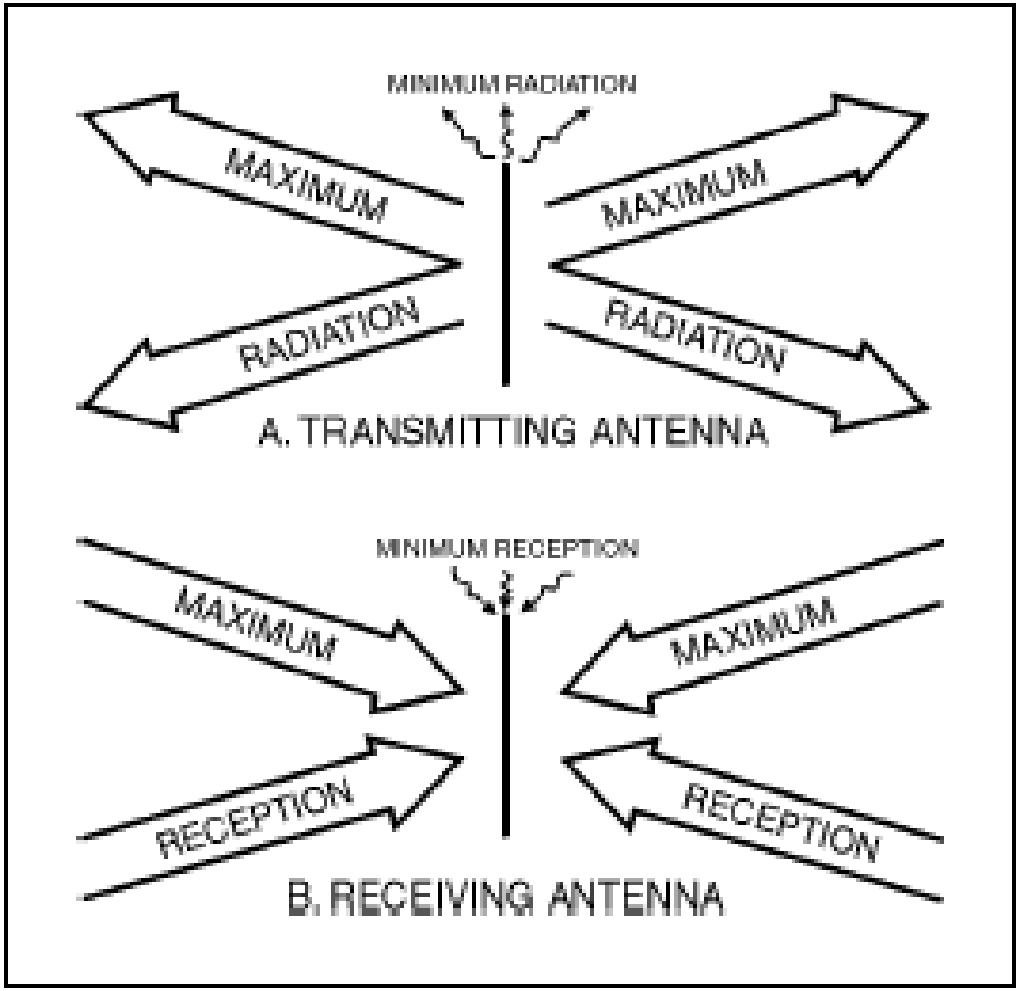
# Omni-directional antenna vs. Directional antenna

# Where is the antenna located ?

- … in a open field
- … in a motor pool.
- … adjacent to the buildings



# Antenna Reciprocity



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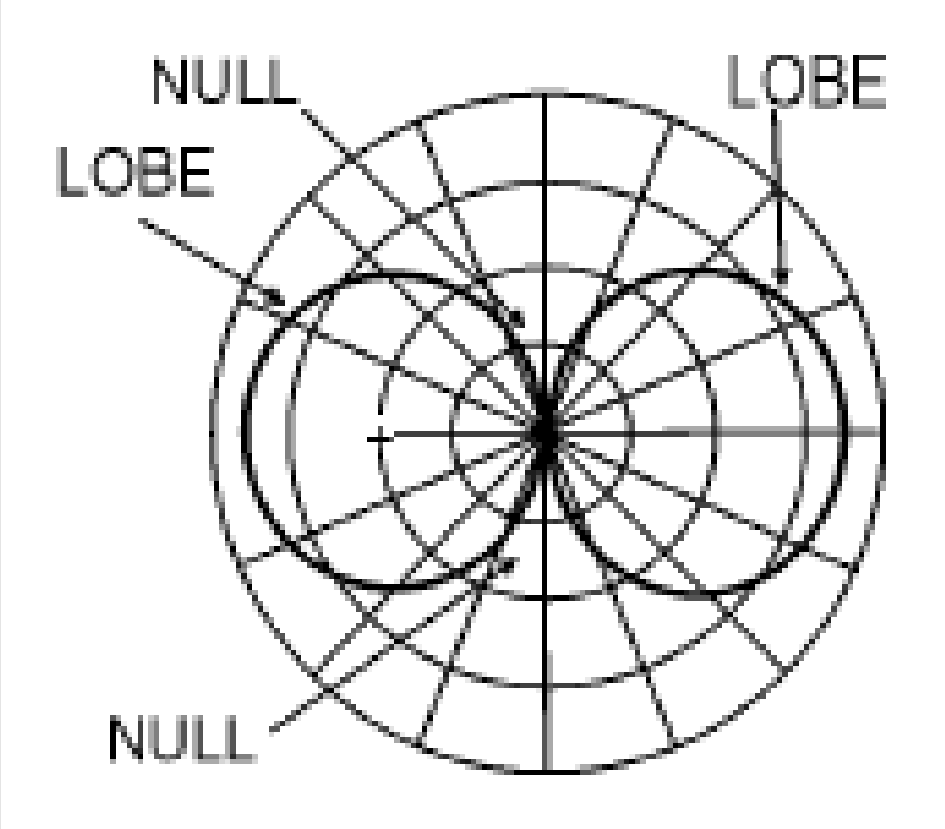
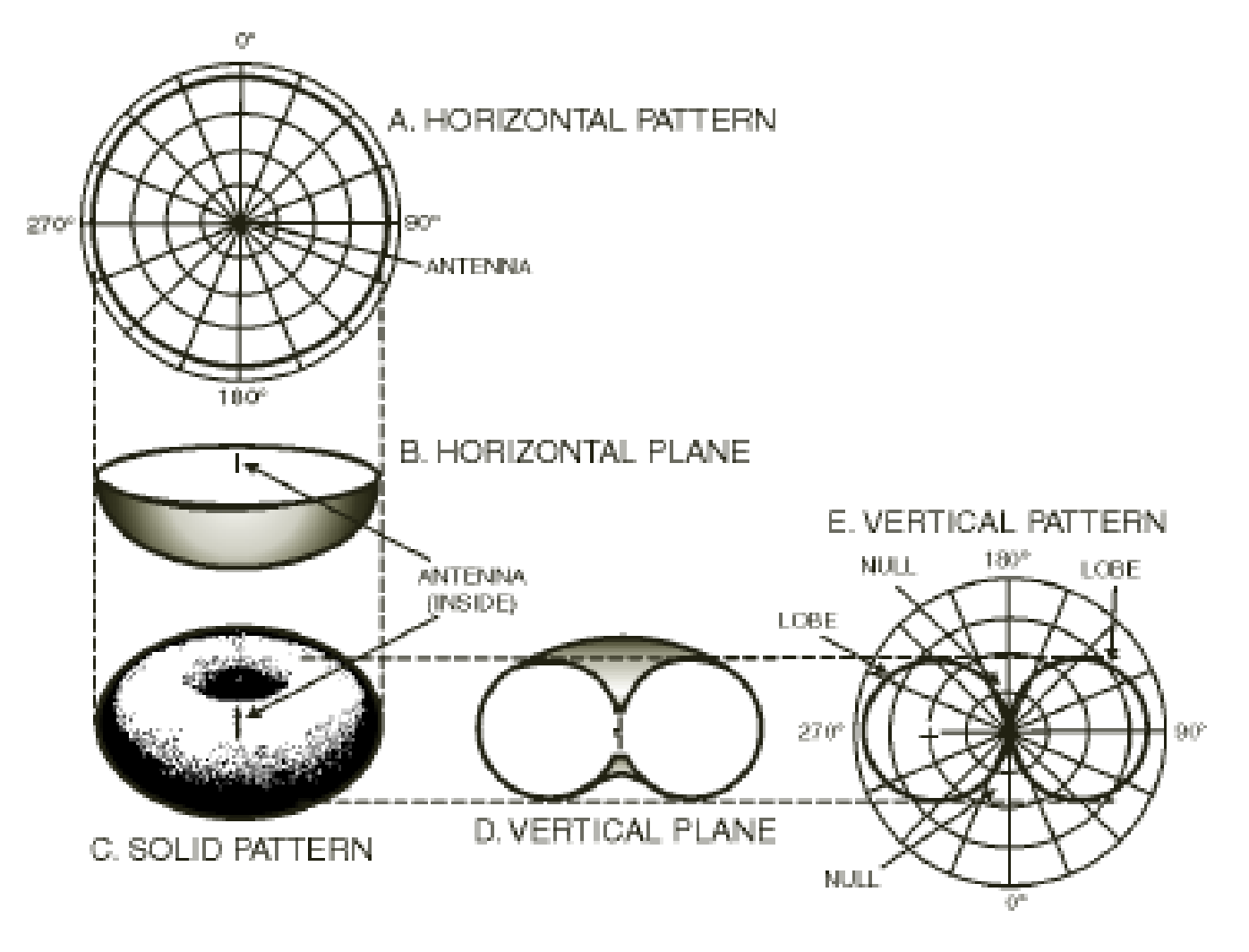
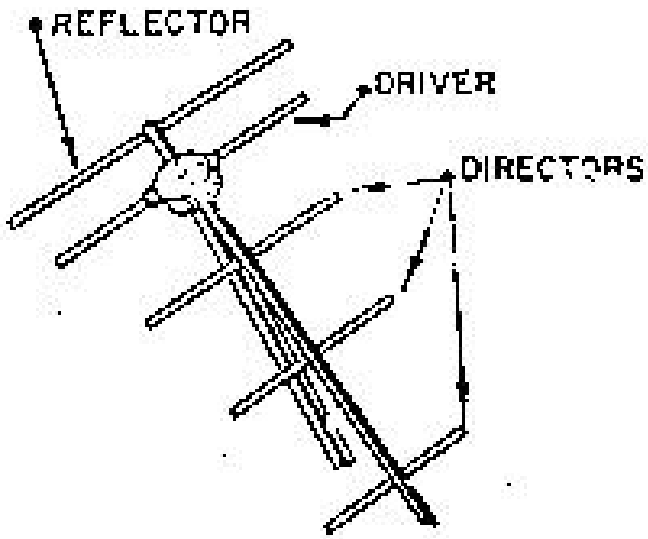
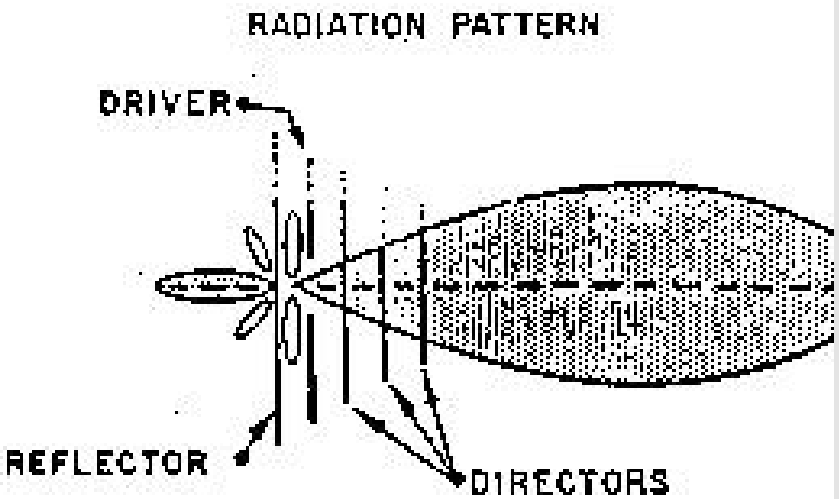

NULL
LOBE
LOBE
NULL


0°
A. HORIZONTAL PATTERN
270°
90°
ANTENNA
180°
B. HORIZONTAL PLANE
ANTENNA
(INSIDE)
E. VERTICAL PATTERN
NULL
180°
LOBE
LOBE
270°
90°
C. SOLID PATTERN
D. VERTICAL PLANE
NULL
0°




YAGI antenna.



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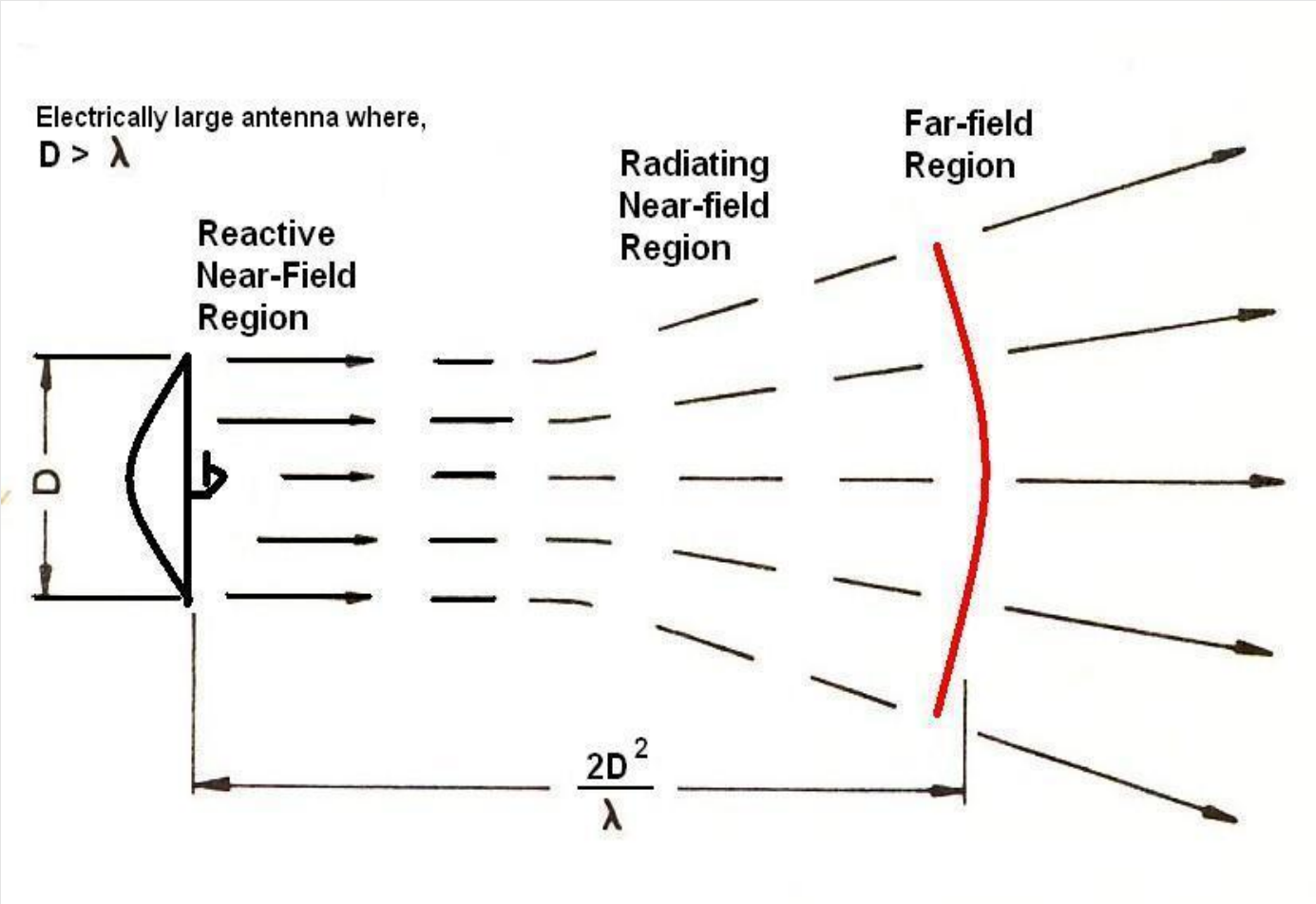
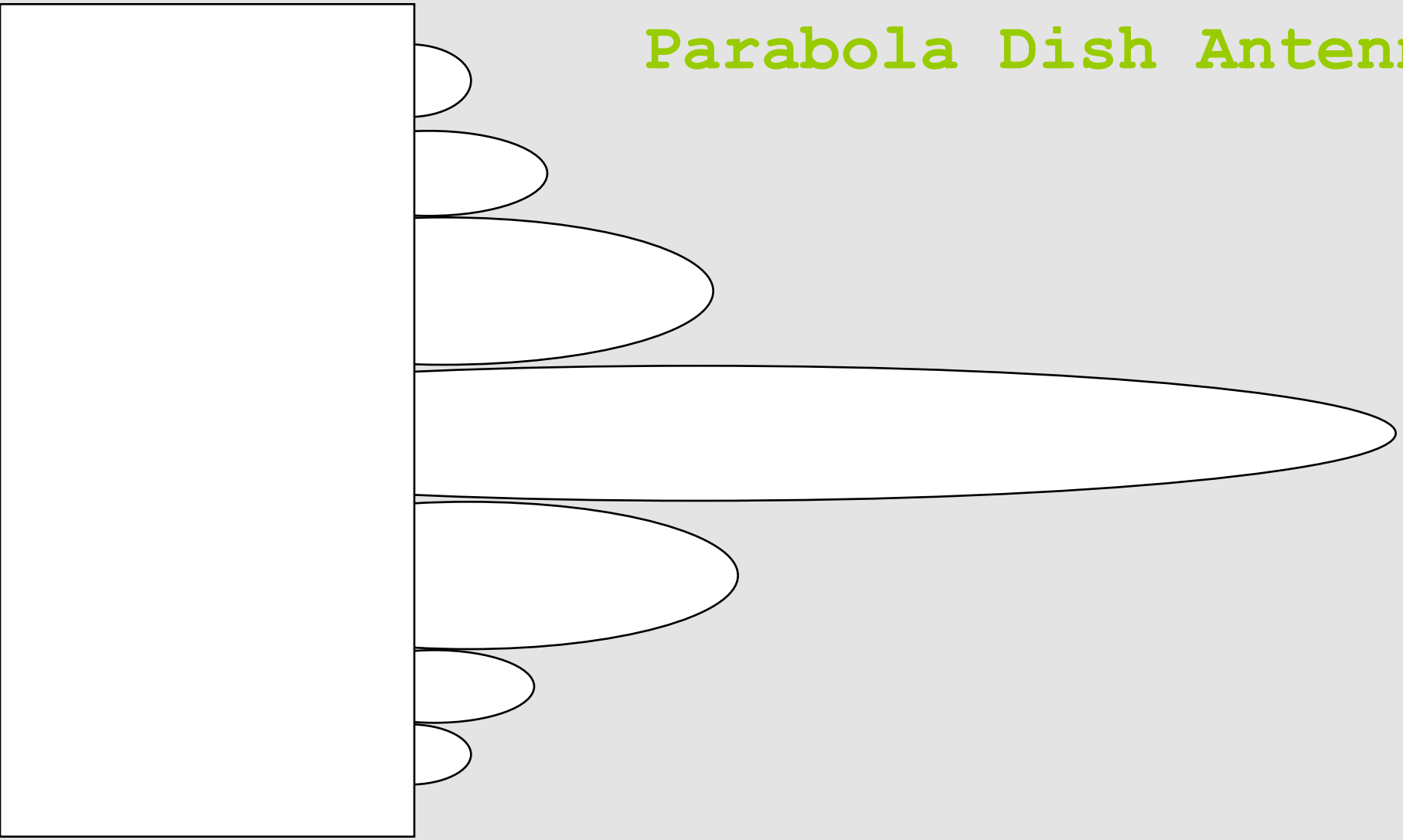
# Parabolic Antenna

# Field Regions (D > λ)



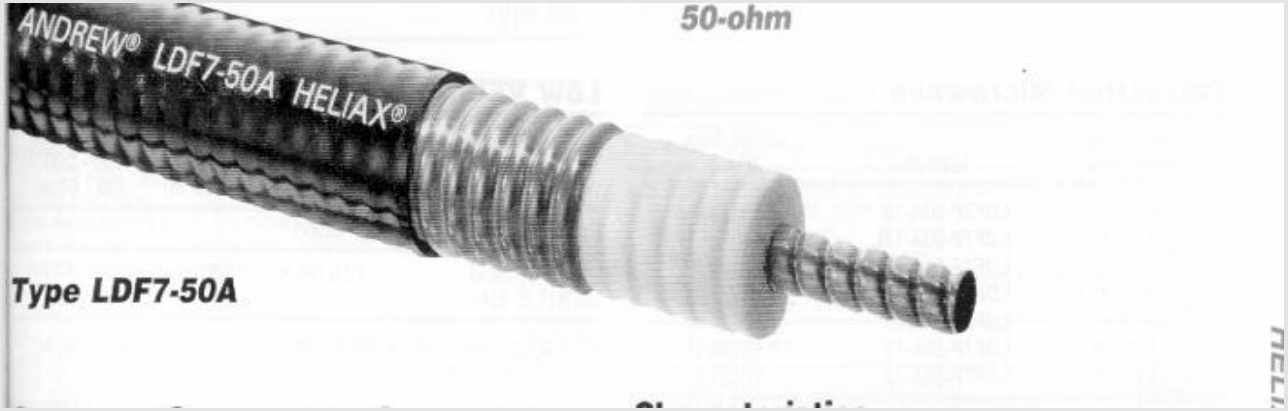
# Radiation Pattern
# Parabola Dish Antenna



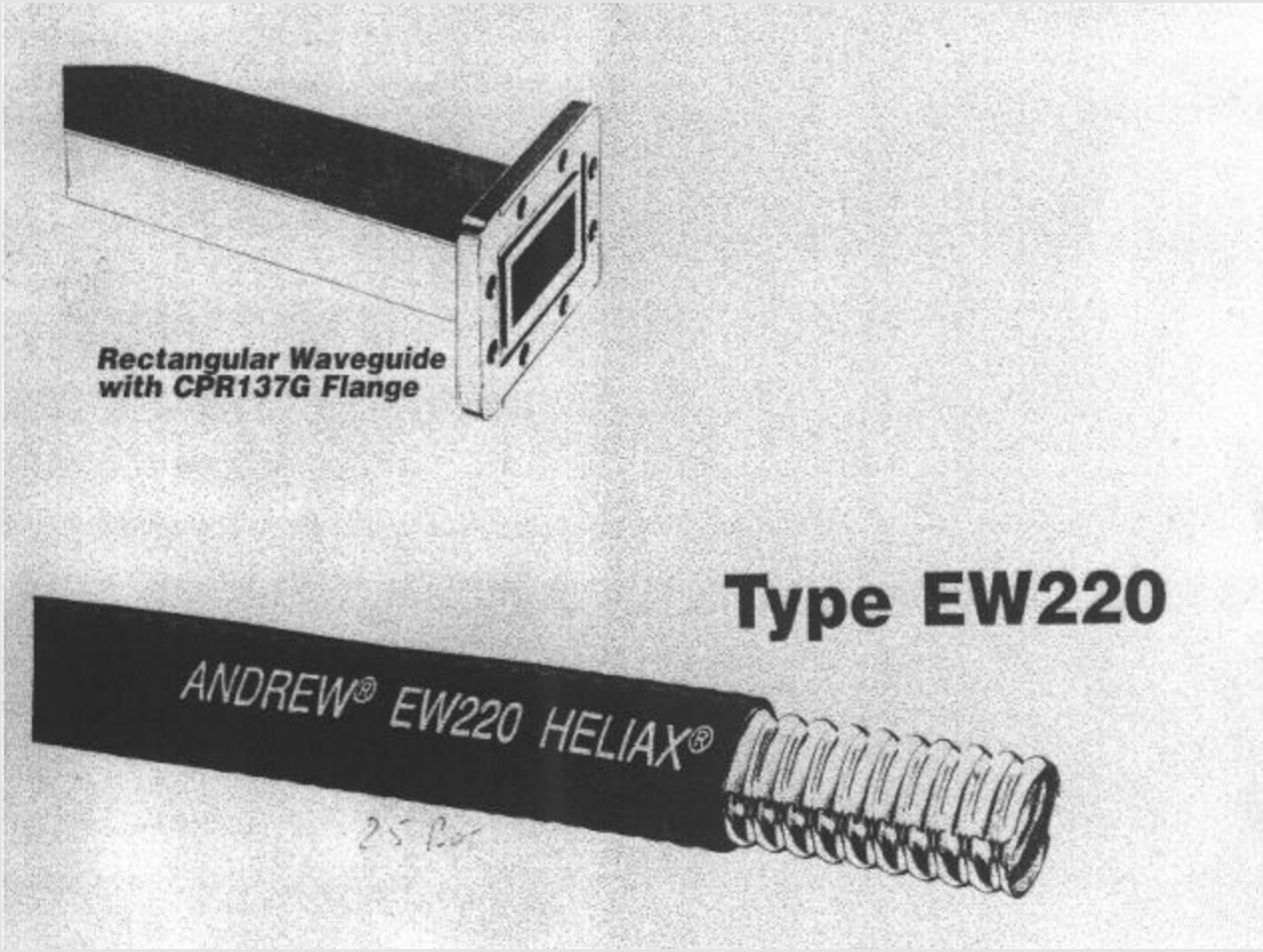
# RF Transmissions

- Two Methods of Transmitting Waves
  - Guided Transmission
    - Cables
    - Waveguides
  - Free Space Transmission
    - Antennas

# Examples of RF Cables

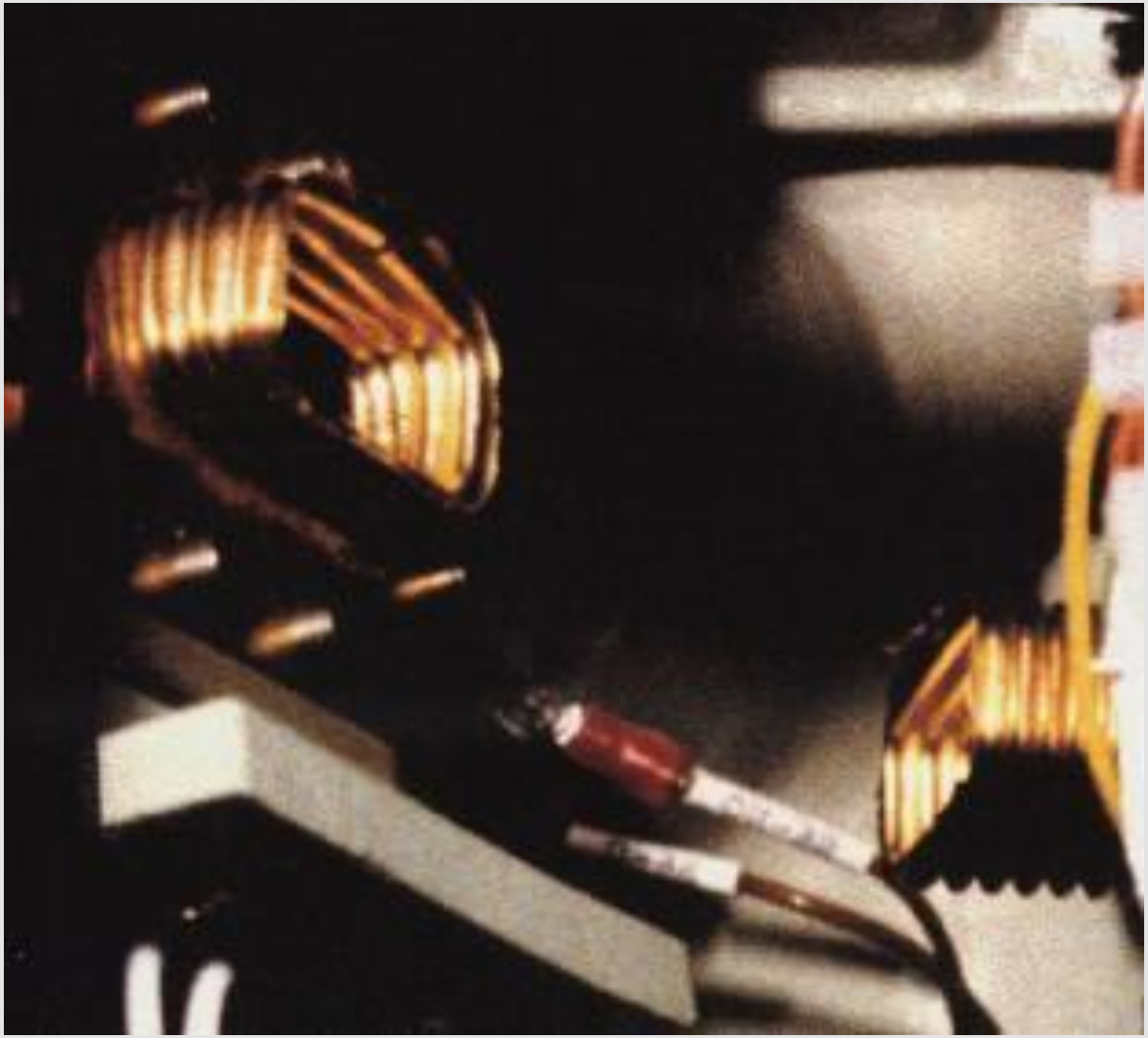


# Examples of Waveguide



# Flexguide quick disconnect

# Broken Waveguide



# Radio Frequency Radiation Biological Effects

# Biological Effects

Biological damage through tissue heating is considered the primary health hazard from exposure to RF Energy



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# "Non-Thermal" Effects

- Non-Thermal: No measurable temperature increase, either localized or core.
- Epidemiological and Animal Studies
  - End points: Ocular, Cancer, Reproductive, Mortality
  - Groups: Occupational, Population, Gender
  - Generally these studies are
    - Inconclusive (population size too small)
    - Incomplete (did not consider confounding factors)
    - Inconsistent (attempts to replicate fail)



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# Biological Effects
## Eye Hazard

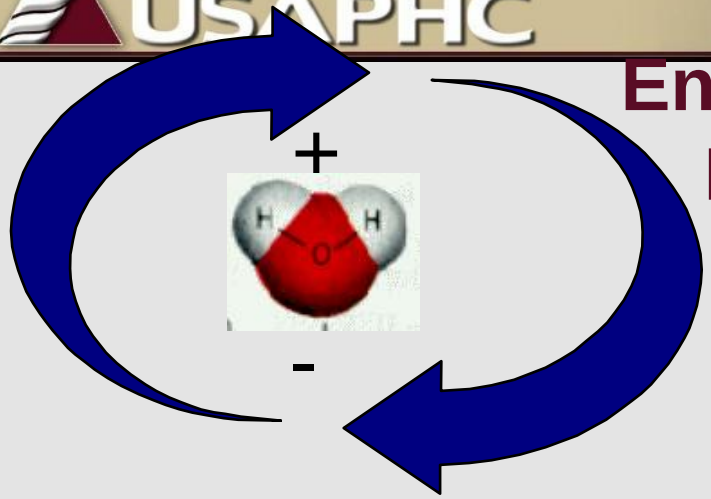
- The eyes are most susceptible to irreversible effects of RF radiation
- Exposing the eyes to excessive levels of RF radiation can result in cataracts -

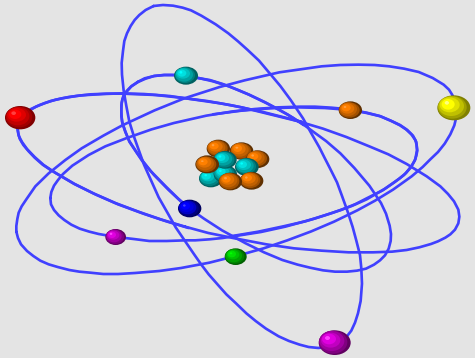
  *Highly Unlikely However - No proven cases of Cataracts in DA. It would take an exposure of over an hour. You would feel heat on your face first.*

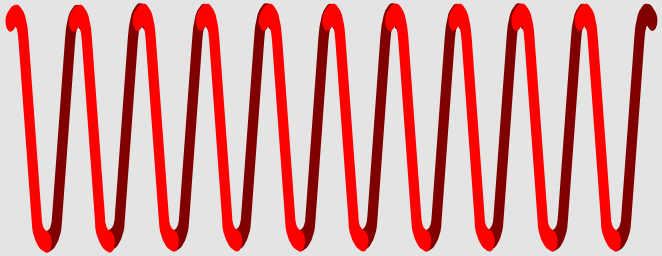
# Nonthermal Effects

- Scientific controversy over the existence of nonthermal effects
- No clear cause-and-effect connection between nonthermal phenomena and adverse effects of human health

# Energy Transfer Mechanism

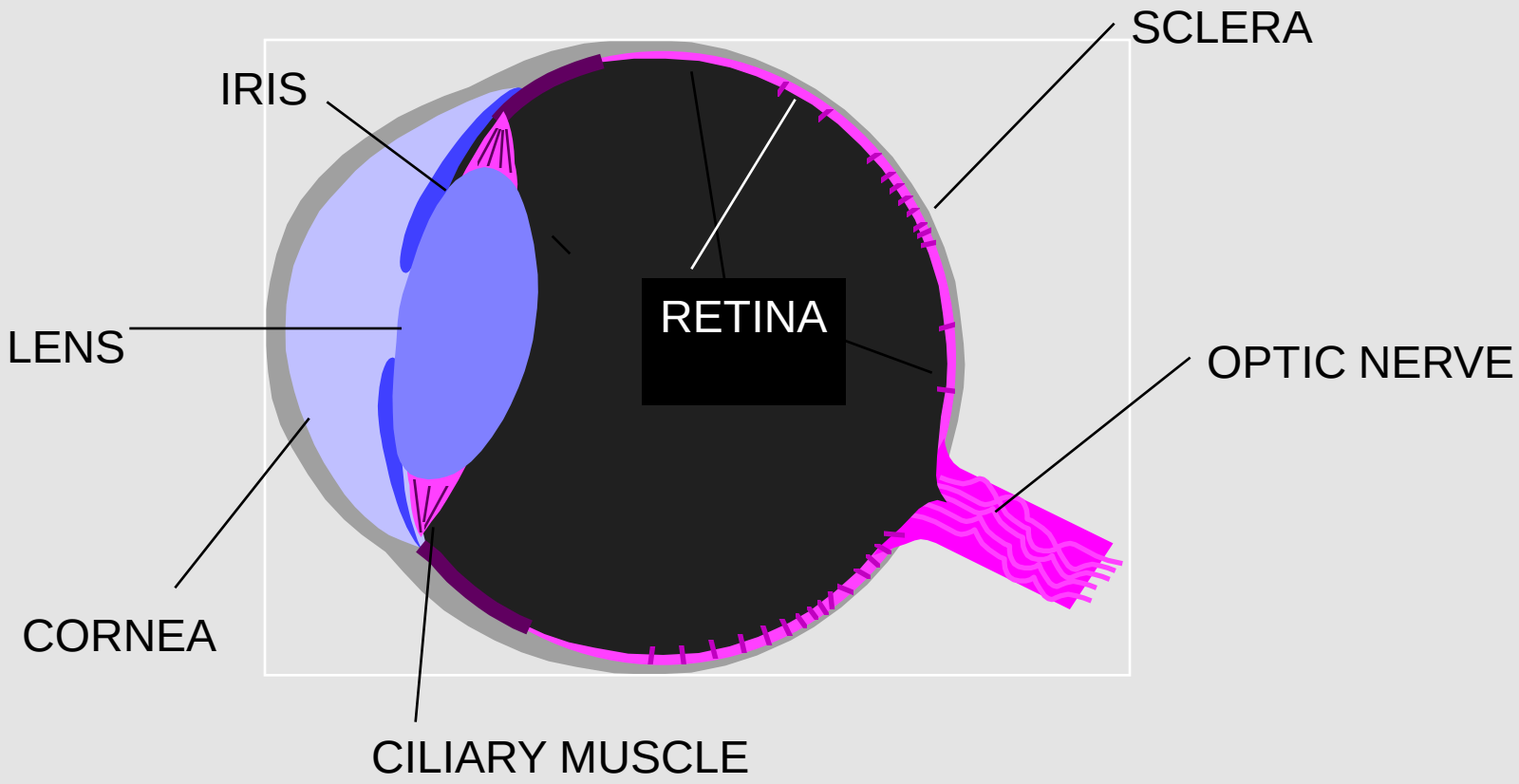


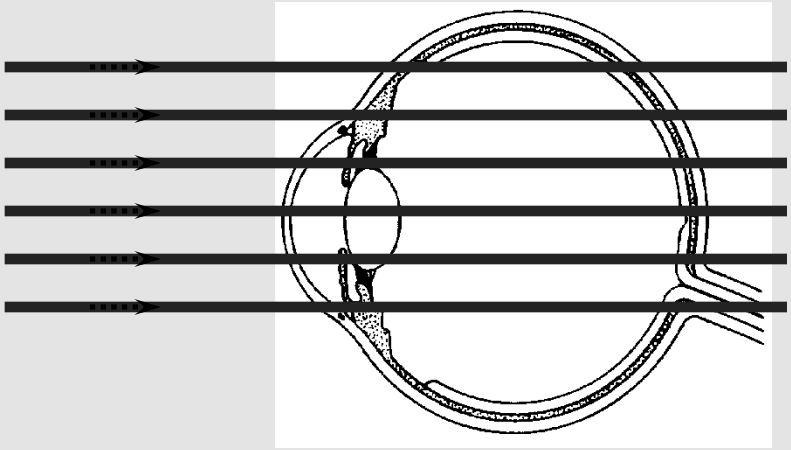


- Polar Rotation
  - Primary > 300 MHz
  - Heat
- Kinetic Energy Transfer
  - Ion transport
  - 0.1-300 MHz: Thermal
  - < 0.1 MHz: Neural Stimulation

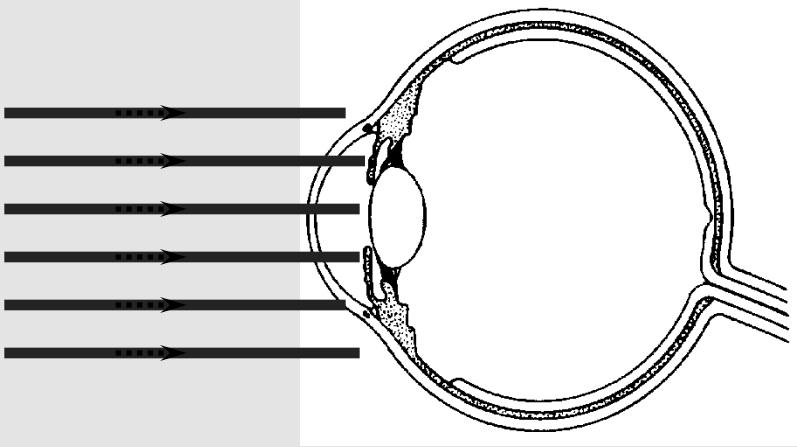
# Anatomy of the Eye



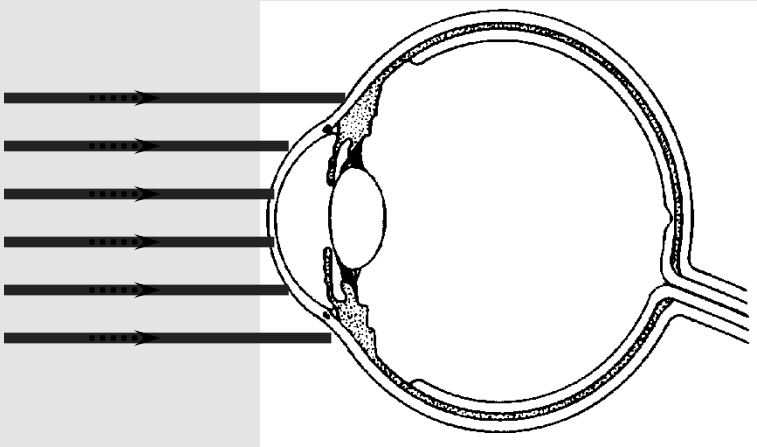
- Gamma Rays



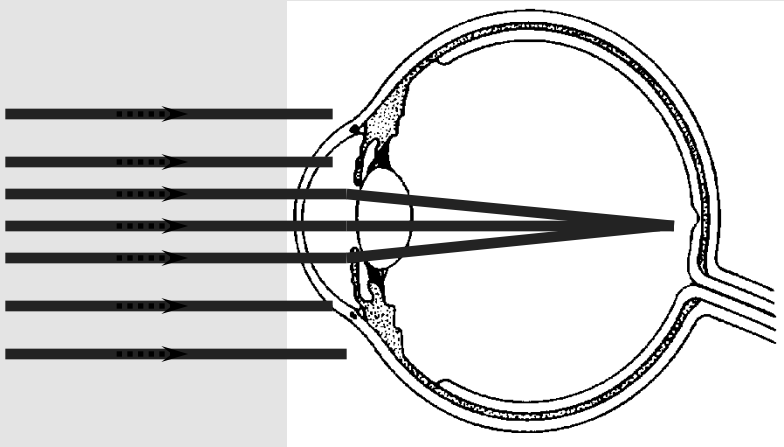
- Microwave and Near Ultraviolet



- Far Ultraviolet and Far Infrared



- Visible and Near Infrared





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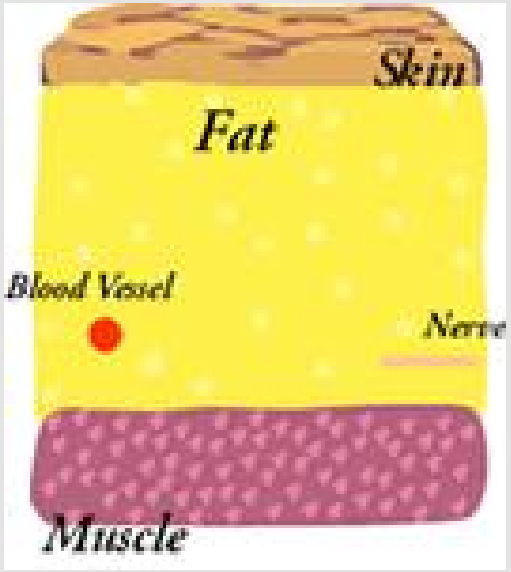
# Heat Perception

## Power Density = 10 mW/cm$^2$

- 3 GHz: λ = 10 cm
- Penetration = 2 cm




- 30 GHz: λ = 1 cm
- Penetration = 0.08 cm

- *Increased*
  - *Localized SAR*
  - *Localized Temperature*
- *Decreased*
  - *Latency to Perception*



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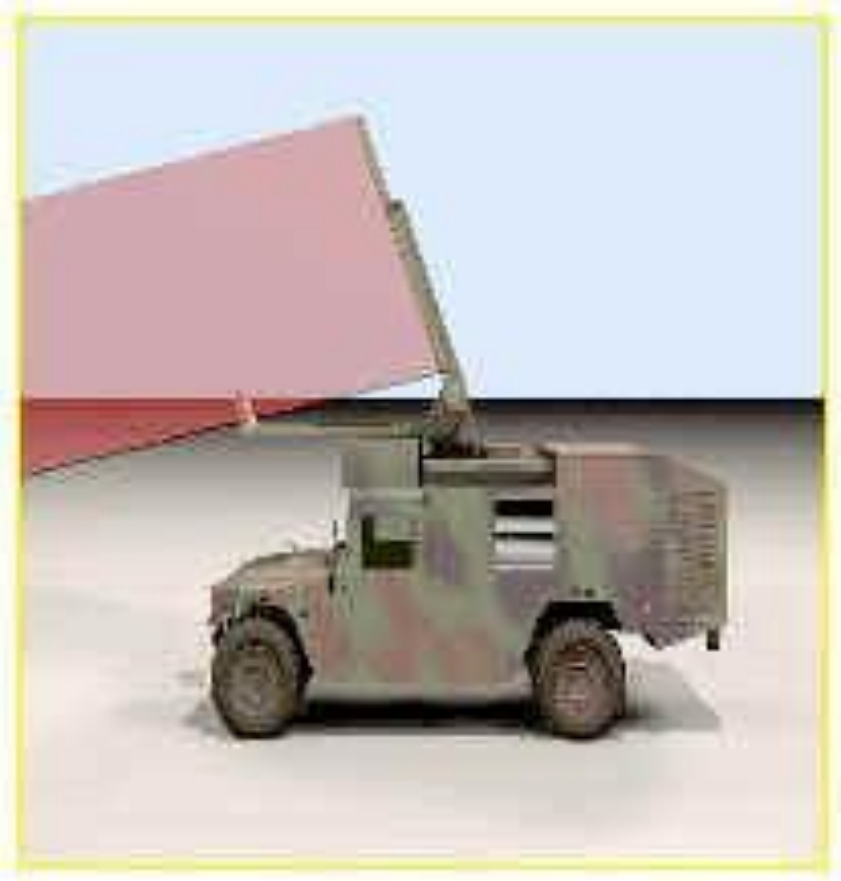
# Active Denial System

- Causes ‘instantaneous’ pain using millimeter wave energy.



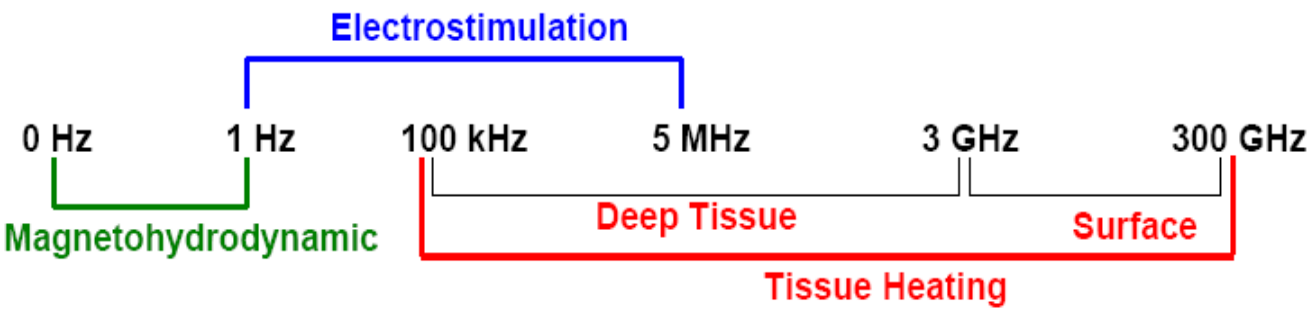
# Human Responses to Heat

- Perspiration
- Respiration
- Radiation (Infrared)
- Vascular Dilation
- Behavioral
  - Seek out cooler environment
  - Rest

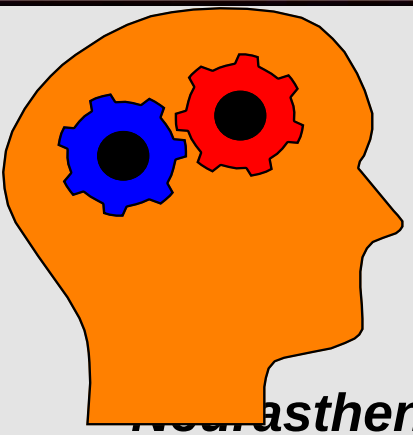
# Summary of Verified Effects

## Potential Harmful Biological Effects As a Function of Frequency

- (0 to 1 Hz) Magnetohydrodynamic effects (forces on moving charging in flowing blood and other body fluids potentially stressing circulatory systems)
- (1 Hz to 5 MHz) Electrostimulation (Excitation of neurons or direct alteration of synaptic activity within the brain potentially causing involuntary muscle contraction thereby potentially causing falls, Cardiac excitation)
- (100 kHz to 300 GHz) Tissue heating (with potential thermal damage; for deep tissues between 100 kHz and 3 GHz and surface heating (skin) between 3 GHz and 300 GHz).




- Note: Under some conditions, touching conductive (metal) objects that are in the vicinity of a radiating RF antenna could result in a flow of RF current of sufficient magnitude to be painful or that may produce a burn (RF Burn) at the point of contact. Can occur at almost any frequency.



# Radio Frequency Radiation Non-thermal Effects?

***Neurasthenic Syndrome*** or "Microwave Sickness"

- Symptoms include irritability, headache, lethargy, insomnia, irascibleness, impotence, and mnemonic disorders.
- Reported primarily by Eastern Europeans and Scandinavians at field intensities less than PELs.
- Studies affirming this syndrome suffer from methodological defects.



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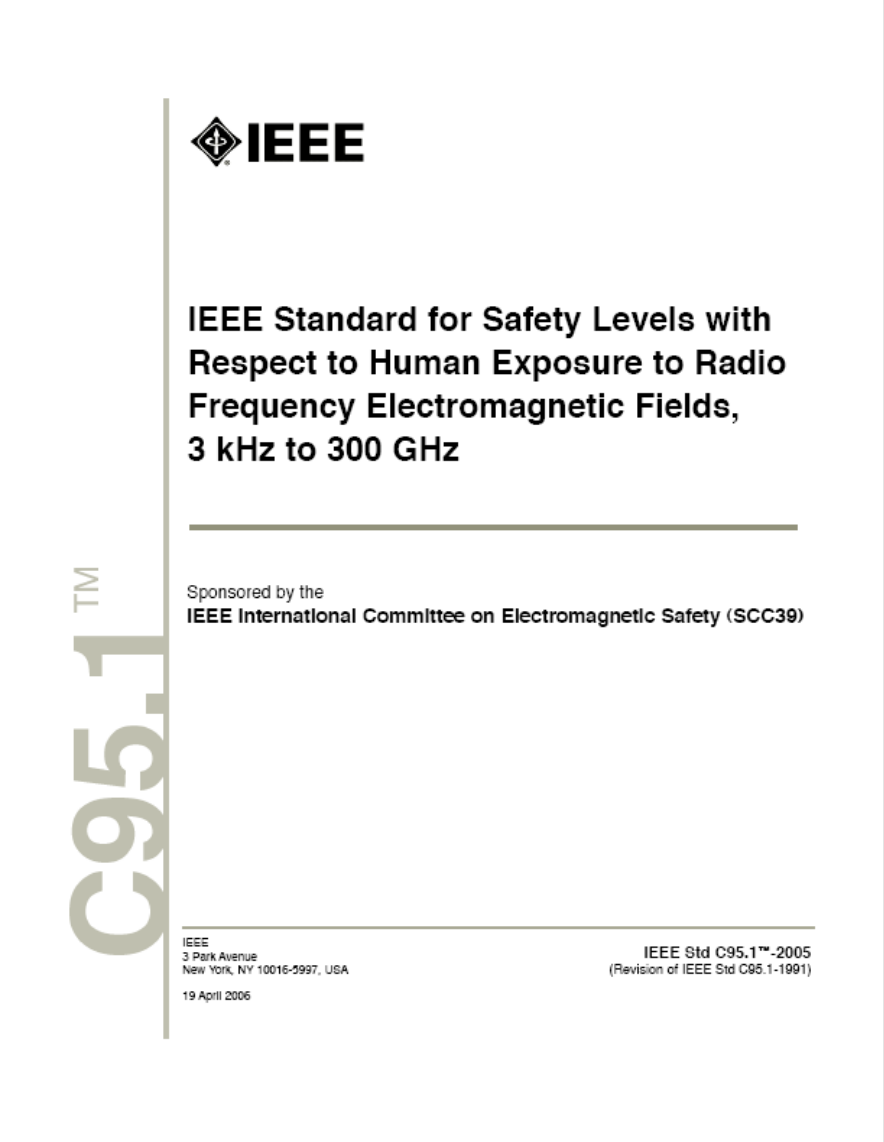
# Neurasthenic Syndrome

- Published **provocation studies** of VDU workers in Scandinavian countries.
  - Participants could not guess better than random whether the fields (i.e. VDU) were “on” or “off”.
  - No relationship between hormonal levels and fields.
  - Symptom changes were related to the worker’s guess as to whether the fields were “on”, not the actual field.

# Radio Frequency Radiation Standards

# IEEE C95.1-2005

# (3 kHz to 300 GHz)



IEEE

IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

C95.1™

Sponsored by the
IEEE International Committee on Electromagnetic Safety (SCC39)

IEEE
3 Park Avenue
New York, NY 10016-5997, USA

19 April 2006

IEEE Std C95.1™-2005
(Revision of IEEE Std C95.1-1991)

# IEEE C95.1-2005

- Two Tier Documents
  - Controlled Environment
  - Action Levels (General Public)

- Addresses Max Permissible Exposure (MPE) as a function of Frequency and Time



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# IEEE C95.1-2005

- There is No Reliable Scientific Data To Support That:
  - High Risk Groups Exist.
  - RFR Exposure at ANSI/IEEE Poses a Health Risk.
  - Damage from EMF is Cumulative.
  - Non-thermal Effects are Significant to Human Health, Except for Shock.
- Standards Do Not Protect Against Spark Discharge.

# RFR Exposure Units

- Specific Absorption Rate (SAR) - W/kg
- Electric Field - V/m
- Magnetic Field - A/m
- Power Density - mW/cm$^2$ or W/m$^2$

# Basis of Controlled Exposure Standards

- Safety Margin (a Factor of 10) is Applied to the Accepted Threshold of Effect (4 W/kg)
- SAR Exposure Criterion of 0.4 W/kg (0.1 MHz - 3 GHz)

# Basis of Action Level (Public) Standards

- Safety Margin (a Factor of 50 or greater) is Applied
- SAR Exposure Criterion of 0.08 W/kg (0.1 MHz - 3 GHz)

# PEL: Permissible Exposure Limit (MPE: Maximum Permissible Exposure)

- Sometimes referred to as MPE (maximum permissible exposure)
- Expressed as:
  - Power density - $mW/cm^2$
  - Field strength - V/m or A/m
  - Induced and contact current: A or $A/m^2$
- Intensity and duration of exposure factored in
- Based on NO harmful effects and safety factor

# Controlled Environment

- **Controlled Environment** translates to "AWARENESS".
- In 'Controlled Environments', people/workers are "familiar" with electromagnetic energy and have control over their RF environment

# General Public Environments (Action Level)

- In '**General Public Environments**', People are Not Familiar with Electromagnetic Phenomenon.
- They are in Public Areas, Such as Living Areas, and Have No Control Over The RF Environment.



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# Maximum Exposure Limit Comparison

| Frequency (f) (MHz) | Power Density (S) ($mW/cm^2$) |
|---|---|
| ***Controlled Environment*** | |
| 100-300 | 1.0 |
| 300-3000 | f/300 |
| 3000-15,000 | 10 |
| 15,000-300,000 | 10 |
| ***General Public (Action Level) Environment*** | |
| 100-400 | 0.2 |
| 400-2000 | f/200 |
| 2000-100,000 | 1.0 |
| 100,000 | $(90f_G-7000)/200$ |

# Example: RF Environment

Restricted to Everyone

> 10 mW/cm$^2$

**Controlled Area**

< 10 mW/cm$^2$ but
> 5 mW/cm$^2$

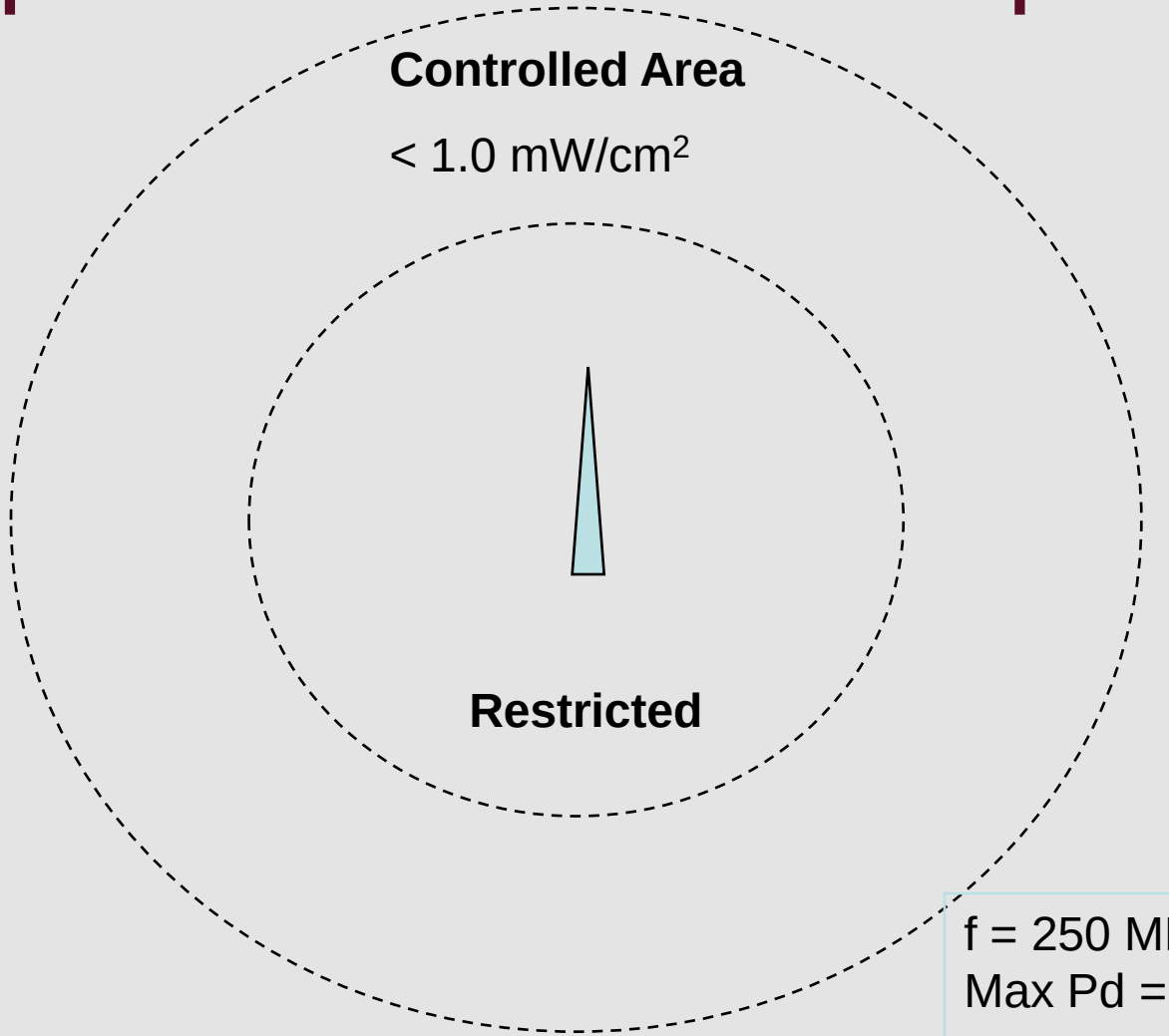
**Public Area**

**(action level area)**

< 1 mW/cm$^2$

Example: System operating at 3 GHz, Max Power Density = 30mW/cm$^2$

# Example: RF Environment – Monopole Antenna




f = 250 MHz
Max Pd = 2 mW/cm$^2$

# RFR Standards for Pregnant Workers

- Additional RFR Exposure limits or exposure restrictions are not imposed in case of pregnancy.

- Sufficient evidence exists to indicate that a fetus is at no greater risk than the mother during pregnancy. A fetus will not receive any greater exposure than the mother and cannot be shown to be more radiosensitive.

# Local Exposure (Partial Body Exposure)

- **Controlled Environment**: Local SAR shall not exceed 10 W/kg "except" for the wrist, hand, ankle, and foot which should not exceed 20 W/kg
  - **Below 300 MHz** - The peak value of the E-Field or H-Field shall not exceed "20 times" the spatial average of the E-Field or H-Field Squared.
  - **Between 300 MHz and 3 GHz** - A PEL or MPE of 20 $mW/cm^2$ applies
  - **Between 3 GHz and 96 GHz** - A PEL or MPE of $<20(f/3)^{1/5}$ $mW/cm^2$ applies (f is in GHz)
  - Above 96 GHz - A PEL or MPE of 40 $mW/cm^2$ applies



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# RFR Measuring Instruments

# Why Measurements are Sometimes Required

- Verification of Calculations
- Compliance with Standards
- Assess RF Overexposures
- Address Public Concerns

# Probe Selection

- Frequency Range
- Max Power Density or Field Strength Level
- Electric or Magnetic Field
- Flat Response or Shaped Frequency Response
- Size & Minimum Measurement Distance

# Narda 8712 Electromagnetic Radiation Survey Meter

# Meter Readout

- Desirable to have readout calibrated to units of RF protection guidelines (i.e. in $mW/cm^2$ or $W/m^2$ for S)
- Probes actually respond to field intensities (i.e. in V/m, $V^2/m^2$, A/m, or $A^2/m^2$).
- Determination of equivalent power density requires use of derived relationship between S, E, H, and free-space impedance value, 377 Ω.

# Radio Frequency Radiation Safety Program

# Elements of a Radio Frequency Radiation Safety Program (RFRSP)

- Radiation Safety Officer
- Inventory of Sources
- Training of Personnel
- Control of Sources - Administrative & Engineering

# Elements of RFRSP (Cont.)

- **Published Standing Operating Procedures (SOPs)**
- **Medical Surveillance**
- **Person (s) to be Contacted in Case of Suspected Overexposure**
- **Procedures to be Followed in Case of Suspected Overexposure**

# Controls Used in Protecting Personnel from RF Overexposure

- **Installation of RF Warning Signs That State Control Distances**
- **Roping Off of Areas**
- **Use of Flashing Lights and/or Sirens**
- **Use of Dummy Loads or Roof-mounted Antennas**

# TYPES OF RF SOURCES

- Radar Systems
- Vehicular Radio Sets
- Satellite Communications (SATCOM) Systems
- Industrial Heaters/Sealers
- Electronics Countermeasures Equipment (Jammers)
- Backpack and Handheld Radios
- Avionics Equipment
- Millimeter Wave Radars
- Any Other Sources Which Emit RF
- RF Diathermy Sets, MRI's

# Dummy Load

# Controls Used in Protecting Personnel from RF Overexposure (Cont.)

- **Placing Azimuth and Elevation Angle Limits on Systems to avoid Radiating in Potentially Occupied Areas**

- **Periodic Briefings to Personnel**

# SYSTEM PARAMETERS CONSIDERED WHEN ASSESSING FOR OVEREXPOSURE

- Transmitter Frequency
- Average Power Output of Transmitter
- Duration of Transmitter-On Time
- Type/Gain of Antenna
- Location of Antenna
- Terrain of Surrounding Area
- Controls Incorporated in System

# Instances When Measurements Are Necessary

- Developmental Items
- Newly Installed Systems or Relocated Systems
- Modified Systems (especially ones with Increased Transmitter Power)
- Actual or “Suspected” Overexposures
- Public Relations (when deemed necessary to foster good will)

# Radio Frequency Radiation Sign

# RF Overexposure Procedures

- **Local Installation Procedure:**
  - **Care for the Victim**
  - **Eye Exam if > 5 x PEL /Other if Deemed Necessary**
  - **Incident Evaluation**
  - **Ensure MTF inputs info into New Medical Surveillance System**
  - **Contacts RF Prog at CHPPM**
- **USAPHC:**
  - **Consults with Affected Installation**
  - **Conducts On-site Investigation if > 5 x PEL**

# PERSONAL DOSIMETRY

- No Suitable Personnel Dosimetry Devices Available
- Can Give a False Sense of Security
- Do NOT Provide a reliable means of measuring field strength



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# RFR OCULAR EXAMS

- **Preplacement - Not Required**
- **Periodic - Not Required**
- **Immediate - Required if Suspected Overexposure is > 5 x MPE**
- **Termination - Not Required**

# Overexposure

- Personnel exposures that exceed the PEL.
- All potential overexposure incidents are investigated

- Includes Whole-body and Local body
- Does not imply injury

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IEEE

# IEEE Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz

C95.7™

**IEEE Standards Coordinating Committee 39**

Sponsored by the
IEEE International Committee on Electromagnetic Safety

IEEE
3 Park Avenue
New York, NY 10016-5997, USA

22 March 2006

IEEE Std C95.7™-2005

Table 1—Summary of RFSP categories based on RF exposure conditions

| RFSP Category | Exposure condition[a] | Control actions required |
|---|---|---|
| 1 | Operational characteristics of source(s) would not cause the action level to be exceeded. | None, unless maintenance or other conditions alter category. |
| 2 | Operational characteristics of source(s) could cause the action level to be exceeded, but would not cause the exposure limit to be exceeded in accessible areas. | See Clause 4 and Table 3. |
| 3 | Potential to exceed the exposure limit in accessible areas, if mitigating controls are not applied. | See Clause 4 and Table 3. |
| 4 | Exposure will exceed exposure limit in accessible areas. | Restrict source output to achieve Category 3, 2, or 1 conditions, or prevent personnel access (see Clause 4 and Table 3) |

[a]In assessing the characteristics of an RF environment, consideration should be given to the potential for excessive exposure in the case of an accidental failure of systems that normally preclude excessive exposure such as breaks in waveguides. See text in this subclause for more information.

## RF Safety Program Exposure Categorization

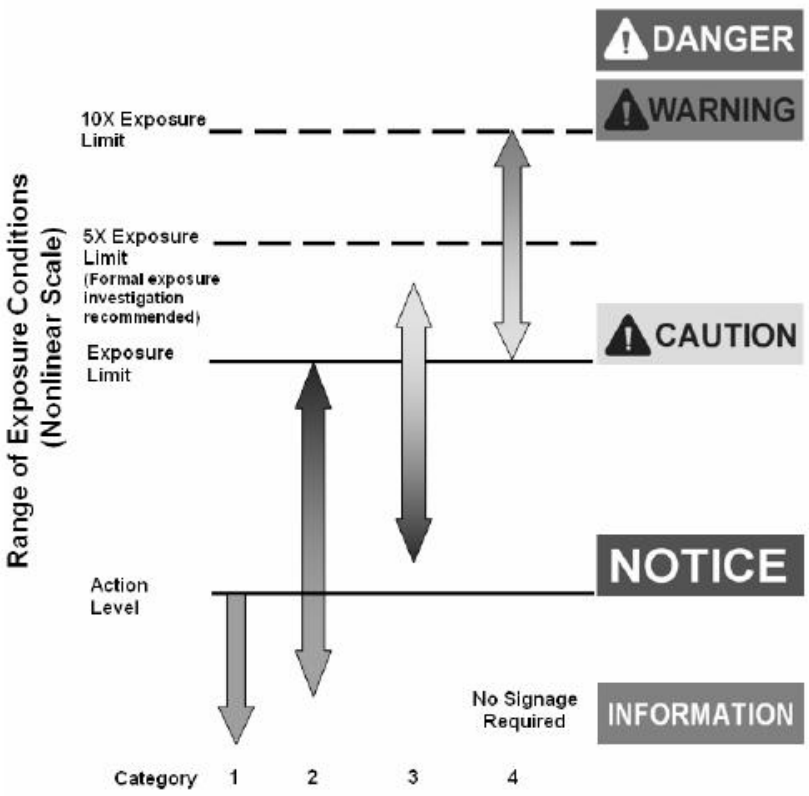
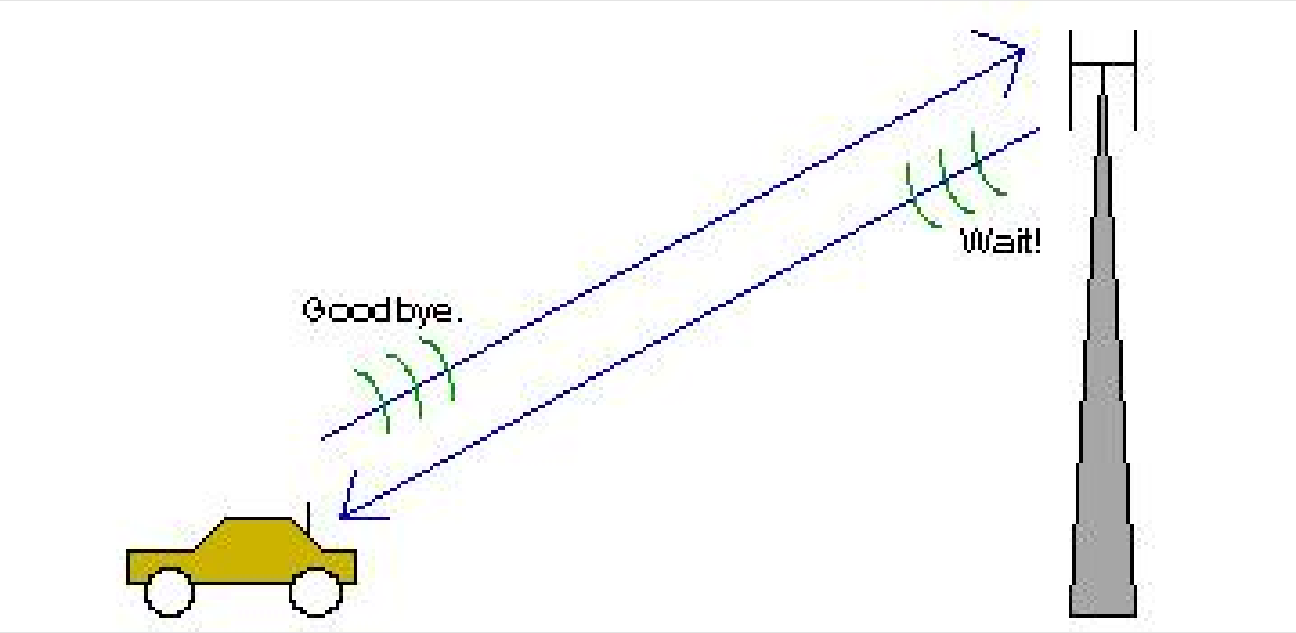



Figure 1—Graphical representation of the RFSP categorization process corresponding to Categories 1–4 of Table 1

# Wireless Communication

# How Do Cellular Telephone Systems Work?



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# INTER-PHONE

- The INTER-PHONE Study by the International Agency for Research on Cancer (IARC)
  - 13 countries involving 7600 tumor cases.
  - Case–control studies
  - Purpose was to determine whether mobile telephone use increased the risk of cancer and whether RFR emitted by mobile telephones is carcinogenic.
- IARC Radiation Group
  - **http://www.springerlink.com/content/x88uu6q103076p53**
  - **http://www.iarc.fr/ENG/Units/RCA4.php**

# Epidemiologic Studies of Cellular Telephones and Cancer Risk

## September 2002 Report

- Investigations of the association between cellular phone use and brain tumor risk:
  - Four in the United States
  - Two in Sweden
  - One each in Denmark and Finland
  - No significant associations
  - Relative risk ranging from 0.9 to 1.3

## Committee on Man and Radiation

# USE OF "PROTECTIVE DEVICES" FOR CELLULAR TELEPHONES

- Devices on the market purport to shield or protect users from RF energy.
- Handsets are designed to comply with exposure limits.
- Device effectiveness in reducing exposure is negligible or unproven.
- Any protective device that interferes with communication between the handset and the base station may cause the handset to *increase* its output.

## Expert Opinion

- **Environmental Protection Agency**

"The information base on non-thermal effects has not changed significantly since the EPA's original comments in 1993 and 1996. A few studies report that at non-thermal levels, long term exposure to RF energy may have biological consequences. ***The majority of currently available studies suggests, however, that there are no significant non-thermal human health hazards***. It therefore continues to be EPA's view that the FCC exposure guidelines adequately protect the public from all scientifically established harms that may result from RF energy fields generated by FCC licensees."

## Expert Opinion

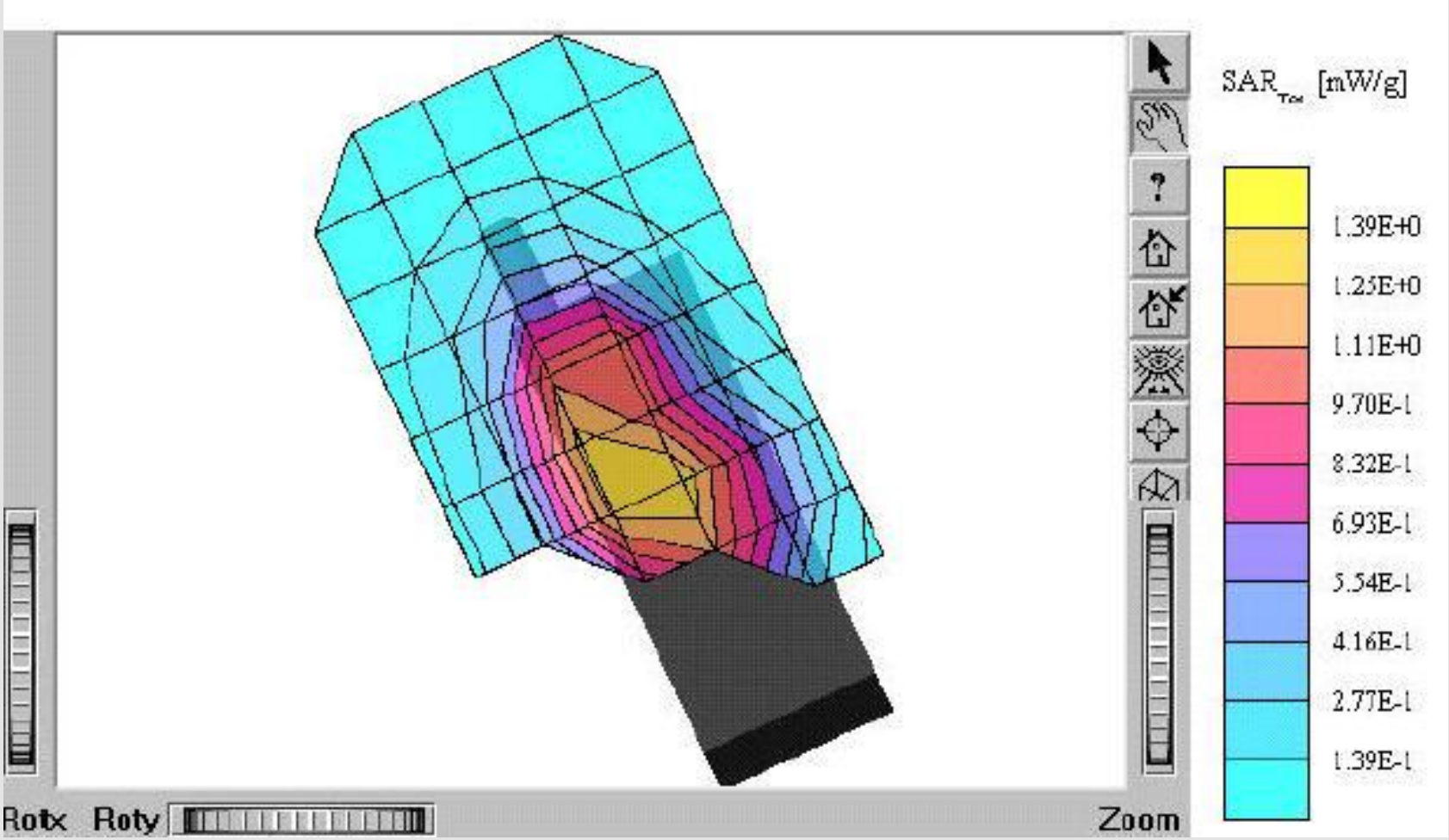
- **World Health Organization**

  "Current scientific evidence indicates that exposure to low levels of RF fields, including those emitted by mobile phones and their base stations, is ***unlikely to induce or promote cancers***."

http://www.fda.gov/cellphones/

- Description
- Safety
- Interference with Medical Devices
- Research

# Distribution of maximum SAR in 800 AMPS band.



# Newman vs Motorola

- Plaintiffs' experts do not pass the Daubert test:
  - Their reasoning, theories, and methodology have not gained general acceptance in the scientific community.
  - Neither Dr. Hardell's work nor Dr. Lai's animal studies, heavily relied on by the plaintiffs' experts, have been replicated or otherwise validated by other scientists.
- Motion to exclude the testimony of plaintiffs' proposed experts was granted.
- <u>Case Dismissed</u>.


Unclassified

# USAPHC Fact Sheets

## http://phc.amedd.army.mil

- ***Radiofrequency Radiation from Cellular Telephones***
  - ***http://phc.amedd.army.mil/PHCResourceLibrary/CellPhoneApr10.pdf***
- ***Radio-frequency Identification (RFID)***
  - ***http://phc.amedd.army.mil/PHCResourceLibrary/RFIDJan2010.pdf***
- ***Radio Frequency Radiation Electronic Countermeasures***
  - ***http://phc.amedd.army.mil/PHCResourceLibrary/CREWJan2010.pdf***

# RISK COMMUNICATION

# Wireless Communication Concerns are a Risk Communication Challenge

- What is Risk Communication?

  Two-way dialogue of information/ opinion about a risk (real or perceived) in situations where concern is high and trust is low.



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# Risk Perception & Communication

- When someone is concerned about exposure to low level EMF we should view this as a Risk Communication Challenge.
- Challenges:
  - Confronting low trust & high concern
  - Communicating highly scientific, technical information to a non-technical audience
  - Composing risk management actions

# Risk Perception & Communication

- Learn to be a risk communicator
- Obtain or develop resources for addressing the issues before being confronted
- People can make rational choices when confronted with the right information presented in the right manner.
- Sometimes, no matter what you say or do, individuals will be unmoved.

# QUESTIONS?

# Contact Information

**U.S. Army Public Health Command (Provisional)**
**ATTN: MCHB-IP-ORF (Radio Frequency Program)**
**5158 Blackhawk Road**
**Aberdeen Proving Ground, MD 21010-5403**

Commercial: 410-436-3353

*http://phc.amedd.army.mil/home*

http://phc.amedd.army.mil/organization/institute/dohs/Pages/RadioFrequency.aspx

Brad Roberts, RF Program, 410-436-6604
Brad.Roberts@us.army.mil

# NASA
# Interim Response Team (IRT) Training

# Summary

- **Understand NASA incident response concept**
- **Understand IRT roles and responsibilities per NPR 8621.1B**
- **Understand IRT support role to the safety investigation of a laser incident**

# What does the IRT do? NPR 8621.1B says-

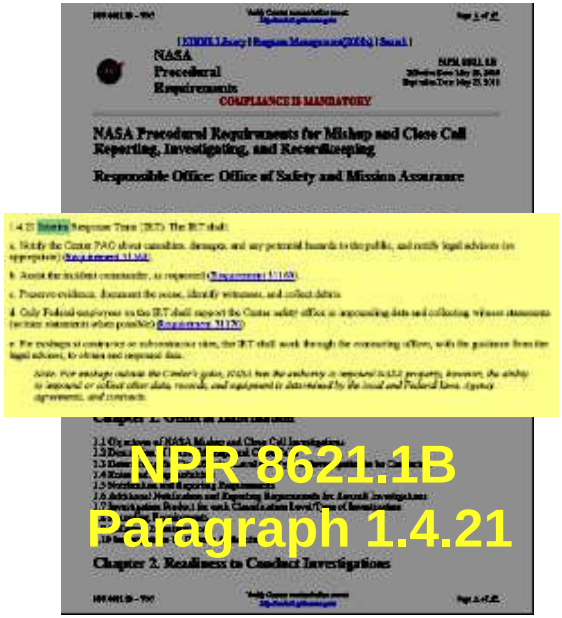
## "The IRT shall:

a. **Notify the Center PAO** about casualties, damages, and any other potential hazards to the public, and **notify legal advisors** (as appropriate).

b. **Assist the incident commander**, as requested.

c. **Preserve evidence, document the scene, identify witnesses**, and **collect debris**.

d. Only Federal employees on the IRT shall support the Center safety office in **impounding data and collecting witness statements** (written statements when possible).




e. For mishaps at contractor or subcontractor sites, the IRT shall work through the contracting officer, with guidance from the legal advisor, to **obtain and impound data.**.

f. **Advise the supervisor if drug testing should be requested** per the NPR 3792.1, Plan for a Drug-Free Workplace.

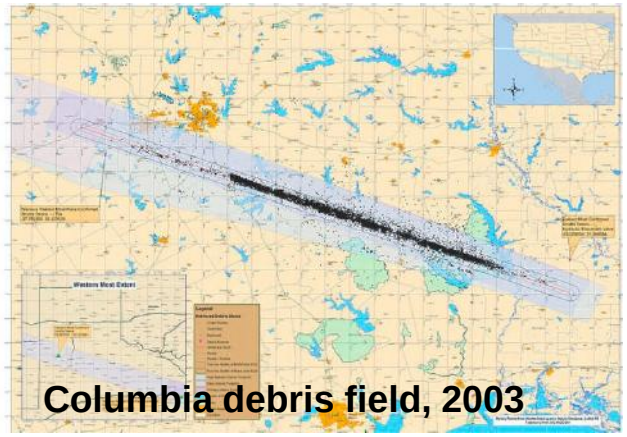
g. **Provide all available mishap data and evidence** to the investigating authority."

# Incident Response: Small to Massive

- **NASA responds to incidents PROPORTIONALLY, including the IRT response.**
  - **Minor damage or injury…maybe 1-2 IRT members called to respond.**
  - **Major incident…national disaster, responders from many Centers and Programs.**

**In all cases, the IRT has the same set of requirements (tasks) to fulfill per NPR 8621.1B.**

ARC vault fall scene, 2008

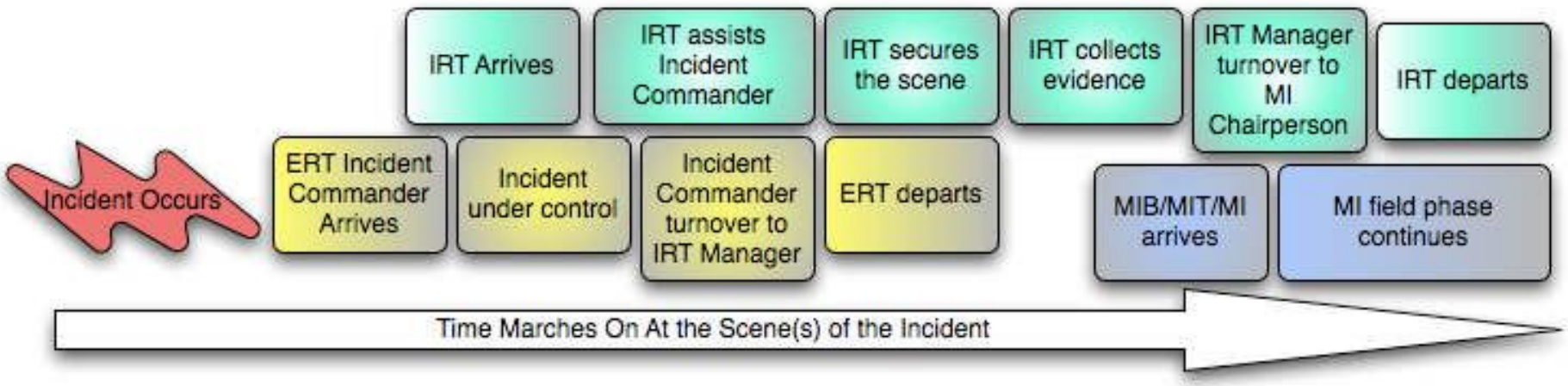

Columbia debris field, 2003

# Who will be on your IRT?

- Your Center/Program/Project decides who is needed to fulfill all IRT requirements based on credible incident scenarios (proportional response).

- One person with the necessary knowledge and skills can meet the IRT response need for a small incident.
- Some typical positions for the full team include:
  - IRT Manager
  - Impound Coordinator
  - Photographer
  - Security
  - Subject matter experts as required,I.e explosives handler

# How does the IRT fit in to incident response?
# 1. On-site, major response scenario

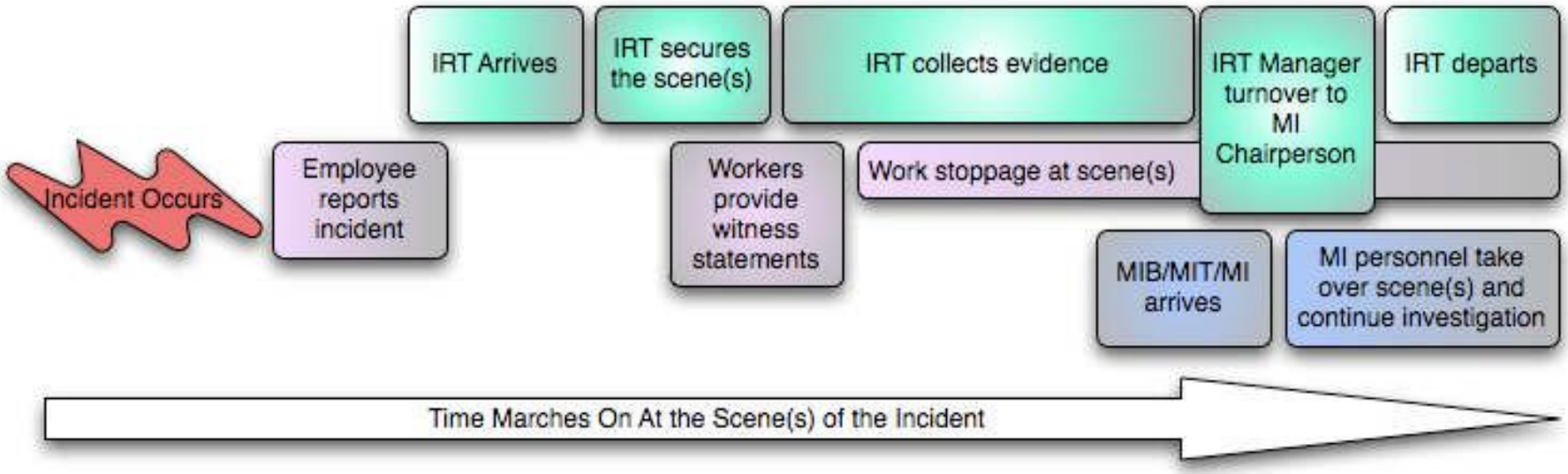



- **Should be an orderly sequence of teams taking control and passing it on: 'I'm the (incident commander, IRT manager, Mishap Investigation Board (MIB) chairperson) and I have the scene'**

**How can the IRT assist the incident commander?**

**Expertise on an involved high-energy system… IF IRT has the expert.**
**NOTE: YOUR IRT IS SUPPORTING A SAFETY INVESTIGATION.**

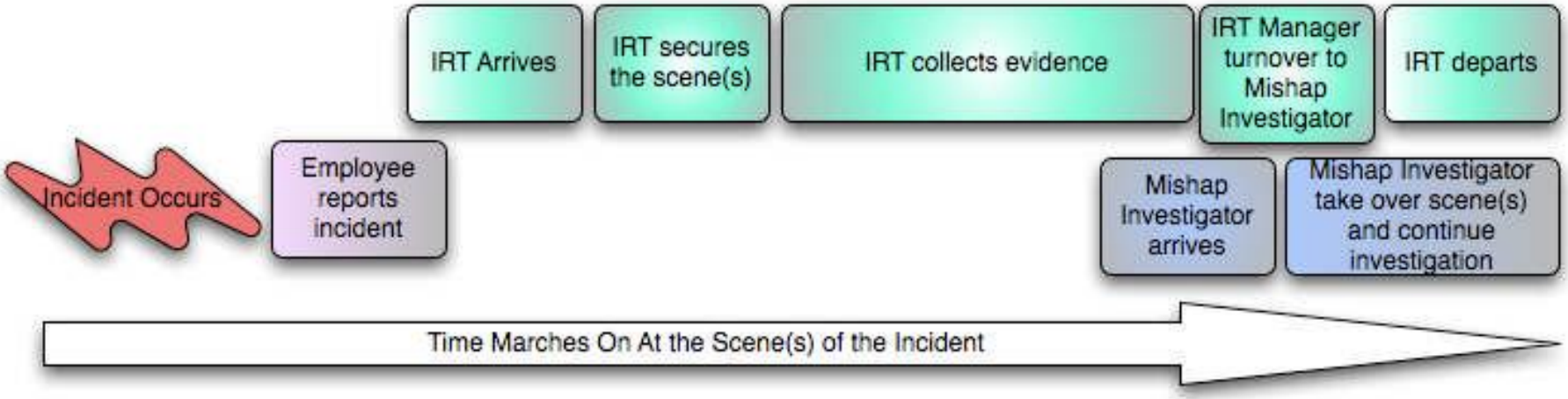
# How does IRT fit in?
# 2. On-site, stop-work scenario




**Could be you in front of employees at work: 'When can we get back on the job? We're losing (time, money,daylight,data)'**

**How does the IRT have the authority to control the scene?**
**The Center or Program should grant it via planning.**

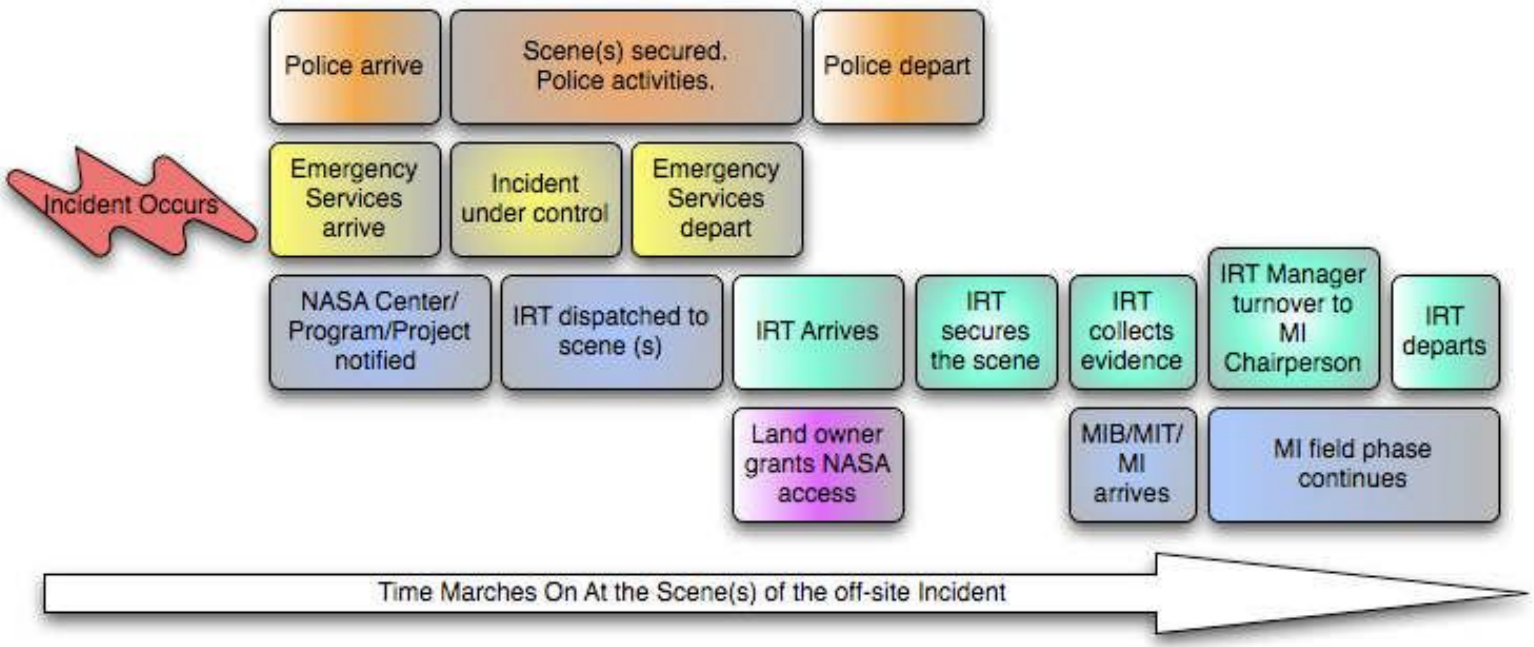
# Where does the IRT fit in?
# 3. On-site minor response




- **Could be a one-person IRT: 'Peaceful…but I have to do everything'**

**Planning and training for multiple credible response situations makes all the difference.**

# Where does the IRT fit in?
# 4. Major response off-site




- **Landowner can intervene off-site: 'This is my land, NASA, keep off'**

  **What do you do? Call for help (legal counsel)**

**Planning and training for multiple credible response situations makes all the difference.**

# Roles and Responsibilities:
# How we will trace NPR 8621.1B requirements today

1) **Prepare for IRT activities.**
   - **Plan, train and equip for anticipated response levels.**

2) **Notify Public Affairs (and Legal Counsel) about *facts*: casualties, damage, hazards to the public.**
   - **Update PAO with changes. Do not speak to the press.**

3) **Secure the scene.**
   - **Identify hazards to people and evidence. Determine PPE needs.**
   - **Assist the Incident Commander as requested.**
   - **Physically protect personnel from evidence and evidence from damage.**

4) **Document evidence via photography, notes and diagrams.**

# IRT Roles and Responsibilities (2)

5. **Impound evidence (Chain-of-Custody implemented by Federal employee).**

6. **Collect evidence at the scene.**
   - **Federal employees-Identify witnesses and collect written statements.**
   - **Preserve material evidence for the Mishap Investigation Board (MIB). Collect perishable evidence.**
   - **Advise the supervisor to request illegal drug testing for all involved civil servants. Advise the Contractors (CO) per the contract, to initiate illegal drug and alcohol testing.**

7. **Provide all evidence and knowledge to the MIB.**
   - **Prepare a <u>summary of actions</u> and <u>a list</u> impounded evidence for the Mishap Investigation Board (MIB). Present in briefing to MIB.**

**Note: this graphic will appear in the following training modules to highlight the task at hand.**

# Mishap Preparedness & Contingency Plan Requirements per NPR 8621.1B

- Incident Commander procedures
- Local mishap/close call policies and procedures
- Relationship/precedence versus other plans
- Program/Project-special procedures for safing, handling, or containing hazards present in hardware
- Program/Project-offsite mishap procedures
- Management responsibility-establishing mishap investigations
- IRT appointment procedures

# Mishap Preparedness & Contingency Plan per NPR 8621.1B (2)

- Type C/D/ Close Call MIT/MI appointment/ report approval
- Impoundment procedures (including release)
- Support for immediate acquisition of investigation needs
- Mandatory schedule for mishap simulations
- IT plan for data retrieval and archiving by the Investigating Authority
- Security clearances for Investigating Authority
- Chain of custody process
- Plan expiration date

# Prepare for IRT Activities-Access Expertise

- **Acquire resources for the IRT continued:**
- **Identify Photographer/Videographer**
  - Experienced in outdoor and field work.
  - Forensic experience a plus.
  - Skilled in digital or film cameras.

- **Other experts as dictated by the anticipated response:**
  - Fire investigator
  - Dive team
  - Explosives handler
  - Data retrieval
  - Hardware expert
  - Coroner

# Prepare for IRT Activities-Train for Knowledge

- Introduction to Mishap Investigation-SATERN SMA-002-06
- Blood borne Pathogens, SATERN course OCC-001-07.
- Confined Space Entry, SATERN course SMA-SAFE-NSTC-0806.
- Hazard Communications (Center's course number)
- National Incident Command System Online Training (IS-100, IS-200)
- This course
- Other training as your Center requires (high-crew, fall protection, Continuous Risk Management, etc.)

# Training for IRT Knowledge and Skills-Exercises

- **Tabletop exercise**
  - **Benefits-Many scenarios, explores knowledge, no resource constraints**
  - **Risks-lacks fidelity (very artificial, many assumptions)**
- **Walkthrough exercise**
  - **Benefits-Stages anticipated scenario and tests skills, allows immediate and later feedback.**
  - **Risks-no sense of immediacy imposed (artificial).**
- **Timed exercise**
  - **Benefits-Adds proficiency to skills, tests decision-making under uncertainty.**
  - **Risk of actual injury or damage if not expertly controlled. Physical conditioning an issue.**

➢ **Exercises represent time WASTED unless lessons are put to use!**
  - **Hurricane Katrina example-Federal & State exercises pointed out many shortfalls that were not addressed.**

# Equip the IRT-"Go-Kit": What will your team bring to the scene?

- **Kit inventory excerpt** from Mishap Investigator's Handbook, Appendix 2.
- Your Center or Program equips your IRT to respond.
- **What you can actually do is limited by the presence or lack of the tools you need immediately!**

| | | | | |
|---|---|---|---|---|
| | CO | Audio Recorder - Recommended mini audio cassette recorders w/counter | 2 | |
| | CO | Audio recorder batteries and spare batteries for recorder | 12-hour operation time | cu |
| | CO | Audio recorder cassette Tapes | 8 | cu |
| | P | Bag with supply of clean clothes, personal medications, prescription drugs, extra contacts and/or glasses and toiletries | 1 per investigator | cu |
| | O | Binoculars - Water resistant binoculars with laser range finder, 8x | 1 pair | |
| | CO | Biohazard bags, w/doc pouch, 8- by 10-inch | 10 | cu |
| | P | Boots - Rubber over boots or waterproof boots (ANSI Z41 steel toe recommended) | 1 per investigator | |
| | P | Boots - Work boots (ANSI Z41 steel toe and shank recommended) | 1 per investigator | |
| | CO | Bottles - Fluid sample bottles: For oil, hydraulic fluid or fuel, should be 2- to 4-oz nalgene or plastic bottles with labels | 6 | cu |
| | CO | Brushes - Small nylon brushes (stiff and soft bristled) | 1 each type per investigator | |

O= Off-Site: Recommended for ALL off-site go-kits
C= Center: Recommended for ALL Center go-kits
P= Personal equipment required for each investigator's personal bag
E= Extra-Optional
cu= Consumable

# Our scenario for today:
# Laser Injury report from DOE

**"The person injured had 15 years experience with lasers. The experiment was running 1 rd, 500 *HZ,* and femtosecond pulse length, with a beam size of several centimeters. The beam was aimed in an upward direction toward a periscope. The beam output was not lowered, because it burns through the neutral density filters.**

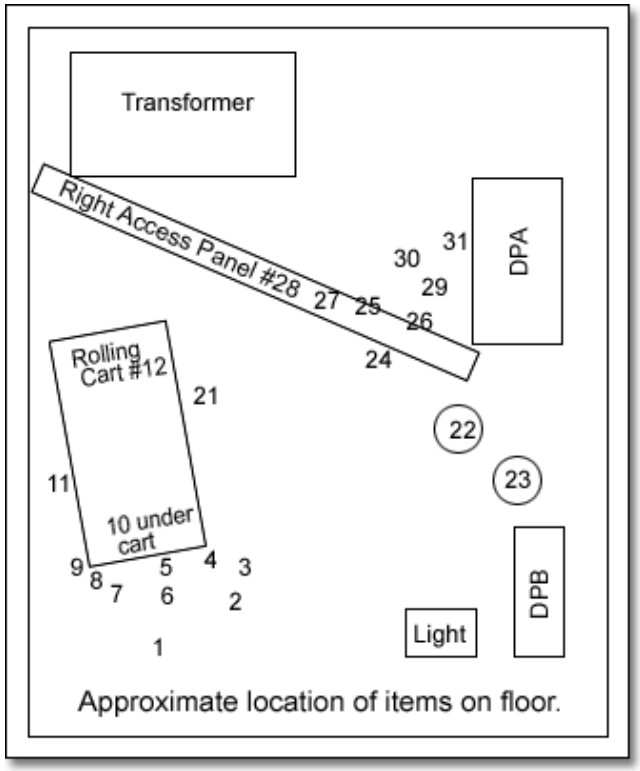
**The two researchers decided if they were careful, it would be all right to insert a mirror into the full-power beam path. This activity was a violation of written procedures for the experiment. An IR viewer was not used. One researcher was placing the mirror into the beam path and was struck by reflection from the comer of the mirror. The person heard a popping sound from his eye, followed by swelling of the eye. The result was a 100-micron spot size injury. Vision went from *20/50* to near blindness; the researcher still cannot read large print."**

# “Notify Public Affairs”-Early PAO Release

## Release ONLY Factual Information

### What is Factual Information?

- **Potential hazards to the public and controls**
- **Information that does not require analysis**
  - Quantities like distance person fell, or pipe flew, time before fire was put out
  - Descriptors like type and color of gas released
  - Documentation like system’s most recent maintenance check
  - Documentation like certification of operator
  - Description of goal of mission, process or operation involved in mishap.



Approximate location of items on floor.

# "Secure the Scene." OK, but What is the incident "scene"?

- **NFPA 1561, Emergency Services, 2002: "The location where activities related to a specific incident are conducted."**

- **'Your mileage may vary.' Each incident leaves a unique footprint on its environment. Questions that help:**

  - **What is the worst credible energy release pattern for each source? Identify energy sources, patterns and warn accordingly until each source is verified safe.**

  - **What is the wind strength and direction versus airborne particulates, fumes or vapors?**

  - **What are the boundaries of incident-related property damage?**

  - **Are there multiple scenes?**

# “Secure the Scene:” assess the scene

- **Initial Walk-through:**
  - **Get an ERT/responder to accompany you…knows area, can describe what changed as a result of the response**
  - **Note types of evidence present, perishability**
  - **Look for an energy pattern**
  - **Estimate boundaries of evidence present**
  - **Estimate resources needed**
  - **Audio/video useful**

# "Secure the Scene" versus hazards to evidence

- **Think…how can individuals put people and property at risk?**
  - **Good intent- Non-IRT persons vs. hazards at scene (no physical security), unsafe IRT actions**
  - **Others- Souvenir hunters, gawking drivers**
  - **Abnormal human-controlled events outside NASA control (power loss, connectivity loss, firemain pressure loss, HVAC loss)**
- **How can individual-related evidence be at risk?**
  - **Mental evidence- memory recall fades over time**
  - **Mental evidence- memory recall changes due to stimulus**
  - **Physiological evidence- Blood alcohol content (BAC) dissipates over time; bloodborne pathogen (BBP) hazard**
  - **Physiological evidence- effects of transport and medical treatment**

# "Secure the Scene" versus hazards to the IRT: Bloodborne Pathogens

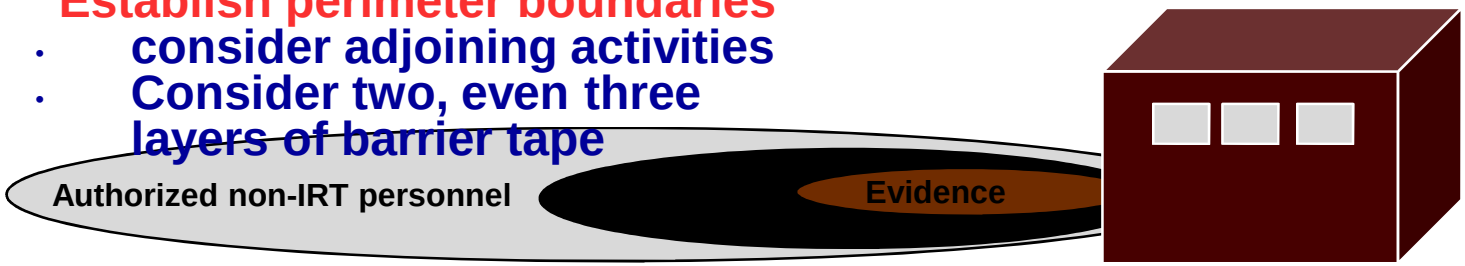
- **The risk-an exposure incident:**
  - **A specific eye, mouth, other mucous membrane, non-intact skin contact with blood or other potentially infectious material at the scene or handling evidence**

- **Worst credible outcomes:**
  - **Hepatitis variant (more every year) vs. liver**
  - **HIV positive**

- **Barriers and Controls:**
  - **Exposure Control Plan**
  - **Access to Blood Borne Pathogen (BBP) Standard**
  - **Work Practice Controls**
  - **Advanced planning**
  - **Prevent contamination**
    - **PPE, containment, time/distance**
    - **<u>No eating, drinking, smoking at scene</u>**
    - **Hand washing required**

# "Secure the Scene"
# (Assessment's complete… now act!)

- **Take control. Call security to assist. Provide instructions:**
  - **Establish perimeter boundaries**
    - **consider adjoining activities**
    - **Consider two, even three layers of barrier tape**




  - **Establish a safe entry-exit point**
  - **Provide an "authorized personnel" list**
  - **If working with an Emergency Operations Center, advise them that a perimeter is set.**
  - **Multiple scenes? Get help fast.**
  - **How long does the IRT secure the scene? Until the MIB can take over. This can be a challenge (ARES "B" example)**

# “Secure the Scene” (Remote Locations)

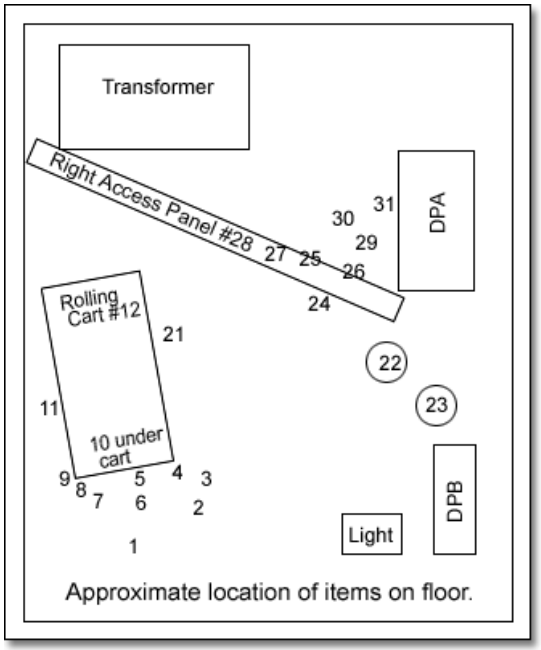
- Secure all active support sites (like Mission Control Rooms).
  - The IRT will secure all support sites that were actively providing input and/or flight commands.
  - Notify and instruct security to assist.
  - No documentation should leave the support site.
  - Impound all documents.
    - All copies of work authorization documents, procedures, logs, etc must be impounded.
    - All hand written notes must be impounded.

# “Document the Scene” Photo/Video

- **The IRT should include an expert photographer who members direct. Technical skill is critical.**
  - **When victims involved, the IRT medical member has priority until all medical-related photos are done.**
- **IRT leader should prioritize photo/video needs:**
  - **Fatalities/ human remains**
  - **Life support equipment**
  - **Impact marks on environment (scars, scorching, skid marks, broken tree limbs)**
  - **Vehicle switch positions and instrument indications**
  - **Control surface positions, actuators, exits/ panels**
  - **Significant wreckage or debris**

# Documenting the Scene: Diagram/Survey

**See Mishap Investigation Handbook Appendix 6**




- **You may need to draw planview (overhead) and side view (profile)**
- **Choose a reference system (geographic, magnetic, relative)**
- **Consider energy path(s) and debris distribution and choose a diagram technique**
- **Sketch major components, witness locations, damage to property**
- **Measurements added to the diagram allow later calculation of speeds and forces if weather or personnel disturb the scene before the MIB can arrive.**

# Documenting the Scene-Marking Evidence

- **Have you RECORDED its location and condition first (photograph, log position)?**
- **Will the act of tagging and moving the evidence damage it? LEAVE IT IN PLACE!**
- **Does it need to be transported for analysis (flight data recorder)?**
- **Read the tag…follow its guidance for each item.**
- **What should be tagged? Every item at the scene that must be moved (ideally the IRT won't have to move any evidence, but the possibility exists)**
- **Every impounded item (documents, etc.). The IRT will be tagging a lot of these items.**

**NASA Mishap Investigation Evidence Property Tag**

| | |
|---|---|
| **LOG NO.** | **DATE - TIME COLLECTED**<br>Month____Day____Year_____Time_____Time Zone_____ |
| **FOUND LOCATION OF ITEM**<br>Latitude/Longitude and/or distance/magnetic bearing from reference point) | **NASA PERSON WHO COLLECTED ITEM**<br>Name:<br>Center:<br>Phone Number: |

**DESCRIPTION OF ITEM** (Model No., Serial No., Identifying marks, Condition, and Value if known)

**OWNER OF ITEM**

| Name | Company | Phone No. | Address | City | State |
|---|---|---|---|---|---|
| | | | | | |

**HAZARDS ASSOCIATED WITH ITEM**

- Is the item hazardous? (Yes or No) _____
- If hazardous, are MSDS sheets attached? (Yes or No) _____
- Does the item require special PPE for handling? (Yes or No) _____
- If yes, what PPE is required? _____
- How does the item have to be stored to ensure safety and preservation of evidence? (Please describe any special precautions (e.g., cold dark room, away from ignition sources or flammable products).

**S THIS ITEM NASA SENSITIVE BUT UNCLASSIFIED BECAUSE OF THE FOLLOWING? Please select appropriate categories)**

- Privileged Testimony
- Proprietary Information
- International Traffic Arms Regulations (ITAR)
- Export Administration Regulations (EAR) information
- Privacy Act Information
- Personnel Effect of Injured or Deceased

**Additional Comments or Notes:**

**Draft-Pilot Course Only**

# “Impound Evidence” Impound Lead actions

**The IRT should impound evidence in the order of priority established during preparation.**

- **The Impound Lead should initiate the phone tree to start the impound process.**
- **The Impound Lead should verify that the impound area has been activated and is secure. Only IRT members can enter the impound area once activated. Keep all pertinent investigation materials in a secured location.**
- **For mishaps at contractor or subcontractor sites, the IRT Lead shall contact the Contracting Officer (or other mechanism previously established) to obtain and impound data.**

- ***Note: For mishaps outside the Center’s gates, NASA has the authority to impound NASA property, however, the ability to impound or collect other data, records, and equipment is determined by the local and Federal laws, Agency agreements, and contracts.***

# “Impound Evidence” Handling and Storage

- Original hard copies should be taken to the Impound Area.
  - Documents needed for critical operations will not be removed until the operations have concluded.
- An evidence voucher will be created for each item impounded.
- Evidence will be tagged NASA Sensitive But Unclassified (NASA SBU). It is important to protect sensitive and classified information and the privacy of persons involved in the mishap (e.g., witnesses)
- Evidence will be “logged in” when it arrives at the Impound Area and is stored in locked cabinets.
- Electronic documents can be stored on the PBMA website.
- An impound log will generated. This log will list all items collected, source, date, time, and where it is stored in the cabinets. Electronic files on PBMA will also be listed in the evidence log.

Two types of impoundment-Chain of Custody and everything else

# “Impound Evidence” Chain of Custody

- **When is it required?**
  - **For personal effects and sensitive information related to injured or deceased individuals**
- **Establish custody-paper trail of:**
  - **Seizure**
  - **Custody**
  - **Control**
  - **Transfer**
  - **Analysis**
  - **Disposition**
- **Where are the procedures?**
  - **Your Mishap Preparedness and Contingency Plan**

# “Impound Evidence” Chain of Custody (2)

- **Who controls?**
  - **IRT Impound Lead, then Investigating Authority**
- **Transaction of Custody-document:**
  - **Conditions under which evidence is gathered**
  - **Identity of all evidence handlers**
  - **Duration of custody**
  - **Security conditions while handling or storing evidence**
  - **How evidence is transferred for each transfer**
  - **Disposition**
- **Document receipt**
  - **Original custody form + 3 copies…custodian copy=receipt**

# “Collect Evidence” comes with risks

‘Collect evidence’ means reassessing risks after ‘Secure the Scene’…both while planning and doing.

- **Risk to your team:**
  - Sharp edges
  - Friable materials (asbestos, composites)
  - Bloodborne Pathogens
  - Fall hazards (obstacles, edges, shafts, weakened structures)
  - Energy hazards (mechanical, pressure, electrical, radioactive)
  - Immediately Dangerous to Life and Health (IDLH) atmospheres
  - Fatigue
  - Dehydration

Reassess what can go wrong and how to prevent…also how to treat if it happens (e.g. first aid, evacuation criteria)

# “Collect Evidence” risks continued

- **Risk to your evidence:**
  - Location is disturbed (True, Magnetic, Relative)
  - Damage can be done (fracture surfaces, contamination)
  - May undermine MIB investigation (witness recall, MIB analysis)
  - Collateral investigation may be affected
- **Weigh against benefits:**
  - Off site: theft, damage by intruders, environment
  - On site: work resumption
  - Reduced work area hazards
- **Is debris collection really necessary?**
  - If the decision is Yes, read on…

# "Collect Evidence"
# Priority: Perishable Evidence

- **Perishable evidence first.**
- **What are major constraints to evidence collection?**
  - **Volatile Memory. Witness memory fades or changes after conversations. Data can be overwritten (Such as security camera video, Programmable Logic Computer (PLC) output). RAM can be lost when power is removed.**
  - **Environment. Attack by temperature, moisture, pressure. Fluids leach into the ground or evaporate or metabolize.**
  - **Special Expertise. Is an expert needed to access or discover?**
  - **Physical Access. Underwater, remote/rugged terrain. Skills, transport resources needed.**
  - **Fear. Witnesses may refuse to provide a statement.**
- **How to overcome?**
  - **A risk-informed Mishap Preparedness and Contingency Plan.**
  - **Adapt to change with resources available.**

# The perishable evidence is collected. Now what?

- A large hardware debris field presents a challenge, especially offsite. Answering these questions will help your decision-making process:
  - Is the scene on NASA property?
  - Is the scene protected from the environment and/or public access?
  - Who is pressuring to clear all debris and resume operations?
  - How soon will MIB be on scene?
- Best case- If NASA owns the scene real estate and all evidence is protected, best to LEAVE IN PLACE for the MIB.
- Worst case- If the scene impacts public safety and commerce (airport, highway, railway, restricted waters) you will need to expedite all evidence collection and removal.
- Scenarios in between the two extremes above demand judgment over jurisdiction and negotiation over time.

# Leave-It-Be or Bag-and-Tag?

- **Evidence collection may be beyond the resources and charter of your Center's IRT…best to LEAVE IN PLACE and PROTECT FOR the Investigating Authority when:**
  - **Spotting evidence of failure modes requires additional training and experience**
    - **Example: brittle fracture of metal structures due to high-velocity impact versus ductile fracture from metal fatigue (a needle in a very large haystack)**
    - **Example: hidden fracture of composite fiber/resin matrix**
  - **Collection techniques that minimize change to evidence prior to analytic tests might be needed.**
    - **May involve large-scale salvage and Non-Destructive Inspection (NDI) testing**
- **But it could be as simple as one pair of gloves! Well within IRT resources and training.**

# Tagging and Bagging

**Perishable evidence only unless directed by higher authority**

- **Medical samples**
- **Fuel/lubricant**
- **Memory/recordings**
- **Ice shapes**
- **HAZMAT-BBP requires PPE!**

**Location**

- **Coordinate with diagramming effort**
- **GPS (true) or measuring tape (relative)? Best?**
- **Public participation**
- **Coordinate with photo effort**

# Evidence and the Control Room

- **What if there's no "scene" (OCO, DART, MCO, CONTOUR, etc)?**
- **What are major constraints to evidence collection?**
  - **<u>Planning</u>. This type of response focuses on data collection and impound (witness statements, telemetry, procedures, etc.) Lack of an "IT PLAN or "DATA IMPOUND PLAN" can hamper the IRT.**
  - **<u>Communication</u>. The key personnel in the room should know who the IRT members are and why they are present; otherwise, time will be lost in explaining functions and seeking data owners. Two hours prior to launch is too late for these introductions.**
  - **<u>Multiple locations</u>. Where is the data, besides the control room?**
  - **<u>Who are the data owners</u>. Head IT person, people taking notes…what about visitors? Obtain all sign-in sheets.**

# Post-Mishap Drug and Alcohol Testing

**Per NPR 3792.1: NASA Drug Free Workplace**

***Note: Per NPR 3792.1 the supervisor shall initiate drug testing after a mishap if the mishap results in a fatality or personal injury requiring immediate hospitalization or in damage estimated to be in excess of $10,000 to government or private property. This applies to Federal employees only. Drug testing of contractors is dependent upon their contract.***

**Civil Servant Testing Required By Law:**

**Policy Letter: Requirements for Post-Accident Testing of NASA Civil Service Employees for Illegal Drug Use (Aug. 2007).**

**Supervisor can initiate post-accident testing 24 hours a day, 7 days a week, in the United States, Alaska, Hawaii, and Puerto Rico by contacting the NASA Shared Services Center at 1-877-677-2123.**

**Contractor Testing Required By Law:**

**Implemented per contract: Contracts need to be reviewed so it is clear how the IRT can activate testing in the event of a mishap.**

# ‘Collect Evidence” Written Statements

- **Among the most important and perishable evidence!! Keep searching for witnesses throughout your IRT activities.**

- **All written witness statements obtained within the first 24 hours of the occurrence of a mishap or close call shall be considered privileged and protected. (Must be collected by a Federal Employee). *The IRT should strive to locate all witnesses and obtain a statement from each within 24 hours.***

- **All verbal witness statements and written statements given after 24 hours as part of a NASA mishap investigation, where the witness was explicitly informed that his/her account will not be released, shall be considered privileged and protected.**

- **When privilege has been granted by the IRT, Center safety office, or investigating authority, NASA shall make every effort to keep witness testimony (both written and verbal) confidential and privileged to the greatest extent permitted by law. This privileged information will be strictly limited to only the information provided directly by the witness for the safety investigation.**

- **Mark these SBU immediately and seal in an envelope. Store in locked cabinets immediately.**

# Privileged Witness Testimony and the Inspector General (IG)

- **In an unusual case, the MIB chair shall release privileged witness testimony and related material to the OIG upon receipt of a written request that is signed by the Inspector General or Deputy Inspector General, addressed to the NASA Administrator or Deputy Administrator, and forwarded to the MIB chair from the Administrator's office.**

- **Note: The OIG respects and will generally defer to the disclosure restrictions attendant to NASA mishap investigations. Upon receipt of such testimonial information, the OIG will consider it to be confidential witness testimony and will treat it as such to the full extent required by the Inspector General Act of 1978.**

  - ***Law: "Inspector General, in carrying out the provisions of this Act, is authorized— (1) to have access to all records, reports, audits, reviews, documents, papers, recommendations, or other material available to the applicable establishment which relate to programs and operations with respect to which that Inspector General has responsibilities under this Act"***

# "Collect Evidence" Statement to Witnesses

**From NPR 8621.1B**

**The purpose of this safety investigation is to determine the proximate cause(s) and root cause(s) of the mishap that occurred on _____ and to develop recommendations toward the prevention of similar mishaps. It is not our purpose to place blame or to determine legal liability. Your testimony is entirely voluntary, but we hope that you will assist the investigating authority to the maximum extent of your knowledge in this matter.**

**Your testimony will be documented and retained as part of the mishap report background files but will not be released with your name as part of the mishap report.**

**The investigating authority will make every effort to keep your testimony confidential and privileged to the greatest extent permitted by law.**

**For the record, please state your full name, title, address, employer, and place of employment.**

# "Collect Evidence" Protection of Privilege

- **The witness shall not be given a copy of the privileged written statement or transcripts of verbal witness statements given in the course of a NASA mishap investigation.**

- **WHY? If witness statements or transcripts of witness testimony are provided to a witness, NASA cannot ensure that it remains privileged and confidential.**

**Same is true for written statements….**
**If you provide witness with a copy of their written statement, the statement is no longer privileged.**

**DO NOT GIVE WRITTEN STATEMENTS TO ANYONE**
**CONTRACTORS, SECURITY OR OTHERS**

# “Collect Evidence” Tips

- Never discard anything — even items that appear trivial at first may prove useful later in the investigation.
- Carefully document evidence at the time it is obtained or identified.
- Enlist the aid of technical experts when making decisions about handling or altering physical evidence.
- Intact and complete evidence is the foundation of a successful accident investigation.
- Fluids emanating from equipment or vehicles may quickly evaporate or be absorbed by surrounding materials. Therefore, fluid samples should be taken quickly.

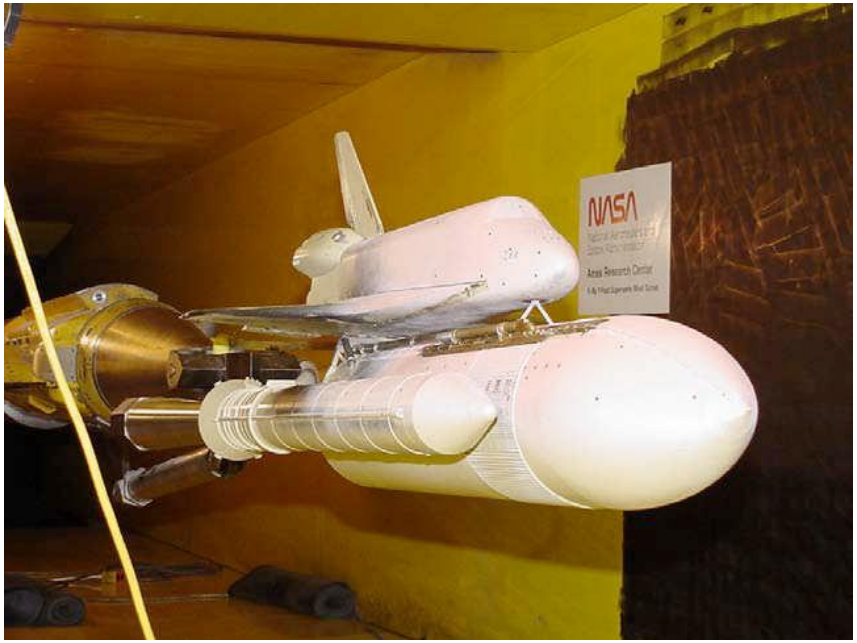
# IRT Manager-Concluding Activities

- **Prepare a summary of actions. Mishap Investigation Handbook recommends:**
  - **Location and condition of mishap site(s), including collateral property damage.**
  - **Actions taken by Incident Commander and IRT affecting the debris field.**
  - **Location/ Condition of participants, including bystanders killed or injured.**
  - **Status of next-of-kin notification.**
  - **Wreckage or debris location/condition.**
  - **Presence of explosives, pathogens, or other hazardous materials at scene.**
  - **Civil authorities involved in managing scene and/or casualties.**
  - **Status of impoundment actions.**
  - **Status of witness search/statement collection.**
  - **Technical assistance immediately available, offered, en route.**
  - **Media interest/statements made to date.**
  - **Logistical arrangements in place for MIB.**

- **Provide all data and evidence to the MIB. Turn over control of IRT impound area. Hand over the keys to the impound room. IT person may remain to assist with PBMA site (as requested).**

Thanks for your time!
QUESTIONS?

**TABLE TOP EXERCISE**




# Unitary Plan Wind Tunnel 9X7 Test Section Accidental Laser Activation

# Mission Highlights, Relative Risk, and Radiological Contingency Planning and Response for the Mars Science Laboratory (MSL) Mission

April 20, 2011

By:

Randall Scott

KSC Radiation Protection Officer/NASA Radiological Contingency Planning Lead

# Mission Highlights

# NASA Launch History

NASA Ulysses Launch 1990

NASA Galileo Launch 1989

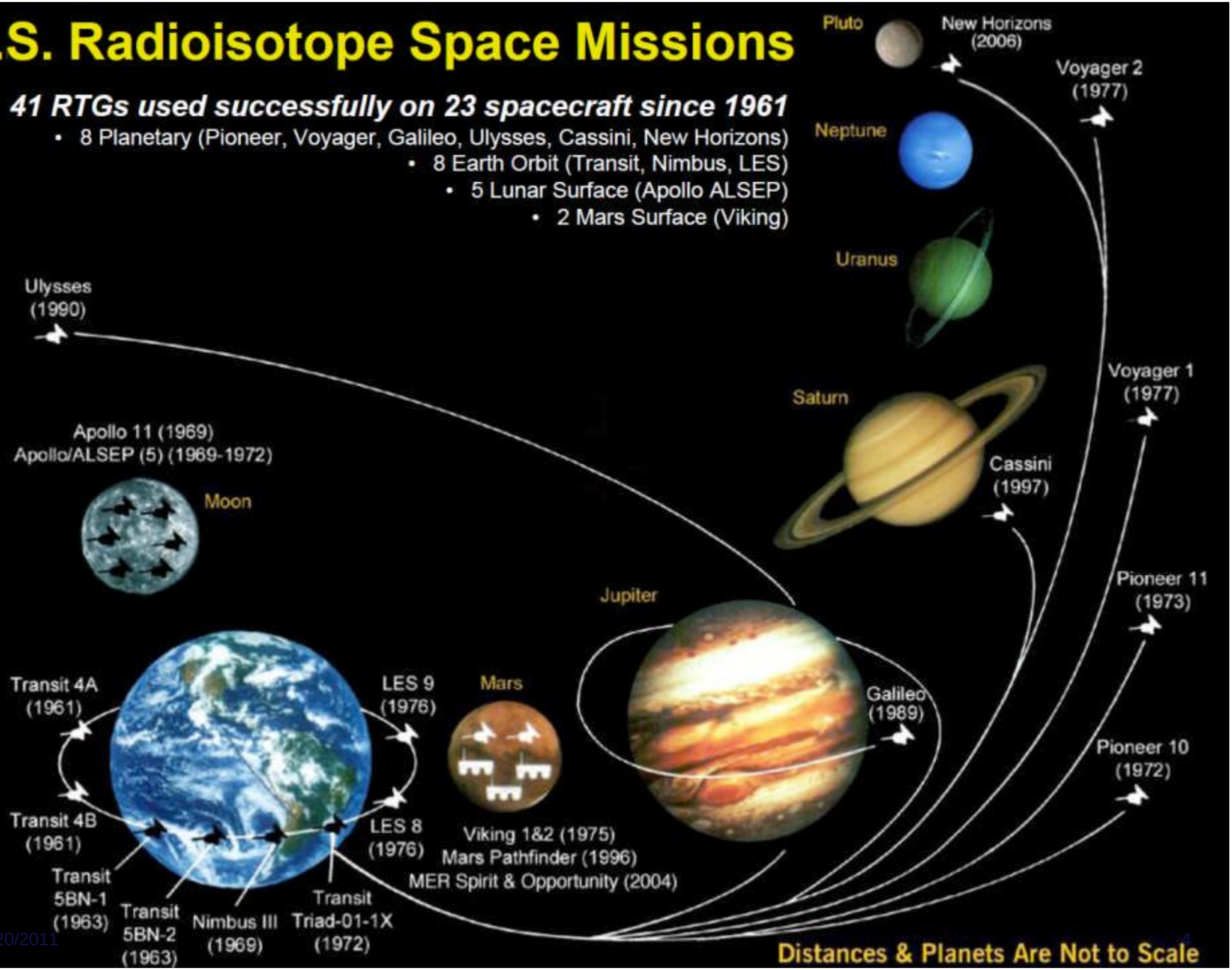
NASA Cassini Launch, 1997

NASA New Horizons Launch, 2006

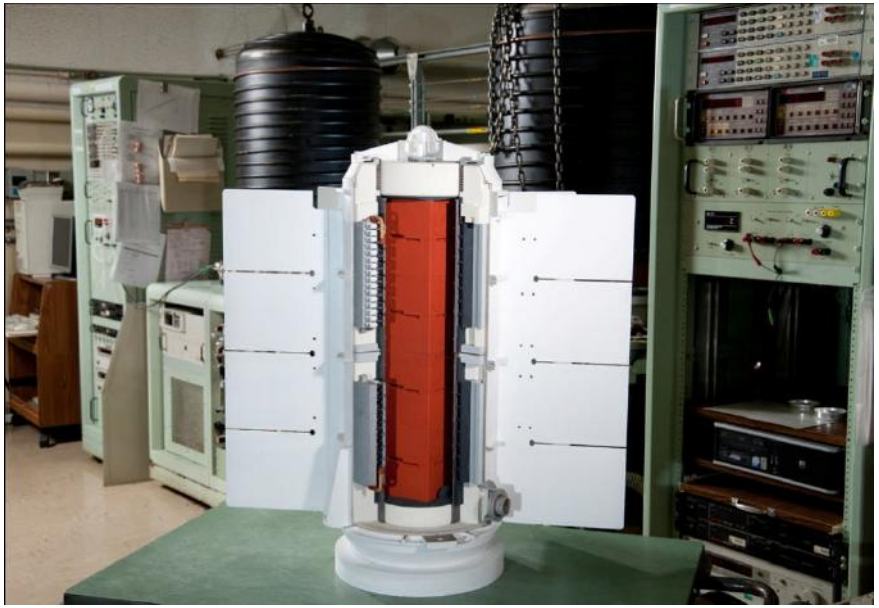
# U.S. Radioisotope Space Missions

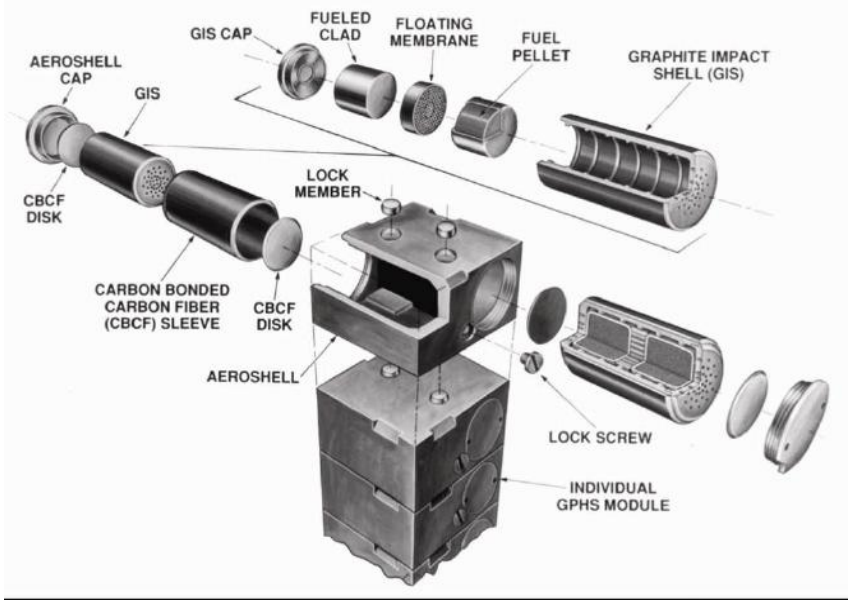
***41 RTGs used successfully on 23 spacecraft since 1961***

- 8 Planetary (Pioneer, Voyager, Galileo, Ulysses, Cassini, New Horizons)
- 8 Earth Orbit (Transit, Nimbus, LES)
- 5 Lunar Surface (Apollo ALSEP)
- 2 Mars Surface (Viking)

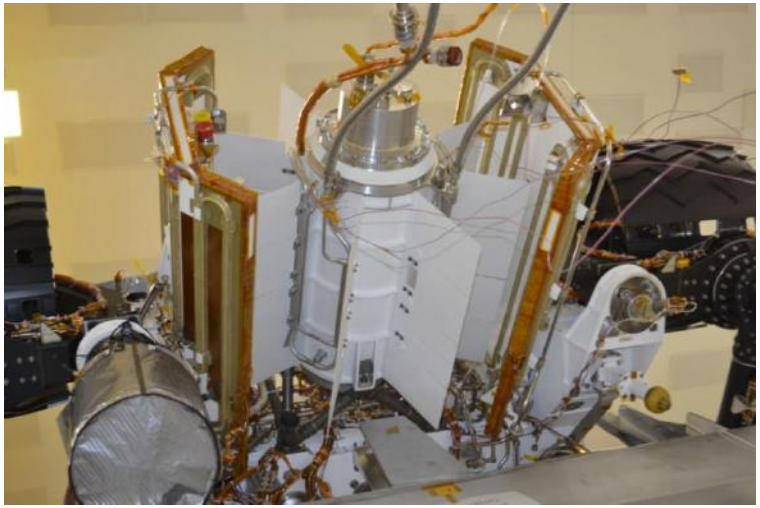


# Radioisotope Power Source





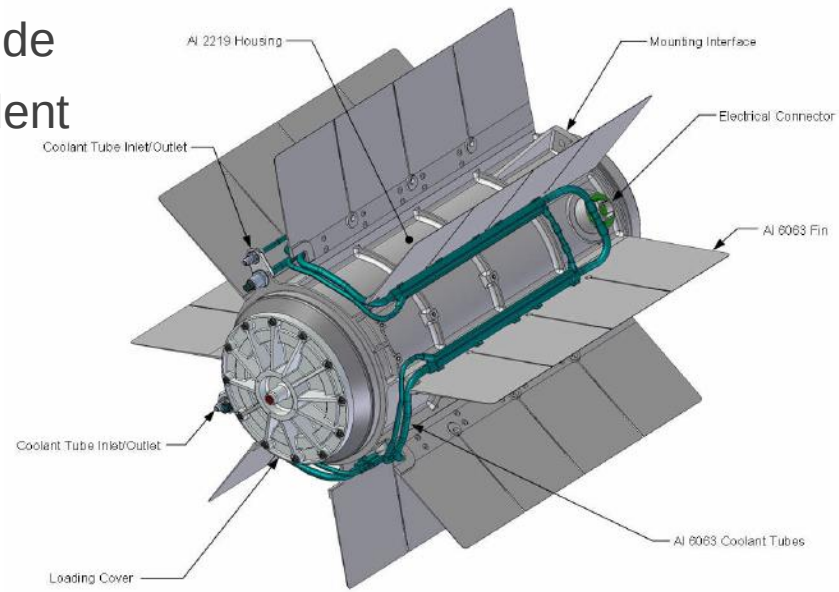

**Heat generated through alpha decay of Plutonium 238 passing through thermocouples produces approximately 110 watts of power to charge rover batteries.**



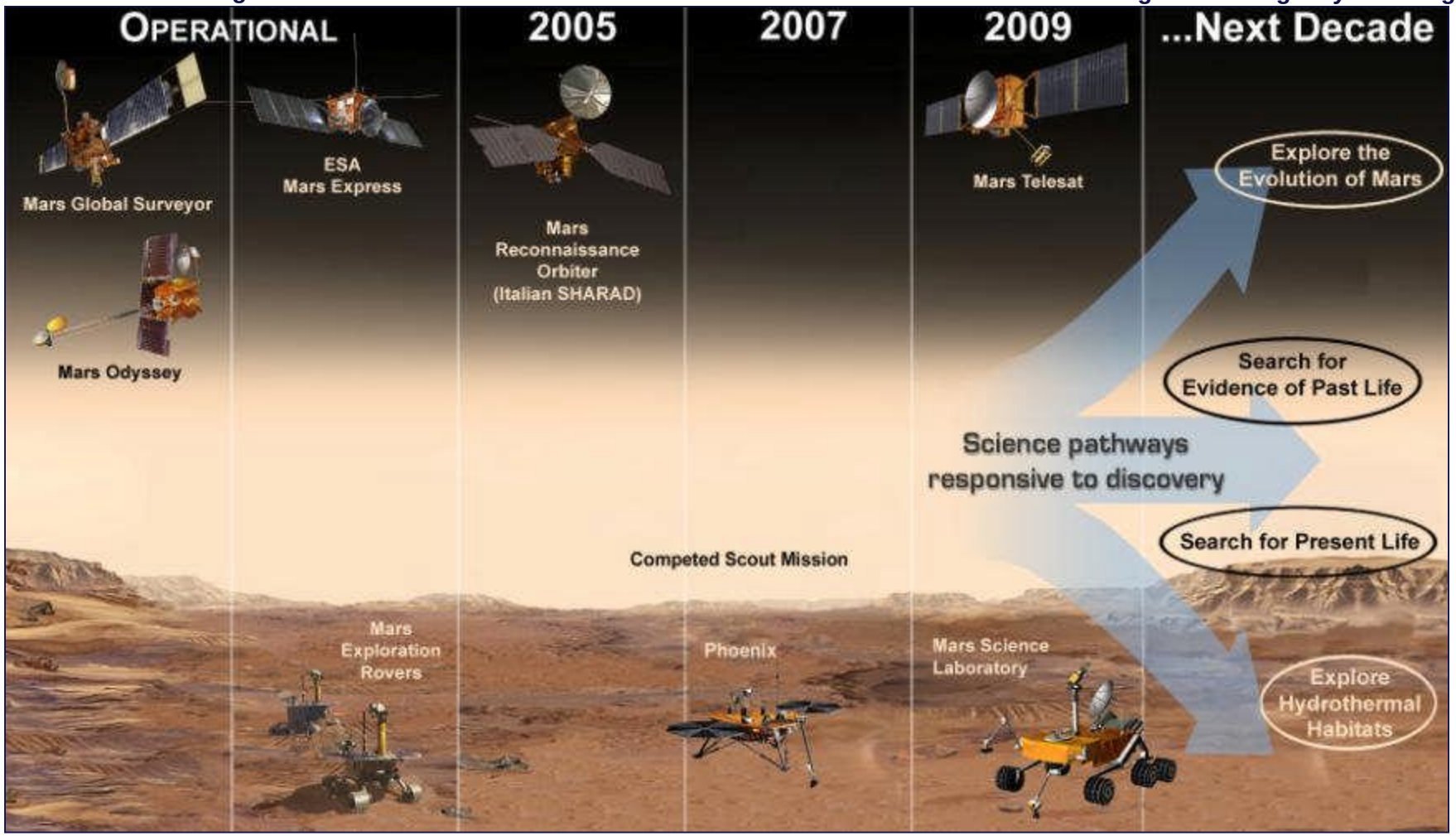
# Radioactive Materials Inventory

The Multi-Mission Radioisotope Thermoelectric Generator (MMRTG) provides power for the Rover. This power source is required to explore expanded latitudes above or below the Martian equator where there is insufficient sunlight for solar cells. Additionally, there are minor radioactive sources used on instrumentation contained on the Rover. The MMRTG:

- contains about 4.84 kg (~10.6 lb) of plutonium dioxide ($^{238}PuO_2$) representing approximately 60,000 Curies
- has been extensively tested and designed to contain the plutonium dioxide under a wide range of launch and orbital reentry accident conditions.



# NASA's Mars Exploration Program



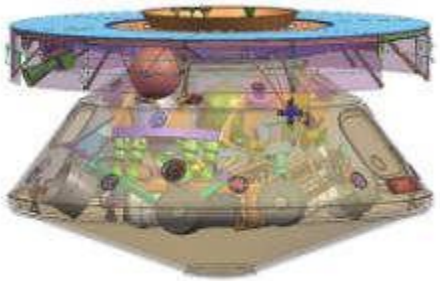

Strategy: Follow the water, assess habitability, return a sample, prepare for humans.MSL concept: Mobile laboratory to assess habitability

# Scientific Objectives of MSL

*Explore and quantitatively assess a local region on Mars' surface as a potential habitat for life, past or present.*

- Assessment of present habitability requires:
  - An evaluation of the characteristics of the environment and the processes that influence it from microscopic to regional scales.
  - A comparison of these characteristics with what is known about the capacity of life, as we know it, to exist in such environments.
- Determination of past habitability has the added requirement of inferring environments and processes in the past from observation in the present.
- Such assessments require integration of a wide variety of chemical, physical, and geological measurements and analyses.
- These analyses would be accomplished by a diverse set of instruments, a sophisticated sampling system, and a rover capable of bringing the payload to a range of sites and supporting it over one Mars year at a carefully chosen landing site.

# MSL Mission Overview

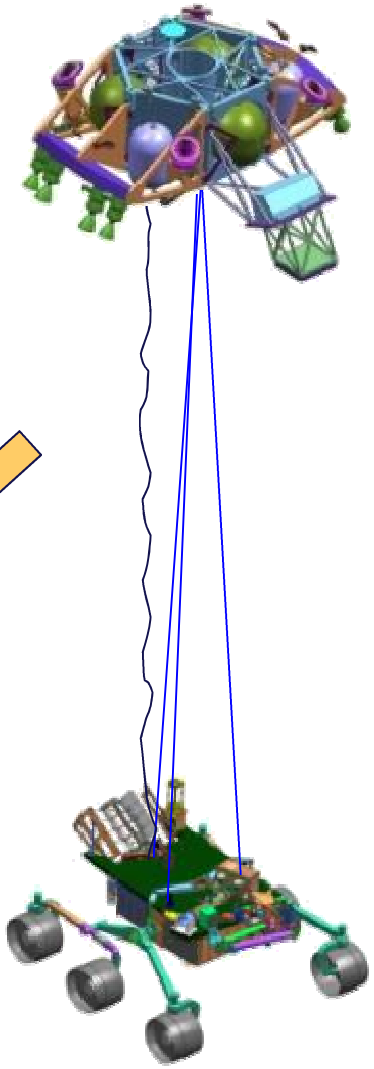


## CRUISE/APPROACH

- 10-12 month cruise
- Arrive N. hemisphere summer ($L_s$=120-150)

## ENTRY, DESCENT, LANDING

- Guided entry and controlled, powered "sky crane" descent
- 20-km diameter landing ellipse
- Discovery responsive for landing sites ±60° latitude, <+2 km elevation
- 800-kg landed mass



Conceptual Design

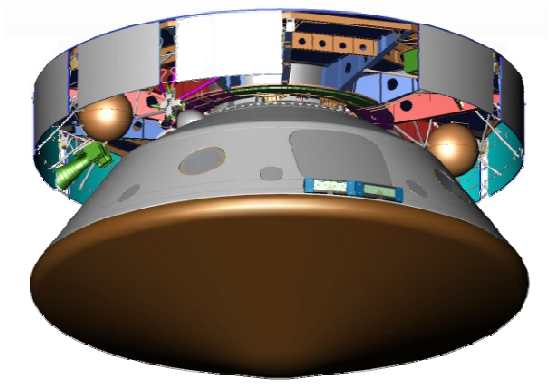
## SURFACE MISSION

- Prime mission is one Mars year
- Latitude-independent and long-lived power source, pending approval
- 20-km range
- ~75 kg of science payload
- Would acquire and analyze samples of rock/regolith
- Large rover, high clearance; greater mobility than MPF, MER

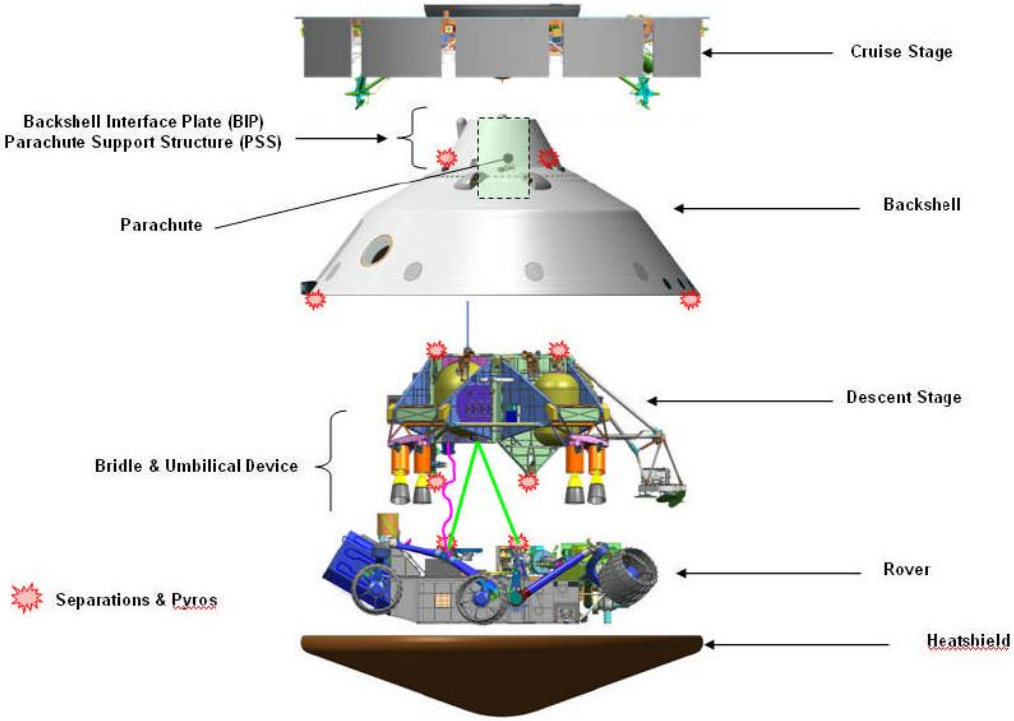
## LAUNCH

- Sept. 15 to Oct. 4, 2009
- Atlas V (541)

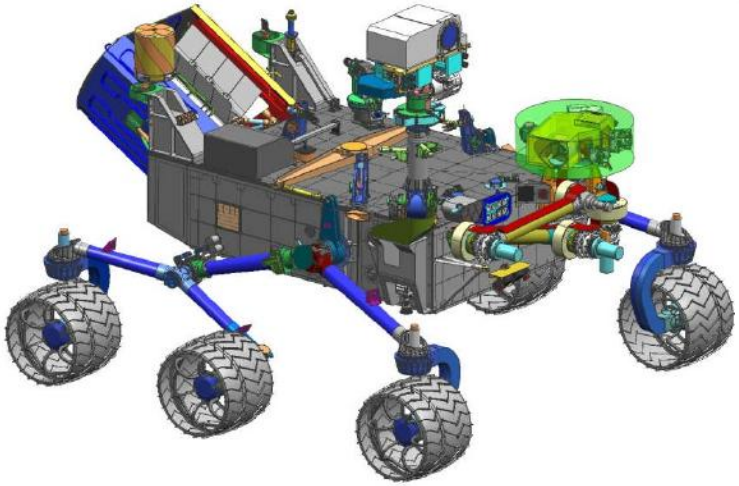
# MSL Spacecraft



**Cruise Stage (CS)**

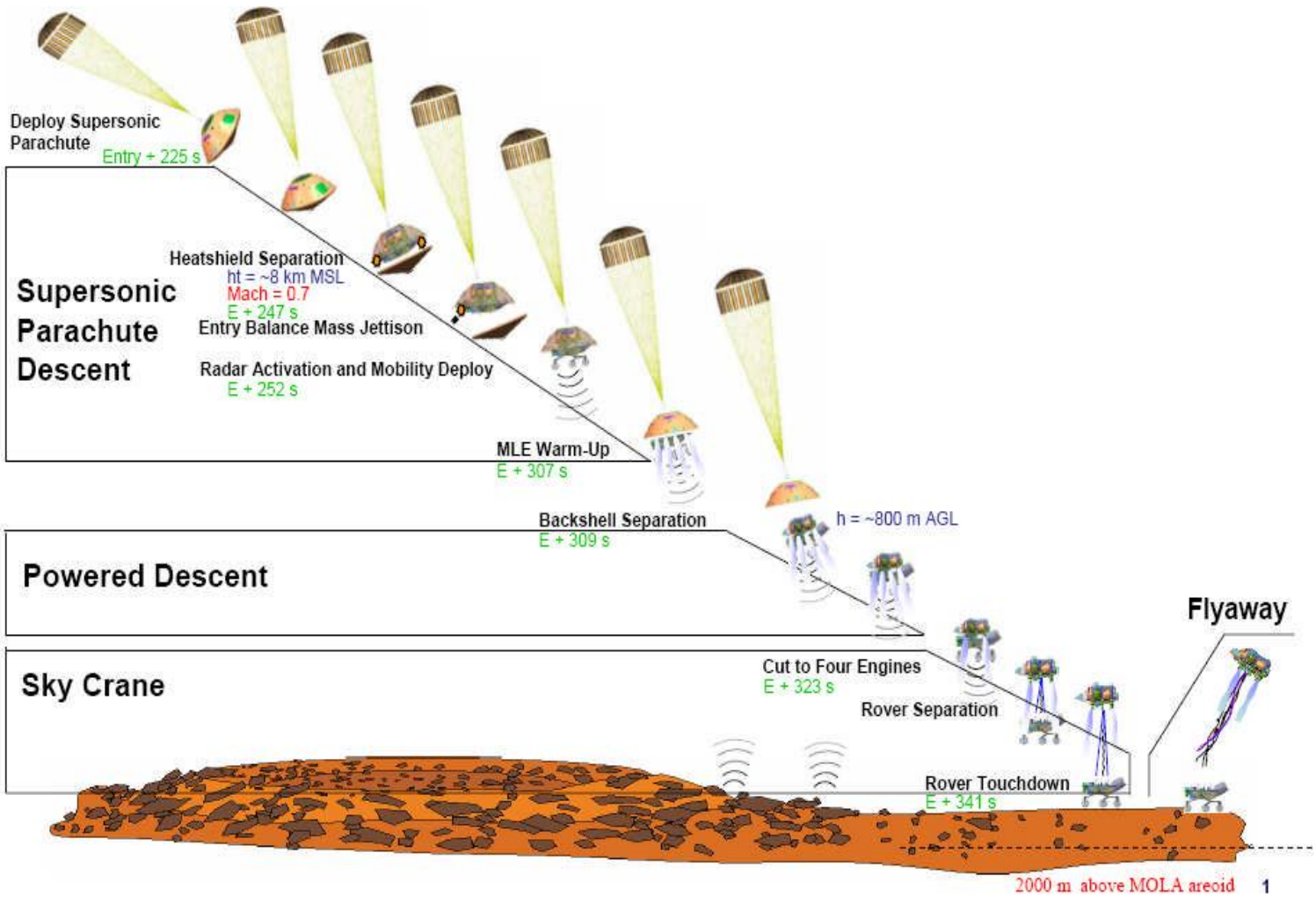



**CS Expanded View**

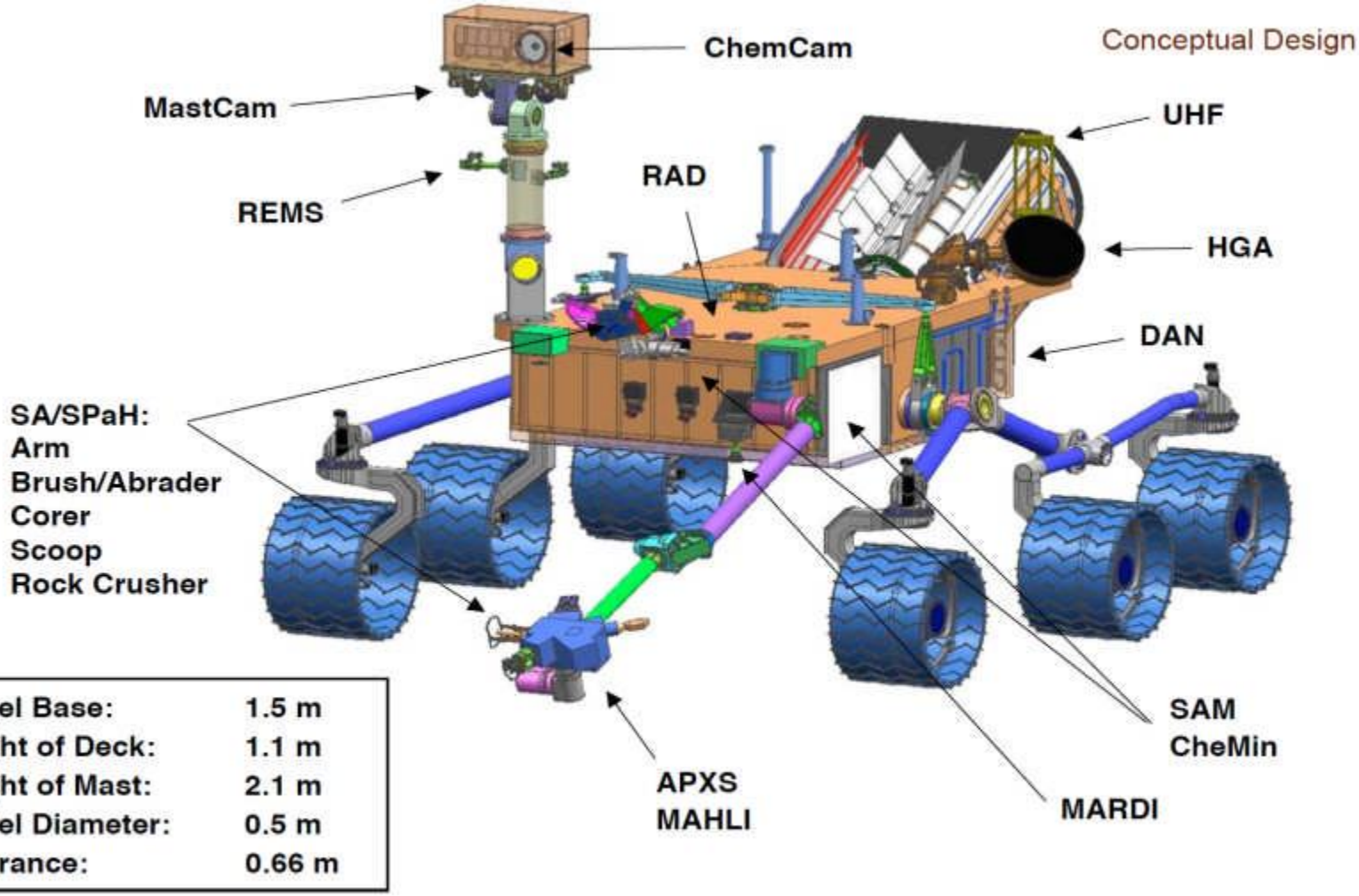


**MSL Rover (Curiosity)**

# Entry, Descent and Landing Events on Mars



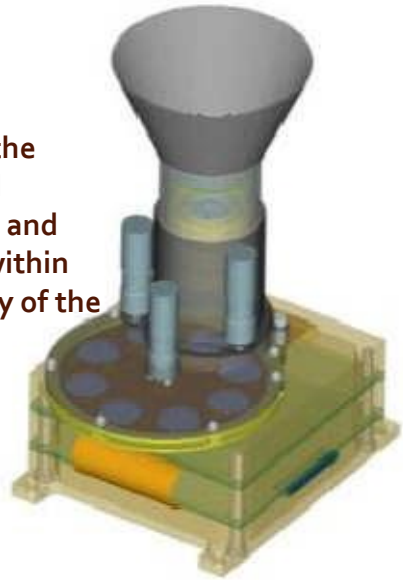
# MSL Mission Overview (cont'd)

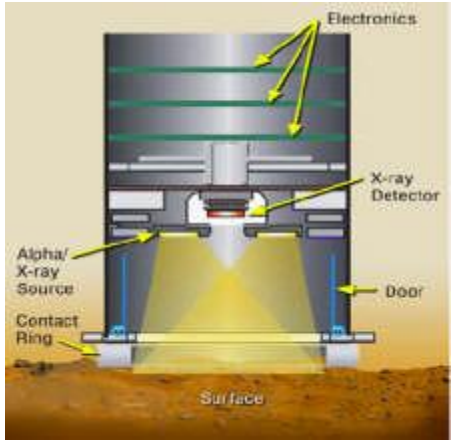



| | |
|---|---|
| Wheel Base: | 1.5 m |
| Height of Deck: | 1.1 m |
| Height of Mast: | 2.1 m |
| Wheel Diameter: | 0.5 m |
| Clearance: | 0.66 m |

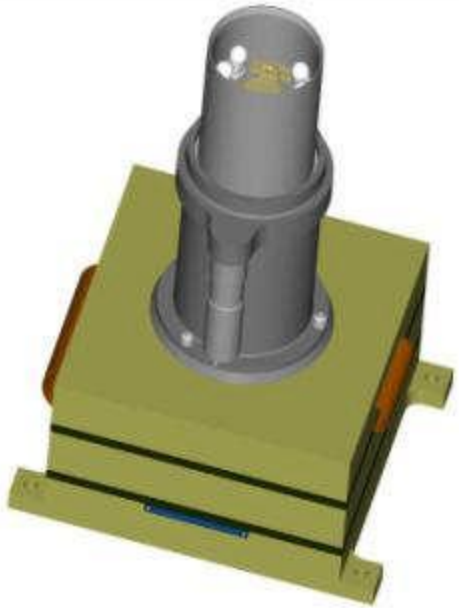
# MSL Mission Overview (cont'd)

MastCam observes the geological structures and features within the vicinity of the rover

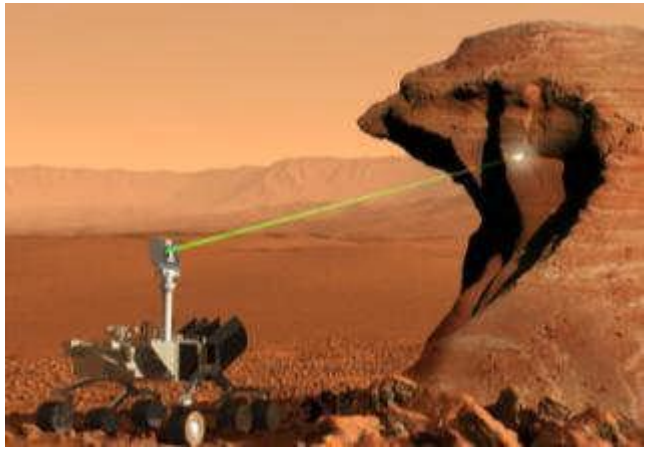




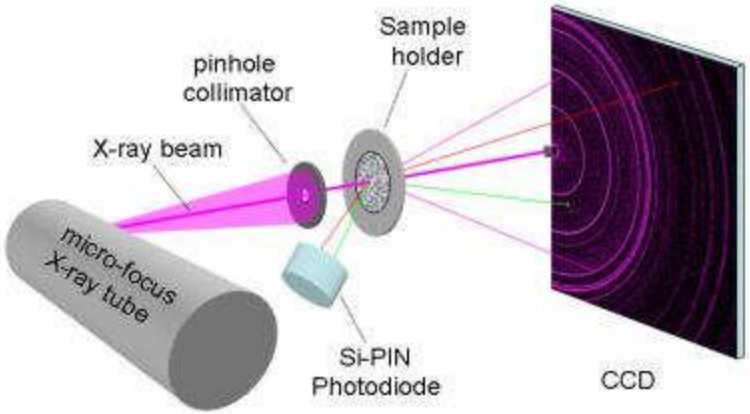

APXS determines the chemical composition of rocks, soils, and processed samples



Mars Handheld Lens Imager (MAHLI) characterizes the history and processes recorded in geologic materials encountered

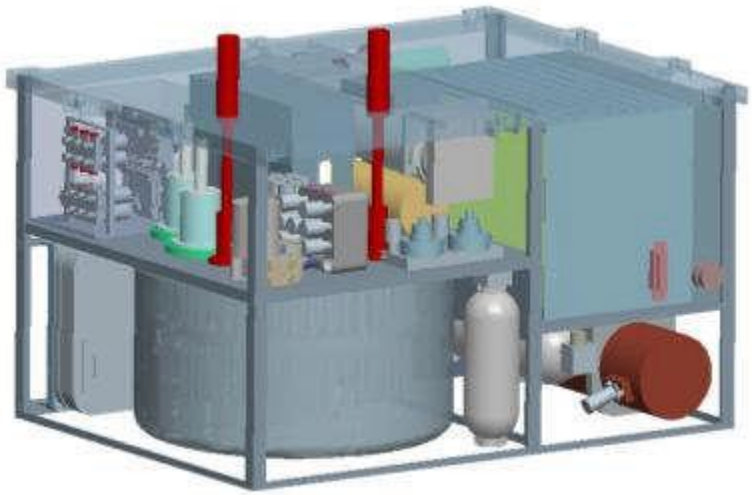


ChemCam performs elemental analyses through laser-induced breakdown spectroscopy




Chemistry and Mineralogy (CheMin) performs quantitative mineralogy and elemental composition

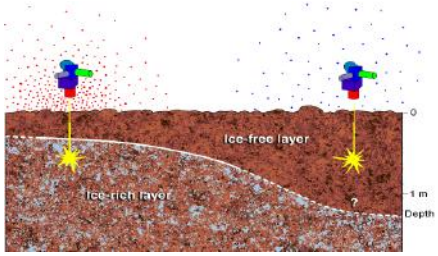
# MSL Mission Overview



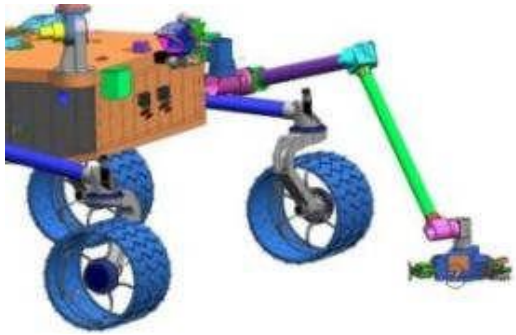
SAM Suite Instruments

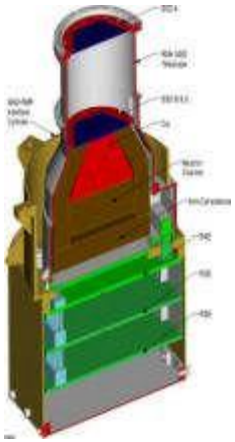
- -Quadrupole Mass Spectrometer (QMS)
- -Gas Chromatograph (GC)
- -Tunable Laser Spectrometer (TLS)

Mars Descent Imager (MARDI) provides detailed imagery of the MSL landing region




Dynamic Albedo of Neutrons (DAN) measures the abundance of hydrogen (e.g., in water or hydrated minerals) within 1 meter of the surface

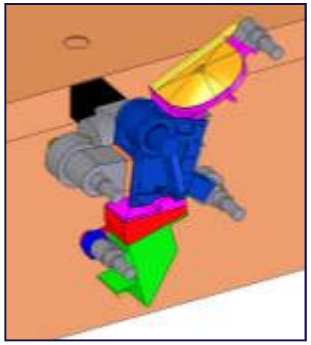


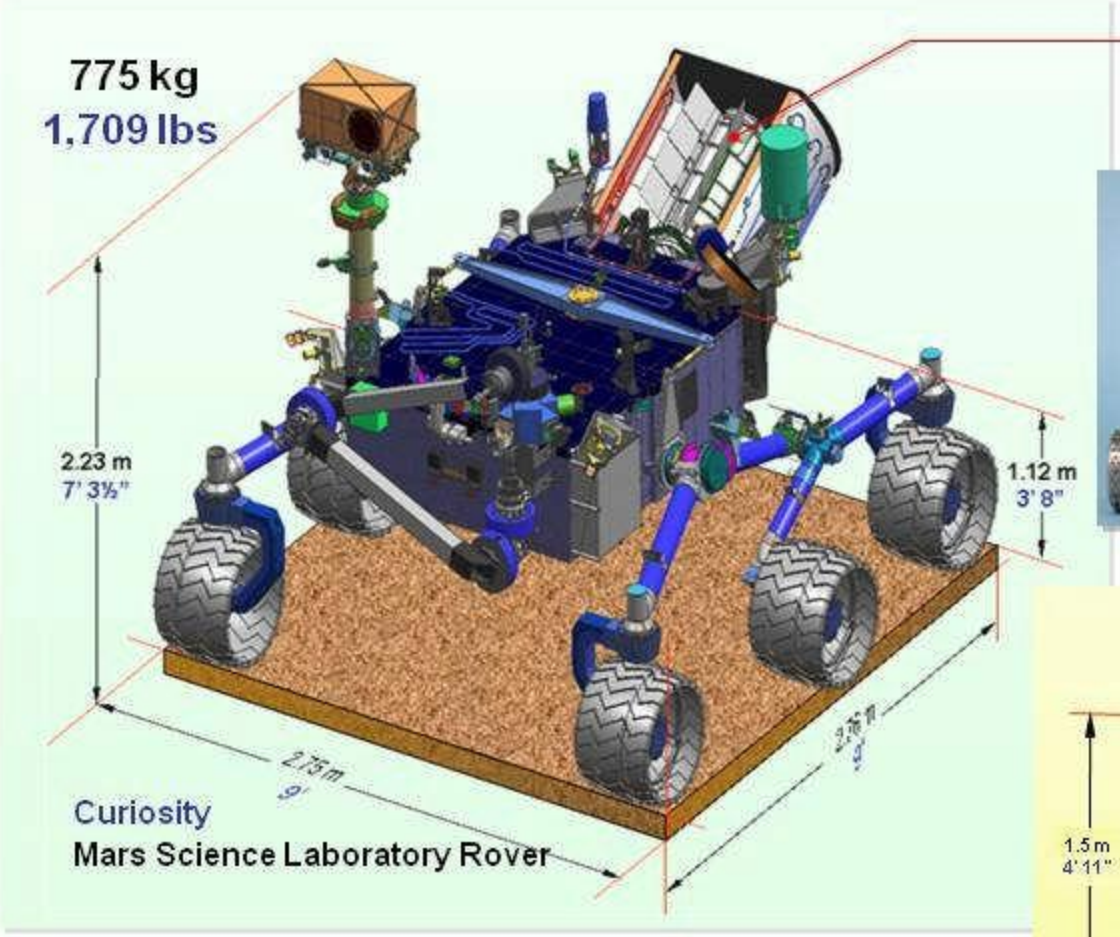


Radiation Assessment Detector (RAD) characterizes the radiation environment on the surface of Mars

Rover Environmental Monitoring Station (REMS) measures the meteorological and UV radiation environments.

Sample Acquisition, Sample Processing and Handling (SA/SPaH) Process rock cores, small pebbles, or regolith into smaller particles and deliver the processed material to the analytical lab instruments

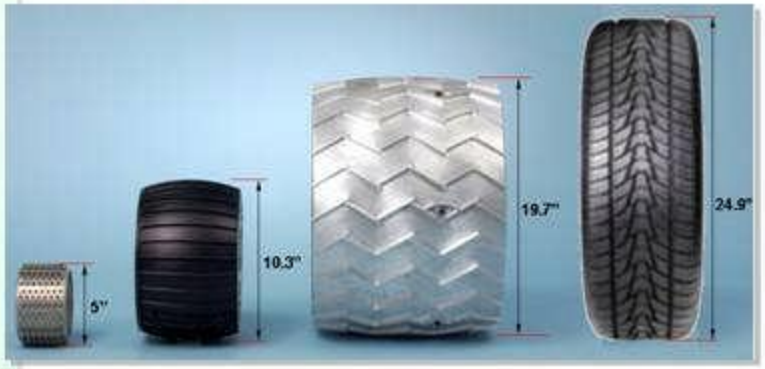





1 Multi-Mission Radioisotope Thermoelectric Generator (MMRTG) - 110 $W_e$

10.6 lbs $^{238}PuO_2$

53,778 Ci



8 Light Weight Radioisotope Heater Units (LWRHUs)

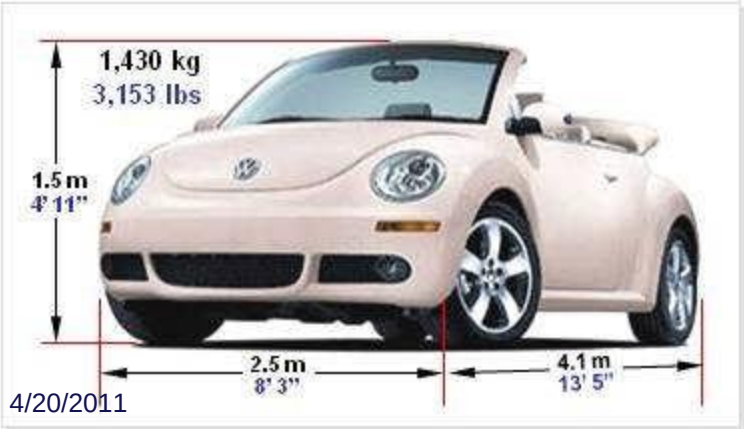
0.8 oz $^{238}PuO_2$

265.8 Ci

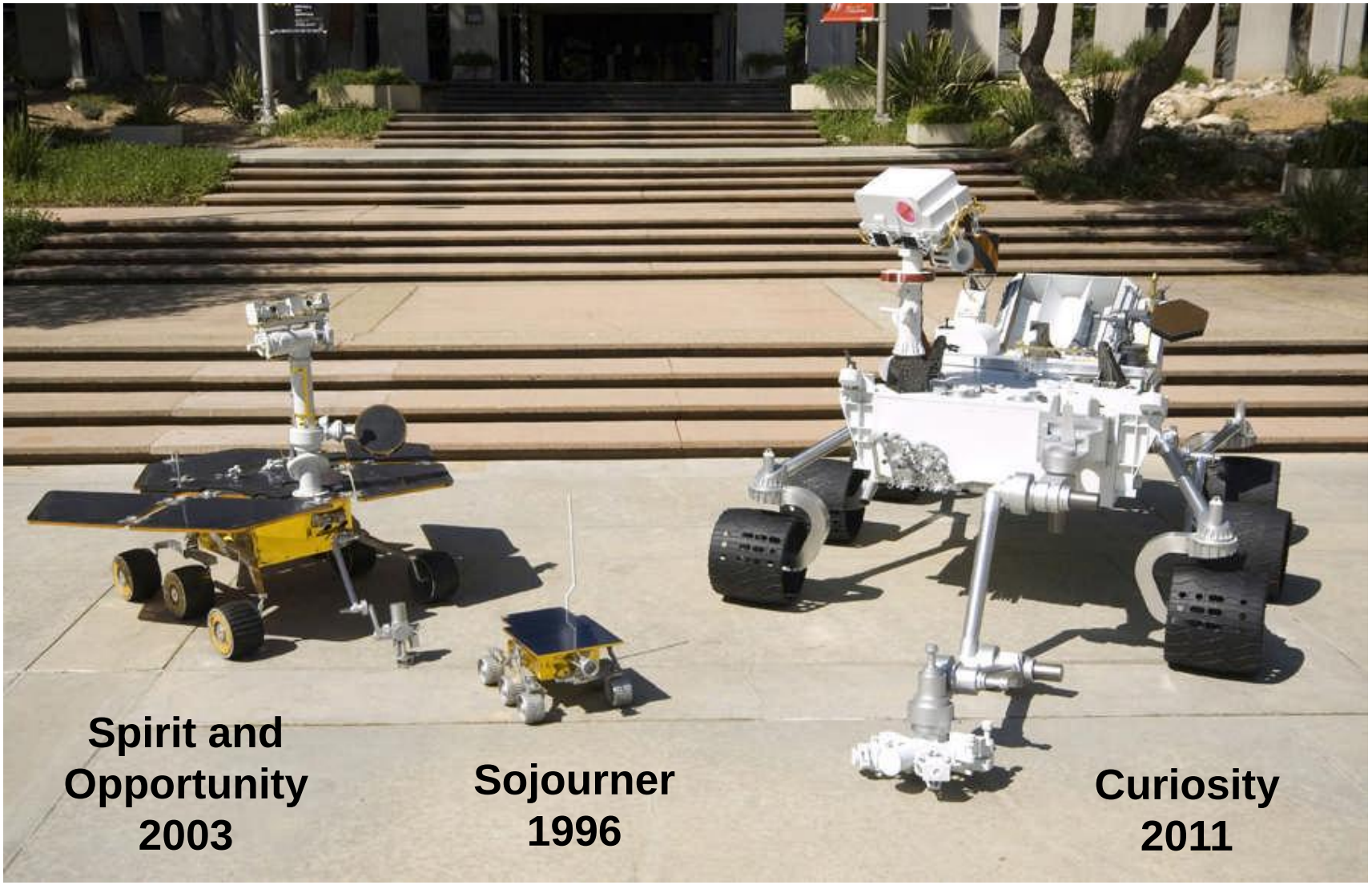
3 Light Weight Radioisotope Heater Units (LWRHUs)

0.3 oz $^{238}PuO_2$

99.7 Ci



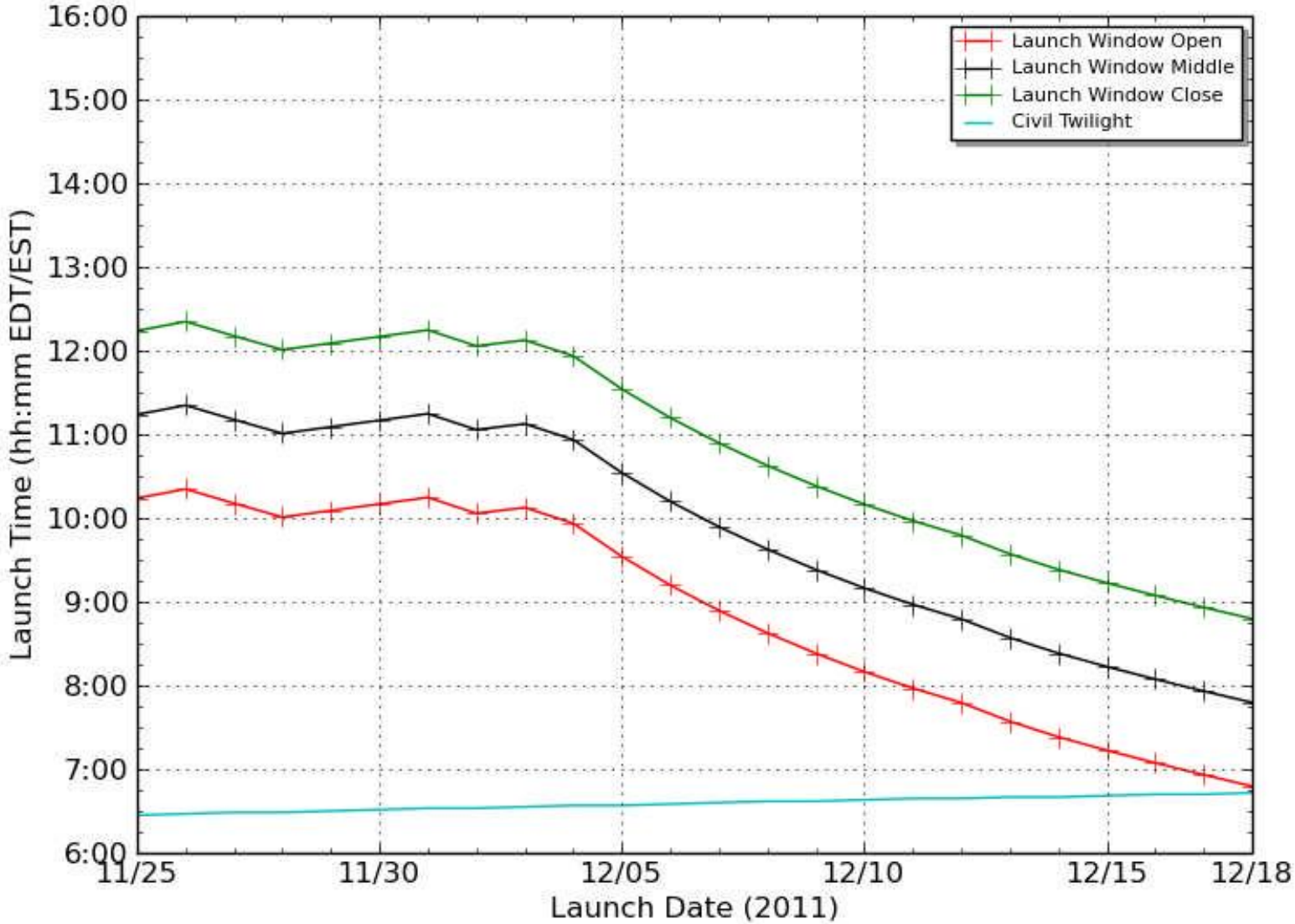
# Rover Family Portrait



# MSL Rover Undergoing Testing at JPL

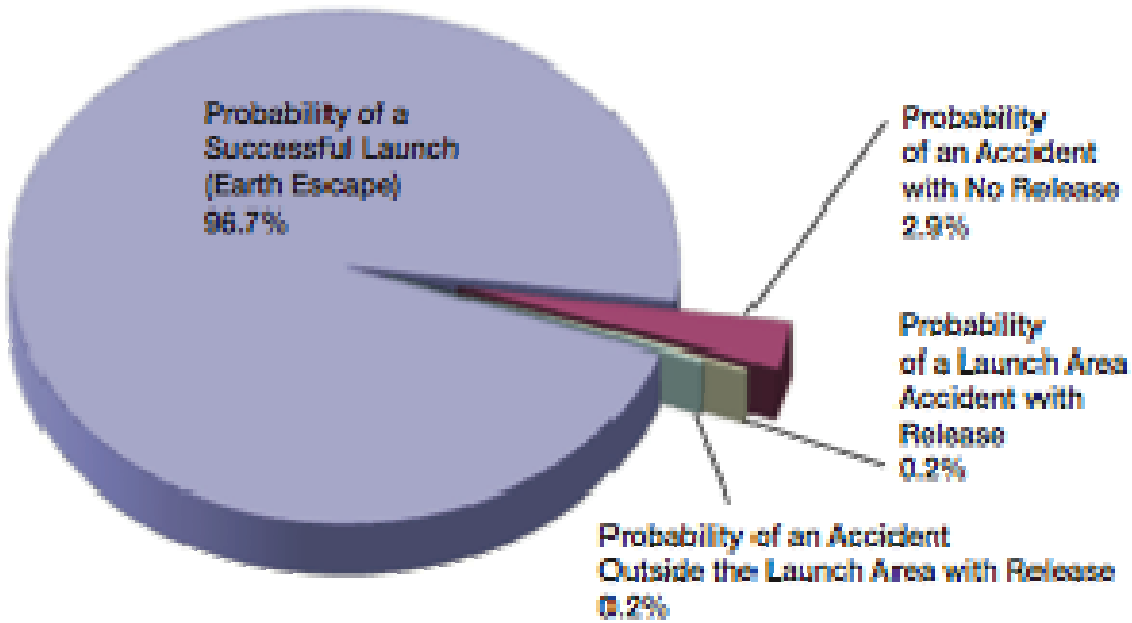
*USAF C-17 Used for Transport of Mars Science Laboratory Rover to KSC*

# Launch Times, EDT/EST



# Launch Accident Risk

# MSL Launch Nuclear Safety




- **Chances of a launch accident are small and the chances of an accident with release are 10 times smaller**
- **Unlikely that anyone would be exposed to nuclear material**

# Launch and Launch Area Risk

- Accidents that could result in a release of nuclear material in the launch area could only occur in the earliest phases of launch, before the launch vehicle clears the Florida coastline. No release would be expected from any launch accidents involving spacecraft impact in the ocean.
- If an accident with a release were to occur at or near the launch site, the greatest portion of any released material would be expected to remain onsite (KSC and CCAFS) where it presents very low risk to the public.
- In the unlikely event of an accident, public exposure to radiation, if any, is expected to be very small:
  - Most people would not be exposed to any radiation.
  - If there was a release, on average any individual dose (5-10 millirem) would be equal to about a week of exposure to the background radiation that people receive from living on Earth.
  - Americans are exposed to an average of 360 millirem of background radiation annually, mostly from sources like radon and cosmic rays.
  - If there were an off site release the maximum dose to any individual from a launch accident (which is received over 50 years) would be comparable to less than half of the annual dose from background sources of radiation.

# Radiological Contingency Planning

# Overview

- MSL contingency planning and response will be in compliance with the National Response Framework Nuclear/Radiological Incident Annex (NRF/NRIA)
  - Brevard County, State of Florida, and the Federal Government (principally NASA, DOE, and USAF) have been planning a coordinated and effective response
  - State of Florida and County of Brevard have primary responsibility for implementing protective measures for the public (the federal government provides recommendations to State and County for offsite response)
  - Special circumstances exist for launch of nuclear materials whereby the federal government is exercising a larger role
    - Time of risk is known and defined by the launch day
    - CCAFS would be the location of a launch accident presenting risk to local area
    - Agreement for federal support in monitoring the local area outside of CCAFS/KSC
  - An incident involving the potential release of radioactivity may require implementation of protective measures, such as shelter-in-place

# Overview

- For accidents involving the release (or potential release) of nuclear/radioactive materials from NASA spacecraft, NASA is the Federal Coordinating Agency
  - NASA provides the leadership, expertise, and authority to implement critical and specific nuclear/radiological aspects of the response
  - NASA is the primary Federal source for information of a technical nature regarding the onsite area conditions and the potential for real offsite radiological effects
  - The emergency management structure being utilized integrates three key organizational constructs:
    - Incident Command
    - Multiagency Coordination
    - Public Information

# Radiological Contingency Response Goals

- Notify appropriate organizations and agencies in the event of an accident involving potential release of radioactive material
- Generate public information releases on the status of an MSL launch accident that are accurate, timely, consistent, and easily understood
- Assess whether a release of radioactive material has occurred
- Quantify the magnitude and character, and predict the dispersion of any radioactive material released to the environment
- Formulate appropriate and prudent protective actions to be taken onsite and provide recommendations for offsite agencies' consideration
- Support smooth transition to Federal response model per National Response Framework
- Address out-of-launch area accidents resulting in sub-orbital or orbital reentry of the MSL spacecraft
  - If possible, safely command a de-orbit of the spacecraft to a water impact
  - Provide notifications and debris footprint information for reentering spacecraft hardware

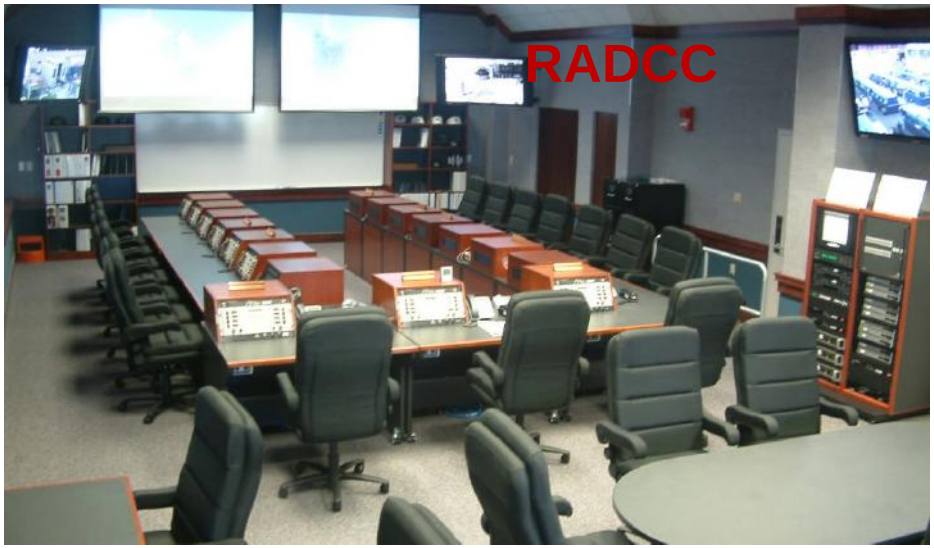
# NASA Radiological Contingency Planning - History

| Mission | Launch | RPS | NASA Planning Basis | DOE Support |
|---|---|---|---|---|
| Galileo | Oct 1989 | 2 RTGs | Federal Radiological Emergency Response Plan (FRERP) | Pre-Deployed Offsite Federal Radiological Monitoring and Assessment Center (FRMAC), Onsite Technical & Assessment, Instrumentation and Equipment |
| Ulysses | Oct 1990 | 1 RTG | FRERP | Same |
| Cassini | Oct 1997 | 3 RTGs | FRERP | Pre-Deployed Offsite Advance Launch Support Group (ALSG), Onsite Technical & Assessment, Instrumentation and Equipment |
| MER A & B | Jun – Jul 2003 | 8 RHUs (per Rover) | FRERP | Onsite Technical & Assessment, Instrumentation |
| Pluto New Horizons | Jan 2006 | 1 RTG | National Response Plan | Offsite ALSG, Onsite Technical & Assessment, Instrumentation and Equipment |
| Mars Science Laboratory | Nov 2011 | 1 MMRTG | National Response Framework | Onsite Technical & Assessment, DOE Consequence Management Home Team (CMHT) on phone bridge |

# Emergency Response Support to Launch

- Launch Site Radiological Control Center (RADCC)
  - Coordinating Agency Management Group (CMG)
  - Joint Information Center (JIC)
- Pre-deployed Field Monitoring Capabilities on-site & Off-Site
  - Environmental Continuous Air Monitoring System – ECAMS
  - Field  Radiation Monitoring Teams
- Consequence Management Home Team – CMHT

# On-Site Radiological Contingency Control Organizations



RADCC
- Monitoring Assessment from ECAMs & Field Teams
- Plum Projection From NARAC using 45 SW Weather Data
- Protective Action Recommendations

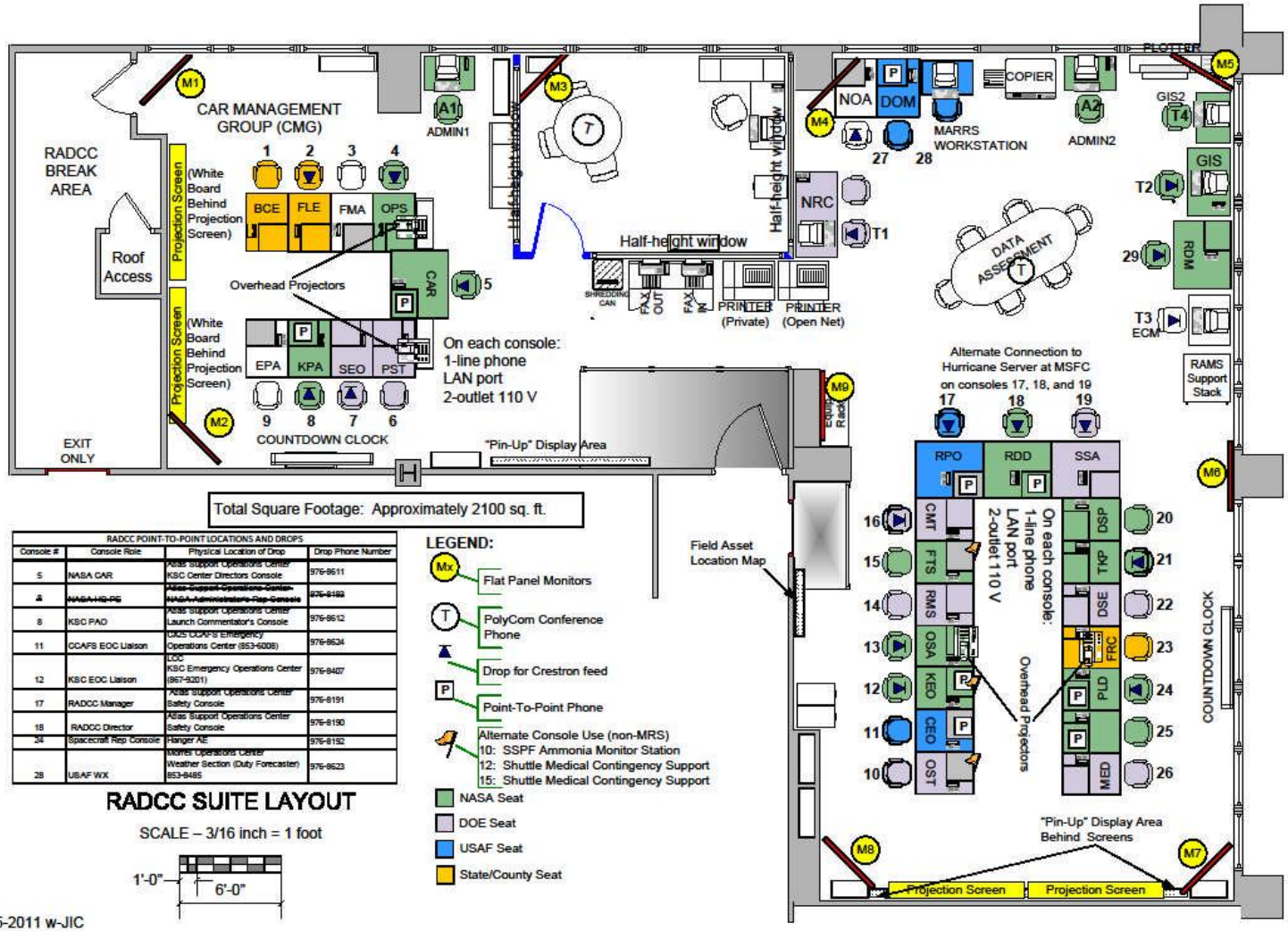
CMG
- Senior Management Reps from NASA, DOE, EPA, FEMA, State of FL & County EOC's

JIC
- PAO's from NASA, DOE, 45 SW, Launch Vehicle, EPA, State & County

# On-Site Radiological Control Center (RADCC) & Coordinating Agency Management Group (CMG)

| RADCC PHONE NUMBERS | |
|---|---|
| Console/ Location | Phone |
| 1 | 867-0005 |
| 2 | 867-0015 |
| 3 | 867-0016 |
| 4 | 867-0018 |
| 5 | 867-0030 |
| 6 | 867-0038 |
| 7 | 867-0043 |
| 8 | 867-0044 |
| 9 | 867-0045 |
| 10 | 867-0052 |
| 11 | 867-0060 |
| 12 | 867-0061 |
| 13 | 867-0063 |
| 14 | 867-0064 |
| 15 | 867-0068 |
| 16 | 867-0070 |
| 17 | 867-0072 |
| 18 | 867-0073 |
| 19 | 867-0075 |
| 20 | 867-0076 |
| 21 | 867-0078 |
| 22 | 867-0083 |
| 23 | 867-0094 |
| 24 | 867-0095 |
| 25 | 867-0224 |
| 26 | 867-0159 |
| 27 | 867-0160 |
| 28 | 867-0161 |
| 29 | 867-0175 |
| T1 | 867-0204 |
| T2 | 867-0179 |
| A1 | 867-0177 |
| A2 | 867-0178 |
| 4297A (Office) | 867-6958 |
| Polycom Unit | 867-0197 |
| Fax Out | 867-0205 |
| Fax In | 867-0207 |

| MONITOR PROPERTY #s | |
|---|---|
| MONITOR | PROP # |
| M1 | 2236897 |
| M2 | 2236894 |
| M3 | 2236893 |
| M4 | 2236896 |
| M5 | 2236895 |
| M6 | 2217586 |
| M7 | 2217589 |
| M8 | 2217588 |
| M9 | 2217587 |




| RADCC POINT-TO-POINT LOCATIONS AND DROPS | | | |
|---|---|---|---|
| Console # | Console Role | Physical Location of Drop | Drop Phone Number |
| 5 | NASA CAR | Atlas Support Operations Center KSC Center Directors Console | 976-8511 |
| ~~6~~ | ~~NASA HQ PE~~ | ~~Atlas Support Operations Center NASA Administrator's Rep Console~~ | ~~976-8193~~ |
| 8 | KSC PAO | Atlas Support Operations Center Launch Commentator's Console | 976-8512 |
| 11 | CCAFS EOC Liaison | CKS CCAFS Emergency Operations Center (853-6008) | 976-8534 |
| 12 | KSC EOC Liaison | LCC KSC Emergency Operations Center (867-9201) | 976-8407 |
| 17 | RADCC Manager | Atlas Support Operations Center Safety Console | 976-8191 |
| 18 | RADCC Director | Atlas Support Operations Center Safety Console | 976-8190 |
| 24 | Spacecraft Rep Console | Hanger AE | 976-8192 |
| 28 | USAF WX | Mobile Operations Center Weather Section (Duty Forecaster) 853-8485 | 976-8523 |

RADCC Suite Layout 03-25-2011 w-JIC

# MSL Radiological Contingency Response Structure

- Radiological Control Center (RADCC)
  - Staffed by technical and radiological assessment personnel from NASA, DOE, USAF, and State of Florida
  - Performs the data collection and assessment function supporting deployment for launch site and field data collection activities
  - Evaluates field measurements and data from automated monitoring systems to determine if a radioactive material release has occurred
  - Assessment team evaluates data collected and develops recommended actions for review by the Coordinating Agency Representative (CAR)
- CAR Management Group (CMG)
  - Staffed by management authority from NASA, DOE, DHS/FEMA, EPA, State of Florida and Brevard County
  - Performs the management decision making activities governing the overall radiological response
  - NASA HQ Office of Protective Services (OPS) leads NASA response to out-of-launch area accidents
- Joint Information Center (JIC)
  - Staffed by public information and risk communication specialists from NASA, USAF 45th Space Wing, DOE, FEMA, EPA, State of Florida and Brevard County

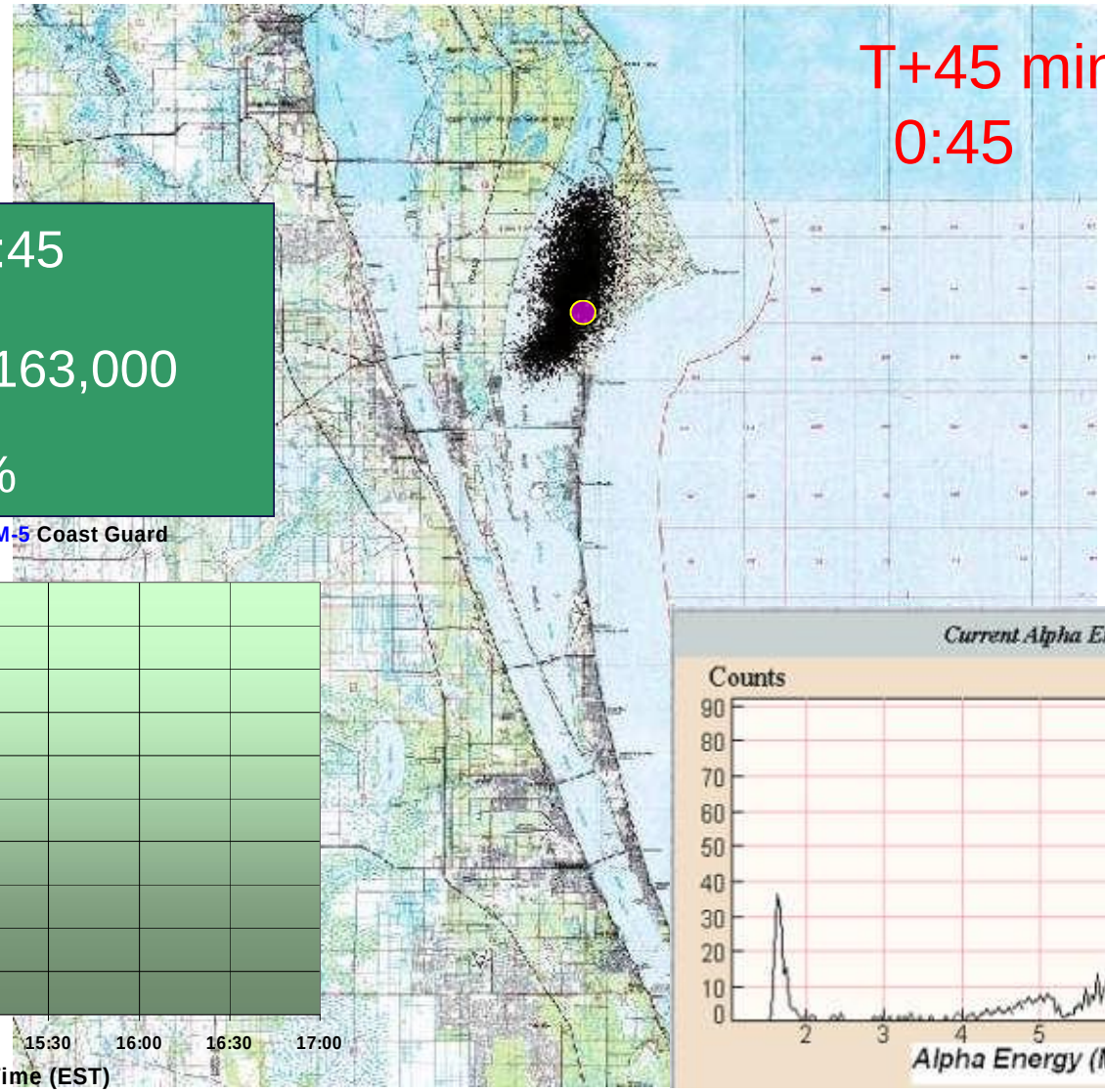
# Changes Since Pluto New Horizons Mission

- Separated Coordinating Agency Representative (CAR) function from the RADCC Director with CMG and RADCC co-location
  - Operations and management functions now performed by two people for better launch day response
  - RADCC Director is the Deputy CAR ensuring close coordination between the two
- Agreement reached in 2010 to monitor launch area more thoroughly by using more Environmental Continuous Air Monitors (ECAMs) than before
  - ECAMs provide lower limits of detection (best equipment available)
  - Now using 30 deployed ECAMs
  - 4 of 30 ECAMs are mobile (deployed just prior to launch based on current meteorology) which enhances specific capability on launch day
  - Retained 16 mobile field monitoring teams so that onsite or offsite needs can be addressed as required, during emergency response phase
- Fewer off site personnel due to use of additional ECAMs
  - The RADCC now directs on site and off site field team response
  - DOE provides assessment personnel in the RADCC rather than offsite
  - Utilizing additional assessment expertise via reachback capability to DOE Consequence Management Home Team (CMHT)

# Environmental Continuous Air Monitor (ECAM)

Typical ECAM Field Installation

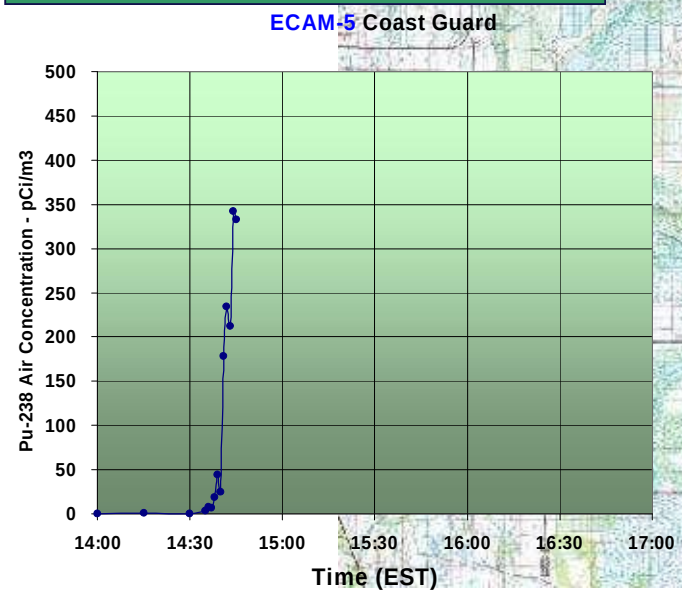
- Developed and tested at National Labs
- Technology utilized in support of Pluto New Horizons (PNH) launch in 2006
- Weather-Resistant
- Available and active 24/7
- Continuous telemetry data stream to RADCC via satellite (upgraded from PNH line-of-sight configuration
- Direct measurement of breathing zone concentrations
  - Selects for respirable particle sizes
  - Alpha spectrometer
  - Very low minimum detectable activity
  - Can distinguish plutonium air concentrations at near-background levels
- Generator or AC powered

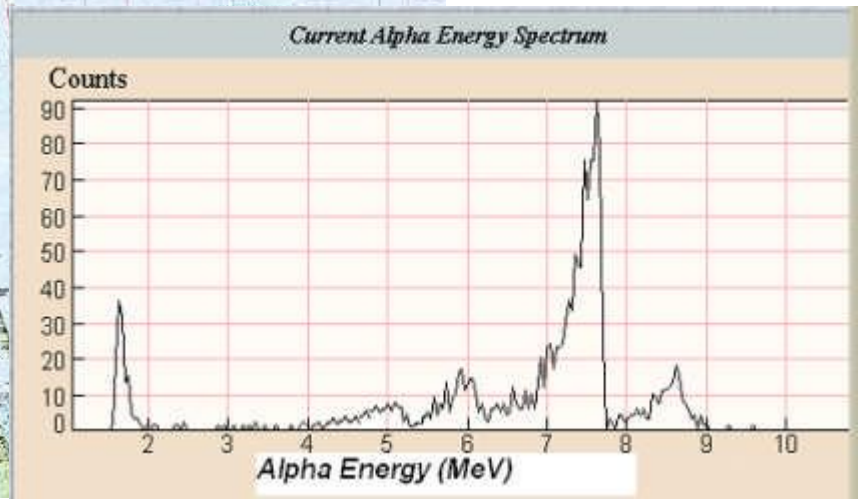


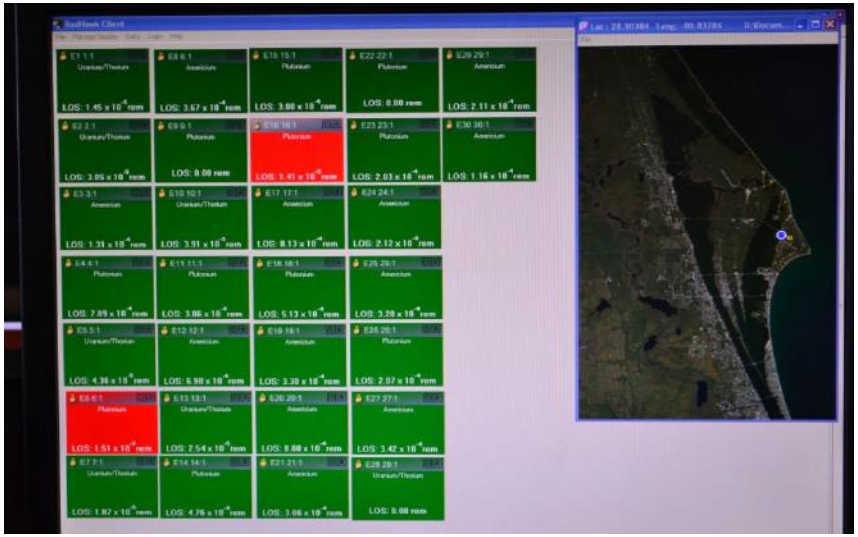

ECAM 5 14:45

(pCi-s)/m3: 163,000

SDEV: 17 %

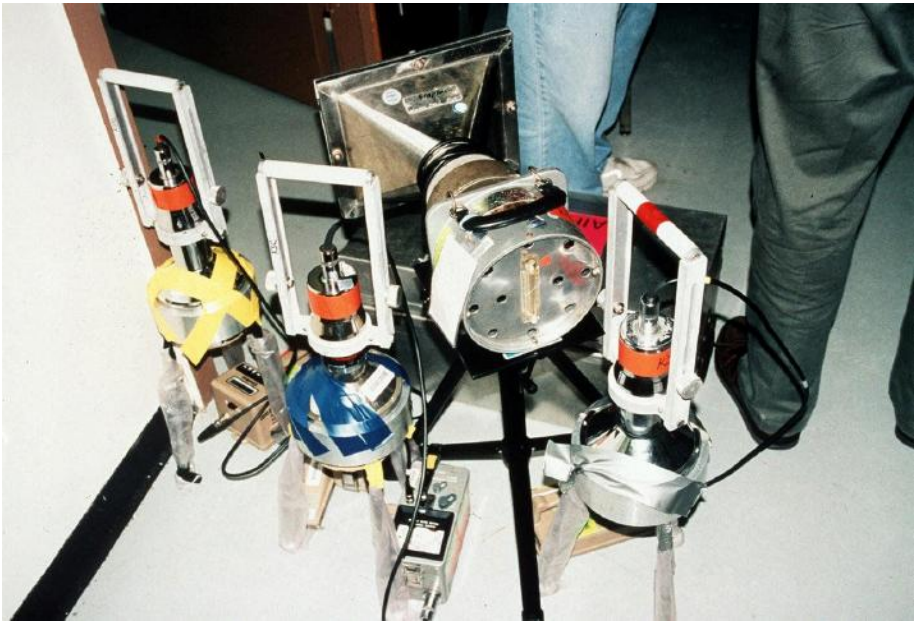




# Field Monitoring Teams

- On-site & Off-Site deployment of field monitoring teams equipped with FIDLER detectors, Alpha survey meters, and hi volume air samplers. Field teams made up of personnel from NASA KSC, DOE, Air Force, and State of Florida Bureau of Radiological Health. Instrument readings will be electronically sent to the RADCC & CMHT RAMS servers via use of DOE Tables and MPCD's.



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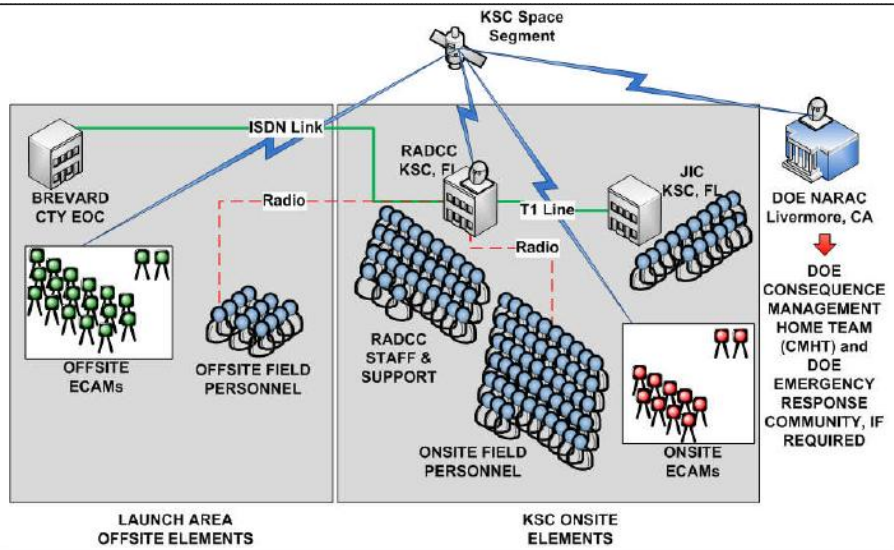
1249

## RAMS Overview – Mission and Primary Functions

- Provides centralized collection and management of all data used during a response to a nuclear or radiological event
- Provides information management and analysis support to scientific personnel
- Supports production of work products (i.e. Maps)
- Provides integration and data exchange between multiple response assets, technologies, and personnel

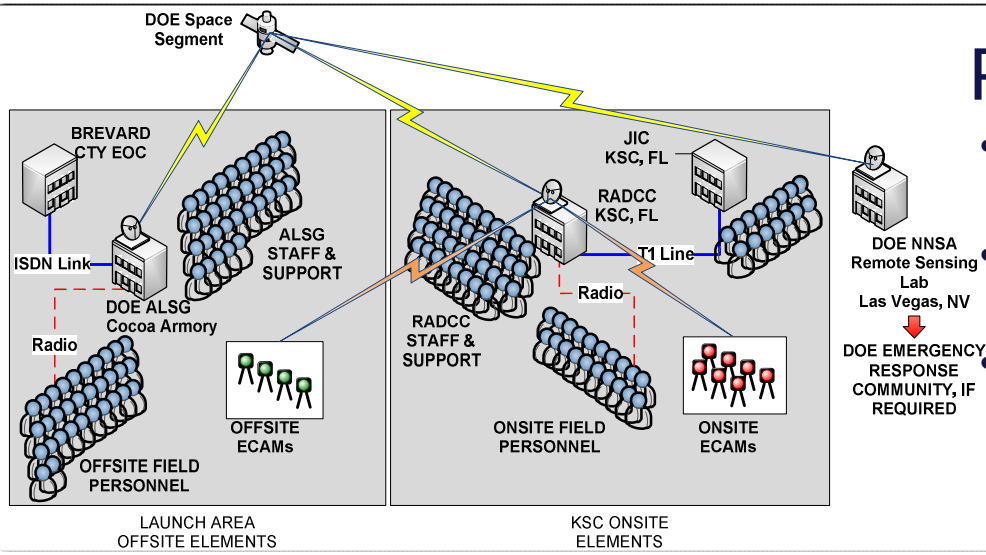
# State of Florida MERL

# Launch Site Deployment
# Mars Science Laboratory (MSL) and Pluto New Horizons (PNH)




## MSL

- ~ 114 personnel deployed
- 26 ECAMs at fixed locations plus 4 mobile units
- 16 mobile field monitoring teams total
- NARAC Backup ECAM Downlink Station
- DOE CMHT on station



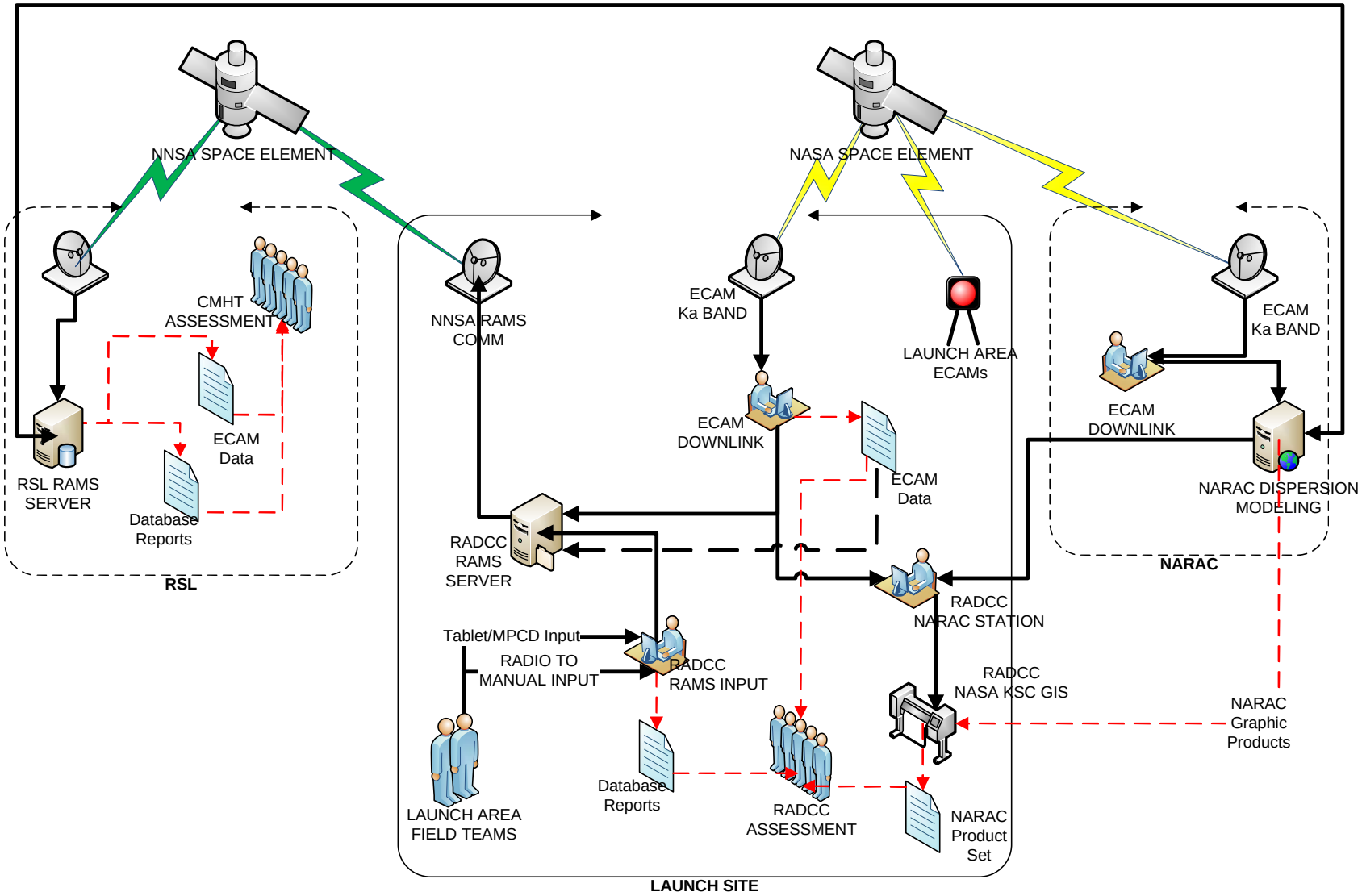

## PNH

- ~ 140 personnel deployed
- 11 ECAMs at fixed locations
- 16 mobile field teams total

Key:

- ALSG – Advance Launch Support Group
- ECAM – Environmental Continuous Air Monitor
- EOC – Emergency Operations Center
- JIC – Joint Information Center
- NARAC – National Atmospheric Release Advisory Center
- NNSA – National Nuclear Security Administration
- RADCC – Radiological Control Center

# Data Communication Flow



# Representative MSL Launch Monitoring Locations

Legend:

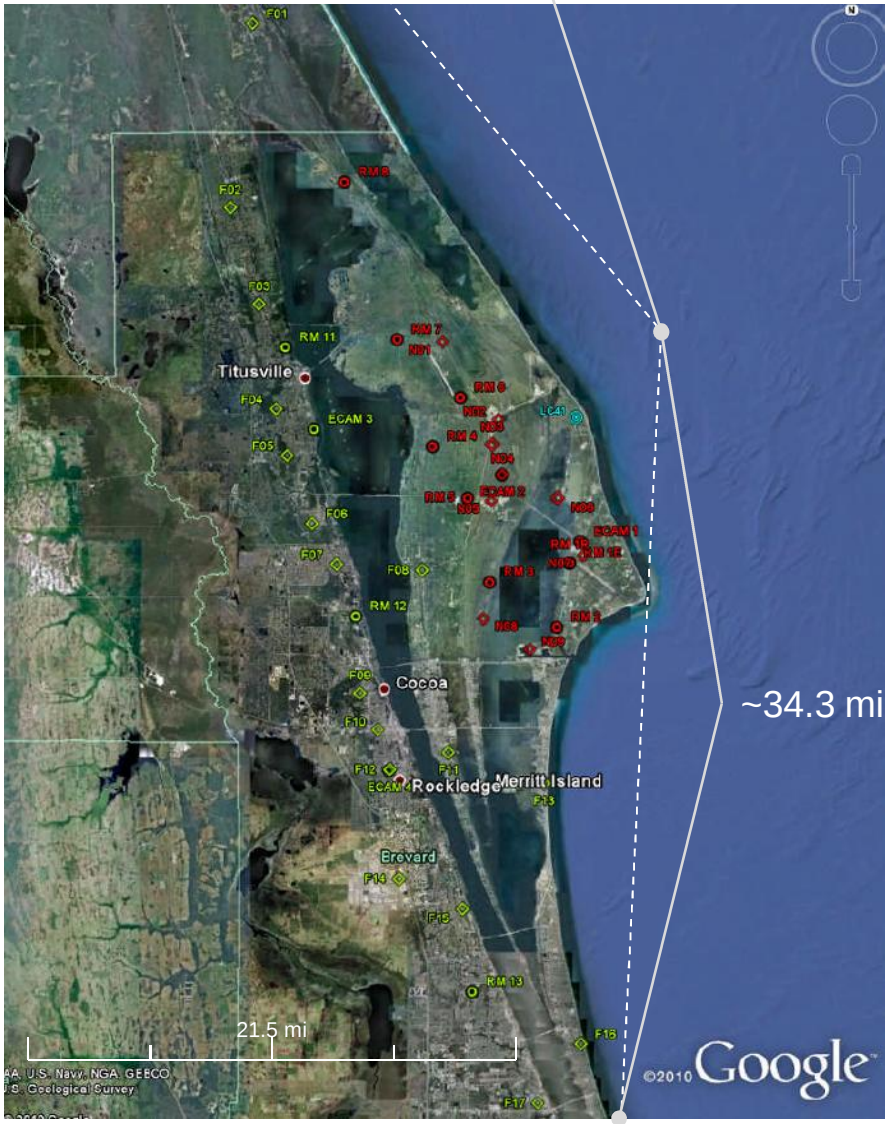
Fxx = Offsite ECAM (Green Diamond)

Nxx = Onsite ECAM (Red Diamond)

RM xx = Mobile Monitoring Team

Offsite (Red Circle)

Onsite (Green Circle)



# MSL Radiological Contingency Planning Readiness

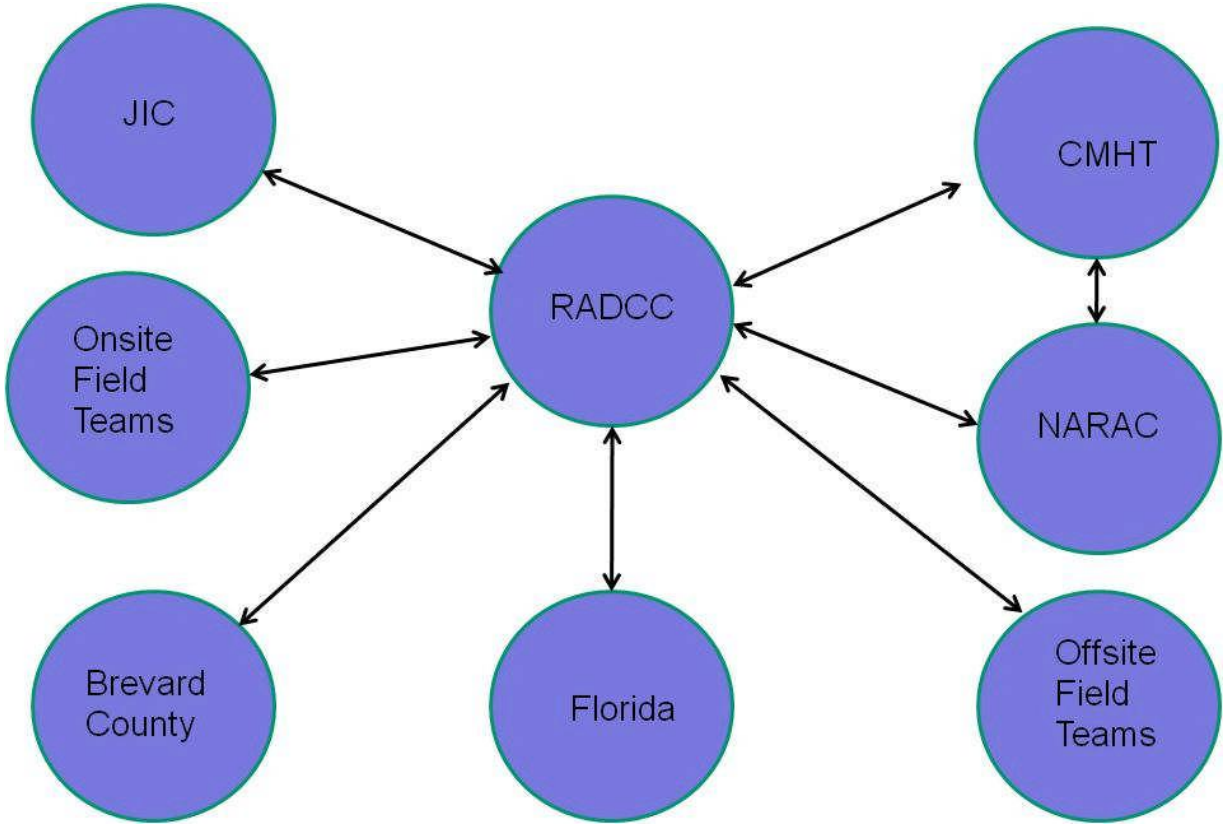
- A comprehensive verification and validation activity is in process to ensure readiness for the November 2011 launch of MSL
  - Data and communication systems testing at element and system level
    - ECAM system validation test just completed
    - Instrument and equipment calibration activities continue through June 2011
  - Out-of-launch area accident exercise planned for June 2011
  - Data system end-to-end validation test is planned for August 2011 in actual launch environment
  - Verification and validation matrix used to ensure contingency planning requirements are met and assets are ready for support, planned for completion September 2011
  - A final launch contingency readiness review is planned for late September 2011

# MSL Command Post Exercise (CPX)

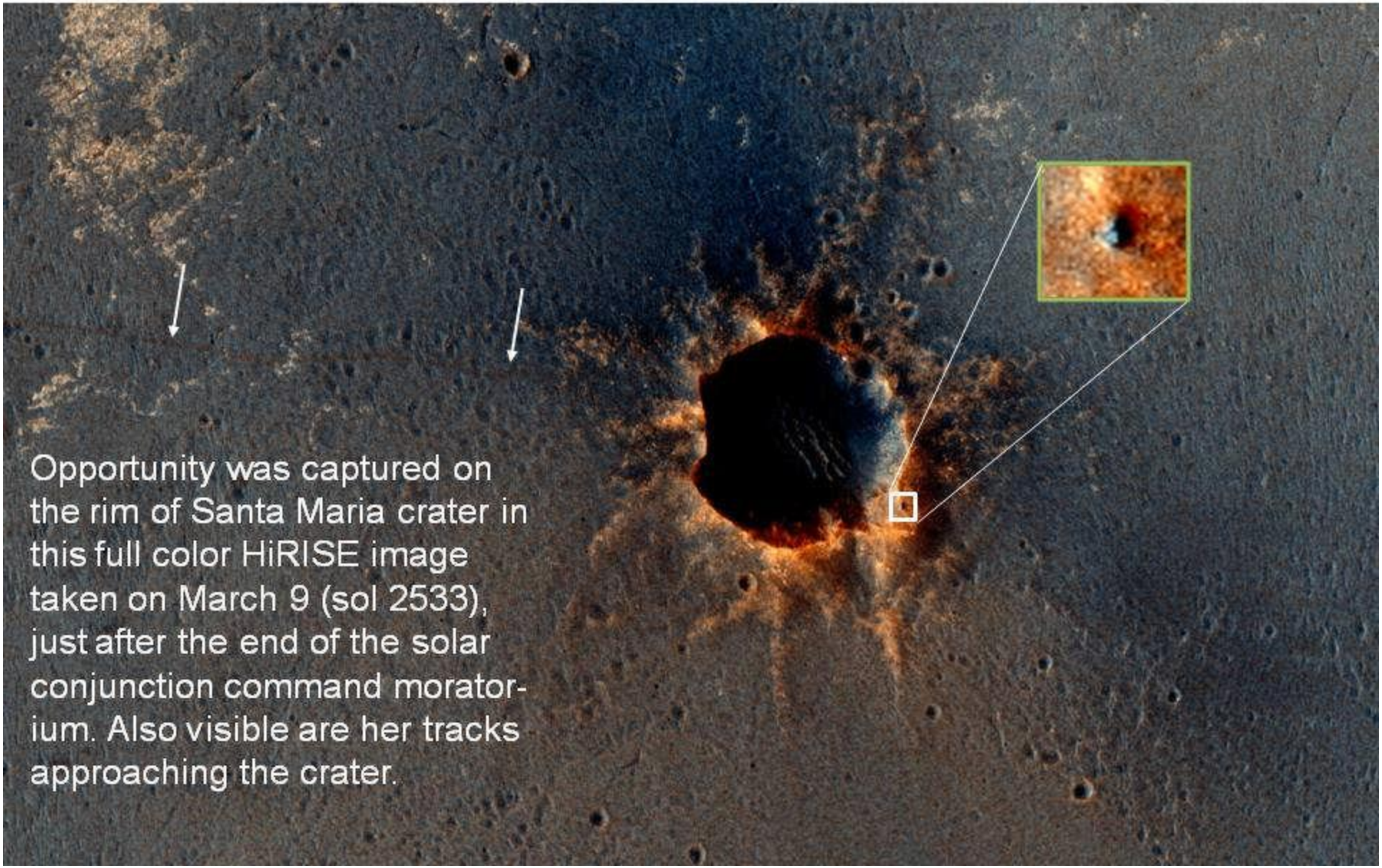
- An integrated Command Post Exercise (CPX) for a launch area accident was conducted on March 1-2, 2011
  - Simulated a release well into the local community warranting shelter in place and comprehensive radiological deposition assessment activities
  - Involved all Federal, State and local agencies involved in contingency planning and near-term response
  - Used simulated and injected monitoring data to drive development of protective action recommendations
  - Included a tabletop walkthrough of transition from KSC emergency management to an off-site unified command

# Summary

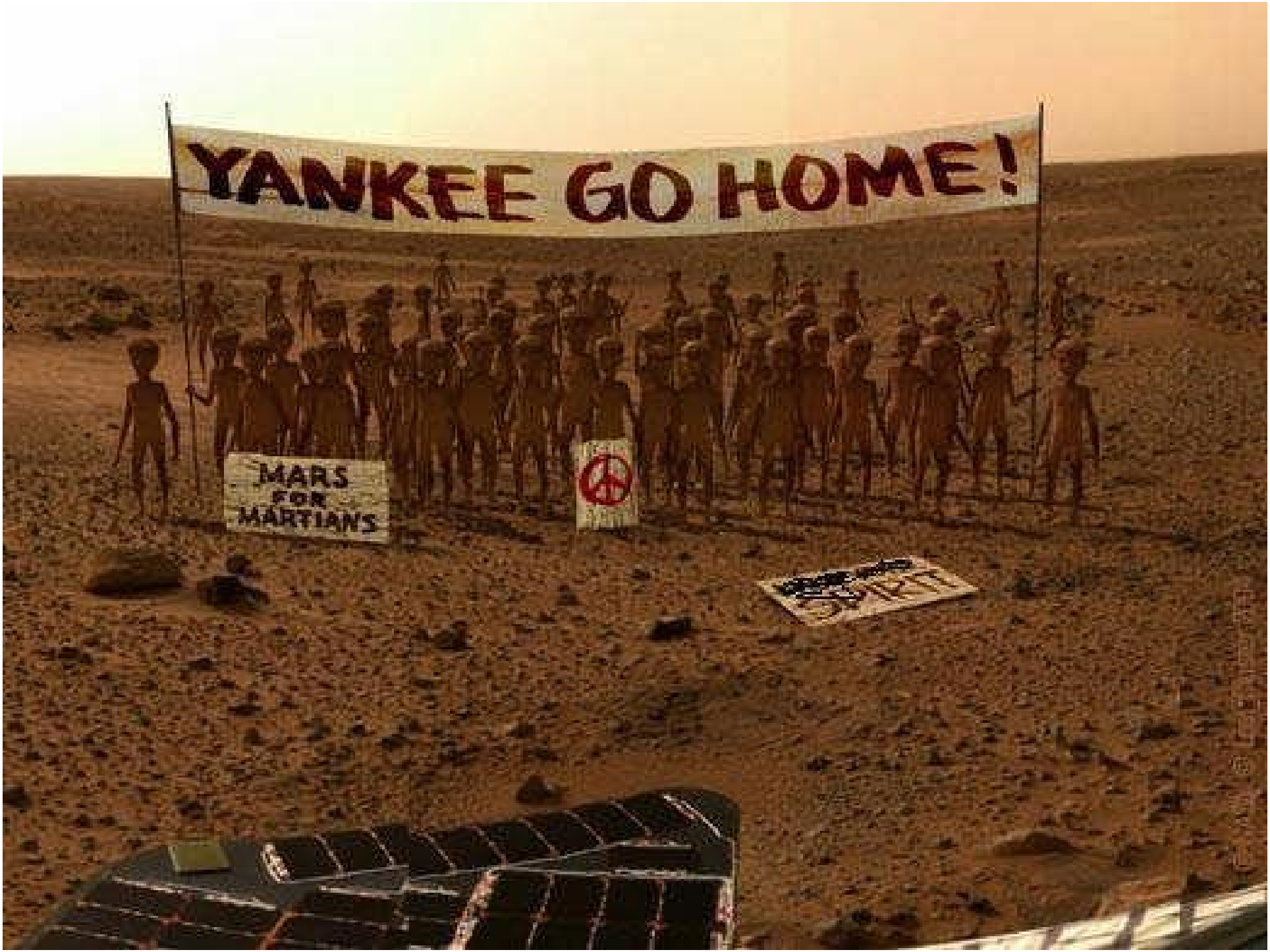
Combined NASA, DOE, Air Force, State & County assets & personnel are working together to insure a robust deployment will be in place to make prompt & comprehensive assessments and take appropriate protective actions



# Portrait of Opportunity at Santa Maria Crater



Opportunity was captured on the rim of Santa Maria crater in this full color HiRISE image taken on March 9 (sol 2533), just after the end of the solar conjunction command moratorium. Also visible are her tracks approaching the crater.


YANKEE GO HOME!
MARS
FOR
MARTIANS

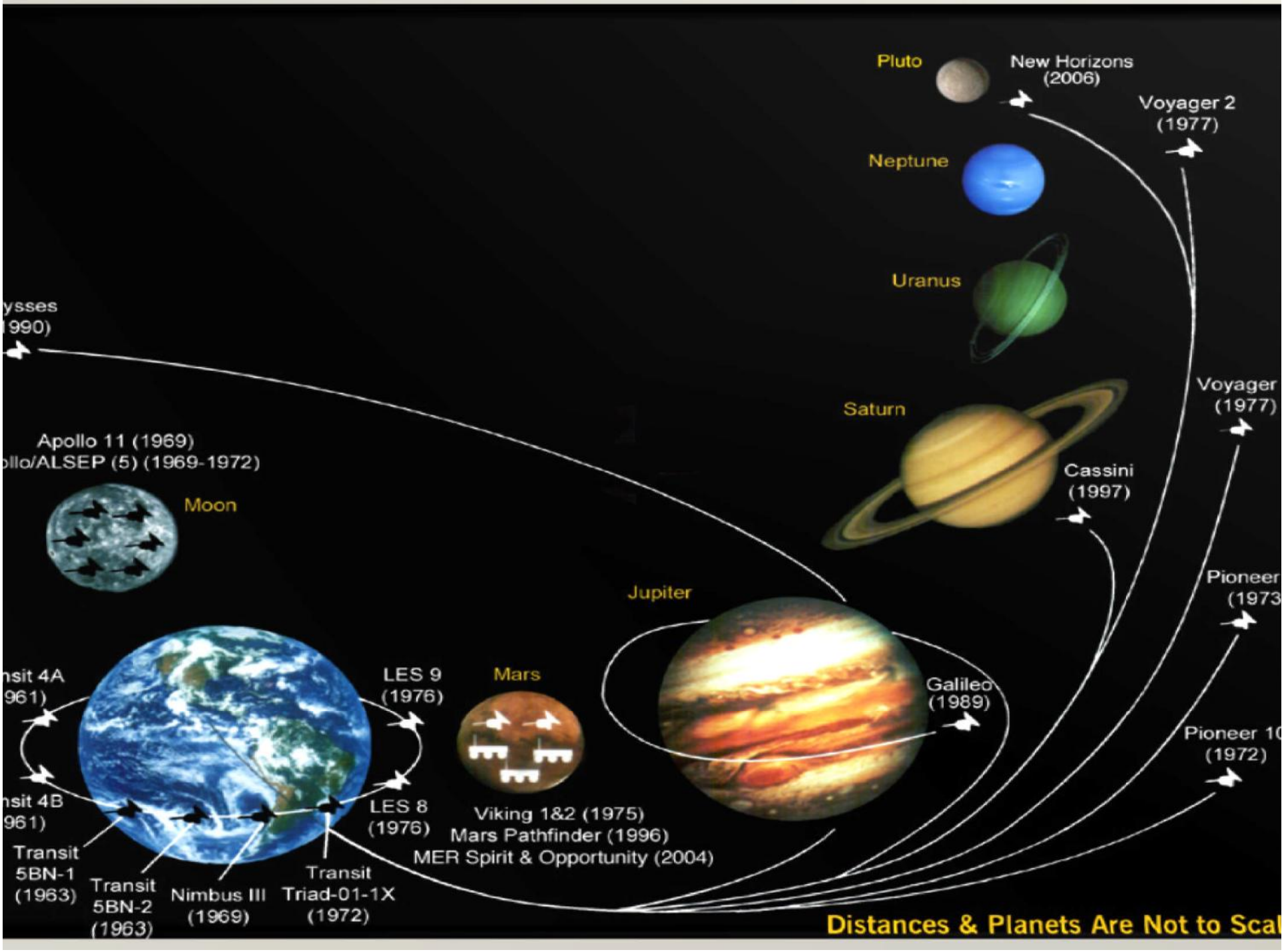
# *Nuclear Mission Safety Analysis and Risk Assessment for the Launch of Radioactive Material into Space*

April 20, 2011

John W. Lyver, IV and Peter G. Prassinos
Office of Safety and Mission Assurance
NASA Headquarters
Washington, DC

# *Background*

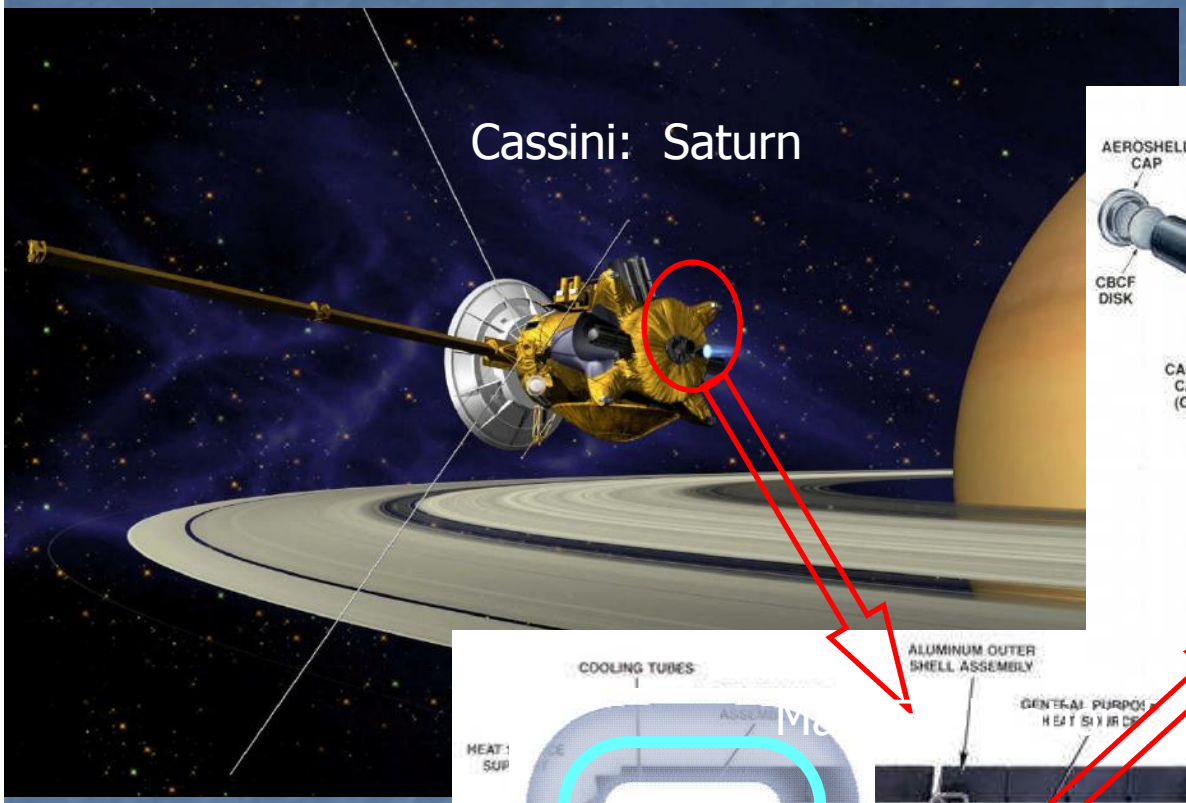
- For the past half century, NASA and other US Government Agency spacecraft have explored our solar system. Currently NASA operates spacecraft:
  - In Earth Orbit
  - Orbit around: The Sun, Moon, Venus, Mars, Jupiter, and Saturn
  - In transit to: Pluto, Comets, and the Solar System Heliopause
  - On the surface of: The Moon, and Mars
- For exploration missions where the power and/or thermal control requirements exceed that available from solar or chemical sources, radioactive sources are in use.
- The use of radioactive materials in space has been the subject of several United Nations Treaties and International agreements.

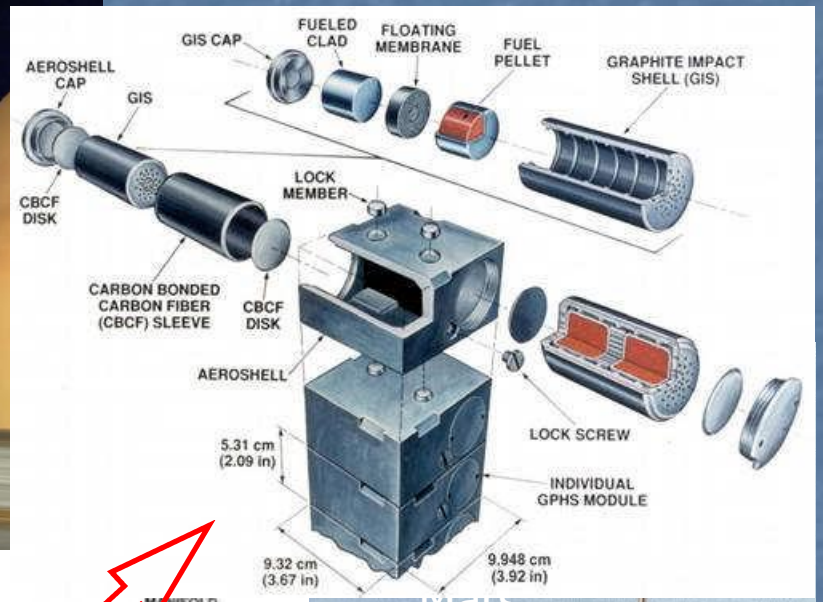

Pluto
New Horizons
(2006)
Voyager 2
(1977)
Neptune
Uranus
ysses
990)
Saturn
Voyager
(1977)
Apollo 11 (1969)
llo/ALSEP (5) (1969-1972)
Moon
Cassini
(1997)
Jupiter
Pioneer
(1973
nsit 4A
961)
LES 9
(1976)
Mars
Galileo
(1989)
Pioneer 1
(1972)
nsit 4B
961)
LES 8
(1976)
Viking 1&2 (1975)
Mars Pathfinder (1996)
MER Spirit & Opportunity (2004)
Transit
5BN-1
(1963)
Transit
5BN-2
(1963)
Nimbus III
(1969)
Transit
Triad-01-1X
(1972)
Distances & Planets Are Not to Scal

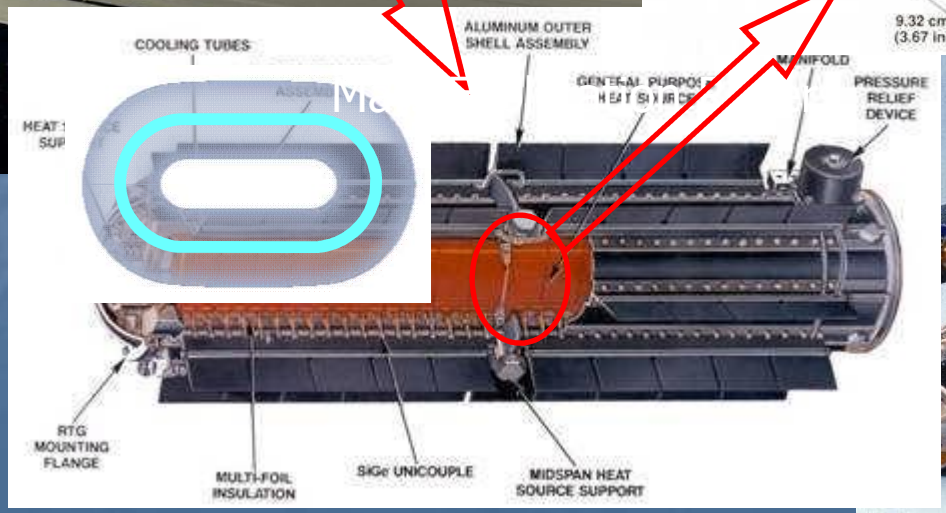
# *Introduction*

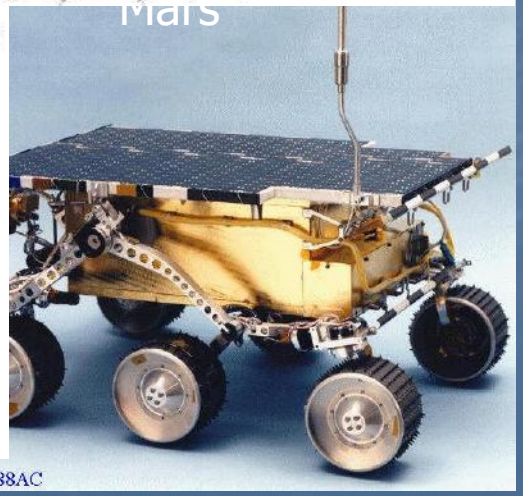
- Missions have resulted in 20 planetary encounters
  - All Planets except Mercury
  - Examined Numerous Planetary Moons
  - Five Apollo Missions
  - Mars Landers / Rovers
  - Polar and Elliptical Observations of the Sun
  - Five Missions beyond edge of Solar System
- Nuclear Systems include radioisotopic thermal-electric generators (RTGs), Radioisotopic Heater Units (RHUs) and one Nuclear Reactor (SNAP 10A)
- Isotopic content ranges up to 400,000 Curies

# Examples of Nuclear Missions

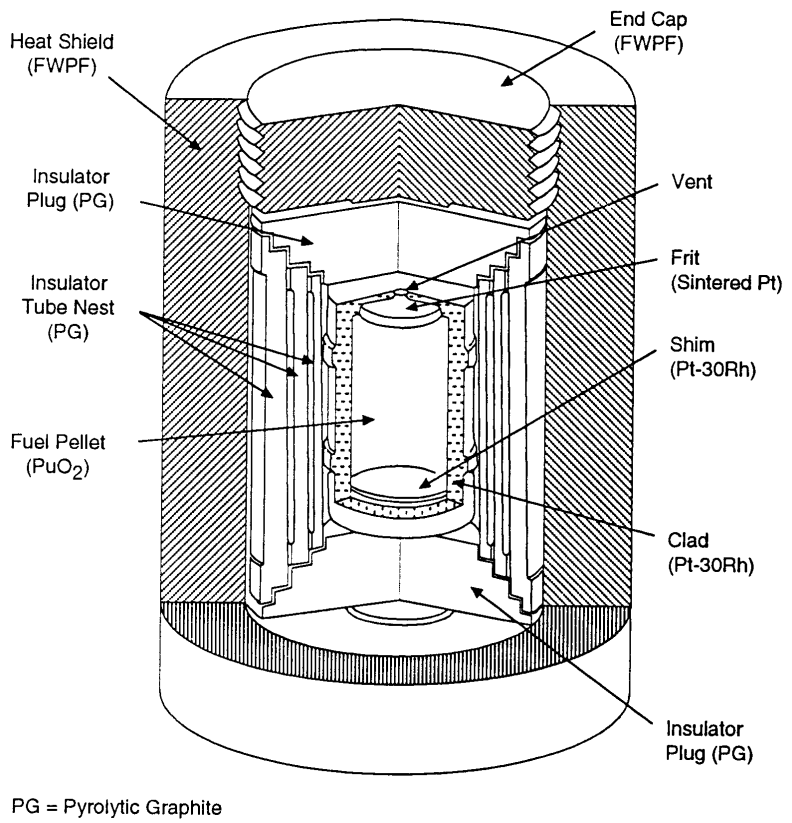


# Other Nuclear Materials




Radioisotope Heater Unit (RHU)

There are small quantities (<1000 $A_2$ ) of radioactive material used in space flight including check sources for instrumentation (for example: Tritium, Curium) and material used in smoke detectors onboard the Space Shuttle And Space Station (Americium).

# *Nuclear Launch Approval Requirement*

Requirements for the approval of missions involving radioactive material are given in NASA Procedural Requirement (NPR) 8715.3, General Safety Program Requirements, Chapter 6.

| Total Mission $A_2$ | NASA/HQ Notification | Notification Before Launch | Safety Assessment | Safety Review | OSTP Notified | Approval Authority |
|---|---|---|---|---|---|---|
| $0<\Sigma A_2<0.001$ | Yes | > 1 months | None | NASA INSRP Member | No | NASA INSRP Member |
| $0.001<\Sigma A_2<10$ | Yes | ~3 months | Statement of ALARA | NASA INSRP Member | Periodic Report | NASA INSRP Member |
| $10<\Sigma A_2<100$ | Yes | ~6 months | Safety Analysis White Paper | NASA INSRP Member | Periodic Report | NASA Chief Safety Officer |
| $100<\Sigma A_2<1000$ | Yes | ~1 year | Safety Analysis Summary (SAS) | NASA INSRP Member with external review | Via NASA Administrator | NASA Administrator |
| $1000<\Sigma A_2$ | Yes | >3 years | Full Safety Analysis Report (SAR) | INSRP Safety Evaluation (SER) | Via NASA Administrator | OSTP/Office of the President |

# *Interagency Nuclear Safety Review Panel*

Nuclear launch approval is conducted in accordance with PD/NSC-25, "*Scientific or Technological Experiments with Possible Large-Scale Environmental Effects and Launch of Nuclear Systems into Space*" (12/14/77, as amended in 1996)

- Ad-hoc panel assembled for nuclear missions with greater than 1000 $A_2$ quantities of radioactive material (based on IAEA Safety Series #6).
- Empanelled by request from the NASA Administrator for NASA Missions or Head of Agency Sponsoring the nuclear mission
- Members: DoD, DOE, EPA, and NASA with an NRC Technical Advisor
- INSRP team: Subject matter experts and consultants independent of the FSAR Program
- Provides a Safety Evaluation Report to NASA Administrator and OSTP
- Dissolved after mission cancelled or after launch when there is NO chance of mission return to earth (in writing from empanelling Agency Head)

# *INSRP*
# *Subject Areas, Steps, and Activities*

| | | |
|---|---|---|
| **LAUNCH ABORT and REENTRY** | Accident Environment Definition | Accident Scenarios<br>Accident Probabilities<br>Accident Environments |
| **POWER SYSTEMS** | Source Term | Conditional Release Probabilities<br>Source Term Amount & Location<br>Particle Size Distribution<br>Vaporization & Agglomeration |
| **METEOROLOGY** | Environmental Transport | Meteorology Data Sets<br>Atmospheric Transport - Dispersion<br>Environmental Contamination |
| **BIOMEDICAL & ENVIRONMENTAL EFFECTS** | Radiological Consequences | Radiological Doses<br>Health Effects |
| **RISK INTEGRATION** | Risk Analysis | Risk Integration<br>Uncertainty Analysis |
| **INSRP COORDINATORS** | Risk Quantification | Manage and Direct INSRP Process<br>Mission Risk Evaluation<br>SER |

# The Goal of the INSRP Process

- Review, evaluate and document the radiological risk to the general public from the MSL Mission for launch approval Decision Makers
- The SER output MUST be
  - Complete of available documents
  - Defensible
- INSRP's Customers include:
  - The White House
  - The American People
  - Secretaries of Defense and Energy, the Administrators of NASA and EPA, the NRC Commissioners, …

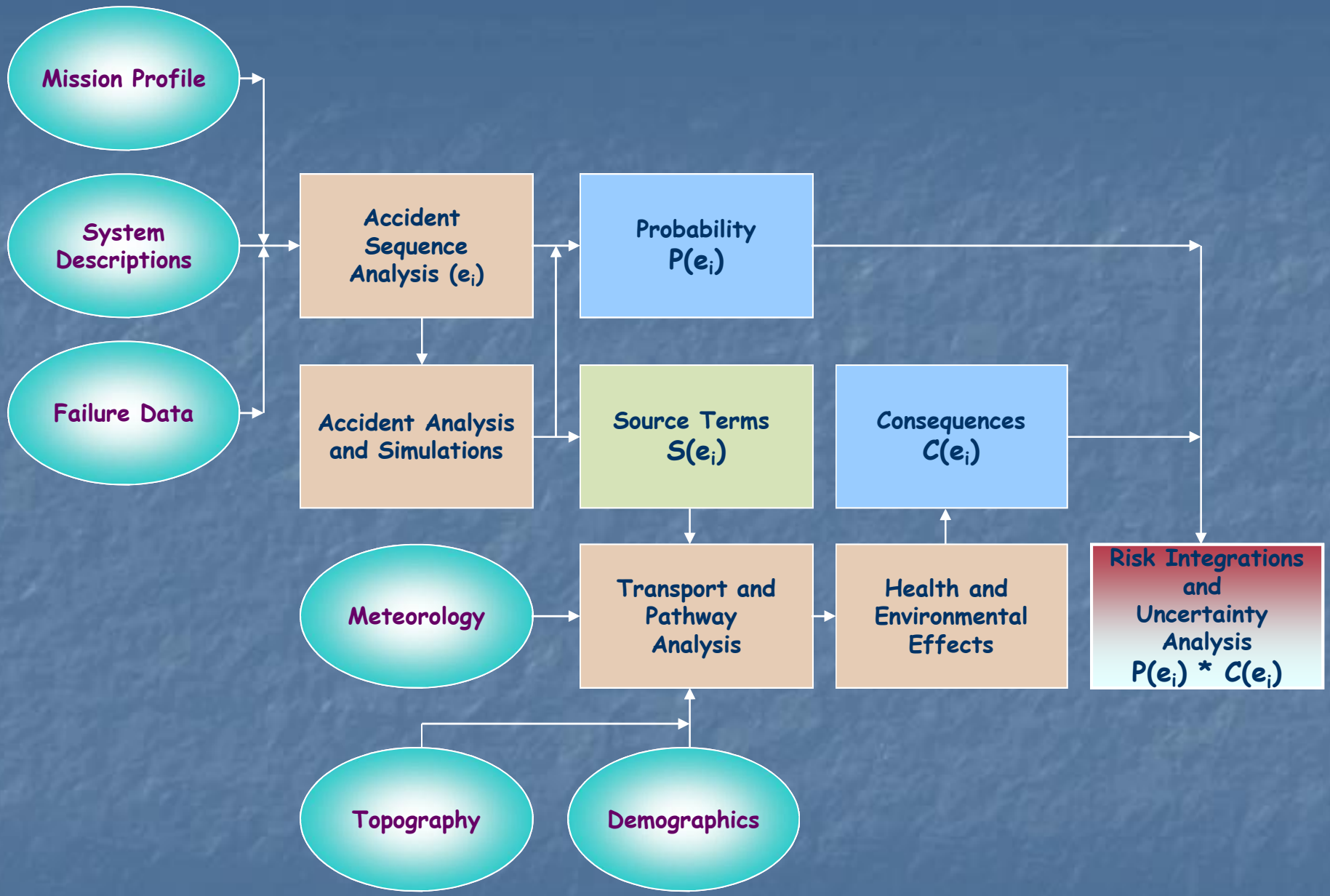
# Safety Analysis Report

- NASA requires the program to produce a Safety Analysis Report (SAR) using a full-scope probabilistic risk assessment (PRA) that follows:
  - NPR 8705.5, "*Probabilistic Risk Assessment (PRA) Procedures for NASA Programs and Projects*" (7/12/04) and
  - "*Probabilistic Risk Assessment Procedures Guide for NASA Managers and Practitioners*" (August 2002)
- As part of the SAR development, the program develops a Databook for the launch vehicle
- The SAR, PRA and Databook provide input to Range Safety evaluations

# *Nuclear Mission PRA follows a typical scenario-based assessment*

- Define Analysis Objective
- System Familiarization
- Accident Sequence Analysis - Initiating Event Identification and Failure Analysis
- Accident Analysis
- Atmospheric Transport and Consequence Analysis
- Risk Integration and Uncertainty Analysis

Sensitivity analysis and importance ranking are used to identify risk drivers for further analysis




# Nuclear Mission PRA Process

# *Objective of the PRA*

Quantify the population risk (public and on-site workers) associated with the response of the payload (nuclear material) to environmental conditions imposed by potential accidents and abort conditions during the mission

- End States include potential health effects and contamination area

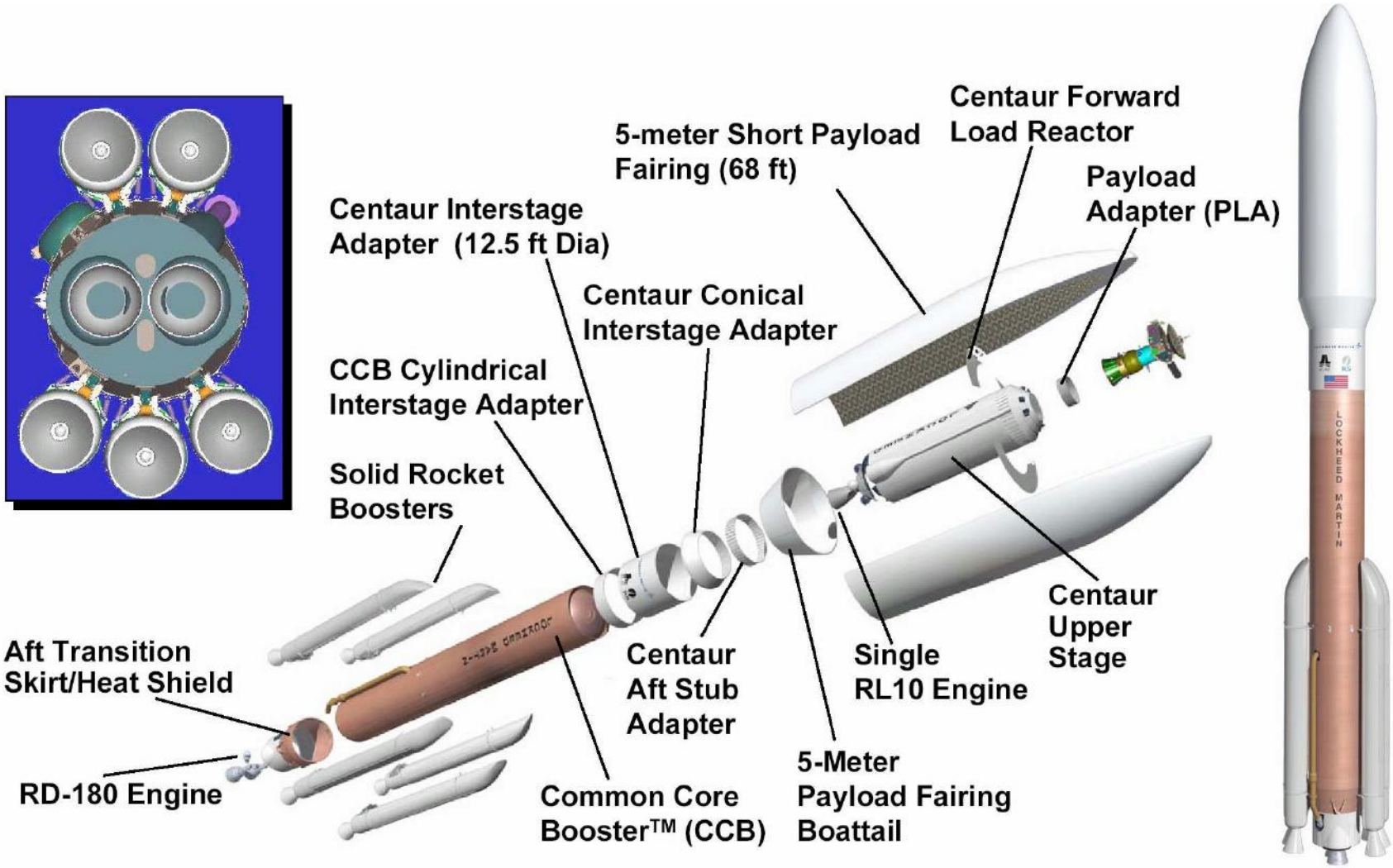
# *System Familiarization*

The purpose of this activity is to gain an understanding of the complete system and its success states (conditions or parameters of success) needed for proper operation.

- Review of all relevant design and operational information, including engineering and/or process drawings, as well as operating procedures
  - Mission profile (trajectory and timeline), launch vehicle and payload descriptions including flight safety systems
  - Launch complex descriptions and launch process
  - Information about past launches, system behavior and component/system failures

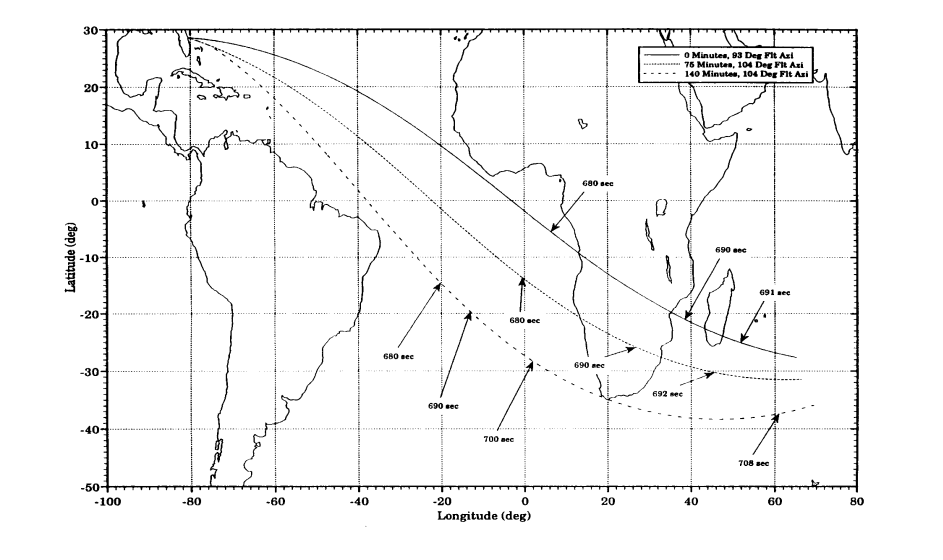
# Example of a Launch Vehicle and Payload





# *Phased-Mission Assessment*

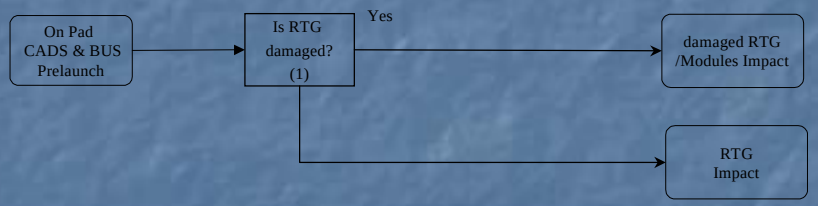
- To facilitate the assessment, the mission is divided into phases depending on changes in system configuration, changes in success criteria and the potential for consequences.
- Typical phases include:
  - Pre-launch Operations
  - Early Launch
  - Late Launch / Sub-orbital
  - Orbital
  - Earth Escape
  - Near-Earth Operations




Example Ground Track

# Accident Sequences Analysis

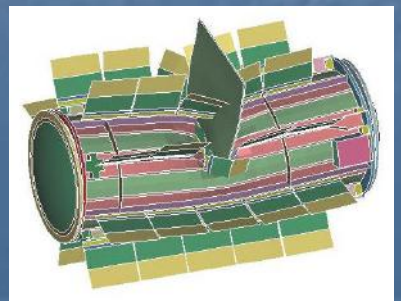
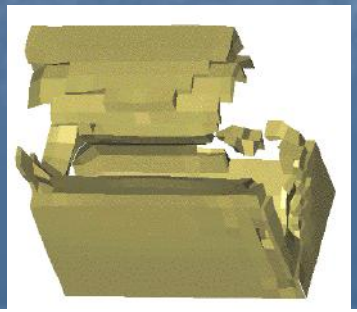
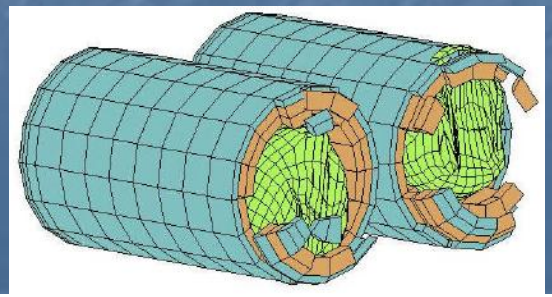
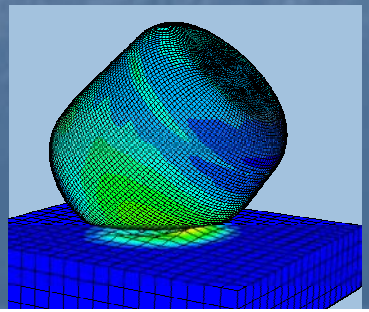
- Identifies and quantifies accident sequences (initiating events and subsequent pivotal events) that can lead to insults (accident environments) to the Payload
  - Types of insult include:
    - Functional failures
    - Explosive events from liquid and solid propellant in the launch vehicle or payload
    - Ground Impacts
    - Sub-Orbital and Orbital atmospheric reentry environments



- If there is a functional dependence between the payload and launch vehicle, the insults may be loss of needed services (cooling, power, guidance, communication, etc.)

# *Accident Analysis and Simulation*

- Mechanistic and probabilistic evaluation of the response of the payload to the accident environments
  - Blast over-pressures and thermal heating from explosive events – at-altitude and on the ground
  - Fragment field and debris distributions (primary and secondary) - density (size), velocity and direction
  - Ground impact loading at multiple orientations
  - Ground thermal heating from vicinity solid propellant burning fragments
  - Reentry thermal and g-loading
  - Material release

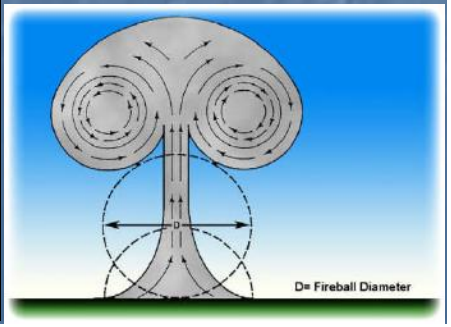





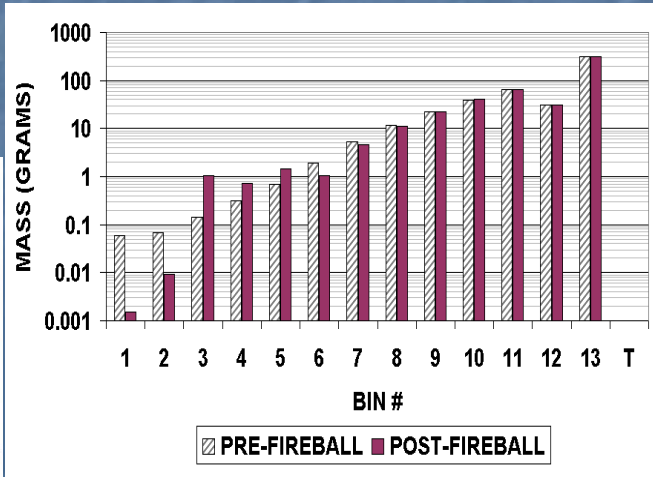
# Source Term

The accident analysis and simulation results in the location and characterization of the source term (radioactive-material released):

- Release Type
- Altitude
- Energy
- quantity
- Particle Size Distribution

| Release Type | Description |
|---|---|
| 1 | Ground Release with No Fireball |
| 2 | Ground Release in Core Ground Fireball |
| 3 | Ground Release in SV Core Fireball |
| 4 | Ground Release in Core and SV Ground Fireball |
| 5 | Air Release with No Fireball |
| 6 | Air Release in Core Air Fireball |
| 7 | Air Release in Core Ground Fireball |
| 8 | Breached Fueled Clad in Core Ground Fireball |
| 9 | Breached Fueled Clad in Core Air Fireball |
| 10 | Breached Fueled Clad in SV Ground Fireball |
| 11 | Breached Fueled Clad in SV and Core Ground Fireball |
| 12 | Breached Fueled Clad Ocean Impact |
| 13 | Ground Release in SRB Propellant Fire |
| 14 | Ground Release in STAR 48B Propellant Fire |
| 15 | Breached Fueled Clad in SRB Propellant Fire |
| 16 | Breached Fueled Clad in STAR 48B Propellant Fire |
| 17 | Melted Fueled Clad in SRB Propellant Fire |
| 18 | Melted Fueled Clad in STAR 48B Propellant Fire |



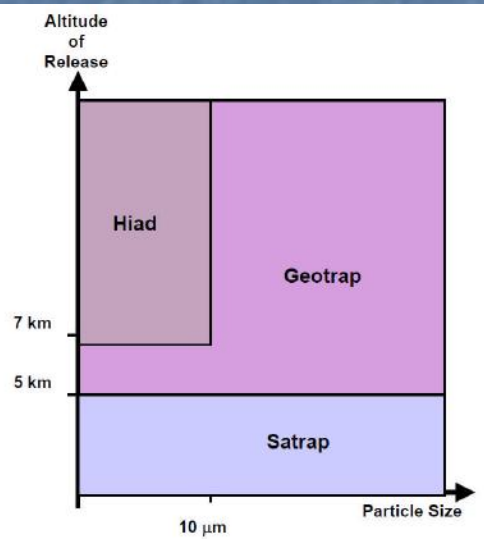

| BIN | MIN. DIA. (µm) | MAX. DIA. (µm) |
|---|---|---|
| 1 | < 0.1 | 0.1 |
| 2 | 0.1 | 0.215 |
| 3 | 0.215 | 0.464 |
| 4 | 0.464 | 1 |
| 5 | 1 | 2.15 |
| 6 | 2.15 | 4.64 |
| 7 | 4.64 | 10 |
| 8 | 10 | 21.5 |
| 9 | 21.5 | 46.4 |
| 10 | 46.4 | 100 |
| 11 | 100 | 215 |
| 12 | 215 | 484 |
| 13 | 484 | > 484.0 |

# *Atmospheric Transport*

Atmospheric Transport evaluates the dispersion and deposition of released material

- Uses global or local meteorological conditions (recorded data set) dependent on release altitude
- Considers spatially transient conditions, local topography (terrain and vegetation), mass released, particle size, cloud diameter and trajectories

Results include particle size dependent transient air concentration, and ground and vegetation deposition (contaminated area)

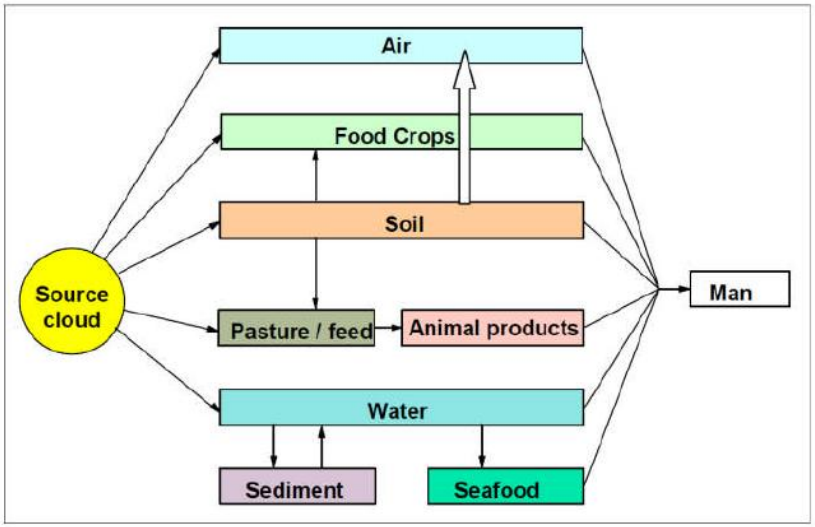


# Consequence Analysis

Consequence Analysis evaluates the health effects of direct (shine) and ingested hazardous material including

- Inhalation (direct and re-suspension), cloud-shine, ground-shine and food consumption
- Organ doses: lung, liver, bone surface, bone marrow, skin, thyroid, gonad
- Particle size distribution for dose calculations

Results include maximum individual dose and population health effects

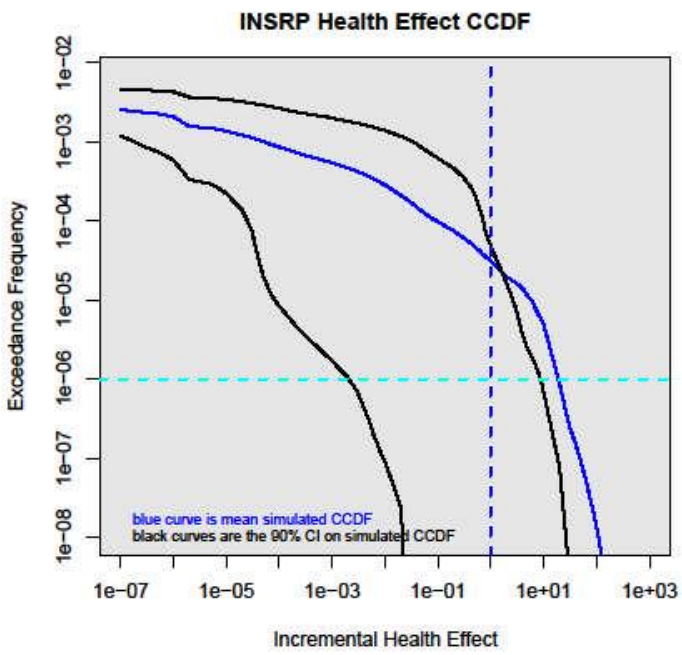



Dose Conversion Factors and Health Effects Coefficients are particle size dependent from ICRP-66 / ICRP-71

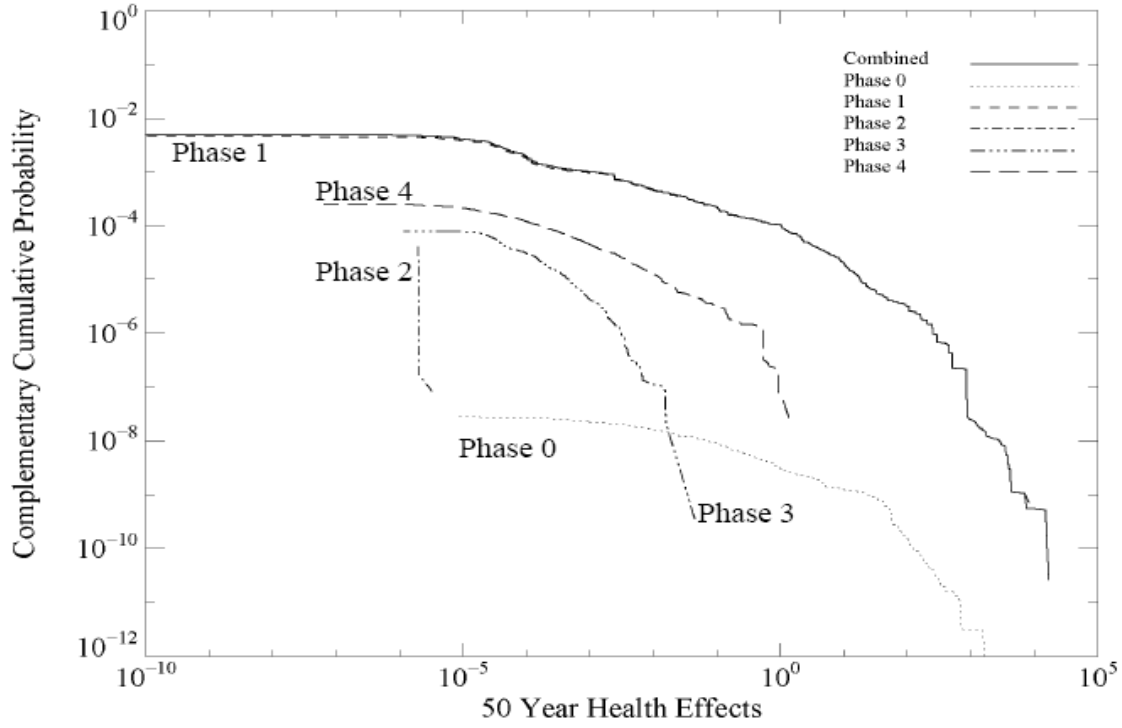
# *Risk Integration and Uncertainty*

Provides an overall characterization of risk

- Combines the probability of the accident with the conditional probability of release and the consequences for each accident sequence, mission phase and the entire mission
- Evaluate the risk to gain insights into the dominant risk drivers and identify areas where risk reduction modifications to the launch and payload systems designs can be made.
- Evaluates the uncertainty in both the probabilities and the consequences to gain insights into the uncertainty in the risk (both model and random uncertainty are considered)




# Risk Integration and Uncertainty



***Questions ?***

# 2010 Rad/Nuc Risk Assessment Consequence Modeling

Prepared for the Department of Homeland Security by:
Brooke Buddemeier, CHP
Lawrence Livermore National Laboratory
Brooke2@llnl.gov
(925) 423-2627

Homeland Security



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LLNL-PRES-409771

Presentation Unavailable

# Excellence and Activities in Radiation Protection Programs

*2011 Triennial NASA Health Physics Training Meeting*
*April 20, 2011*

***Donald A. Cool, Ph.D.***
***Senior Advisor Radiation Safety and International Liaison***

# Outline

- Source Security
- National Source Tracking System
- Radiation Protection Regulation
- Safety Culture

- USG Fukushima Response

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# Part 37 – Source Security

- Physical Protection of Byproduct Material
- Objective to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material for malevolent use
- Provisions:
  - Access Authorization Program – Subpart B
  - Security During use – Subpart C
  - Transportation Security – Subpart D

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# Comment Summary

- 110 comment letters
- Commenters made more than 1900 individual comments
- Binned/summarized into 323 comments

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# Major Issues

- Reviewing official fingerprinting
- Background investigation
  - Credit history
  - Local criminal history check
- Local Law Enforcement Agency (LLEA) coordination
- LLEA notification for temporary jobsites
- Too much burden, stick to order provisions

# Schedule

- Final rule due to Commission December 2011
- Implementation Plan to accompany final rule
- Guidance document published with rule

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# National Source Tracking System

- Requirements in 10 CFR 20.2207
  - Nationally tracked sources – sealed sources of Cat 1 or 2 IAEA radionuclides of concern plus four others (actinium-227, polonium-210, thorium-228 and thorium-229) (twenty radionuclides in all)
  - Source transaction required for all receipts and transfers of individual sources; transaction include the transfer from one license to another (even if in the same organization), or transfer of a source from and to a license to and from DOE
  - Transaction executed by the close of the next business day
  - Annual inventory reconciliation of current inventory in NSTS in January of every year

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# Resources

- **NSTS blog site:** **http://www.nrc.gov/security/byproduct/nsts/blog.html**
- **NSTS brochure:** **http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0472/br0472.pdf**
- **NSTS helpdesk**
  - **Hours:** **Monday – Thursday: 8:00 am to 5:00 pm (EST)**
    **Friday: 8:00 am to 3:00 pm (EST)**
  - **Phone:** **1-877-671-6787**
  - **Email:** **NSTSHelp@nrc.gov**

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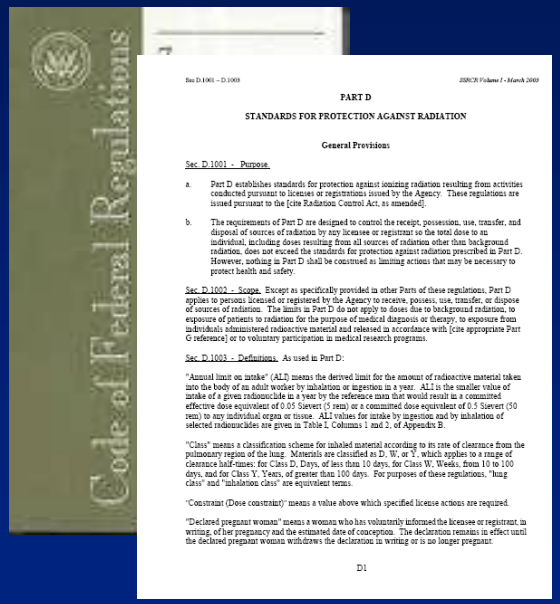
# Radiation Protection Regulations

- **10 CFR Part 20 – Standards for Protection Against Ionizing Radiation**
  - **Definitions**
  - **Radiation Protection Programs**
  - **Occupational Dose Limits**
  - **Public Dose Limits**
- **Agreement State Regulations**
  - **Adequate and Compatible**
- **Use Specific Requirements**
  - **Part 30, 40, 50, 60, 70 …**

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# Background

- ICRP revised recommendations in late 2007
- NRC staff analysis indicated areas warranting consideration for revisions
- Commission approved staff recommendation to engage stakeholders and initiate development of technical basis materials on April 2, 2009

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# Outreach Activities

- **Phase I of outreach included:**
  - **Presentations to numerous organizations and groups**
  - **FRN published inviting inputs (72 FR 32198)**
  - **Dedicated web address for comments Regs4RP@nrc.gov**
- **Phase II Workshops**
  - **FRN published with issues and questions (75 FR 59160)**
  - **Workshops in Washington, Los Angeles, and Houston**
  - **Comments accepted through January 31, 2011**

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# Issues

- Effective Dose and Numerical Values
- Occupational Dose Limits
- Dose Limits for Special Populations
- ALARA planning

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# Future Plans

- **Phase III – Validation of information received, Spring 2011**
- **Staff recommendations to Commission – Fall 2011**
- **Development of Technical Basis to support Commission decisions**

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# Resources

- **Web pages**

  **http://www.nrc.gov/about-nrc/regulatory/rulemaking/opt-revise.html**

- **Email Address: regs4rp@nrc.gov**

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# Safety Culture

- Operating experience has demonstrated nexus between safety culture and events
- Safety culture contributes to the safe and secure use of radioactive materials
- NRC recognizes that licensees and other users of regulated material bear the primary responsibility for the safe and secure use of nuclear materials while the NRC, as the regulator, must consider the importance of safety culture in its oversight programs and activities

# Safety Culture Definition

*Nuclear Safety Culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.*

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| Leadership Safety Values and Actions | Problem Identification and Resolution | Personal Accountability |
|---|---|---|
| Leaders demonstrate a commitment to safety in their decisions and behaviors | Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance | All individuals take personal responsibility for safety |
| **Work Processes** | **Continuous Learning** | **Environment for Raising Concerns** |
| The process of planning and controlling work activities is implemented so that safety is maintained | Opportunities to learn about ways to ensure safety are sought out and implemented | A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination |
| **Effective Safety Communications** | **Respectful Work Environment** | **Questioning Attitude** |
| Communications maintain a focus on safety | Trust and respect permeate the organization | Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action |

# Tiers for the Policy Statement

**Tier 1**

**Safety Culture Definition**

Overarching definition that applies to all of the nuclear industry
- Easy to understand
- Timeless
- Inclusive

**Tier 2**

**Safety Culture Traits**

Set of high level descriptions of what constitutes a strong safety culture
- Applies to everyone who engages in NRC licensed activities
- Speak to all levels of the organization

**Definition and Traits**

**Tier 3**

**Application**

Illustrates how the high level descriptions are translated to lower level descriptions that are applicable to different environments
- Describes programs, processes, procedures, practices, behaviors, etc.
- Details may vary depending on licensee type and environment (potential for different sets)

**Next Steps**

# Example of Tier 2 & 3

**Tier 2**

**Leadership Safety Values and Actions**

Leaders demonstrate a commitment to safety in their decisions and behaviors

**Tier 3**

- Management in the field enforcing standards
- Commitment to maintaining equipment
- Resolves conflict
- Actions match words
- Rewards (incentives) and sanctions used to reinforce desired positive nuclear safety behaviors
- Respects differing opinions
- Schedules are realistic and do not challenge safety standards

These Tier 3 behaviors were developed through an "affinity diagraming" exercise by external stakeholders at an NRC-sponsored public workshop in February 2010. They are provided as an example of how behaviors could be developed and do not constitute an all-inclusive or NRC-endorsed listing.

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# Policy Statement Current Status

- The Commission approved, with revisions, the safety culture policy statement on March 7, 2011
- The staff is continuing to engage in activities to increase an awareness and understanding of the benefits of a positive safety culture for those entities covered by the safety culture policy statement
- Implementation activities require prior Commission review and approval

# Policy Statement Current Status

- A summary of the policy statement has been forwarded to OMB for review under the Congressional Review Act (CRA) prior to publication in the Federal Register
- Publication in the Federal Register expected to occur in the June/July timeframe

# Resources

- **NRC safety culture website: http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html**
  - **Policy Statement meeting summaries**
  - **Regulatory Issue Summary – 2006 changes made to the Reactor Oversight Process to more fully address safety culture**

- **Eric Fries, Safety Culture Program Manager**

  **(e-mail: eric.fries@nrc.gov or external_safety_culture.resource@nrc.gov)**

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# USG Response to Fukushima

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# Chronology

- March 11, Earthquake and Tsunami
- March 12, Unit 1 Explosion
- March 14, Unit 3 Explosion
- March 15, Unit 2 Explosion
- March 15, Unit 4 Explosion and Fire

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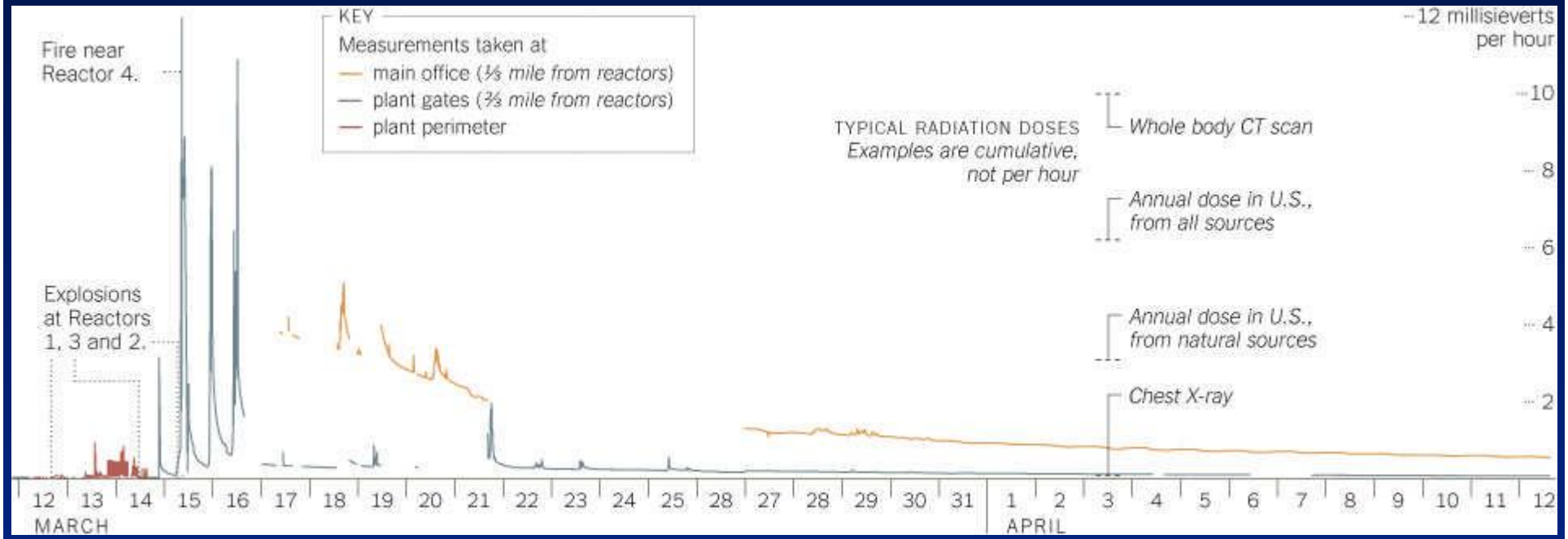
# Releases of Radioactive Material




Source: NY Times

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# Distribution of Contamination

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# USG in Japan

- Multiple agency response
  - NRC team supporting U. S. Embassy and interactions with Japanese regulator and licensee
  - DOE Areal Monitoring and Ground Monitoring
  - USAID overall lead for humanitarian aid
  - DOD support for humanitarian aid

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# U. S. Interagency

- Coordination of decision making through White House and National Security Council
- Multiple agencies involved including DOS, OSTP, NRC, DOE, DHS, DOD, CDC, DOT, CBP…
- Continuing to monitor
  - Support to US Embassy Japan
  - Continued event response support
  - Movement of airborne radioactive materials to US
  - Contamination of cargo, etc.

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# REGULATION OF TRITIUM EXIT SIGNS

**Angela R. McIntosh**
**Regional Nuclear Materials Events Coordinator**
**Office of Federal and State Materials and Environmental Management Programs**
**U.S. Nuclear Regulatory Commission**

# Overview

- NRC Actions to Address Control of Tritium Exit Signs
- Demand for Information: Background and Challenges
- Lessons Learned: Manufacturers, General Licensees, and NRC
- Inventory Issues Encountered by General Licensees
- General Licensing Tracking System
- Petition for Rulemaking 32-6 Assertions, Recommended Remedies and Status
- NRC Path Forward

# NRC ACTIONS TO ADDRESS CONTROL OF TRITIUM EXIT SIGNS

(*Past and Current*)

- Issued Information Notice 99-26 (dated August 24, 1999).
- Implemented rule for improved accountability (65 FR 79161, effective February 2001).
- Issued Regulatory Issue Summary 2006-26 (dated December 7, 2006).

# NRC ACTIONS TO ADDRESS CONTROL OF TRITIUM EXIT SIGNS

(*Past and Current*)

- Issued Demand for Information, dated January 16, 2009.
- Engaged manufacturers for submission of guidelines used to collect information from general licensee customers. (2010)
- Processed Petition for Rulemaking 32-6. (2011)

# DEMAND FOR INFORMATION: BACKGROUND

- February 2008: Walmart notified NRC of potentially large number of unaccounted for tritium exit signs.
- August 2008: Walmart provided draft inventory report.[1]
- January 2009: Walmart provided final report.[2]
- January 2009: NRC issued Demand for Information.

[1] Slightly fewer than half of signs could be accounted for.
[2] Approximately 15,000 signs unaccounted for.

# DEMAND FOR INFORMATION: CHALLENGES ENCOUNTERED

- Contacting a cognizant individual
  - Manufacturer-identified name of organization may have changed
  - Manufacturer-identified responsible person not necessarily available or may not realize he/she was identified as responsible person
  - Address in General License Tracking System may be outdated
  - Entity may be out of business

# DEMAND FOR INFORMATION LESSONS LEARNED: MANUFACTURERS

- Apparent inadequate notification:
  - To general licensees, concerning their licensee status and associated regulatory responsibilities.
  - To NRC, concerning responsible individual.

# DEMAND FOR INFORMATION LESSONS LEARNED: GENERAL LICENSEES

- General lack of awareness of general licensee status.
- General lack of awareness of associated responsibilities.
- General lack of ability to account for signs (could account for half of tritium exit signs, on average.)

# DEMAND FOR INFORMATION LESSONS LEARNED: NRC

- Communication efforts with most tritium exit sign general licensees not effective.
- General License Tracking System not adequately updated/informed.

# INVENTORY ISSUES ENCOUNTERED BY GENERAL LICENSEES

- Contractor purchased signs (approx. 10%)
- General licensee status unclear or “lost” over time (approximately 30%)
  - Recordkeeping (lack of centralized recordkeeping; lack of comprehensive recordkeeping; lack of any recordkeeping)
  - Signs “likely” disposed or disposed “improperly”
  - NRC regulations “not clear" or broadly publicized
  - Signs lost due to sale of facility/demolition/renovation

# INVENTORY ISSUES ENCOUNTERED BY GENERAL LICENSEES

- Miscellaneous
  - General licensee disputed GLTS numbers
  - Lack of consistent method to procure signs
  - Lease vs. ownership of facility
  - Illegible serial numbers

# GENERAL LICENSING TRACKING SYSTEM

- Numbers are approximate:
  - Some entries are the same company under slightly different name.
  - The numbers of signs in some cases are over stated because licensee did not report disposals to the NRC.
  - The numbers of signs in some cases are under stated because contractor purchased the sign.
- Generally, half of licensees had +/- 50% of GLTS number.

# PETITION FOR RULEMAKING 32-6

- Asserts:
  - "Majority" of tritium exit signs disposed into solid waste landfills.
  - Manufacturers inadequately inform customers of ownership requirements and disposal options.
  - Online vendors inadequately inform potential customers of the radioactive nature of tritium exit signs and associated requirements.

# PETITION FOR RULEMAKING 32-6

- Recommended remedies:
  - Label signs in several locations.
  - Use larger font in labeling.
  - Add expiration date of sign.
  - Implement a national collection effort to dispose expired and disused signs.
  - “Ideal” solution:  replace tritium exit signs with alternate technology.

# PETITION FOR RULEMAKING 32-6: STATUS

- Anticipated *Federal Register* notice publication date of NRC decision:

June 2011

# TRITIUM EXIT SIGNS PATH FORWARD

- Use manufacturer input to update GLTS.
- Meet with stakeholders.
- If needed, in accordance with NRC decision regarding PRM 32-6, adjust regulations and/or guidance.

# QUESTIONS?

# National Institutes of Health

# Radiation Safety Program at the National Institutes of Health

*Capt. William F. Holcomb, Capt. Robert A. Zoon, Sean M. Austin, and Nancy E. Newman*
*National Institutes of Health, Radiation Safety Branch*

## BACKGROUND

At the National Institutes of Health (NIH), one of the world's foremost biomedical and clinical research institutions, much of the research is performed using radiation or radioactive materials. To maintain a safe environment, minimize risks, and protect the health and safety of employees, patients, visitors, and the surrounding community, a radiation safety program is required. Under US Nuclear Regulatory Commission (NRC) licenses and NIH policies, the radiation safety branch (RSB), administers a comprehensive radiation safety program covering over 3,000 NIH laboratories and over 6,000 laboratory and 2,700 ancillary staff workers. The radiation safety program provides for the effective supervision, control, and monitoring of all radioactive materials and radiation sources at NIH. This includes activities such as personnel monitoring, laboratory inspections, waste management, consultation, environmental monitoring, and training. As a result of this comprehensive program, exposure of NIH employees to external and internal radiation has been kept well below the NRC's radiation dose limits and consistent with the NRC's As Low As Reasonably Achievable (ALARA) concept.

## INTRODUCTION

The National Institutes of Health (NIH) is the federal government's principal facility for the conduct of biomedical and clinical research on the causes, effects and treatment of disease in humans. Table 1 lists the institutes and centers comprising the NIH. The NIH's mission is to uncover new knowledge leading to improved health by:

a) conducting research in its own laboratories;

b) supporting the research of non-federal scientists in universities, medical schools, hospitals and research institutions throughout the country and abroad;

c) helping in the training of research investigators; and

d) fostering and supporting biomedical communications.[1,2]

The NIH is one of eight health agencies of the US Public Health Service, a component of the US Department of Health and Human Services. The principal laboratories, clinics, offices, animal quarters, and other specialized facilities of NIH are located on a 306-acre campus in Bethesda, Maryland, and at several off-campus sites located in Rockville, Poolesville, Kensington, Gaithersburg, and Baltimore, Maryland. Although NIH has several other sites (e.g., North Carolina, Arizona and Montana), only Bethesda and its associated sites are included under the Bethesda NRC license. The other locations have their own licenses. Along with its many research institutes, the NIH has a 350-bed clinical research hospital

***Table 1.*** *The National Institutes of Health Components*

| |
|---|
| Office of the Director |
| National Cancer Institute |
| National Eye Institute |
| National Heart, Lung & Blood Institute |
| National Human Genome Research Institute |
| National Institute on Aging |
| National Institute on Alcohol Abuse & Alcoholism |
| National Institute of Allergy & Infectious Disease |
| National Institute of Arthritis & Musculoskeletal & Skin Diseases |
| National Institute of Child Health & Human Development |
| National Institute on Deafness & Other Communication Disorders |
| National Institute of Dental & Craniofacial Research |
| National Institute of Diabetes & Digestive & Kidney Diseases |
| National Institute on Drug Abuse |
| National Institute of Environmental Health Sciences |
| National Institute of General Medical Sciences |
| National Institute of Mental Health |
| National Institute of Neurological Disorders & Stroke |
| National Institute of Nursing Research |
| Warren G. Magnuson Clinical Center |
| Center for Informational Technology |
| National Center for Research Resources |
| National Library of Medicine |
| John E. Fogarty International Center |
| Center for Scientific Review |

and an ambulatory care research facility. The NIH employs over 19,000 scientists, physicians, dentists, veterinarians, technicians, administrative staff and support personnel. More than 4,500 of the NIH staff have advanced education with either medical or research doctoral degrees. In addition, numerous guest scientists from the US and abroad collaborate in NIH research activities.[1,2]

The NIH intramural programs involve the use of a wide variety of radionuclides and radiation-producing equipment in research as well as in medical diagnostic and therapeutic applications, including research involving animal and human subjects.[3,4] Much of the biomedical research involves the use of radiation and radioactive materials. Radioactive materials and radiation sources are the most strictly regulated tools used in biomedical research, medical diagnosis and treatment.

The NIH radioactive materials program is among the largest of biomedical research institutions in the world in terms of the numbers of radionuclide and radiation users (approximately 6,000), numbers of laboratories (over 3,000) and shipments of radioactive materials (approximately 20,000 per year).

## LICENSING AND ADMINISTRATION

The NIH radiation safety program employs both in-house and contract personnel to ensure radiation activities are in compliance with applicable NRC and governmental regulations and NIH employees, patients, visitors and the surrounding environment, including members of the general public, are protected from the potential harmful effects of radiation.

Most radioactive-tracer work done at NIH is conducted with NRC-licensed byproduct material under a broad-scope, Type A, specific license, while certain radioactive sources, such as irradiators, are licensed separately by the NRC.[5] Other radiation-producing devices such as x-ray machines, accelerators and cyclotrons are not regulated by the NRC and do not require licensing, but radiation exposure from such devices fall under the regulation of the US Department of Labor. There are also certain radionuclides which are not byproduct materials ($^{201}$Tl,

$^{67}$Ga and $^{57}$Co are some of the more commonly used isotopes) and therefore are regulated by agreement and licensing states rather than the NRC. However, the NIH Radiation Safety Program oversees the use of all radioactive materials, whether NRC- licensed or not, and all instruments or machines capable of producing ionizing radiation.

The NRC routinely inspects the NIH to determine if activities with licensed materials or sources are being conducted in accordance with applicable NRC regulations and the conditions of the licenses issued. These inspections focus not only on the program but also on individual laboratories, authorized users (AUs) and individual users (IUs) working under the supervision of AUs. The NRC has an enforcement program, wherein they report violations of regulations in the *Federal Register* and the press, and can impose civil penalties (i.e. monetary fines) on the licensee. Severe or repeated violations can result in suspension or revocation of the license.

In addition to the NRC regulations and licenses, the NIH radiation safety program must conduct operations in accordance with other federal, state, and local regulations and requirements. These include the US Department of Transportation (DOT), US Department of Labor (DOL), US Environmental Protection Agency (EPA), State of Maryland and the Washington Suburban Sanitary Commission.

The radiation safety program[6-8] is a joint effort of the NIH radiation safety committee (RSC) and the radiation safety branch (RSB). The RSC, mandated by the NRC, establishes the policies, requirements, and guidelines for the use of radiation sources at the NIH in accordance with the NRC license and regulations. The RSC, acting on behalf of the director of the NIH, provides advice and approval to the radiation safety officer (RSO) for the conduct of the radiation safety program. Members of the RSC are appointed by the director of the NIH.

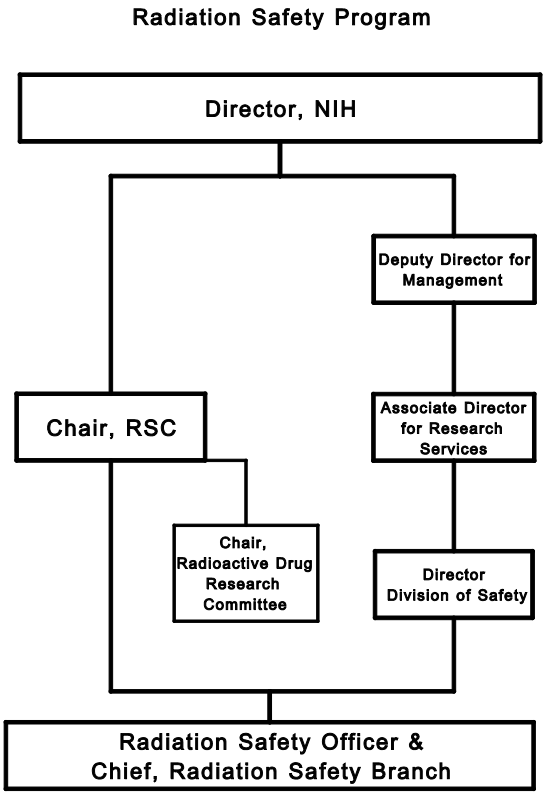
The program is administered under the authority and supervision of the RSO. The RSO is appointed by, and reports to the director of the NIH for the program's content and execution. The RSO is also the chief of the radiation safety branch, whose staff and contracting resources conduct the daily activities required by the program.

The RSO is bound by federal regulations to conduct a program in compliance with the requirements of Title 10 of the *Code of Federal Regulations*,[9] and can be held personally liable for failure to do so. The RSO must enforce the regulations and requirements of the NRC, and the management of the licensed institution is expected to support the RSO's compliance and enforcement responsibilities. Figure 1 is a chart showing how the radiation safety branch and radiation safety committee relate to the overall NIH radiation safety program management organization.

To carry out the radiation safety program in compliance with the NRC license requirements and the NIH rules, a comprehensive radiation protection program is administered by the RSB. The objective is to provide a program with the administrative, technical, and surveillance support necessary to ensure safe use of radiation sources and to ensure NIH is in compliance with the regulations and guidance of the NRC and other authorities. Another important objective is to provide support to the biomedical research mission of NIH.

To maintain a line of communication between the RSB and the radiation and radioactive materials users, two levels of users have been defined. "Authorized users" have been specifically trained to accept the responsibility of supervising the use of and complying with the regulations governing the radioactive materials, as established by the program. "Individual users" are workers engaged in patient care, clinical and laboratory research, and research support activities involving actual use and handling of materials and devices producing ionizing radiation. Authorized users' responsibilities include accountability for radioactive materials, maintenance of laboratory records, oversight of the IUs, and cooperation with RSB in any matters relating to radiation safety.

***Figure 1.*** *NIH radiation safety program management organization*




To support the objectives of this program, a comprehensive computer-based information system was developed, beginning in 1988. The major task of the system includes data input:

a) for over 36,000 personnel files to track radiation exposures, training activities, bioassay results, and radioactive materials usage;

b) to track the ordering, receipt and distribution of over 20,000 radioactive materials packages each year;

c) to track over 50,000 laboratory surveys per year;

d) to track over 100,000 radioactive waste tags collected each year for inventory and disposal actions; and

e) for many other files including sealed sources, x-ray machines, protocols, etc.

## THE RADIATION SAFETY PROGRAM

The radiation safety branch is divided into three sections.

*The radiation safety operations section* is responsible for area health physicist (HP) coverage of the NIH. An area HP is assigned to a certain building, and provides radiation safety consultation for that area's laboratories, facilities, and individuals. The HP conducts laboratory inspections for each area, assuring compliance with NIH policy and all federal regulations involving the use of radiation sources. The HP acts as consultant in the design and conduct of experiments using radiation sources to ensure that:

a) exposures to personnel are maintained ALARA;

b) proper and effective shielding and other protective measures are employed during the conduct of research; and

c) all personnel are properly trained and monitored for exposure based on license requirements.

*The radioactive materials control section* is responsible for:

a) receiving, checking, verifying, delivering and shipping all radioactive materials entering and/or leaving the NIH campus;

b) storing all radioactive materials not in current use;

c) managing and maintaining the materials inventory system; and

d) administering the radioactive waste management program.

As an example of the annual radionuclide usage at NIH, Table 2 lists the most frequently ordered radionuclides received for the years 1994-1998. Table 3 shows the number of radioactive orders received at NIH for the years 1991-1998.

***Table 2.*** *Radioactive materials receipts at the National Institutes of Health, 1994-1998**

| Radionuclide | Half-life | Radioactivity (mCi) | | | | |
|---|---|---|---|---|---|---|
| | | 1994 | 1995 | 1996 | 1997 | 1998 |
| H-3 | 12.3 y | 8,977 | 11,963 | 4,193 | 4,199 | 4,867 |
| C-14 | 5730 y | 286 | 241 | 133 | 150 | 126 |
| P-32 | 14.3 d | 29,162 | 18,293 | 16,368 | 13,917 | 12,648 |
| P-33 | 25 d | 367 | 456 | 528 | 592 | 522 |
| S-35 | 87.9 d | 13,648 | 12,424 | 10,737 | 10,570 | 8,086 |
| Cr-51 | 27.8 d | 4,704 | 4,510 | 3,982 | 2,818 | 2,632 |
| Ga-67 | 77.9 h | 1,573 | 1,950 | 2,581 | 2,102 | 1,376 |
| Tc-99m | 6 h | 13,626 | 15,963 | 16,307 | 17,738 | 12,530 |
| Mo-99 | 66.7 h | 331,000 | 349,210 | 355,060 | 447,960 | 395,920 |
| I-131 | 8.1 d | 4,068 | 3,553 | 3,696 | 5,128 | 6,087 |
| Tl-201 | 74 h | 3,104 | 3,054 | 3,130 | 3,108 | 2,750 |
| All Others | | 13,907 | 11,743 | 5,232 | 6,728 | 7,643 |
| TOTAL | | 415,422 | 433,360 | 421,947 | 515,010 | 455,187 |

** Data for years 1991-1993 in archives and currently not available.*

***Table 3.*** *Annual radioactive orders received at NIH, 1991-1998*

| YEAR | Number of Orders |
|---|---|
| 1991 | 36,024 |
| 1992 | 35,359 |
| 1993 | 33,546 |
| 1994 | 30,071 |
| 1995 | 27,907 |
| 1996 | 25,252 |
| 1997 | 23,354 |
| 1998 | 21,065 |

*The technical services section* is responsible for analytical and support services for the radiation safety program, including:

a) external personnel monitoring;

b) bioassays;

c) radioactivity analysis:

d) environmental monitoring;

e) instrument maintenance and calibration;

f) internal dosimetry; and

g) radiation safety training.

The various parts of the radiation safety program fulfilling the license requirements include:

*The Laboratory Survey Program.*

The NRC requires all laboratories, corridors, and storage areas where workers or the general public may be, or are likely to be, exposed to radiation levels or radioactive materials to be surveyed as necessary to ensure compliance with federal radiation safety regulations.[10] The RSB has engaged a contractor to survey these areas on a bimonthly, quarterly, or semi-annual basis depending on the activities and radionuclides used in each laboratory. Completed surveys are submitted to the area HP, who initiates an investigation of those items not in compliance with radiation safety requirements or where the survey results indicate a radioactive contamination level exceeding the regulatory limit of 2,200 disintegrations per minute per 100 square centimeters for beta- and gamma-emitters (restricted areas).

Additionally, the program requires that each laboratory be surveyed monthly by the users for potential contamination. The contamination survey reports are required to be submitted to RSB for review by the area HP. An AU who neglects to submit these monthly laboratory surveys will get two warnings and, if unresponsive, the AU will be prohibited from using or ordering radioactive materials until the matter is rectified. The RSB staff also performs required inspections and surveys of the laboratories and other areas on an as-needed basis.

*Training Program.*

The NRC regulations require "all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem"[9] to receive radiation safety training. The primary training course, *Radiation Safety in the Laboratory*, is presented several times a month and is required by NIH of all researchers working with radioactive materials. Approximately 1,500 new NIH research staff per year take the course. This training session is designed to acquaint users with the hazards of radioactive materials and the methods of protection against these hazards. Other training courses presented include an annual *Radiation Safety Orientation for Nurses*, a computer-based course to familiarize the nurses with the concept of radiation, its uses, benefits and hazards and the situations in which they it may be encountered. Approximately 700 individuals take this course during the year. *Radiation Safety for Authorized Users* is a three-day course required to qualify for AU status, (i.e. to order and supervise the use of radioactive materials under the NIH program and NRC license). It is designed to give attendees an understanding of the evaluation of hazards associated with the use of radionuclides in biomedical research and the responsibilities of an NIH AU. Approximately 100 individuals per year attend this course. Other radiation safety training sessions are conducted as needed for NIH personnel who may encounter radioactive materials in their work, for example house-keeping, maintenance, police, and fire-fighting personnel. Individualized training sessions are also arranged for research groups encountering special radiological safety problems.[6,11-14]

*Personnel Monitoring Program.*

Personnel monitoring involves the measurement of an individual's external exposure through the use of dosimeters, either thermoluminescent (TLD), or optical stimulated luminescence (OSL) devices and internal exposure through bioassay.

NRC regulations require employees who are likely to exceed 10% of the occupational dose limit of 5000 mrem to be monitored.[9] The

dosimeters available include whole body and ring badges. The dosimeters are processed by a contractor, monthly, bimonthly, or quarterly, as determined by the type of dosimeter. All cumulative whole body exposures equal to or greater than 500 mrem and cumulative extremity exposures equal to or greater than 5,000 mrem are investigated by the area HP. More extensive investigations are conducted when cumulative whole body exposures equal or exceed 1,500 mrem or when cumulative extremity exposures equal or exceed 15,000 mrem. A complete history is kept on the computer database for each individual. Table 4 shows the annual whole body radiation exposure to NIH during the years 1991 through 1998. As shown, the external whole body doses have been well below the occupationally allowed dose and 98-99% of the workers are regularly below the maximum permissible dose allowed to the general public.

The bioassay techniques employed at NIH to determine internal radiation exposure are urinalysis and thyroid counting. Whole-body counting is also available, if required. The RSB has adopted the recommendations of certain NRC regulatory guides for iodine and tritium bioassays to determine when they are required for NIH radiation workers.[15] Bioassays are routinely required for tritium and radioiodine only. Bioassays for other radionuclides are performed on a case-by-case basis. Bioassays for NIH employees are requested following review of records of radioactivity usage and from submission of breathing zone air samples from labs which are permitted certain activities. If the usage exceeds the established threshold activity, the investigators are requested to submit a urine sample or schedule a thyroid count, depending on the specific radionuclides used. Bioassays may also be required following spills or accidental injury involving radioactive material, unusual readings on personnel monitors, elevated readings from air samples, or as a protocol requirement. Additionally, bioassays may be scheduled at the discretion of the RSO or area HP. Failure to respond within a set time limit can result in suspension of the individual's privilege to work with radioactive materials.

The area HP is informed of all positive bioassay results. For results exceeding action levels specified within the license, the bioassay results, probable cause, and recommended corrective action are discussed with the user and other involved workers.[9] Table 5 presents the bioassay results for the years 1991-1998. As shown in the table, less than 7 % of the bioassays were positive. In all positive cases, the resultant radiation doses were well below the maximum permissible dose allowed by the NRC regulations.

*Environmental Monitoring.*

Environmental air monitoring is conducted continuously in certain areas and facilities where there is a potential for radioactive material release. This includes the radioactive-waste processing areas in the radiation safety branch building, various exhaust ducts from the laboratory research buildings, and outside fume hoods (in the breathing zone) where radioiodinations are performed.

*Radioactive Waste Management Program.*

On a radioactivity basis, the magnitude of the waste management program associated with NIH is small compared to that associated with fuel-cycle activities such as reactor operation and fuel reprocessing. Nonetheless, the proper management (handling, treatment and disposal) of radioactive wastes is an inherent part of the materials control and radiation protection policies and procedures at NIH. The NIH is among Maryland's top three generators of low-level radioactive waste (LLW). The LLW generated at NIH includes varied physical and chemical forms with levels of radioactivity ranging from minimally detectable radioactivity to levels high enough to require shielding for transport and handling. Radioactive waste forms at NIH include:

***Table 4.*** *Annual external whole body radiation exposure to NIH personnel, 1991-1998*

| Year | Total Monitored | No Measurable Exposure | 10-100 mrem/yr | 100-250 mrem/yr | 250-500 mrem/yr | 500-5000 mrem/yr |
|---|---|---|---|---|---|---|
| 1991 | 6181 | 5324 | 816 | 27 | 9 | 5 |
| 1992 | 6239 | 5306 | 869 | 47 | 12 | 5 |
| 1993 | 6680 | 5993 | 593 | 59 | 24 | 11 |
| 1994 | 6314 | 5193 | 1046 | 51 | 19 | 5 |
| 1995 | 6431 | 5988 | 389 | 31 | 18 | 5 |
| 1996 | 5850 | 5585 | 219 | 27 | 15 | 7 |
| 1997 | 4114 | 3896 | 174 | 23 | 19 | 2 |
| 1998 | 887 | 519 | 301 | 42 | 19 | 6 |

*The average annual whole body exposure for the NIH researchers was less than 10 millirem.*

*In 1996, the NIH revised its criterion for issuing a dosimeter, based on the cumulative activity handled by an individual in a year. The new program was based on 20 years of NIH experience that has shown that the small quantities of radioactivity used by researchers in most laboratories do not produce exposures that approach the NRC regulations for dosimetry requirements.*

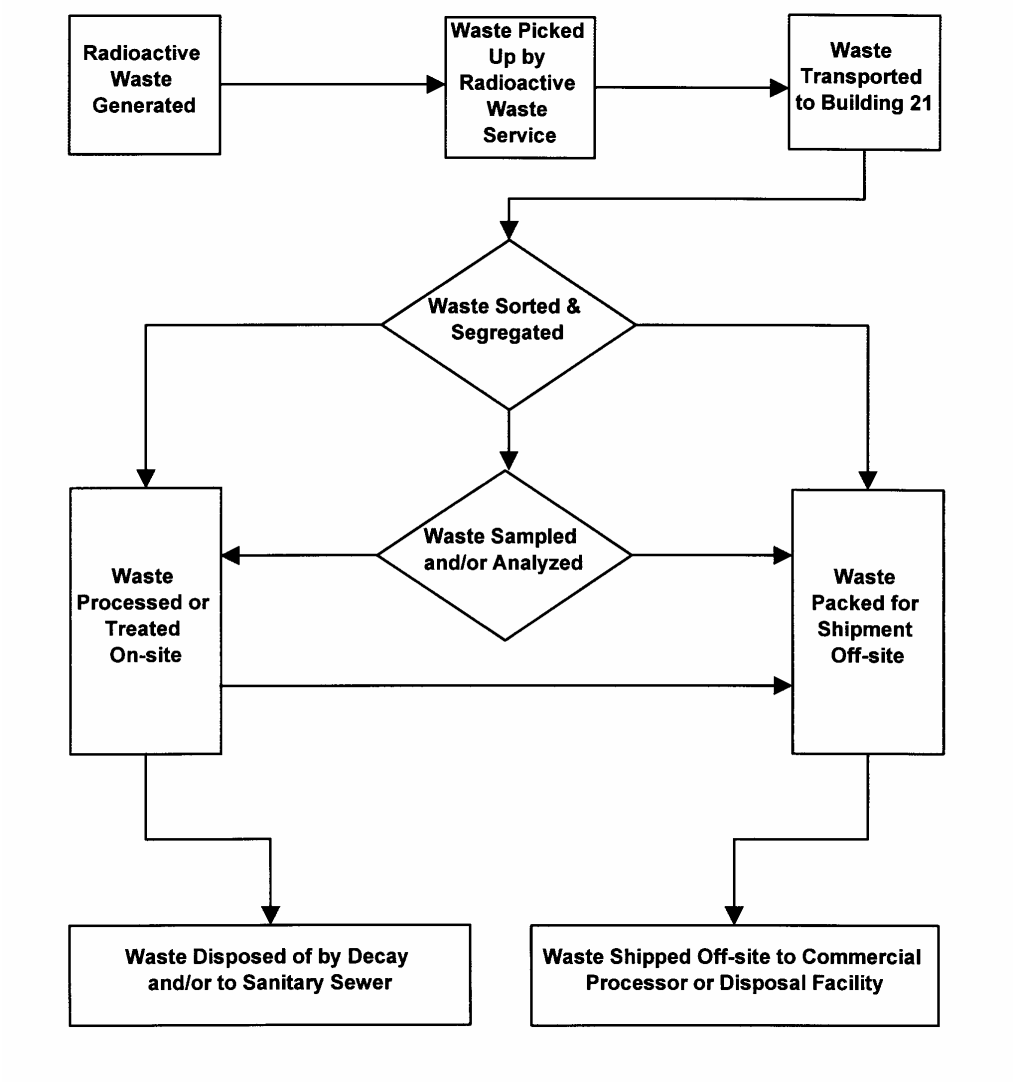
***Table 5.*** *Bioassay results for NIH personnel, 1991-1998*

| Year | Number of persons monitored (Number of positives obtained) | | |
|---|---|---|---|
| | Urine Bioassay | Thyroid Scan | Whole Body Scan |
| 1991 | 333 (9) | 870 (31) | 202 (18) |
| 1992 | 362 (29) | 806 (84) | 203 (10) |
| 1993 | 223 (13) | 471 (56) | 41 (0) |
| 1994 | 167 (12) | 362 (55) | 5 (1) |
| 1995 | 1100 (33*) | 339 (35) | 0 (0)** |
| 1996 | 300 (4) | 326 (25) | 0 (0) |
| 1997 | 170(7) | 242(32) | 0(0) |
| 1998 | 184(0) | 299(14) | 1 (0) |

** 27 of the positives were associated with the intentional contamination of drinking water in Building 37.*

*** Beginning in 1995, whole body scans are conducted only on an as-needed basis, to be determined by the Radiation Safety Officer.*

***Figure 2.*** *Flow diagram for the NIH waste management process*




a) research laboratory waste;

b) patient-care related wastes;

c) animal carcasses and tissues;

d) filters;

e) solidified liquids;

f) sealed sources;

g) contaminated equipment parts;

h) cleaning solutions;

i) aqueous liquid wastes and mixed wastes consisting of acidic and basic solutions;

j) complexing agents;

k) organic solutions; and

l) other wastes containing hazardous wastes or exhibiting characteristics causing the waste to meet the definition of hazardous waste.

The RSB radioactive waste facility serves as the central collection area for handling, treating, and disposing of all radioactive and mixed wastes generated at NIH. Figure 2 shows a general flow diagram for the waste management process at NIH. Current methods used by RSB for radioactive waste management include:

a) storage for radioactive decay;

b) on-site compaction;

c) shipment off-site for processing, volume reduction, incineration; and/or burial at a permitted and licensed commercial disposal facility;

d) solidification of liquids;

e) release to the sanitary sewer of aqueous liquids;

f) filtration to remove organic chemicals from liquid waste;

g) ultraviolet peroxidation to treat aqueous mixed wastes and render it suitable for discharge to the sanitary sewer; and

h) other bench-scale treatments for small, unusual waste streams for which traditional waste management techniques are unsuitable.

Generally, the majority of the radionuclides utilized for research at NIH are of moderate or slight activity, having relatively short radioactive half-lives (less than a year). The NIH employs a contractor who provides laboratories with the necessary waste containers and supplies on request, such as containers for liquids and waste step-cans for dry waste. The radioactive wastes are ultimately collected by contractor staff from the laboratories, transported to the waste handling facility, and then sorted by physical and chemical form, with samples taken, when appropriate, to determine radioactivity level and processed as follows:

- Dry radioactive waste containing long-lived radionuclides (half-life greater than 120 days) are sorted by physical form, packaged, and shipped to a commercial waste processor for volume reduction and disposal. The waste must be sorted before packaging to meet the waste- acceptance criteria of the commercial processor, so it may be properly treated and disposed. These wastes are sorted into non-combustible and combustible waste streams.
- Non-combustible waste is compacted in drums on-site and shipped off-site to a commercial LLW processor for supercompaction and burial at a licensed LLW facility.
- Combustible waste is packaged and shipped for either incineration or vitrification, followed by disposal of residue at a licensed LLW facility.
- Dry and medical pathological waste, including animal carcasses and tissues, contaminated with radionuclides with short half-lives, typically less than 10 days, are stored on-site for radioactive decay and eventually disposed as normal trash. Wastes contaminated with radionuclides with half-lives less than 120 days are packaged in drums and shipped to a commercial storage facility for radioactive decay. After radioactive decay, the non-radioactive waste is disposed as normal trash.
- Animal carcasses contaminated with radionuclides with long half-lives are packaged and shipped off-site for incineration or vitrification followed by disposal of the residue at a licensed LLW facility.
- Aqueous liquids are sampled and analyzed to determine the radionuclides and activity levels. The liquid is then treated using activated carbon filtration, to remove trace organic chemical contaminants and placed into one of nine 8,500-liter tanks and held until the radioactivity level has decayed to allowable levels. It is then discharged into the NIH sanitary sewerage system. The NRC license allows NIH to dispose of up to 7 curies of liquid waste per year via the sanitary sewer, 3 curies of $^{3}H$, 3 curies of $^{14}C$, $^{35}S$ and $^{33}P$ combined, not to exceed one curie of $^{14}C$, and one curie of all other radionuclides.
- Liquid scintillation media contained in vials, is packaged in 55-gallon drums with absorbent material and shipped off-site for recovery of liquids and recycling as a fuel.

***Table 6.*** *Radioactive Waste Disposal Data, 1991-1998*

| Year | Volume of dry waste shipped, cubic feet | Drums of LSC vials shipped | Volume of mixed waste generated, liters | Liquid waste volume discharged to sewer, liters |
|---|---|---|---|---|
| 1991 | 7395 | 757 | 24,890 | 151,551 |
| 1992 | 0* | 624 | 16,910 | 175,719 |
| 1993 | 12,480 | 551 | 26,270 | 140,299 |
| 1994 | 29,228 | 474 | 21,180 | 152,457 |
| 1995 | 23,066 | 409 | 11,210 | 185,409 |
| 1996 | 22,880 | 364 | 11,354 | 134,481 |
| 1997 | 23,088 | 310 | 11,111 | 118,800 |
| 1998 | 14,315 | 268 | 4,833 | 123,813 |

* *All waste was placed in storage this year.*

*The adoption of stricter laboratory security policies in response to heightened oversight by the US NRC has changed the way biomedical research is conducted today. The use of nonradioactive research methods as alternatives to using radioactive materials is gaining widespread acceptance, and as a result, the amount of radioactive material ordered and radioactive waste generated has been decreasing in the past few years.*

- Contaminated equipment parts are decontaminated, when possible, and disposed as non-radioactive waste.
- Mixed waste, LLW also meeting the EPA definition of a hazardous waste, is treated on-site using ultraviolet peroxidation, neutralized to render it non-corrosive and managed as aqueous liquid waste after testing to assure complete treatment. Alternatively, mixed waste can be shipped off site for treatment and disposal as LLW.

At present, the majority of the wastes sent off-site for disposal go to the commercial waste LLW facility at Barnwell, South Carolina.

All wastes shipped off-site are shipped in accordance with the DOT's regulations for shipping and manifesting.[9] Table 6 shows the various quantities of waste disposed for the years 1990-1998. The major radionuclides disposed:

1. via burial: $^{3}H$, $^{35}S$, $^{125}I$, $^{45}Ca$, and $^{192}Ir$;
2. via the sanitary sewer: $^{3}H$, $^{14}C$, $^{35}S$, $^{32}P$, $^{125}I$, and $^{51}Cr$; and
3. via off-site incineration: $^{3}H$, $^{14}C$, $^{125}I$, $^{131}I$, and $^{35}S$.

Responsible and effective management of radioactive and mixed wastes at the NIH is a priority of the radiation safety program. The current annual cost of radioactive and mixed waste management and disposal is about $2.5 to $3 million. The unit costs of disposal are expected to increase each year. To combat the accelerating rate of LLW generation and expensive waste disposal problem at the NIH, the radiation safety branch and the NIH environmental protection branch have embarked upon a number of programs for reducing the generation of wastes. NIH waste managers believe minimization is the first step in a successful strategy to decrease costs. Surveys have shown that NIH investigators are keenly aware of the need to reduce the generation of radioactive wastes and, in particular mixed wastes. Many investigators have achieved dramatic reductions in their mixed waste generation rates; in some cases, the generation of mixed waste was totally eliminated. Better communication about minimization techniques

has helped to achieve the NIH goals.[6,7,12,16] As a result, the generation of mixed wastes the past few years has dramatically decreased.

To carry out the NIH program of minimizing both radioactive and mixed radioactive wastes, a strategy was developed to include:

a) planning—select reagents and procedures to minimize the volume and toxicity of all wastes;

b) procurement control—avoid ordering chemicals and radioactive materials exceeding intended usage;

c) strict waste segregation;

d) use of non-radioactive tracers and methods for common assays;

e) substitution of short-lived radionuclides where feasible to allow for disposal of the radioactive waste, after storage and decay, as non-radioactive;

f) volume and activity reduction to decrease the amount of waste generated; and

g) substitution with chemicals not regulated as hazardous or mixed waste.

## NRC INSPECTIONS

Licensees are inspected at varying frequencies as part of the NRC's licensing program. NRC inspections over the last 10 years have cited NIH for apparent violations in the following program areas:

a) radioactive waste;

b) control and security of radioactive materials;

c) contamination surveys;

d) eating and drinking in restricted areas;

e) occupational radiation dose to individuals or extremities;

f) verifying stated contents of a package of radioactive materials with the order placed;

g) personnel monitoring;

h) training for individuals working in restricted areas;

i) a medical misadministration; and

j) bioassay measurements of researchers who handled volatile iodine.

These citations generally have been for isolated cases of noncompliance with license conditions, and were generally self-identified and corrected by the program prior to inspection.

During the past several years, the NIH radiation safety program has enhanced its procedures, guides, recommendations and policies to reflect correcting these violations, thus making the program one of the best, if not the best, in the nation.[17] Increased radiation safety management review of audits and prompt implementation of corrective actions have been implemented. In addition, enhanced communication between the radiation safety staff and the laboratory personnel to properly implement training, personnel monitoring, and other radiation-protection programs has been implemented. The RSB has increased the use of its computer-based information system to track new personnel involved with use of radioactive materials to ensure they are properly trained, have the proper personnel dosimetry, and respond in a timely manner to RSB requests such as bioassays.

## CONCLUSION

At the National Institutes of Health, the use of radionuclides requires a comprehensive radiation safety program to maintain a safe environment for the employees, patients and the general public. The program provides effective supervision, control, protection and monitoring of radioactive sources, ensuring all employees, visitors, patients and the surrounding community are not subjected to any undue risks to their health and safety, and the activities of NIH do not compromise the quality of the natural environment. Based on personnel monitoring and other data, it can be concluded the NIH radiation safety program is in substantial compliance with all regulatory requirements as well as with prudent practices to maintain radiation doses ALARA.

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**The Authors**

**Capt. William F. Holcomb** joined the Commissioned Corps of the US Public Health Service in 1974, where he has been with the US Environmental Protection Agency and the National Institutes of Health. Since 1990, he has been the radiation safety training officer at the NIH. Prior to his US PHS activities, he worked at the Idaho National Engineering and Environmental Laboratory, the Nevada Test Site, and Aerojet Nuclear Division. He has a BS in chemical engineering from New Mexico State University and an MS in metallurgical engineering from the University of Idaho. He is a registered professional chemical engineer.

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**Capt. Robert A. Zoon** began his career in health physics with the Commissioned Corps of the US Public Health Service's Bureau of Radiological Health in 1970, after receiving a graduate degree in nuclear engineering at New York University. Following a five-year assignment with the US EPA's Office of Radiation Programs, he joined the Radiation Safety Branch of the NIH. During his 22-year tenure at NIH, he has held several positions, being appointed as NIH's radiation safety officer in May, 1995.

**Nancy Newman** is chief of radiation safety operations at the National Institutes of Health. She supervises 12 health physicists who provide comprehensive radiation safety consultation to NIH researchers and support to clinical programs involving radioactive materials and radiation-producing machines. Ms. Newman has a BS in biology from Virginia Tech, an MS in radiation science from Georgetown University, and over 18 years of experience in biomedical health physics.

**Sean M. Austin** is chief of the radioactive materials control section, Radiation Safety Branch, at the National Institutes of Health, and is responsible for overseeing the program to manage the acquisition, inventory, and disposal of radioactive materials for NIH. He is the primary health physicist responsible for assuring the safe handling and disposal of radioactive waste for NIH's radioactive and mixed waste management facilities. He has a BS degree in health physics from Georgia Institute of Technology, and an MS degree in radiation science from Georgetown University. He is a member of the Health Physics Society and was certified by the American Board of Health Physics in 1997.

# NIST

National Institute of Science and Technology

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*Date:* June 27, 2008
*Refer To:* RP-DO-08:017

James Turner, Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, MD 20899-1000

Dear Dr. Turner:

This letter documents my preliminary observations, findings, conclusions and recommendations regarding the June 9, 2008 NIST Boulder plutonium contamination event. I formed these conclusions based on the June 23-24, 2008 subject matter expert on-site review of the event, review of available documentation, and interviews with 10 persons of interest. All persons interviewed were accommodating, cooperative, forthcoming, and professional. They demonstrated serious concern over this event, intent to understand underlying causes, and commitment to prevent recurrence.

Following are my observations and findings, including supporting information where appropriate. Findings are organized in areas of *Management Systems, Hazard Analysis and Control, Work Execution,* and *Response to the Event.* Many of the findings are interrelated, and many are causal to subsequent findings (e.g., a less than adequate hazard analysis resulted in less than adequate controls). Please consider these in the context of the limited scope and duration of the SME review. This information is intended to be useful in conducting further investigation, causal analysis, development of corrective actions, and in helping prevent recurrence of this event.

**Preliminary Observations**

Both NIST Gaithersburg and Boulder personnel took deliberate actions to manage the evolving scope of this work in detector technology.

- Management consideration and decision to fund, support, and expand application of this technology
- Boulder Radiation Protection Program included in Ionizing Radiation Safety Committee (IRSC) charter
- Review of the Boulder Radiation Protection Program conducted by IRSC
- Hiring the Radiation Safety Officer (RSO) at Boulder
- Amending the radioactive material license at Boulder after consideration of license options
- Initiating radiological worker training at Boulder in 2005 and 2007
- Acquiring hand-held radiation monitoring equipment in support of this work
- Performing a hazard analysis for the new radioactive materials
- Propagating NIST Gaithersburg health physics instructions to Boulder

Involved personnel expanded the emergency response as the extent of concerns came to light.

- The breached source was physically isolated
- Personnel were evacuated from immediate hazard
- Personnel were surveyed and decontaminated

- Interviews with involved personnel led to further area surveys that revealed extent of contamination beyond the primary laboratory
- Access control was established for the building and specific rooms
- Localized contamination was managed, and areas of concern were isolated
- Contaminated waste materials were controlled
- Additional resources and expertise were acquired, leading to help with personnel dose assessment (including in vivo and in vitro bioassay), characterization of the remaining material, and stabilization of the contaminated areas.

The planned path forward to recover the laboratory appears appropriate.

- Establishing a recovery plan
- Further isolating the contaminated laboratory
- Acquiring additional radiation protection and safety staff
- Obtaining contractor assistance to fully recover the contaminated areas

**Preliminary Findings**

*Management Systems*

Management attention to safety issues was less than adequate.

- Safety and RP resources were not sufficiently funded (staff, administrative support, instruments, equipment, supplies)
- History of transferring safety responsibilities among other entities (e.g. NOAA)
- Competing priorities and over-stretched existing Safety and radiation protection (RP) resources (e.g. focus on laser safety at the expense of radiological safety)
- Insufficient priorities on safety to ensure training (funding, staff, attendance, management engagement); computer-based training solution not funded
- Demonstrated safety awareness (e.g. engagement through safety processes) varies by organization
- Senior management presence on the floor is sparse
- Expectations for management ownership of safety, responsibility for hazard control, integrated safety management not sufficiently communicated to managers
- Line management relies on Safety and RP to ensure safety without direct line management support, in an R&D environment of principal investigators, in the absence of line management presence
- No systematic approach for establishing safety requirements
- Implementation of safety requirements is highly dependent upon individual personalities rather than requirements and processes

Roles, responsibilities, authorities, and accountabilities (R2A2) and organization structure were either not sufficiently defined or contributed to this event.

- No formal connection or reporting requirements between Boulder and Gaithersburg RP functions
- Gaithersburg RP has no authority at Boulder (e.g. stop work)
- Line managers are license managers at Gaithersburg; RSO is license manager at Boulder
- Line safety representatives lacked focus on radiological safety – this was consigned to RSO
- PI is responsible for worker training under the radioactive material license as opposed to typical line manager function
- Workers look to PI for guidance and mentoring, without much line manager interaction or oversight
- Boulder Safety and RP rely on influence and negotiation to establish programs; unable to establish requirements due to weak line management engagement in safety

- Safety requirements at Gaithersburg not established by Safety or RP, rather require consensus among line organizations

IRSC oversight and follow-through for identified Boulder RP issues was less than adequate.
- No coordination or link of radioactive material licenses between Gaithersburg and Boulder
- Boulder license amendment not reviewed by IRSC prior to submittal
- Recognized new RP program and new work direction but did not engage to provide more direct oversight with respect to this new activity (e.g. newly selected RSO unfamiliar with NIST safety protocols, including Form 364)
- Relied on RSO Boulder to identify deficiencies, concerns, and significant changes without detailed verification

Interface and communication between line management, the PI, the worker (W1) and RSO was informal.
- Dispersible nature of radioactive material not discussed with line management
- No formal tracking of new radioactive material users or followup on informal discussions regarding new workers
- Neither the evolving work practices nor configuration of the radioactive material was communicated to RSO
- W1 and RSO had never interfaced

The line management decision to proceed with expanding this work did not adequately consider safety risks associated with the new radioactive materials to be used.
- Protocols for evaluating cost/risk/benefit of new work not sufficiently established or implemented
- Risks from dispersible material not understood or considered by management decision makers

The NRC radioactive material license amendment process did not assure adequate review of new hazards.
- Amendment request contained inaccurate information (e.g. spent fuel elements)
- NRC did not emphasize dispersible nature of material
- There was no NRC followup / inspection to verify amendment conditions

The NIST change control mechanism (Form 364 *Proposal to Acquire a Radiation Source*) was not formally applied.
- Lacked review and approval by PI and line management

*Hazard Analysis and Control*

The hazards associated with the new radioactive materials were not adequately identified or analyzed.
- No consistent understanding or risk analysis associated with "encapsulated" source vs. "sealed" source
- Lack of understanding the dispersible nature of the new radioactive material by line management, IRSC, and RP in Gaithersburg and Boulder

Controls for these hazards were not adequately established or communicated.
- Form 364 identified powder nature of material, but lacked emphasis on contamination control (containment, monitoring)
- Form 364 overemphasized external radiation hazards and prescribed conservative controls (shielding, remote handling) which could conflict with contamination control

- New Brunswick Laboratory recommended leaving the source in the cardboard tube (and opening the tube should be performed in a glovebox)
- RP directed PI to leave the source in sealed plastic bag (this was not communicated to worker)
- W1 was not issued external dosimetry

Conditions of the radioactive material license were not adequately implemented.
- Radioactive material user training was not conducted as required
- RSO did not "review all uses of radioactive material"
- Sources were not controlled as required
- Workplace monitoring and contamination control measures were not implemented

Training and qualification of radioactive material users was less than adequate.
- Inconsistent application of employee hazards Form 1197
- W1 had no previous experience with radiological materials
- W1 had no safety training
- W1 was not trained on radiological hazards, controls, or emergency response
- W1 was instructed on work, without mention of safety procedures
- W1 misunderstood effects of radiation on electronic equipment (driving placement of lead bricks at detector array)
- No clear definition or threshold of radiological workers and associated training and dosimetry requirements at Boulder
- Established training did not include a focus on response to radioactive material spill
- Source custodian responsibilities not clearly defined or communicated
- Safety training at Gaithersburg not necessarily linked to specific activities or hazards

RP program and infrastructure for routine work and upset conditions with this dispersible material was less than adequate, including insufficient:
- Facility systems (containment/confinement devices)
- Instrumentation (survey and analysis equipment, air sampling and monitoring)
- Contamination control (routine area and personnel surveys)
- Area designation and posting (access control, radiological activity separation, PPE requirements, monitoring)
- Respiratory protection program (equipment and qualified workers)

*Work Execution*

In-field oversight of the work by line management and the PI was less than adequate.
- Risks of dispersible material were not communicated to W1
- Containment requirement was not communicated to W1
- W1 modified configuration and containment without knowledge or oversight

In-field oversight by RSO was less than adequate.
- There was no startup review or observation of work with new materials
- Interaction was informal, focused on transactional duties (e.g. dosimetry exchange) rather than evaluation of frequently changing work and practices
- Confirmatory contamination surveys were not performed
- Assumptions were not confirmed regarding configuration of experiment and implementation of controls

Work control associated with using these materials was less than adequate.
- No procedure or work control document established prescribing hazard control
- Existing Form 364 was not used to guide control of hazards

No formal experimental plan was established or executed.
- Worker was left to modify approach and source configuration through trial-and-error approach
- Safety expectations or controls were not established in the experimental plan

Controls that were established were not adequately implemented.
- Secondary containment was removed
- PPE (gloves) were not worn
- Source was physically mishandled (e.g. tapping)
- Source was not controlled as required (left unattended during experimental run)

Human errors were committed during the experimental work.
- Worker did not keep eyes on work (potentially the direct cause of the source containment breach)
- Worker did not recognize or react appropriately to changes in work practices (evolving source geometry measures – multiple containment configurations, source support configurations (taping to detector array, to block in vise, within can) or controls (torn secondary containment bag(s))

Programmatic pressures contributed to mistakes.
- Experiment was delayed by equipment challenges, causing schedule slip
- PI was not onsite during restart by W1
- W1 felt schedule pressure to achieve results

*Response to the Event*

Emergency preparedness was less than adequate, including insufficient:
- Emergency planning, training and drills
- Instrumentation and equipment (contamination and air monitors, large area swipes, HEPA
- Decontamination capabilities (materials and supplies, collection systems)
- PPE (respiratory protection, PPE for contaminated persons)
- Planned emergency contacts (REAC/TS, RAP, expert consultants)

Immediate emergency response was less than adequate.
- Extent of initial rupture was not recognized, although W1 took mitigating actions (taped up source in can, washed hands)
- Workers not immediately evacuated
- Notification to safety personnel was delayed
- PI made multiple entries (investigating ruptured source, monitoring contamination, isolating ventilation) without safety support, without understanding hazard or implementing appropriate controls (e.g. respiratory protection)
- Workers were instructed to remove shoes
- Workers were allowed to roam

Evolving emergency response was less than adequate.
- RP / Safety were not provided adequate resources in early stages (lacking supplies, administrative support)

- Initial bioassay samples were small volume, not collected away from work site, not prioritized at analysis laboratory
- Nasal swabs were not taken until the next day
- RAP response required interaction with multiple regions, required recall and delays for expertise and equipment, and limited support services at relatively low hazard

**Preliminary Conclusions**

- Safety was not sufficiently integrated into NIST processes, systems, or organization.
- Mechanisms for cost/risk/benefit analysis lacked sufficient communication and full consideration of risks.
- Safety processes (including hazard analysis & control and work control) and requirements were either not established or consistently implemented in Boulder operations.
- The fundamental lack of understanding of the hazards associated with this material and missed opportunities to identify significant change led to the lack of readiness and capability to safely handle this dispersible material and respond to associated emergencies.
- Issues regarding this activity and event may be systemic and reach into other areas of safety.

**Recommendations**

- Conduct further investigation of this incident, identify causal factors, develop and implement corrective actions and evaluate effectiveness of these corrective actions.
- Evaluate the extent of the conditions found in this incident for other radiological operations as well as other hazardous operations.
- Continue with the established recovery plan for this laboratory, ensuring adequate resources, appropriate oversight & involvement of line management and RP, and analysis & control of other safety considerations including electrical and chemical hazards.
- Stand down this work pending analysis, development, and implementation of alternative approaches and commensurate radiation protection program to include appropriate resources, infrastructure, training, and emergency preparedness.
- Establish mechanisms - involving line management and experimenters as well as subject matter experts - to include comprehensive safety review of new or changed work; consistent, formal hazard analysis and control; and worker qualification (with emphasis on new or transfered workers and including associates).

It is important to consider these observations and findings as preliminary and subject to change based on further investigation and confirmation of factual accuracy. I am available for discussion and clarification as needed. I look forward to assisting further as requested in an SME capacity.

Regards,

6/27/08

Paul Hoover
*Radiation Protection Senior Advisor*

PH:ph

cy: Patrick Gallagher, Stop 6100

# OSHA Review and Activities with Radiation

Sven J. Rundman III
Occupational Safety and Health Administration
Office of Health Enforcement
Washington, DC

OSHA Occupational Safety and Health Administration

# The Basics

- Employers have the responsibility to provide a safe and healthful work environment for all working men and women.
  - Federal agencies – Part 1960 & E.O. 12596
  - Private sector (incl. contractors) – 29 CFR 1910, 1926

- Federal agencies can exercise their authority to regulate occupational safety and health hazards.
  - Section 4(b)(1) of the OSH Act
  - If so, then OSHA standard pre-empted

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# OSHA's Interest

- Use of x-ray equipment to inspect luggage, packages, cargo, and people has increased.
- Increased use of ionizing radiation for non-intrusive inspection (NII) of cargo at all U.S. ports of entry (highways, rail systems, airports, seaports).
- DHS has been developing higher-powered accelerator inspection systems.
- Changes in the healing arts, especially for diagnostic and interventional CT scans and fluoroscopy – higher exposures to patients and possibly workers.
- Extensive use in non-destructive materials testing.
- The risk posed by possible terrorist threats (e.g., RDDs/INDs).

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# Ionizing Radiation

- Adopted from Walsh Healy Public Contracts Act
  - Issued 1971 (1969 version of App B to 10 CFR Part 20)
  - 1910.1096 (1926.53)

- OSHA's jurisdiction lies mainly with:
  - X-ray equipment
  - Various accelerators
  - Some NORM (Radon)

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# Ionizing Radiation 1910.1096

- 1.25 rem/calendar quarter
- 5 rem/year
- Surveying, badging, and recordkeeping requirements

- Personal monitoring:
  - Worker enters restricted area and receives or likely to receive a dose of 25% of the quarterly limit
  - Worker enters a “high radiation area” – exposure in excess of 100 mrem.

- Airborne radioactive material (e.g., Radon) – follow Table 1, Appendix B, 10 CFR Part 20

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# Non-Ionizing Radiation

- Non-ionizing radiation
  - 1910.97 (1926.54)
- OSHA limit – 10 $mW/cm^2$
  - 0.1 hr or more
- Expressed in voluntary language
- Specifies design of RF warning signs; newer designs acceptable

OSHA
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# Lasers

- 1926.54
  - Use of laser equipment
  - Potential exposure to direct or reflected laser light
  - Various exposure limits based on light intensity

- Post areas with warning placard
- Don’t direct beam at workers
- Use mechanical or electronic detectors

OSHA
adds value to business, work and life

# Regulatory Action (1910.1096)

- 2005 - Published Request for Information (RFI)
- 2006 – Conducted two site visits
- 2007 – Stakeholder meetings
  - Accelerators, security screening, healing arts, nondestructive testing, radiation-based technologies
- 2008 – RFI delisted from regulatory agenda
  - Continue to pursue interagency commitments and cooperation

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# Working Together

**Interagency Steering Committee on Radiation Standards (ISCORS)**

*Goal is to improve consistency in federal radiation protection programs.*

- Environmental Protection Agency
- Nuclear Regulatory Commission
- Department of Energy
- Department of Defense
- Department of Homeland Security
- Department of Transportation
- Department of Labor, OSHA
- Department of Health and Human Services
- And any successor agencies

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# Jurisdiction issues

- No OSHA jurisdiction if material licensed by NRC ("inside the fence").

- In 2005, Energy Policy Act altered definition of source and byproduct material (includes radium 226 and accelerator produced material).
  - NRC - accelerator operations and occupational exposures during these operations
  - OSHA - occupational exposures to radiation produced directly by the accelerators

- Radon
  - NRC – occupational – 30 pCi/L
  - EPA – public exposure – action level – 4 piC/L
  - OSHA – occupational exposure – 100 pCi/L

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# Letters of Interpretation

- "Possession" – If the presence of radon in a structure controlled by the employer exposes employees to hazardous concentrations of airborne radiation as set forth in the standard, 1910.1096 would apply.

- "Reasonable diligence" – Employer has the reasonable diligence to monitor for radon if he/she knows or could have known existence of artificially enhanced concentrations of radon-222.
  - Excavations, tunnels, buildings

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# Current Issues

- EPA Protective Action Guide
  - Concern for emergency responders responding to RDD/IND incidents
  - Incident commander may need to consider higher levels (>25 rem) for lifesaving and protection of property; other requirements must be followed
    - Training, medical surveillance
  - OSHA limit is still applicable (1.25rem/5rem)

- Fukushima release
  - Working group lead by WH National Security Staff
  - Workers exposed when off-loading contaminated cargo at ports of entry
  - 4 $Bq/cm^2$ – accepted level

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# Other Applicable OSHA Standards

- 1910.120 – Hazardous Waste Operations and Emergency Response
  - releases “outside the fence”
- 1910.132, 1910.133 – Personal protective equipment (Eye protection)
- 1910.147 – Control of Hazardous Energy (Lockout/Tagout)
- 1910.268 – Telecommunications
- 1926.651(g) – Excavations - testing of hazardous atmospheres

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# Enforcement Activities

(2001-2011)

- Ionizing Radiation (1910.1096)
- 97 inspections (40-federal; 57 state plan)
- 139 violations
  - (d)(1) – surveys
  - (d)(2) – supply personal monitoring equipment
  - (i)(3) – posting current provisions/operating procedures
  - (i)(2) – individuals informed of radioactive materials in area
  - (n)(1) – records maintenance

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# Enforcement Activities
(2001-2011)

- Non-ionizing (1910.97)
- 14 inspections (4-federal; 10 state plan)
- 16 violations
  - (a)(3) – warning symbol
  - (a)(2) – radiation guide limits
  - (a)(1) – radiation guide limits should not be exceeded

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# Enforcement Activities

- Radon
  - Case law – 1969 version of Appendix B to 10 CFR Part 20 is the enforceable regulation
  - 100 pCi/L – avg of 40-hour work week
  - If following current NRC regulation (30 pCi/L), then *de minimis*
    - as protective as or more protective

- Lasers
  - Violations mainly of General Duty Cause, Section 5(a)(1)
    - Abatement – follow ANSI Z136.1-2000
  - 1910.133 – eye protection

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# Security Screening Guidelines (Currently in Draft)

- Policies and procedures that will eliminate unnecessary exposure to x-rays from security screening devices.
- Technological developments and applications of x-ray machines for security screening have rapidly increased as our concern for national security and other risks has escalated.
- *Guidelines are advisory in nature and informational in content.*
- *Not a standard or regulation. Voluntary*.

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# Security Screening (Proposed Guidance)

- Potential risks and hazards
- Any regulatory requirements
- Good work practices
- Safety approaches and programs

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# Security Screening (Proposed Guidance)

- All types of uses:

•Baggage
Cargo
Personnel

• Small and large systems

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# Security Screening (Proposed Guidance)

OSHA
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# OSHA Assistance

- www.osha.gov
- Safety and Health Topics
  - Radiation
    - Ionizing
    - Non-ionizing
  - Lasers
- Technical Manual, Chapter 6 – Lasers
- Directives/MOUs

OSHA
adds value to business, work and life

# QUESTIONS?

Sven Rundman
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202-693-2585
www.osha.gov

OSHA Occupational Safety and Health Administration

# LASER EYE INJURY AT LARC

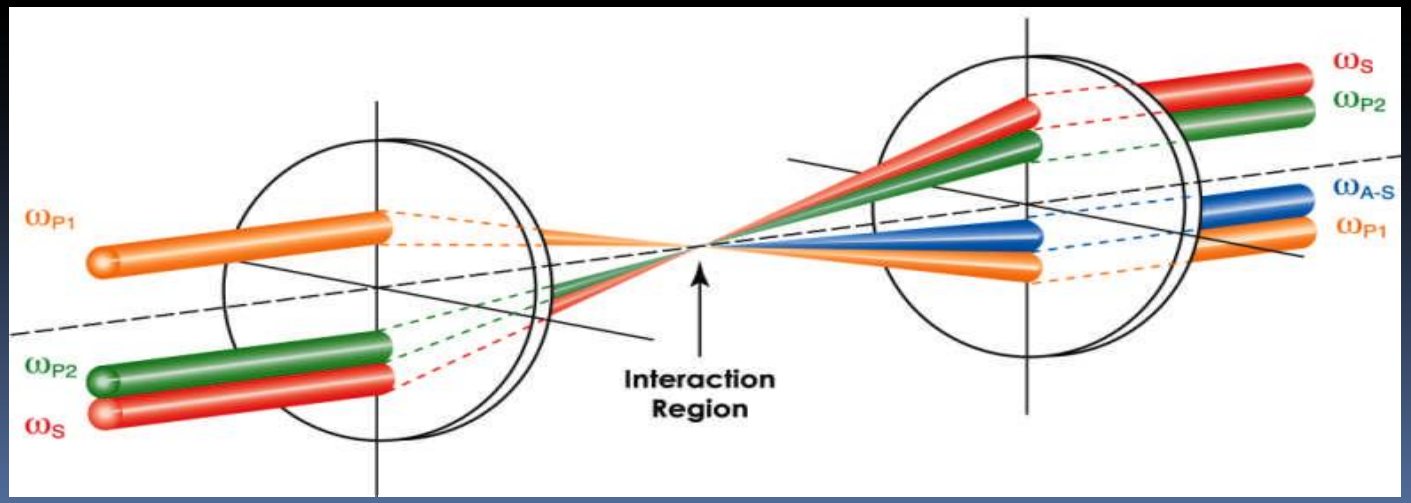
Kim Merritt, CLSO
Radiation/Laser Safety Officer
NASA Langley Research Center

# Agenda

- Experiment description
- Circumstances of the injury
- Investigation findings
- Corrective actions
- Medical information

# Experiment description

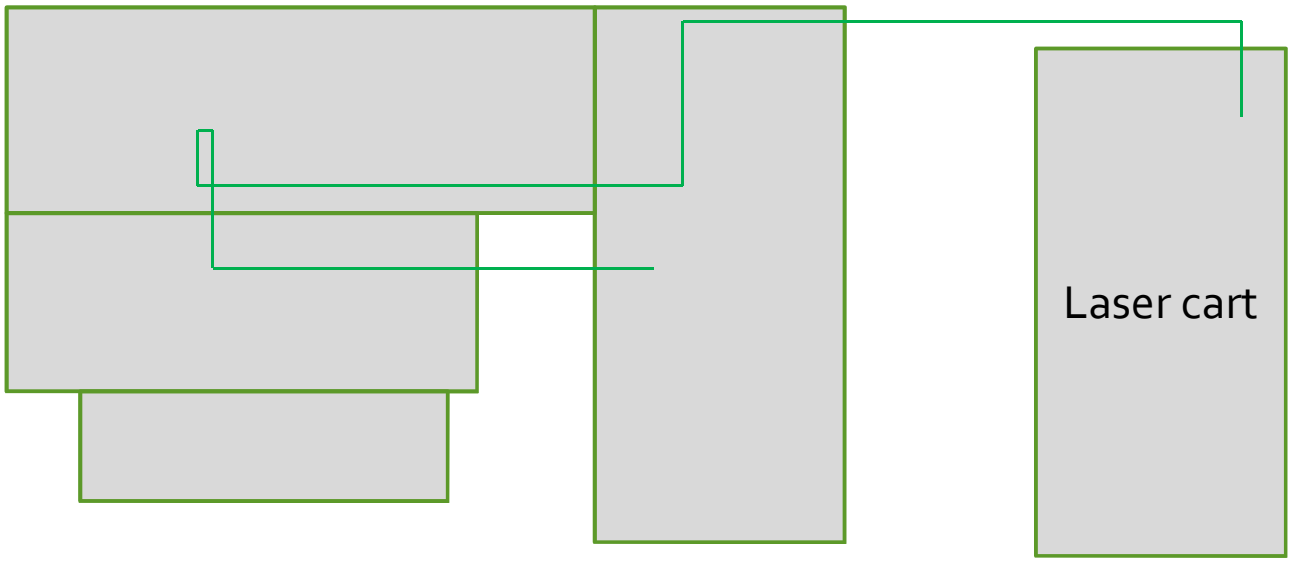
- Coherent Anti-Stokes Raman Spectroscopy
  - Utilizes multiple visible wavelengths that are focused o measure pressure and velocity from a supersonic gas burner
  - This activity had been in this lab since 2005.



# Laser system

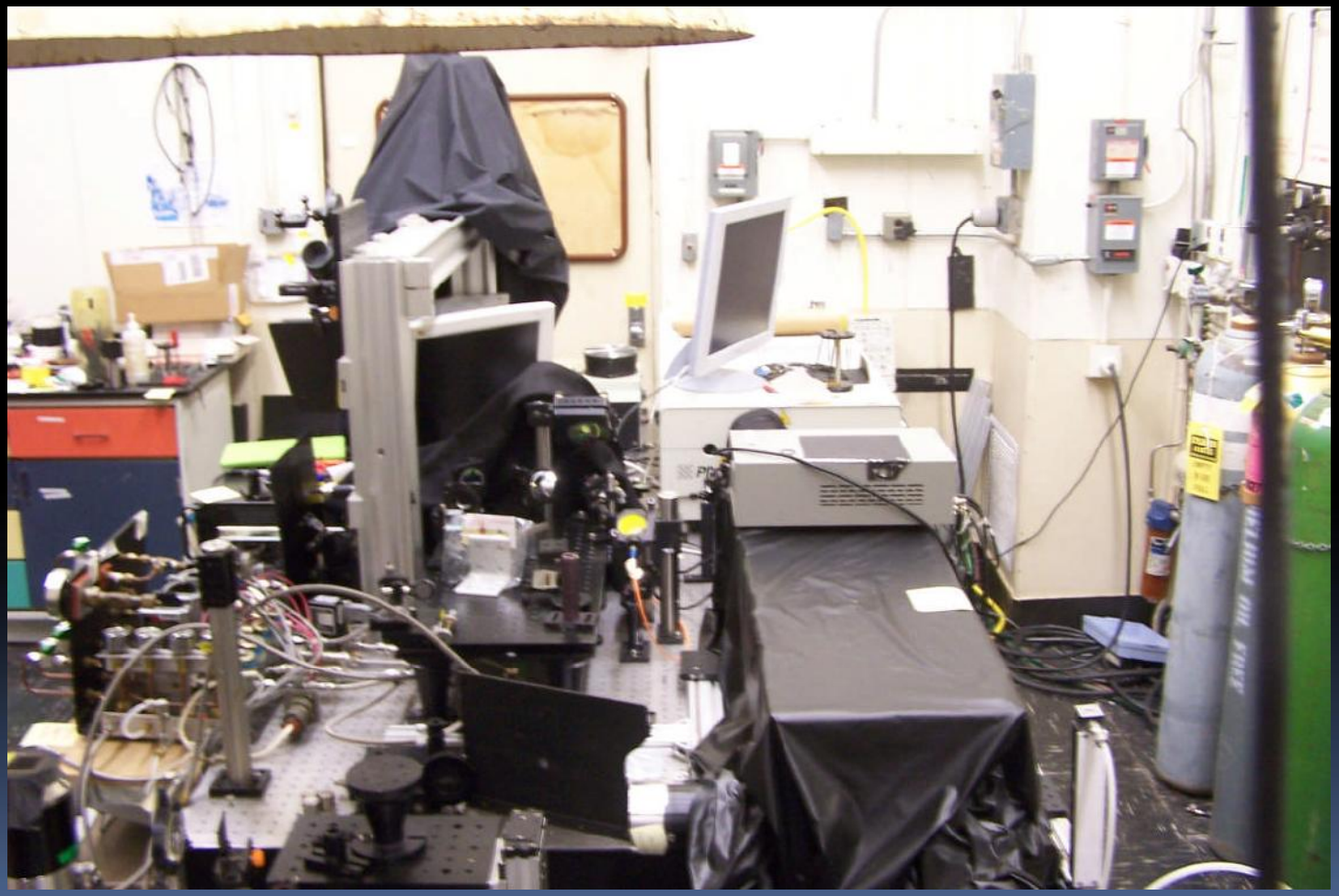
- Spectra-physics Quanta Ray Pro-350 mounted on a "portable" cart with 2 dye cells a doubling crystal
- 2.5 J @ 1064nm
- 1 J @ 532 nm
- 60 mJ @ 566 nm
- 50 mJ @ 606 nm

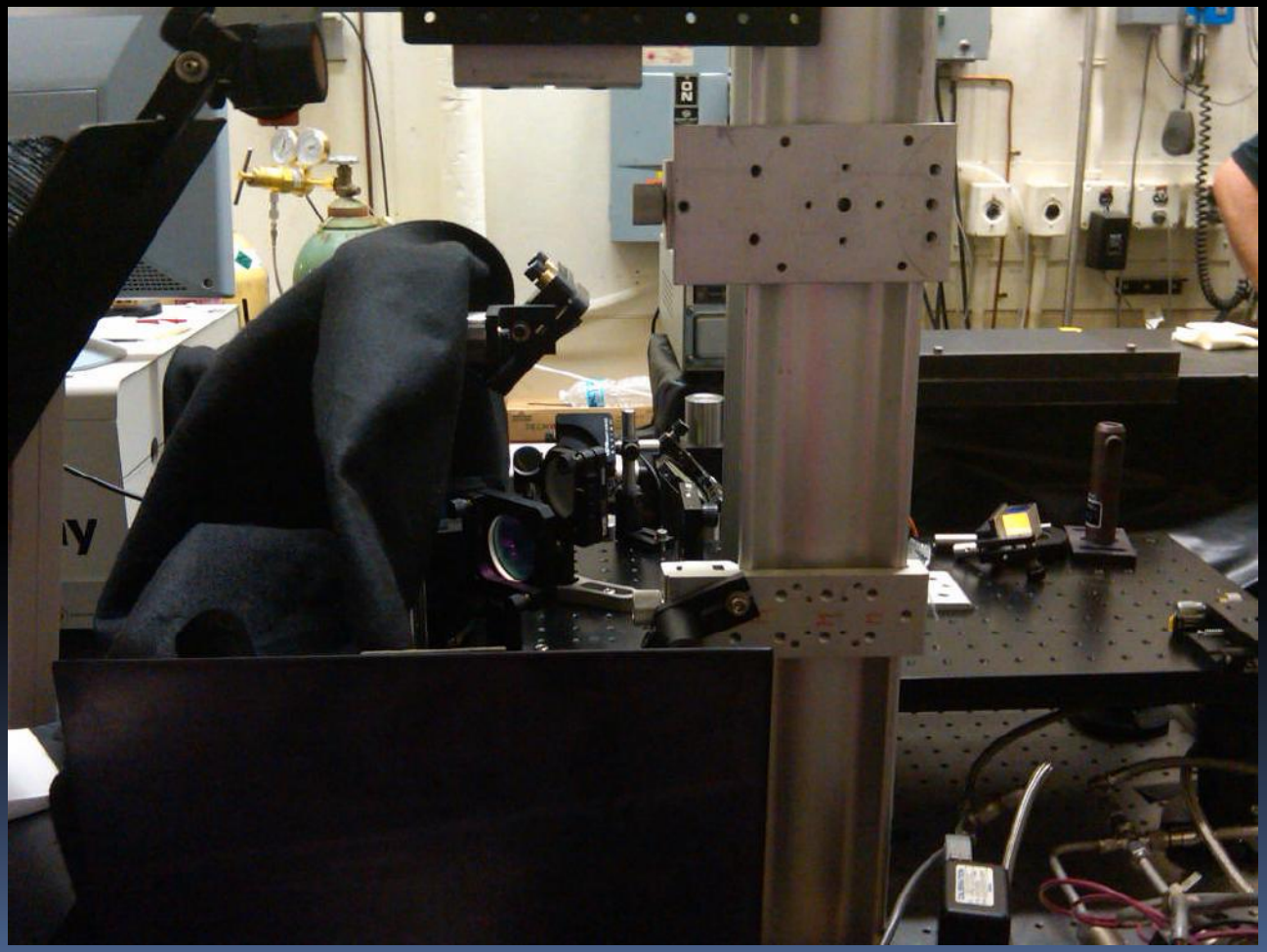
# Beam path (very basic)

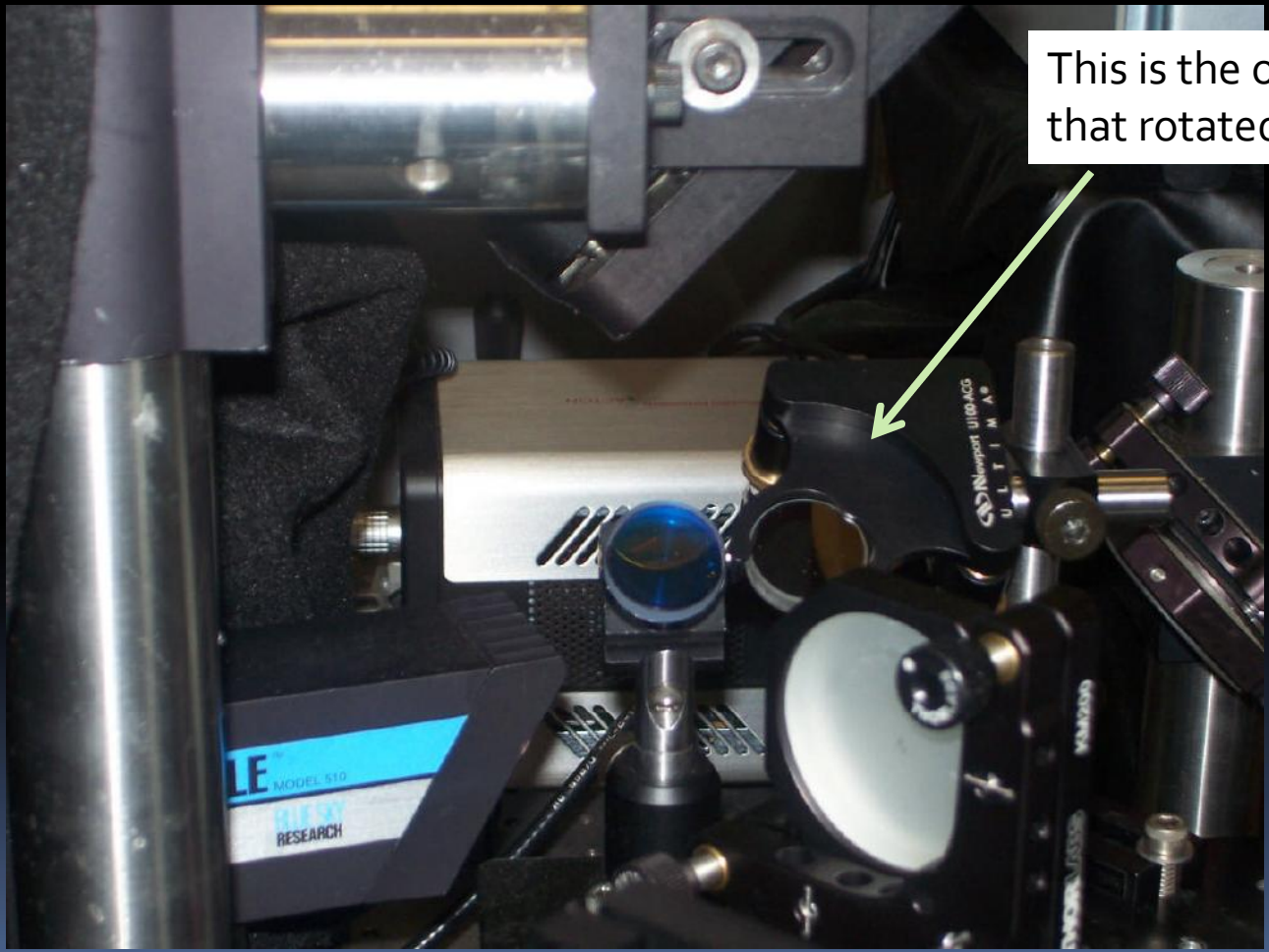


# Injury circumstance

- Operator was a PhD student performing an alignment to take his last set of data for his thesis.
- He was working with only the red beam and had on the eyewear prescribed in the permit.
- He was aligning the beam in a periscope set up
- When he touched one of the optics it rotated in its mount causing the beam to scan across his face.



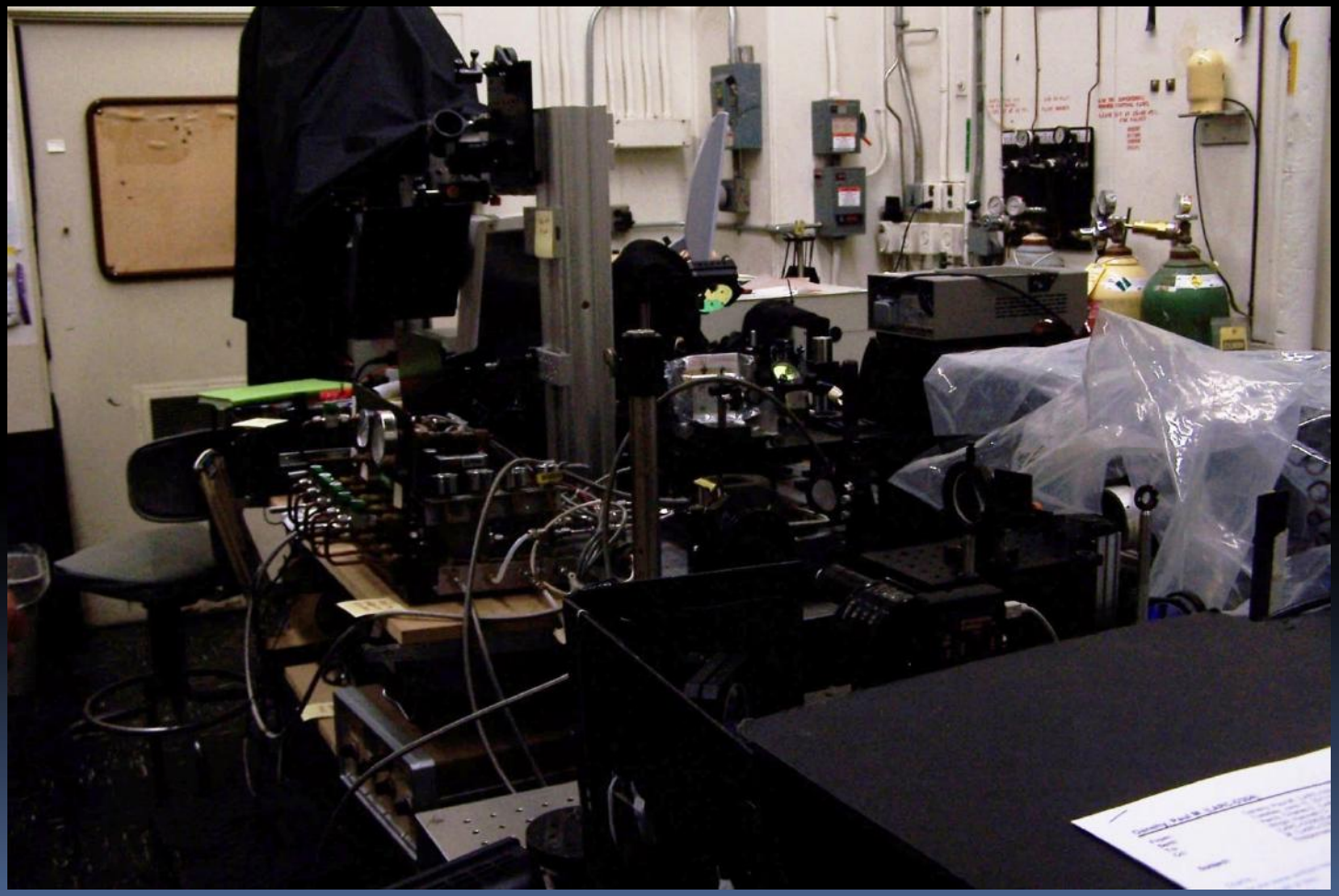



This is the optic
that rotated
MODEL 510
RESEARCH

# Eyewear

- The eyewear specified in the safety permit were broadband YAG/KTP eyewear but DID NOT provide protection from the 566nm and 606 nm beams.
- This was spelled out in the permit and specific alignment procedures were included to reduce the risk from the unprotected beams.
- The decision to leave the beams unprotected was a conscious one and took into consideration the increased risk to physical hazards present if the operator had eyewear on for all the beams.

# View with no eyewear



# View with the approved eyewear

# View with fully protective eyewear

# Investigation findings

- Multiple operations being staged on the optical table required the student to align the beam from a hazardous location
- The use of a single wavelength alignment procedure had not been discussed.
  - There were eyewear available for just the red beam.
- The use of a crossed post optic mount and a periscope assembly was less than ideal

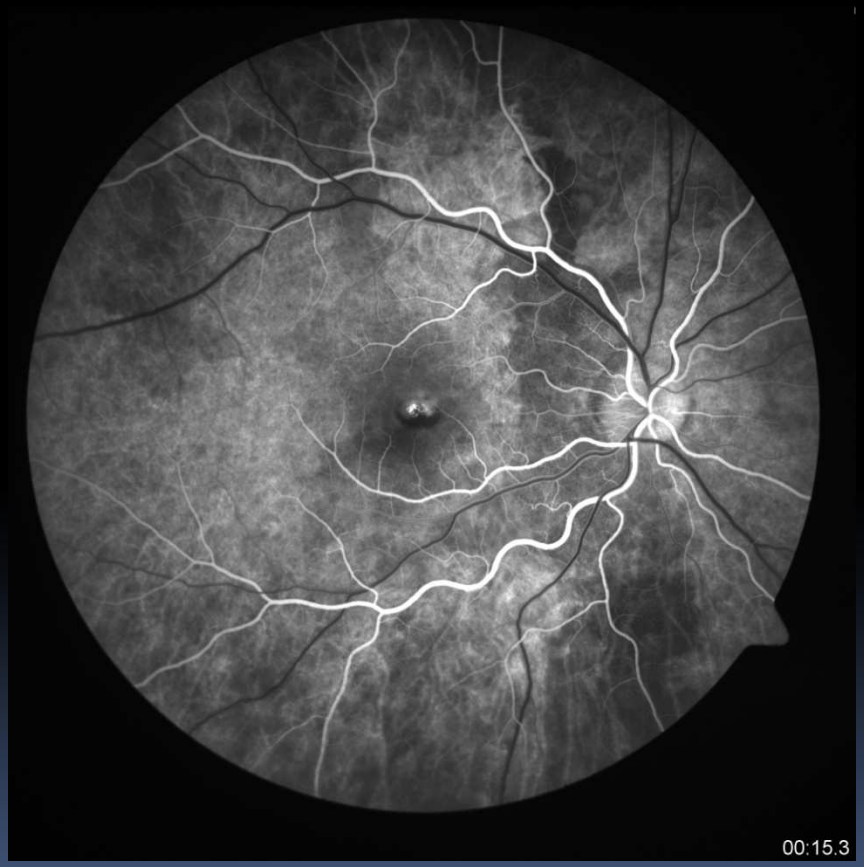
# Corrective actions

- The entire optical train has been redesigned.
  - No periscopes
  - Better beam enclosures
- New alignment procedures
  - Embedded Class 3R lasers using flip up mirrors to insert the beams for course alignment
  - A combination of the YAG and ultrabroad band eye wear are used for the fine alignment
  - Blue LED lights were installed to increase the visibility with the ultrabroad eyewear
  - Components were labeled in colors that could be seen with the eyewear on.
- During burner operations only the YAG eyewear are used but no manual beam manipulations may be done

# Medical assessment

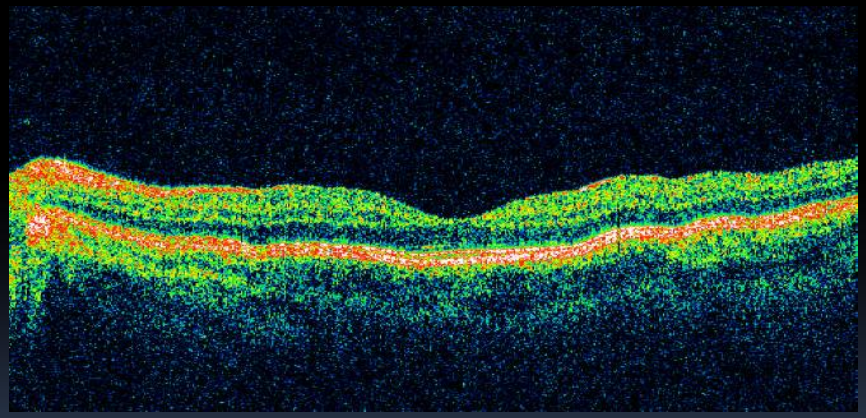
- The student received a photoaccousitc injury to the macula
- Visual perception of the injury was within a few minutes.  Brown "cloud" and grey fuzzy area
- Student sought treatment at 2 local ERs, neither of which had an ophthalmologist available.
- The DoD 24 hr laser injury hotline was found to be no longer in operation
- Saw a Dr. the next day for evaluation

# Images of the injury

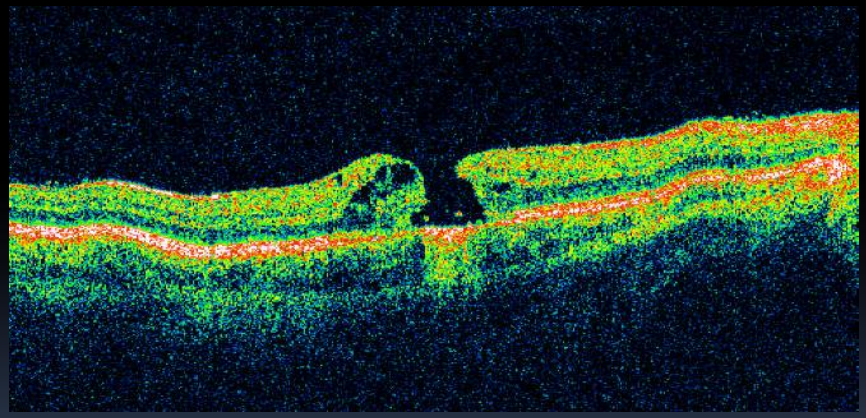


# Optical coherence tomography images

Undamaged eye



Damaged eye



# Prognosis at the time

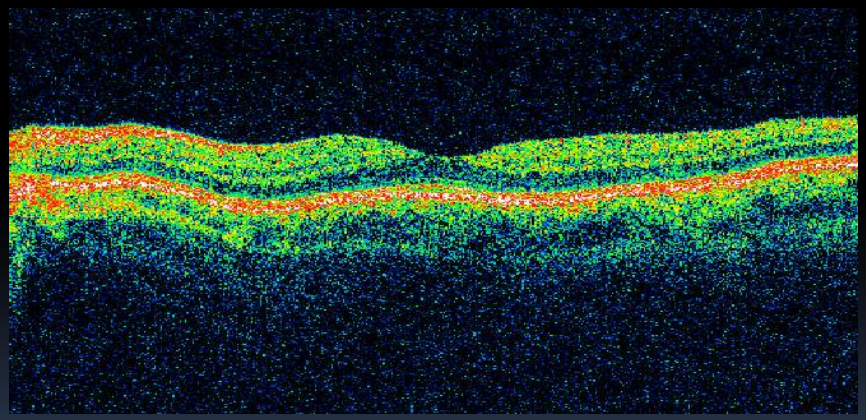
- Traditional belief is that there is very little, if anything, that can be done for retinal injuries.
- He had an blind spot of about ½" at 6 feet and could not read the big E on the standard eye chart.
- He did extensive research on his own and went to Duke Eye Center for evaluation from a specialist.

# Treatment

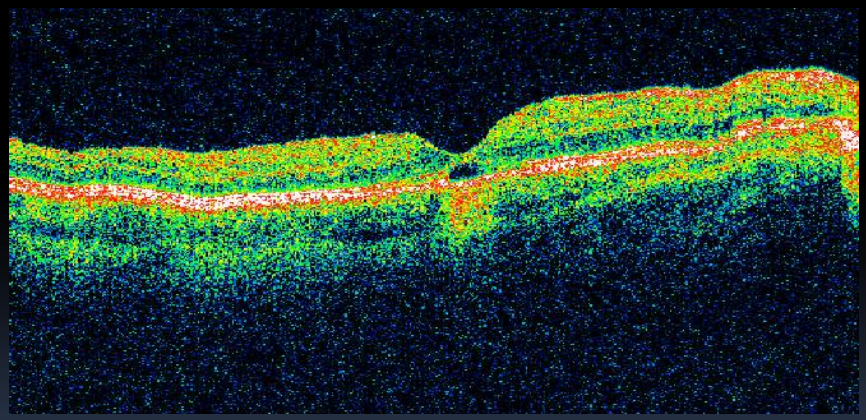
- The student underwent pars plana vitrectomy with air gas exchange.
  - They drain some of the vitreous out and insert a gas bubble against the injured area.
  - This is a common surgery for macular degeneration .
  - Required him to be face down for 2 weeks.
- There is a risk of retinal detachment during the surgery and cataract development within a year.

# Current OCT images

**Undamaged eye**



**Damaged eye**



# Current state of his vision

- Current vision is 30/35 in the injured eye
- Can read easily with both eyes, and for short periods with only the damaged eye.
- Still has a remaining blind spot but it only takes up about a single 12 pt character when sitting at normal distance from a computer monitor.

# Questions??

Kim.d.merritt@nasa.gov

# MOBLAS-7 Satellite Laser Ranging (SLR) Close Call At Goddard Space Flight Center's Goddard Geophysical and Astronomical Observatory (GGAO)


**Patrick Hancock**
Deputy Chief
Occupational Safety & Health Division (Code 350)
Goddard Space Flight Center

**Ted Simmons**
Laser Safety Officer
Radiation Protection Office
Occupational Safety & Health Division (Code 350)
Goddard Space Flight Center

# MOBLAS 7 AT GGAO

**One of the SLR stations at Goddard Space Flight Center**

# SATELLITE LASER RANGING

Satellite Laser Ranging (SLR) is a global network of stations measuring the instantaneous round trip time-of-flight for ultra short pulses of light to orbiting satellites. This provides instantaneous range measurements of millimeter level precision which can be accumulated to provide accurate orbits and a host of important science products.

# SLR Program

## Utilizes a Number of Laser Safety Elements

- Laser Hazard Reduction System (**LHRS aka RADAR**) - Detects aircraft in the vicinity of the transmitted laser energy.
- Laser Interlock - Blocks laser amplifier and oscillator using mechanical beam blocks, high density neutral density filters and inhibits laser fire command.
- Gimbal 10 degree elevation sensor - Detects gimbal elevation angle and inserts high density neutral density filter at 10 degrees to attenuate laser energy to eye-safe level.
- Beam Blocks - Multiple solid beam block units block transmitted laser energy when commanded by radar, mount observer, console operator, mount area pressure pads, door interlock, remote disable box, computer disable or radar failure.
- Fail-Safeness – RF Xmit power monitor, receiver tune verification, watchdog timers (4 µProcessors), cable disconnect, radar to gimbal pointing checks, and radar pedestal level checks.
- High Density ND Filters - Attenuates laser energy to eye-safe level when commanded by 10 degree elevation sensor.
- Telescope Area Pressure Pads - Detects personnel in the area of the MOBLAS telescope causing beam blocks to be energized.
- Laser Goggles - Used to attenuate laser energy to allow operators to maintain laser.
- Laser Safety Procedures - Posted in the vicinity of the laser to inform personnel of laser safety procedures.
- Laser Safety Hazard Signs - Posted on the outside of the Van containing the laser, around the telescope transmitting the laser energy, and in the vicinity of the laser.

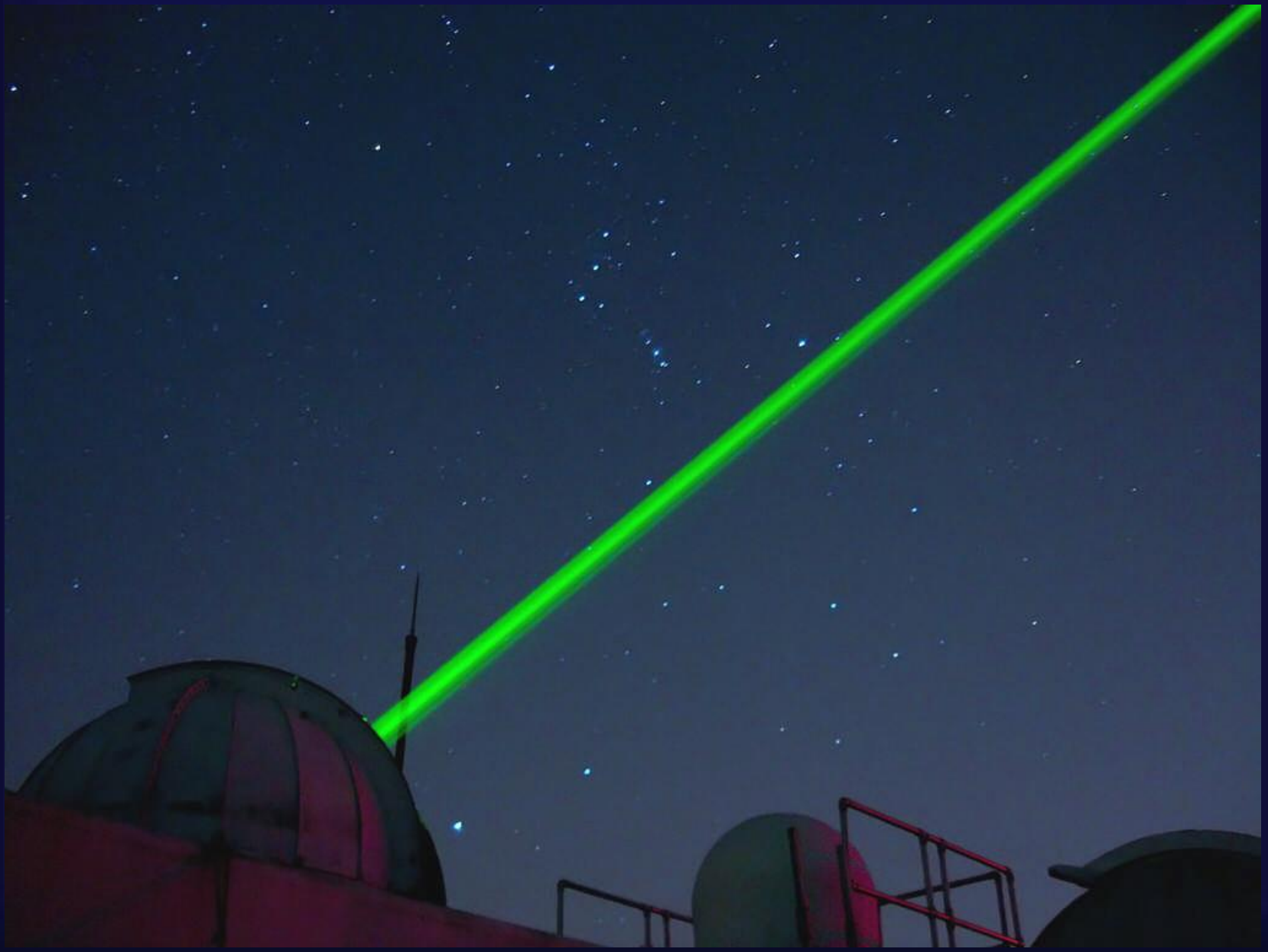
# SLR Safety Program

## Safety Record

- Over 32 years of safe SLR operations at GSFC.
- Over 15 years of safe SLR operations using the Laser Hazard Reduction System (radar).
- Independent safety reviews of SLR systems at GSFC.
  - SLR Laser Safety Officer annual inspection
  - GSFC Radiation Safety Committee annual inspection
  - GSFC Occupational Safety group annual inspection
- Operators had participated in over 43 committee meetings of the Society of Automotive Engineers (SAE) G-10T* and American National Standards Institute (ANSI)* since 1996.
- Participated in development of over 15 FAA/SAE & ANSI documents.

** SAE G-10T and ANSI committees form basis of the FAA laser policies.*

# NASA SLR System with Radar



# MOBile LASer STATION (MOBLAS)

The MOBLAS Satellite Laser Ranging Station is comprised of three vans that contain various components of the system. Electronics and computer systems required by MOBLAS for targeting, data processing, etc. are located in the vans. The radar system to detect aircraft flying in the area is mounted on one of the vans.

# MOBLAS 7 LASER

- The MOBLAS 7 uses a Class 4 laser system for SLR.

- Laser has a Nominal Ocular Hazard Distance (NOHD) of approximately **20 miles**.

- The Laser Free Exposure Distance (LFED) for the MOBLAS 7 is approximately **41 miles**. This is the distance from the site where the radiant exposure from the laser exceeds the laser free level defined in ANSI Z136.6.

- MOBLAS 7 uses a bore-sighted Radar as the Laser Hazard Reduction System (LHRS) to insure operations are conducted in a safe manner.

# Laser Hazard Reduction System (LHRS)

## Laser Hazard Reduction System (RADAR):

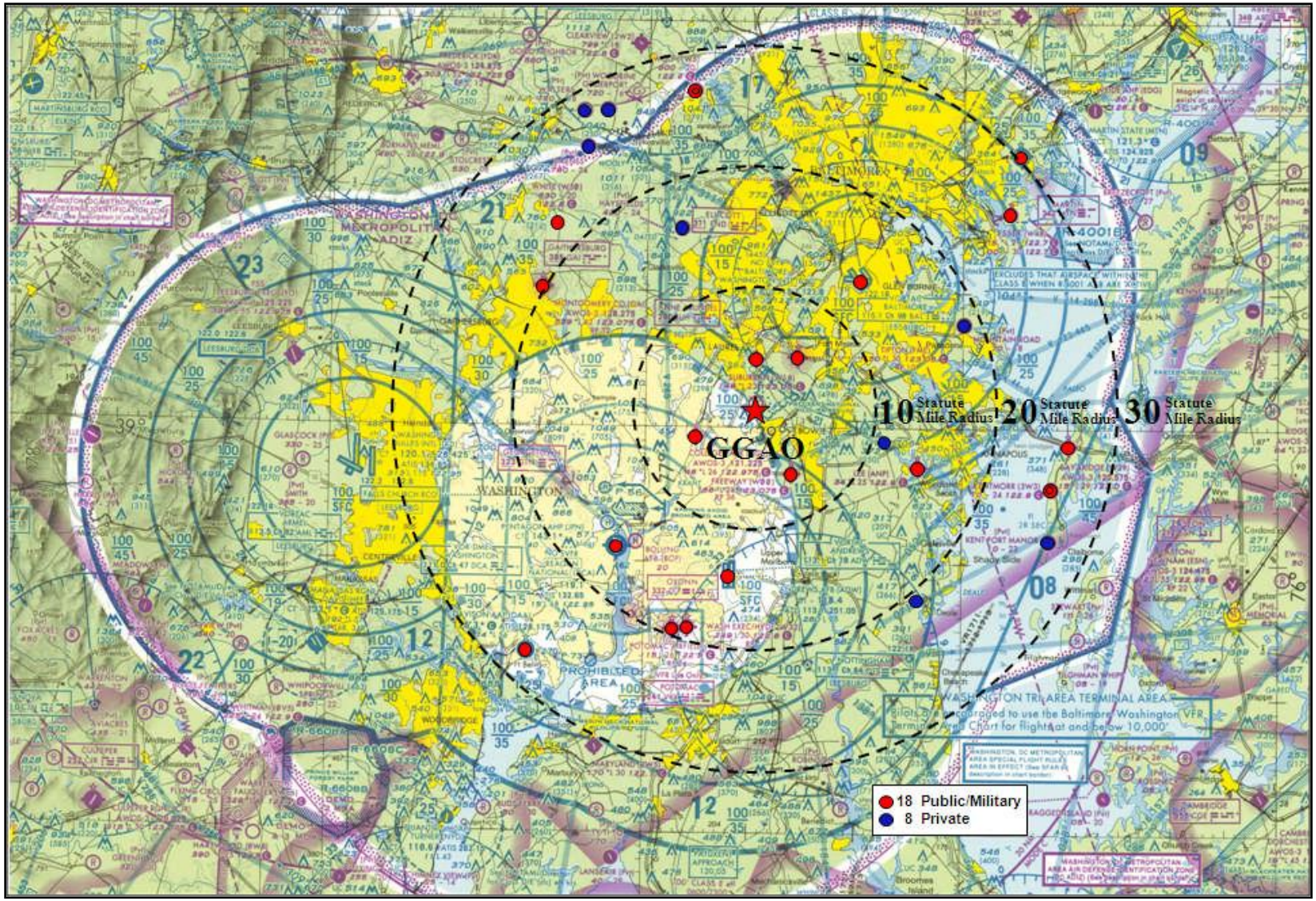
- Safety Component: Radar was developed as an added safety feature to prevent aircraft illumination and to eliminate the need for a mount observer stationed at the laser. This is important given the limitations of a person being able to see to the NOHD or LFED distances for the MOBLAS system.

- Radar has been successfully used for more that 15 years of SLR operations at 6 NASA stations worldwide without any aircraft detection system failures.

- GSFC Radiation Safety Committee approved MOBLAS 7's operational Laser Safety Plan to include the use of the LHRS system.

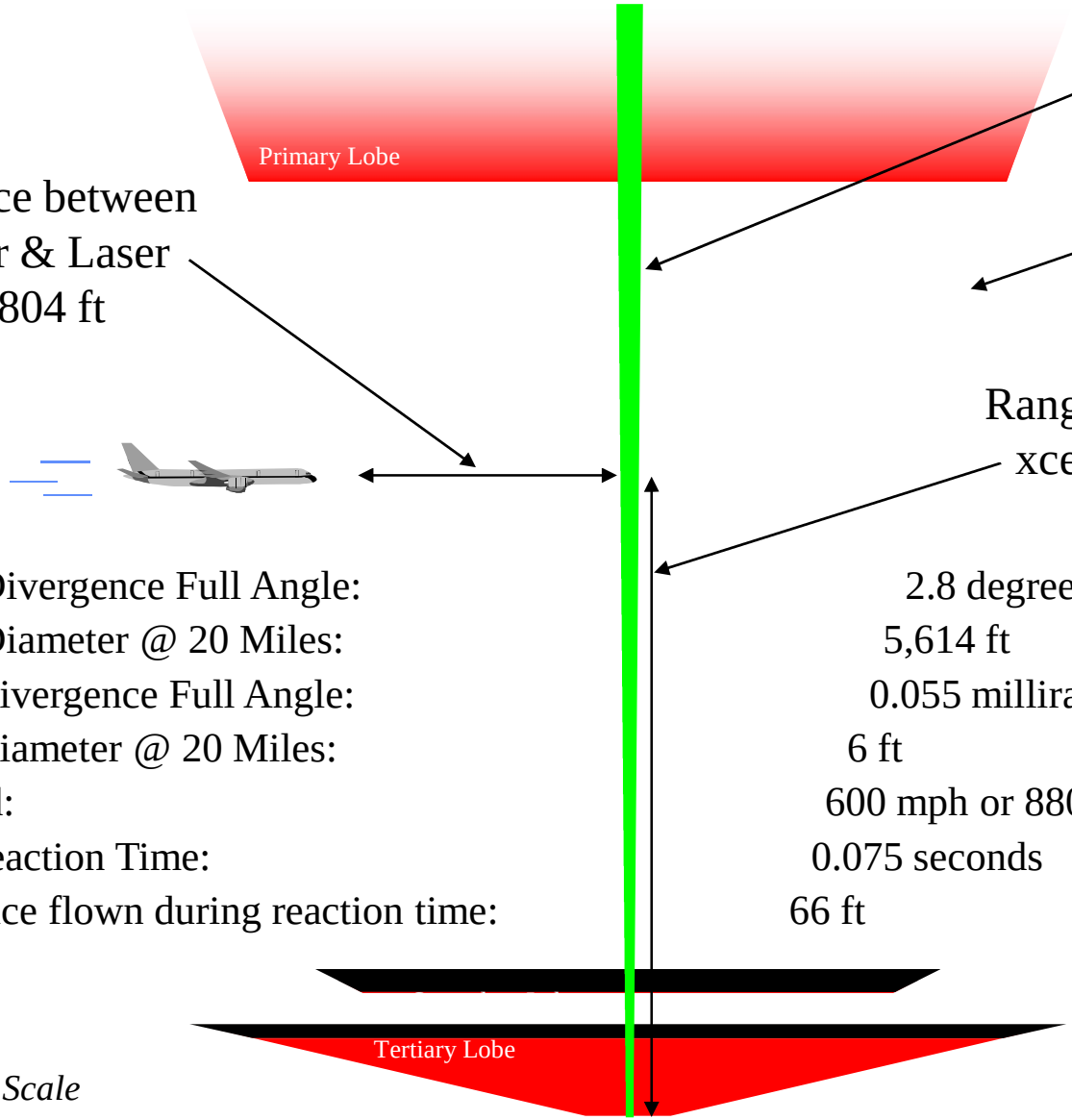
# Airports in the GSFC/SLR Region

## 26 public, private, and military locations



# Laser Hazard Reduction System (LHRS)

## Target Detection vs. Beam Overlap




Laser Beam Dia.
@ 20 miles = 6 ft

Radar Beam Dia.
@ 20 Miles = 5,614 ft

Distance between
Radar & Laser
2,804 ft

Range between radar
xceiver & aircraft
20 Miles

- Radar Beam Divergence Full Angle: 2.8 degrees (Primary Lobe)
- Radar Beam Diameter @ 20 Miles: 5,614 ft
- Laser Beam Divergence Full Angle: 0.055 millirad or 0.0032 degrees
- Laser Beam Diameter @ 20 Miles: 6 ft
- Aircraft Speed: 600 mph or 880 fps
- LHRS + LI Reaction Time: 0.075 seconds
- Aircraft distance flown during reaction time: 66 ft

Radar secondary (12º) and tertiary (20º) lobes detect low flying aircraft increasing reaction time where radar beam is narrow.

*Diagram Not to Scale*

# Close Call Mishap Event

**MOBLAS 7 Satellite Laser Ranging**

**April 28, 2010**

**Close Call**

# Sequence of Events

**April 4th:** The RADAR system for MOBLAS 7 suffered a failure of its drive mechanism and was taken off line.

**April 17th:** RADAR system repairs were completed and tested prior to return to service. As part of the testing a **bypass jumper** was used to disable the auto shut down of the laser system.

**April 18th:** RADAR was bore-sighted with the laser system.

Following the bore sight test the system was turned over for operations with the bypass jumper **left in** the bypass position. This effectively left the RADAR working but not able to shutdown the laser if aircraft were detected.

# Sequence of Events

**NOTE:** Proper procedures for end to end testing and validation of the SLR system was not followed. Safety RADAR aircraft detection system control panel indicating the system was not is proper operational configuration was not noticed by operators.

**April 18th through April 28th:** MOBLAS 7 operated without knowing that the **bypass jumper** was still in place.

Completed 335 tracked satellite passes with 29 aircraft detected by the RADAR.

**April 28th :** On that evening the operator noticed in the bore-sight CCD camera system a glint back from an aircraft. Operator noted it in the log and satellite tracking continued until the following morning.

# Sequence of Events

**April 29th:** On this morning the MOBLAS 7 station manager read the log and all operations were stopped and investigation started.

**April 29th:** SLR stations worldwide taken off line

**April 29th:** GSFC initiates Mishap Investigation

**April 29th:** GSFC Radiation Safety Committee (RSC) rescinded approval to operate MOBLAS 4 at Monument Peak, CA, MOBLAS 7 and the NGSLR at the GGAO Greenbelt, MD.

**May 5th :** RSC requested SLR operations submit new operating procedures for review and approval prior to starting any new satellite tracking operations.

# Sequence of Events

**May 5th:** FAA was notified as soon as it was determined that the MOBLAS 7 operation had potential illuminated an aircraft with the laser beam.

**May 6th:** FAA rescinded their Letter of Non-Objection (LNO) for MOBLAS-7 operations.

**May 10th:** SLR stations worldwide (excluding MOBLAS 7) are authorized to resume operations.

**June 28th:** The MOBLAS-7 SLR Near Miss Mishap Classification: Close Call Executive Summary Investigation report was finalized and approved.

# Summary of Close Call Mishap

## Investigation Report Recommended Actions

- Develop Tag Out, Operability Verification, and Station Operations Procedures.
- Develop formal safety training requirements for all personnel working within the station.
- Provide mandatory orientation for all personnel on the criteria for and the process of reporting mishaps.
- Ensure all NASA SLR outdoor operations are meeting all requirements.

# Summary of Close Call Mishap

## Investigation Report Recommended Actions

- Repair the RADAR safety system and recertify correct station operation.
- Resubmit requests for operation to the GSFC Radiation Safety Committee.
- Resubmit paperwork to the FAA for MOBLAS 7 with updated operating procedures.
- Provide second audio tone when an aircraft is detected at the radar local control panel. Add an aircraft detected light and a laser system safe light in front of area of the operators console where the operator is focused on during satellite ranging passes.

# Sequence of Events

**July 12th :** After the shutdown the SLR Sustaining Engineering updated all safety procedures associated with the MOBLAS 7 operations. These were reviewed, verified and then approved by the RSC on this date.

**August 3rd :** GSFC requested FAA issue new Letter of Non-Objection for the MOBLAS 7 operation.

**September 27th :** FAA issued new Letter of Non-Objection.

Throughout this period of time all recommended actions cited in the Close Call Investigation report were being completed by MOBLAS 7.

**November 24th:** MOBLAS 7 operations were authorized to re-start operations using the RSC approved Laser Safety Plan

# Observations

The RADAR, its safety features, and redundant features (control Panel & audio tone) functioned properly; the laser system could not be shutdown due to the **bypass jumper** being left in place after verification testing.

Human error did not follow proper procedures for repairing (tag out), testing, validation, and viewing safety indicators.

The FAA was available for discussion on the actions that were being taken, visited and reviewed the MOBLAS 7 site, and provided a quick turnaround on the new Letter of Non-Objection.

# Exemptions from FDA Laser Regulations

Patrick J. Hintz, MSIH, CIH
CDR, USPHS
Electronic Products Branch
Division of Mammography Quality and Radiation Programs

Food and Drug Administration
Center for Devices and Radiological Health
Office of Communication, Education
and Radiation Programs

# Outline

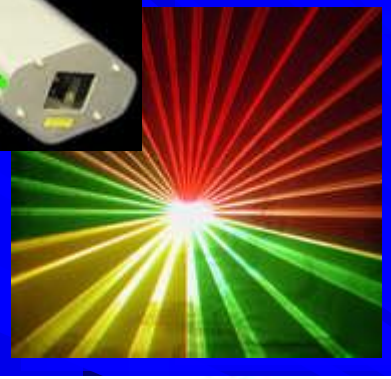
- FDA and Radiological Health
  - Overview of regulations
  - CDRH responsibilities
- Performance standard requirements
- Exemptions for Products Intended for US Government Use
- DOD/DOE Exemptions

# Radiological Health

- Mission
  - To protect the public from unnecessary exposure to radiation from electronic products.
- Authority
  - Electronic Product Radiation Control Provisions of the Federal Food Drug and Cosmetic Act
    - Sections 531 – 542
  - Title 21 of the Code of Federal Regulations
    - Parts 1000 – 1050
  - Applies to **MANUFACTURERS** only
    - No authority over product use

# Non-Medical Products

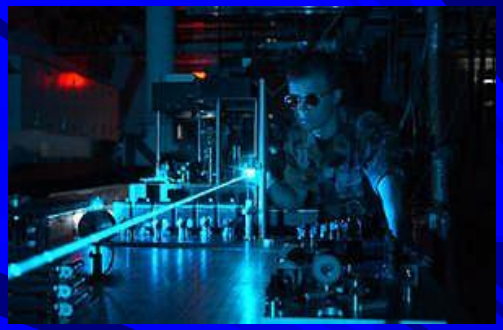
- Televisions receivers and monitors (video displays)*
- X-ray security systems*
- Microwave ovens*
- Laser products (CD players, light shows, welding lasers)*
- Metal halide lighting*
- Cordless and cellular telephones
- Industrial RF sealers of plastics and laminates



* subject to performance standards

# Laser Products

- Medical
  - Surgery, healing, eye treatment, dentistry, veterinary
- Defense
  - Targeting, guidance, countermeasures
- Research
  - Spectroscopy, interferometry, LIDAR, Astronomy
- Entertainment
- Other Industries
  - Communications, Manufacturing, Printing, Surveying, Alignment, Measurement, Analysis, Surveillance, Displays



**$5.4 Billion market**

# Standards Require

21 CFR

- Design & Manufacture to Standard
- Test Procedures for Compliance
- Product Reports:
  - Initial, Supplemental, Annual
- Test and Distribution Records
- Notification of Non-compliance / Defect
- Corrective Action or Exemption

# Performance Standards

- 21 CFR 1020.10 Television Receivers
- 21 CFR 1020.20 Cold-cathode Discharge Tubes
- 21 CFR 1020.30 Diagnostic x-ray systems and their major components
- 21 CFR 1020.31 Radiographic equipment
- 21 CFR 1020.32 Fluoroscopic equipment
- 21 CFR 1020.33 Computed tomography (CT) equipment
- 21 CFR 1020.40 Cabinet X-Ray Systems
- 21 CFR 1030.10 Microwave Ovens
- 21 CFR 1040.10 Lasers and Laser Systems
- 21 CFR 1040.11 Specific Laser Products
- 21 CFR 1040.20 Sunlamps and Sunlamp Products
- 21 CFR 1050.10 Ultrasonic Therapy Products
- 21 CFR 1040.30 High-intensity Mercury Vapor Discharge Lamps

# Product certification

- Products must comply with all applicable performance standards
- Products must be certified by the manufacturer
  - Certification means that the manufacturer ensures its own products comply with the applicable FDA performance standard.
  - Certification is based upon the manufacturer's own quality control testing program.
  - Self-certification does NOT indicate FDA approval.

# EXEMPTIONS
# From
# Electronic Product Regulations

# A Compilation of Exemptions for Electronic Products Found in 21 CFR Chapter I, Sub-Chapter J -- Radiological Health Parts 1000 – 1050

**January 5, 2010**

# INTRODUCTION

Exemption provisions are found throughout the Code of Federal Regulations (CFR) for Electronic Products – Parts 1000-1050. They are typically found within the specific regulation to which they apply. Other types of exemptions and special provisions going back to 1976 are contained in agency letters and Laser Notices. As a result, it is often difficult to find all the exemptions which may apply to a given product.

Exemptions are granted for a wide variety of reasons and many are granted to other branches of the federal government such as the Department of Defense (DOD). Often, being exempt is misinterpreted by manufacturers to mean exempt from any and all of CFR Parts 1000-1050 – this is not correct; exemptions are limited to specified provisions of the CFR. In addition, to have a valid DOD exemption for example, a manufacturer must meet the exemption provisions of the DOD and receive a written notice of same.

To simplify the process of finding all the exemptions provided for in the CFR Parts 1000-1050 and those granted by an agency letter or Laser Notice, this document has been assembled. It is a compilation of all exemptions which relate to the regulations for electronic products found in 21 CFR Parts 1000-1050. The document is organized by Part beginning with a summary section followed by the applicable Part with the word "exemption" highlighted within the text. Agency letters and Laser Notices are also provided as references to the summary sections.

If you have any comments or questions concerning this compilation of electronic product exemptions please contact CDR Patrick Hintz at 301-796-6939 or patrick.hintz@fda.hhs.gov.

# 21 CFR Chapter I, Sub-Chapter J -- Radiological Health Electronic Products Exemptions Found in Parts 1000 – 1050

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# 21 CFR Chapter I, Sub-Chapter J -- Radiological Health
# Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1002 RECORDS AND REPORTS

**SUMMARY:**

Subpart A – General Provisions

Part 1002 describes the requirements of manufacturers of electronic products with respect to records and reporting. The general provisions state that manufacturers, dealers, and distributors are subject to the provisions of Part 1002 as set forth by Table 1 – "Records and Reporting Requirements by Product".

Manufacturers may be granted an exemption by the Director, CDRH from the provisions of Part 1002 under 1002.50 and 1002.51, found in Subpart F – Exemptions from Records and Reports Requirements.

However, all manufacturers are subject to 1002.20, "Reporting of accidental radiation occurrences". There are no exemptions from this section, unless exempted by the Director of CDRH (see Subpart F).

Subpart F – Exemptions from Records and Reports Requirements

Section 1002.50 states that a manufacturer can request an exemption from any records and reporting requirements listed in Table 1, but the request must specify each requirement from which an exemption is requested along with a justification and supporting documentation showing that the product does not pose a public health risk. The manufacturer must also ensure that their product meets at least one of the four criteria found in this section.

The Director, CDRH has the authority to deny or grant exemption requests from all or part of the provisions of Part 1002 provided they are in keeping with the purposes of the Act, and must provide written notification of it. Written notification of granted exemptions must include the product or products for which the exemption was granted, the requirements from which the product is exempted, and conditions of the exemption necessary to protect public health.

The Director may also exempt certain classes of products from the requirements found in Table 1, provided the exemption is in keeping with the purposes of the Act.

Manufacturers of electronic products for which there are no applicable performance standards are also exempt from records and reporting requirements if:

1) The product was granted clinical, investigational device exemption (IDE) under Section 812.30, or

2) The product is a medical device and was granted a premarket approval (PMA) in accordance with Section 814.449(d).

There are three sections of Subchapter J which discuss exemptions for manufacturers of products intended for the U.S. Government. Section 1002.1(c)(3) states that the requirements of Part 1002 as specified in Table 1 of that section are *not applicable* to manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

Section 1002.51 states that a manufacturer may be granted an exemption from the records and reporting requirements for an electronic product intended for sole or predominant use by departments or agencies of the US government with prescribed procurement provisions which govern product radiation emissions.

Section 1010.5 specifically exempts electronic products or classes of products from provisions of performance standards for electronic products intended for use by departments or agencies of the United States. The exemption may be granted to manufacturers, but is typically granted to U.S. Government departments or agencies, who then administer this exemption to their vendors. This will be discussed in more detail in Part 1010.

# PART 1002 RECORDS AND REPORTS

## Subpart A—General Provisions

***Sec. 1002.1 Applicability.***

The provisions of this part are applicable as follows:

(a) All manufacturers of electronic products are subject to 1002.20.

(b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions of part 1002 as set forth in Table 1 of this section, unless excluded by paragraph (c) of this section, or unless an ***exemption*** has been granted under 1002.50 or 1002.51.

## Subpart F – Exemptions From Records and Reports Requirements

***Sec. 1002.50 Special exemptions.***

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in table 1 of 1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Center for Devices and Radiological Health, Office of Communication, Education, and Radiation Programs (HFZ-240), 9200 Corporate Blvd., Rockville, MD 20850.*

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in table 1 of 1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the Act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under 812.30 of this chapter or for which a premarket approval application has been approved in accordance with 814.44(d) of this chapter are exempt from submitting all reports listed in table 1 of 1002.1.

***Sec. 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.***

Upon application therefore by the manufacturer, the Director, Center for Devices and Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

* The Center for Devices and Radiological Health, Office of Communication, Education, and Radiation Programs is now located at 10903 New Hampshire Avenue, Silver Spring, MD 20993

# 21 CFR Chapter I, Sub-Chapter J -- Radiological Health
# Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1003 NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

**SUMMARY:**

Subpart B—Discovery of Defect or Failure to Comply

If the Secretary, DHHS determines that an electronic product fails to comply with 21 CFR or has a defect, he or she shall immediately notify the manufacturer in writing detailing the nature of the discovery and the methods used to detect it. The manufacturer may present its views and evidence to rebut the notice, and will also be given an opportunity for a regulatory hearing on the matter.

Upon receiving the notice, the manufacturer must provide production and distribution numbers of the products in question. If after the time period specified by the notice the Secretary finds that the manufacturer is still not in compliance with 21 CFR or there is a defect, the manufacturer must notify affected people as per Section 1003.21 in 14 days unless the manufacturer has applied for an exemption from the time period specified in notification.

Subpart D – Exemptions From Notification Requirements

The Secretary may exempt a manufacturer from the original time period to present its views and present evidence in rebuttal to the notification if he or she finds that the application for a time extension is based on reasonable grounds.

If within the time extension the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing.

## PART 1003 NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

### Subpart B—Discovery of Defect or Failure to Comply

***Sec. 1003.11 Determination by Secretary that product fails to comply or has a defect.***

(a) If, the Secretary, through testing, inspection, research, or examination of reports or other data, determines that any electronic product does not comply with an applicable Federal standard issued pursuant to the Act or has a defect, he shall immediately notify the manufacturer of the product in writing specifying:

(1) The defect in the product or the manner in which the product fails to comply with the applicable Federal standard;

(2) The Secretary's findings, with references to the tests, inspections, studies, or reports upon which such findings are based;

(3) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

The manufacturer shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) Every manufacturer who receives a notice under paragraph (a) of this section shall immediately advise the Secretary in writing of the total number of such product units produced and the approximate number of such product units which have left the place of manufacture.

(c) If, after the expiration of the period of time specified in the notice, the Secretary determines that the product has a defect or does not comply with an applicable Federal standard and the manufacturer has not applied for an ***exemption***, he shall direct the manufacturer to furnish the notification to the persons specified in 1003.10(b) in the manner specified in 1003.21. The manufacturer shall within 14 days from the date of receipt of such directive furnish the required notification.

### Subpart D – ***Exemptions*** From Notification Requirements

***Sec. 1003.30 Application for exemption from notification requirements.***

(a) A manufacturer may at the time of giving the written confirmation required by 1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to 1003.11(a), apply for an ***exemption*** from the requirement of notice to the persons specified in 1003.10(b).

(b) The application for ***exemption*** shall contain the information required by 1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

***Sec. 1003.31 Granting the exemption.***

(a) If, in the judgment of the Secretary, the application filed pursuant to 1003.30 states reasonable grounds for an ***exemption*** from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with 56.104 or 56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

(c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an ***exemption*** from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

(1) The electronic product or products for which the ***exemption*** has been issued; and

(2) Such conditions as the Secretary deems necessary to protect the public health and safety.

(d) Any person who contests denial of an ***exemption*** shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

# 21 CFR Chapter I, Sub-Chapter J -- Radiological Health
# Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

**SUMMARY**:

Subpart A – General Provisions

This part describes the general performance standards for electronic products including manufacturer certification labeling of products and identification labeling of products, and instructions for determining the applicability and application for variances to the performance standards. Performance standards for specific types of electronic products are found in Parts 1020, 1030, 1040, and 1050 for ionizing radiation emitting products, microwave and radio frequency-emitting products, light-emitting products, and sonic, infrasonic, and ultrasonic radiation-emitting products; respectively.

Section 1010.5, describes the criteria, means, application procedures, and amendment procedures for obtaining exemptions for electronic products or class of products from the provisions of performance standards for electronic products intended for United States Government use. The Director, CDRH may grant exemptions from any performance standard under Subchapter J of Chapter I for an electronic product or a class of electronic products when he or she determines that they are intended for sole or predominant use by departments or agencies of the United States provided:

1) The procuring agency prescribes procurement specifications for the product or class of products governing emissions of electronic radiation and these products, or

2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

This section also recommends that the US Government department or agency which intends to procure or manufacture an electronic product which must deviate from FDA regulations or standards consult with CDRH about the exemption being sought as early as possible in the development of the specifications for the product. The application for exemption must be very specific and include certain applicable elements found in this section. Among those 13 elements is a time limit for the exemption. Should a time limit extension or an amendment to the exemption be necessary, these can be requested through a separate application process. Once the Director has granted an exemption, a written notice specifying the exemptions and all conditions or terms will be sent to the requesting department or agency. The department or agency will be the administrator of the exemption to the vendors. The Director also has the authority to amend or withdraw

any exemption whenever he or she determines that action is necessary to protect public health and communicated immediately to the department or agency holding the exemption. Any equipment covered by the exemption shall also bear a specific caution label or tag stating that the equipment has been granted an exemption from 21 CFR. See 1010.5(f) for specific language.

Subpart C--Exportation of Electronic Products

The performance standards of Part 1010 do not apply to electronic products intended solely for export, which meet all applicable requirements of the export country, and is properly labeled for export as per this section.

**GOVERNMENT EXEMPTION DISCUSSION**:

While government departments have been granted exemptions for laser products on a case by case basis, these will not be discussed in detail here. This discussion will provide examples of exemptions given to departments and agencies of the United States, which have resulted in these departments and agencies administering their own exemptions for a range of laser products. Laser industry notices which highlight key points as to their granting and enforcement will also be discussed.

Department of Defense Exemption. The first exemption granted by the Director of the Bureau of Radiological Health (predecessor to Center for Devices and Radiological Health) was under *1010.5 Exemptions for products intended for United States Government use*, and it was granted to the Department of Defense (DOD) in July 1976 (see Attachments 1 and 2). It is identified specifically as Exemption No. 76EL-01DOD and found in Policy Statement #9, which is currently disseminated to the laser industry as *FDA Notices to the Laser Industry No. 9, "Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products"* (see Attachment 3). The DOD exemption was from the provisions of 21 CFR 1040.10 and 1040.11, the laser performance standards and the provisions of 21 CFR 1002, records and reporting requirements. However, the exemption did not include 1002.20 Reporting of accidental radiation occurrences (ARO).

The basis for the request for exemption was due to labeling requirements of the laser, which did not lend themselves to DOD camouflage requirements or covert operations. The exemption was limited only to those laser products used for combat, combat training, and classified interests of national defense. The exemption would not apply to other laser products such as those used in classroom training, demonstrations, industrial operations, scientific investigations, and medical purposes. The Director also accepted the DOD laser user safety and control procedures as adequate.

Therefore, the exemption was granted with the following additional conditions:

1) DOD must establish monitoring procedures to assure that:

   a. Only laser products designed, purchased, made, and classified by the DOD for combat, combat training operations, or in the interests of national defense conform to conditions of the exemption,

   b. Permanent records will be maintained of the status of all exempted laser products, including their final disposition, and

   c. The exempted products will not be disposed of through excess or surplus property channels without advance authorization by the FDA,

2) DOD will provide an annual report to FDA summarizing the internal records maintained on the exempted products identifying types of laser products and manufacturers,

3) DOD procurement specifications for such exempted products will include the radiation safety provisions of 21 CFR 1040.10 and 1040.11 to the extent practical,

4) Any substantive amendments to the radiation safety and control procedures accepted by the Director will be submitted to the FDA for review,

5) All exempted products must be clearly identified either by a specific caution label or other means as found in Attachments 2 and 3, and that a list of products identified by other than the specified caution label be included in the annual report (from DOD) along with the alternate means and the bases for such alternate means.

The exemption may be withdrawn or amended if any of these terms are not adhered to or if other information becomes available indicating that the public's health and safety are not adequately protected from radiation emitted from exempted electronic products.

<u>DOD Exemption in Practice</u>. Five months later in December 1976, it became known to FDA that manufacturers of certain laser products for the DOD were claiming exemptions from 21 CFR 1410.10 and 1410.11 citing Policy Statement #9 (Attachment 3). Upon contacting the DOD, FDA learned that procedures for processing exemptions had not been implemented as of December 7, 1976 nor had DOD authorized an exemption for any laser product.

Therefore, FDA issued Policy Statement #15, which is currently disseminated to the laser industry as *FDA Notices to the Laser Industry No. 15, "Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products"* (see Attachment 4). In this statement, manufacturers were instructed to secure a written confirmation of their exemption from the DOD along with terms of the

exemption for their specific laser products. All non-exempted laser products manufactured on or after August 2, 1976 had to be certified by their manufacturers in compliance with 21 CFR 1040.10 and 1040.11. Manufacturers in violation of these requirements may have been subjected to penalties described by Section 360C (most likely updated to Section 303) of the Act. The statement also ordered that the introduction of all military laser products into general commerce which were not in compliance with the Federal standard be terminated immediately until an exemption authorization was secured from DOD.

DOD Exemption Amendment. In January 1986, DOD requested an amendment to exemption 76EL-01DOD, which would eliminate the annual report requirement. At the time the exemption was granted, the performance standard for light-emitting products (Section 1040) had not yet been in effect, and the Director retained the annual report requirement as a prudent measure to assure public health without being able to reasonably foresee the magnitude of potential problems and challenges associated with the performance standard.

After 10 years of experience administering these regulations and receiving 9 annual reports from DOD, the Director decided that annual reports were no longer needed as a monitoring tool and revoked the annual report requirement effective September 1, 1985. However, while annual reports were no longer required, the information contained in the annual reports must still be collected and maintained, as this information may be requested by FDA to verify manufacturer DOD exemption claims (See Attachment 5).

2002 DOD Exemption Guidance. In July 2002, a guidance document was written to laser manufacturers regarding DOD exemption 76EL01DOD and was disseminated to the laser industry as *FDA Notices to the Laser Industry No. 52, "Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products (Guidance for Industry and FDA"* (see Attachment 6). The purpose of this guidance document was to clarify and update the conditions for the DOD guidance procured for combat or combat training, or that are for reasons of national security. This guidance was directed specifically to manufacturers regarding the DOD exemption, supplements Laser Notices #9 and #15, and identifies the current military services resources for the administration of this exemption.

The coordinating group for laser safety issues within the DOD is the Laser Systems Safety Working Group (LSSWG). The LSSWG was concerned that laser products were offered to various DOD purchasing authorities and procured without appropriate control measures implemented to assure the safest possible use.

The guidance consists of three basic precepts:

1) Manufacturers must obtain an exemption letter from an authorized DOD procurement office and retain it for subsequent sales.

2) Any subsequent modification to a military exempt laser product by the manufacturer requires a new DOD exemption letter. Any manufacturer selling a product that is not FDA compliant to the DOD or falsely labels a laser product as exempt without a DOD exemption letter is in violation of Federal law; and

3) Once the DOD exemption is applied to a laser system, the system cannot be sold, surplused, or distributed to organizations outside the DOD, unless it fully complies with FDA regulations in 21 CFR.

DOE and NOAA Exemptions. Robert Britain, Director of Compliance, Bureau of Radiological Health approved an exemption for the Department of Energy (DOE) in 1978 and the National Oceanic and Atmospheric Administration (NOAA) in 1979 under Section 1010.5. These exemptions were identified specifically as Nos. 78EL-01DOE, and 79EL-01NOAA for DOE and NOAA, respectively. Both exemptions were the subject of Policy Statement #25, which was disseminated as a memorandum to the laser industry as *FDA Notices to the Laser Industry No. 25, "Exemption of Certain Laser Products Used Exclusively by the Department of Energy or Its Contractors, and by the National Oceanic and Atmospheric Administration, U.S. Department of Commerce"* (see Attachment 7). These exemptions are for exclusive use by NOAA and DOE or its contractors at DOE designated, government-owned, contractor-operated facilities in unique research applications or as components in larger research and development systems. The exemptions are from the provisions of the laser products performance standard, 21 CFR 1040.10 and 1040.11 and associated reporting and recordkeeping requirements of 21 CFR 1002 with the exception of 1002.20 relating to accidental radiation occurrences.

As conditions of the exemptions, all exempted products are to be clearly identified by legible labels or inscriptions upon final assembly as per wording set forth in the exemption letter. Additionally, DOE and NOAA will report annually to FDA on the type of devices procured under the exemption and their manufacturers. Finally, the exemption may be withdrawn or amended if any of the terms of the agreement between FDA and these agencies are not adhered to.

**GOVERNMENT EXEMPTION CONCLUSION**:

Exemptions have been granted to the Government departments and agencies who requested them under 1010.5, and DOD, DOE, and NOAA became the administrators of their exemptions to the vendors from whom electronic products would be procured. The DOD exemption letter is readily available, and it outlines the conditions under which their exemption is granted. Laser Notices 9, 15, and 52 communicate information about the DOD exemption and how it affects manufacturers. Similarly, Laser Notice 25 communicates updated information about the DOE and NOAA exemptions to manufacturers.

One item missing from both the DOD exemption request letter and the FDA letter granting the exemption was the period of time the exemption was to be in effect, but the inference from the letter was that it would be indefinite.

Evidence to date states that all original exemptions contain language requiring these Government agencies and departments to furnish annual reports summarizing the internal records maintained on the exempted products, identifying types of laser products and manufacturers (including those manufactured by the government departments and agencies) as well as a list of those products which are identified by means other than the label and wording specified by the exemption, and if different, information that forms the basis for different means of identification. Additionally, any substantive amendments to the radiation safety procedures enclosed in the exemption request letter must be submitted to FDA for review.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Subpart A – General Provisions

***Sec. 1010.5 Exemptions for products intended for United States Government use.***

(a)Criteria for ***exemption***. Upon application by a manufacturer (including assembler) or by a U.S. department or agency, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an ***exemption*** from any performance standard under subchapter J of this chapter for an electronic product, or class of products, otherwise subject to such standard when he determines that such electronic product or class is intended for use by departments or agencies of the United States and meets the criteria set forth in paragraph (a) (1) or (2) of this section.

(1) The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class shall be of a type used solely or predominantly by a department or agency of the United States.

(2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

(b)Consultation between the procuring agency and the Food and Drug Administration. The United States department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this subchapter should consult with the Center for Devices and Radiological Health, Food and Drug Administration, whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Center for Devices and Radiological Health if it desires to be notified of the approval, amendment, or withdrawal of the ***exemption***.

(c)Application for ***exemption***. If you are submitting an application for ***exemption***, or for amendment or extension thereof, you must submit an original and two copies to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For an ***exemption*** under the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (c)(13) of this section. For an ***exemption*** under the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (c)(13) of this section. An application for ***exemption***, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Division of Dockets Management, except for

confidential or proprietary information submitted in accordance with part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated in this paragraph, the application for ***exemption*** shall include the following:

(1) The procurement specifications for the product or class of products that govern emissions of electronic product radiation.

(2) Evidence that the product or class of products is of a type used solely or predominantly by departments or agencies of the United States.

(3) Evidence that such product or class of products is intended for use by a department or agency of the United States.

(4) A description of the product or class of products and its intended use.

(5) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(6) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard.

(7) An explanation of the advantages to be derived from such deviation.

(8) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard.

(9) The period of time it is desired that the ***exemption*** be in effect, and, if appropriate, the number of units to be manufactured under the ***exemption***.

(10) The name, address, and telephone number of the manufacturer or his agent.

(11) The name, address, and telephone number of the appropriate office of the United States department or agency purchasing the product or class of products.

(12) Such other information required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application. Where such information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that each study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. When such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, either a statement that each

investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with 56.104 or 56.105 and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

(13) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d)Amendment or extension of an ***exemption***. An ***exemption*** is granted on the basis of the information contained in the original application. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the ***exemption***. He also shall submit a request for extension of the ***exemption***, if needed, at least 60 days before the expiration date. The application for amendment or extension of an ***exemption*** shall include the following information:

(1) The ***exemption*** number and expiration date.

(2) The amendment or extension requested and basis for the amendment or extension.

(3) If the radiation safety specifications for the product or class of products or the product's or class of products' use or related radiation control procedures differ from the description provided in the original application, a description of such changes.

(e)Ruling on an application.

(1) The Director, Center for Devices and Radiological Health, may grant an ***exemption*** including in the written notice of ***exemption*** such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his action. The conditions or terms of the ***exemption*** may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus ***exempted*** product of class of products as provided in the Code of Federal Regulations, title 41, subtitle C. Each ***exemption*** will be assigned an identifying number.

(2) The Director, Center for Devices and Radiological Health, shall amend or withdraw an ***exemption*** whenever he determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this subchapter. Such action shall become effective on the date specified in the written notice of the action sent to the applicant, except that it shall become effective immediately when

the Director determines that it is necessary to prevent an imminent health hazard.

(f)Identification of equipment covered by ***exemption***. The manufacturer of any product for which an ***exemption*** is granted shall provide the following identification in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the ***exemption***:

Caution
This electronic product has been ***exempted*** from Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, title 21, chapter I, subchapter J, pursuant to ***Exemption*** No. ___, granted on _____

## Subpart C--Exportation of Electronic Products

***Sec. 1010.20 Electronic products intended for export.***

The performance standards prescribed in this subchapter ***shall not apply*** to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

# 21 CFR Chapter I, Sub-Chapter J -- Radiological Health
# Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1020 – PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

**SUMMARY**:

Sec. 1020.30 Diagnostic x-ray systems and their major components.

(q) Modification of certified diagnostic x-ray components and systems.

Certified diagnostic x-ray comp components and systems in accordance with 1010.2 of this chapter may only be modified if a variance has been granted or an exemption under Section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) has been granted (see Attachment 8).

Sec. 1020.31 Radiographic equipment.

This exemption is for radiation therapy simulation systems from the visual definition requirement of this section.

Sec. 1020.32 Fluoroscopic equipment.

(a)Primary protective barrier

Radiation therapy simulation systems shall be exempt from the limitation of useful beam requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information, and the manufacturer provides precautions concerning the importance of remote control operation to users.

(d)Air kerma rates.

Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this section.

PART 1020 – PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

***Sec. 1020.30 Diagnostic x-ray systems and their major components.***

(q)*Modification of certified diagnostic x-ray components and systems*.

(1) Diagnostic x-ray components and systems certified in accordance with 1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with 1010.4 of this chapter or an ***exemption*** under section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

***Sec. 1020.31 Radiographic equipment.***

The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

(d)*Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems*. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

2)*Visual definition*.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are ***exempt*** from this requirement.

***Sec. 1020.32 Fluoroscopic equipment.***

The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a)Primary protective barrier –

(1)Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the

attenuation block in the useful beam combined with radiation from the fluoroscopic image receptor shall not exceed 3.34*10-3percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be ***exempt*** from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in 1020.30(g). Additionally, the manufacturer shall provide to users, under 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(d)*Air kerma rates*. For fluoroscopic equipment, the following requirements apply:

(4)***Exemptions***. Fluoroscopic radiation therapy simulation systems are ***exempt*** from the requirements set forth in paragraph (d) of this section.

# 21 CFR Chapter I, Sub-Chapter J -- Radiological Health
# Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1030 – PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

**SUMMARY**:

Sec. 1030.10 Microwave ovens.

(c) Requirements

(6) Warning labels.

Upon application, the Director, CDRH may grant an exemption from one or more of the statements (radiation safety warnings) specified in this paragraph and it must be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s).

PART 1030 – PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

***Sec. 1030.10 Microwave ovens.***

(c)Requirements –

(6)Warning labels. Except as provided in paragraph (c)(6)(iv) of this section, microwave ovens shall have the following warning labels:

(iv) Upon application by a manufacturer, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an ***exemption*** from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such ***exemption*** shall be based upon a determination by the Director that the microwave oven model for which the ***exemption*** is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(a ) The specific microwave oven model(s) for which the ***exemption*** is sought.

(b ) The specific radiation safety warning(s) from which ***exemption*** is sought.

(c ) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave oven model(s).

(d ) Such other information and a sample of the applicable product if required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

# Attachment 1

## Request letter to Mr. John Villforth, Director Bureau of Radiological Health from George Marienthal, Deputy Assistant Secretary of Defense (Environment and Safety)

ASSISTANT SECRETARY OF DEFENSE

Mr. John Villforth 2 Jul 1976
Director
Bureau of Radiological Health
Rockville, Maryland 20852

Dear Mr. Villforth:

This is in response to 21 CFR Part 1010 rule changes that the Commissioner of the Food and Drug Administration proposed on September 4, 1974. The changes add a new section 1010.5 and provide for exemptions from standards for electronic products, primarily laser products.

Military laser products have special field-use considerations, such as weight, survivability, camouflage requirements, covert operations, which do not lend themselves to full compliance with all the standards promulgated under PL 90-602, Radiation Control for Health and Safety Act. In most instances, the specified defense mission requirements could not be satisfied if total compliance was accomplished.

I, therefore, propose that an exemption be granted for all military laser electronic products used exclusively by Department of Defense components and designed expressly for actual combat operations, combat training operations, and laser products classified in the interest of national defense. The exemption would not apply to laser products intended primarily for use in indoor classroom training and demonstration, industrial operations, scientific investigations, and medical laser products.

Because of the difficulties to achieve complete product safety with military hardware, the DoD components require proper laser user safety procedures in regulations and user guidance documents. Within the U.S. Army, they are: AR 40-5, Health and Environment, 25 September 1974; AR 40-46, Control of Health Hazards

from Lasers and Other High Intensity Optical Sources, 6 February 1974; TB MED 279, Control of Hazard to Health from Laser Radiation, 30 May 1975. The user guidance document for the U.S. Air Force is AF Manual 161-32, Laser Health Hazards Control, 20 April 1973. Those documents are enclosed. The ANSI 136. 1, 1973, American National Standard for Safe Use of Lasers, was adopted by the U.S. Navy. Additional control procedures include operator training in the safe use of tactical equipment, performing an in-depth hazard analysis of such equipment during various stages of its life cycle, as well as a hazard analysis of training and testing sites, and routine surveys of such equipment located at military installations.

The Department of Defense will establish monitoring procedures to assure that:

- Only products which meet criteria in the third paragraph of this letter will be procured or manufactured by the DoD pursuant to the requested exemption.

- The DoD will maintain a permanent record of the status of exempted laser products, including their ultimate disposition. The products will not be disposed through excess or surplus property channels without advance authorization by the FDA. All exempted products will be clearly identified, either by labeling as set forth below, or by other means.

CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. _____issued on _____. This product should not be used without adequate protective devices or procedures.

- Procurement specifications for such exempted products will include, to the extent practicable. the radiation safety provisions of the applicable Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are to be provided by the Department of Defense. Any substantive amendments to the radiation safety procedures will be submitted to the FDA for review.

The Department of Defense will provide an annual report to FDA summarizing the internal records maintained on the exempted products, identifying types of laser products and manufacturers. Reporting and record keeping requirements prescribed in 21 CFR Part 1002, except for paragraph 1002.20, should be waived by the FDA.

I appreciate the time that you and your staff spent to assist the DOD to resolve a potential problem area. It is most gratifying to see this spirit of interagency cooperation.

Sincerely,

/S/

George Marienthal
Deputy Assistant Secretary of Defense
(Environment and Safety)

Enclosures

# Attachment 2

## Response letter to George Marienthal, Deputy Assistant Secretary of Defense (Environment and Safety) from Mr. John Villforth, Director Bureau of Radiological Health

Mr. George Marienthal July 29, 1976
Deputy Assistant Secretary of Defense
Environment and Safety
Department of Defense
Washington, D.C. 20301

This letter will respond to your letter of July 2,1976, to the Director of the Bureau of Radiological Health of the Food and Drug Administration requesting an exemption from the FDA radiation safety performance standard for laser products (21 CFR §§ 1040.10 and 1040.11) which becomes effective on August 2, 1976.

Under the authority delegated to me by the Assistant Secretary for Health of the Department of Health, Education, and Welfare (21 CFR ~ 5.1), pursuant to sections 358 and 360B of the Public Health Service Act, as amended by the radiation Control for Health and Safety Act of 1968 (42 U.S.C. § 263f and 263j), I hereby exempt from the provisions of 21 CFR §§ 1040.10 and 1040.ll, and from the provisions of 21 CFR Part 1002 (except § l002.20), laser products that are used exclusively by Department of Defense components and that are designed for actual combat or combat training operations or are classified in the interest of national security.

It is my understanding that this exemption is necessary because laser products that are to be used by the military for the purposes stated above require capabilities which do not lend themselves to full compliance with all provisions of the laser standard promulgated under the Act. Your request for exemption acknowledges that in most instances the specified defense mission for which the products are intended could not be fulfilled if total compliance with the standard were required.

In recommending that your request for exemption be granted, the Bureau of Radiological Health considered the laser user safety and control proce¬dures utilized by the Department of Defense. These include: for the U.S. Army, AR 40-5, Health and Environment, 25 September 1974; AR 40-46, Control of Health Hazards from Lasers and Other High Intensity Optical Sources, 6 February 1974; TB MED 279, Control of Hazard to Health from Laser Radia¬tion, 30 May 1975; for the U.S. Air Force, AF Manual l6l-32, Laser Health Hazards Control, 20 April 1973; and for the U.S. Navy ANSI 136.1, 1973, American National Standard for Safe Use of Lasers. Additional control procedures utilized by the Department of Defense include: operator training in the safe use of tactical

equipment, performing an in-depth hazard analysis of such equipment during various stages of its life cycle, a hazard analysis of training and testing sites, and routine surveys of such equipment located at military installations.

The granting of this exemption is also based upon the understanding that the Department of Defense will establish monitoring procedures to assure that (1) only laser products designed expressly for actual combat opera¬tions or combat training operations and laser products classified in the interest of national defense will be procured or manufactured by the Department of Defense pursuant to the requested exemption, and (2) the Department of Defense will maintain a permanent record of the status of all exempted laser products, including their ultimate disposition. The products will not be disposed of through excess or surplus property channels without advance authorization by the FDA.

As a further condition of this exemption, the Department of Defense has also agreed to provide an annual report to FDA summarizing the internal records maintained on the exempted products, identifying types of laser products and manufacturers. Furthermore, Department of Defense procurement specifications for such exempted products will include, to the extent practicable, the radiation safety provisions of the applicable Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are to be provided by the Department of Defense. Any substantive amendments to the radiation safety procedures enclosed with your letter of July 2,1976 will be submitted to the FDA for review.

All exempted products are also to be clearly identified either by the label set forth below, or by other means;

CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. _____ issued on _____. This product should not be used without adequate protective devices or procedures.

We request, as a term of this exemption, that the Department of Defense list in the annual report to this Agency all exempted products which are identified by a means other than by the above label, and provide detailed information as to the alternative means of identification provided, and the bases for such alternative means of identification.

This exemption is granted upon the understanding that all of the above commitments, set forth in your letter of July 2. 1976, are fulfilled by the Department of Defense. The exemption may be withdrawn or amended if any of those terms are not adhered to, or if other information becomes available that indicates that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to this authorization.

This exemption shall be referred to as Exemption No. 76EL-OlDOD issued on July 26. 1976, and any correspondence concerning its implementation should be directed to the Director of the Bureau of Radiological Health. A copy of your July 2. 1976 letter requesting the exemption (with attachments) and this notice of approval will be filed in the FDA Public Records and Documents Center, Room 4-62, 5600 Fishers Lane, Rockville, MD.

We appreciate your cooperation in this matter.

Sincerely yours,

/S/

Sherwin Gardner
Acting Commissioner of Food and Drugs

# Attachment 3

## FDA Notices to the Laser Industry No. 9

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:4026-MA

AUG 23 1976

TO: ALL LASER PRODUCT MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products.

The purpose of this memorandum is to notify all laser product manufacturers of an exemption granted for all laser products which are manufactured after August 2, 1976, and used exclusively by DOD agencies, and which are designed for actual combat or combat training operations or are classified in the interest of national defense (Reference FDA Docket No. 76P-0335). The exemption does not apply to laser products intended primarily for use in indoor classroom training and demonstration, industrial operations, and scientific investigations; and medical laser products. The exemption is from the FDA performance standard for laser products in 21 CFR Part 1040.10 and 1040.11 and the associated reporting and record keeping requirements of 21 CFR Part 1002, except for paragraph 1002.20 relating to accidental radiation occurrences.

Mr. Sherwin Gardner, Acting Commissioner of Foods and Drugs, announced the exemption in a letter dated July 29, 1976, to Mr. George Marienthal, Deputy Assistant Secretary of Defense. The exemption was granted on the grounds that the special military requirements for such devices preclude full compliance with the FDA performance standard. However, DOD procurement specifications will prescribe compliance with the FDA standard to the extent practicable and will be supplemented with safety controls and procedures utilized by DOD. All exempted products are also to be clearly identified either by the label set forth below, or by other approved means:

"CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. 76EL-01DOD issued on July 26, 1976. This product should not be used without adequate protective devices or procedures."

In addition, DOD will restrict surplus disposal of these devices and report annually to FDA on the types of devices procured under the exemption, their manufacturers, and means of identification if different than the above label.

Policy Statement #9

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and Department of Defense are not adhered to, or if other information becomes available that indicates that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to this exemption.

Correspondence concerning the exemption should be directed to the Office of the Assistant Secretary of Defense (Installations and Logistics), Deputy Assistant Secretary of Defense for Environment and Safety, Pentagon Building, Washington, D.C. 20301; the office phone number is (703) 695-0221.

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

# Attachment 4

## FDA Notices to the Laser Industry No. 15

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

REF:DOC:9090 -MA

DEC 8 1976

TO: All Manufacturers and Potential Manufacturers of Laser Products.
SUBJECT: Exemption of Certain Military Laser Products From the FDA Radiation Safety Performance Standard for Laser Products.

A number of manufacturers of laser products for the Department of Defense have informed representatives of the Food and Drug Administration that certain of their products are exempted from the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11. The basis for the exemption is stated to be the agreement of July 1976, between Mr. Sherwin Gardner, Acting Commissioner of the Food and Drug Administration and Mr. George Marienthal, Deputy Assistant Secretary of Defense, whereby an exemption from the performance standard for certain military laser products was granted to the DOD. However the Food and Drug Administration has contacted the Office of the Assistant Secretary of Defense (Installation and Logistics) and found that procedures for processing exemptions have not been implemented by the Department of Defense as of December 7, 1976, nor has DOD authorized an exemption for any laser product.

The exemption to the Department of Defense was granted on the grounds that the special military requirements for such products preclude full compliance with the FDA standard. In granting this exemption the Department of Defense agreed to establish procedures to assure that (1) only laser products designed expressly for actual combat operations or combat training operation and laser products classified in the interest of national defense will be procured or manufactured by the Department of Defense pursuant to the requested exemption, and (2) a permanent record of the status of all exempted laser products, including their ultimate disposition will be maintained. Furthermore, it was agreed that Department of Defense procurement specification for such exempted products are to include, to the extent practicable, the radiation safety provisions of the Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are provided by the Department of Defense.

Manufacturers of military laser products who have not secured in writing a confirmation of their exemption from the Department of Defense along with the terms of the exemption for their specific laser product will not be considered exempt by the Food and Drug Administration and therefore are required by the Radiation Control for Health and Safety Act of 1968, to furnish reports, maintain records on such products and to comply with performance standards as applicable. All laser products manufactured on or after August 2, 1976 and which have not been specifically exempted, must be certified by their manufacturers as in compliance with 21 CFR

1040.10 and 1040.11. Manufacturers who have violated these requirements may be subject to the penalties prescribed by Section 360C of the Act. Introduction of military laser products into commerce which are not certified as being in compliance with the Federal standard must be terminated immediately until an exemption authorization is secured from the Department of Defense.

Manufacturers of a laser product for the Department of Defense who believe their product is eligible for an exemption should contact their contracting officer, as soon as possible, or they may contact the Office of the Assistant Secretary of Defense (Installations and Logistics), Deputy Assistant Secretary of Defense for Environment and Safety, Pentagon Building, Washington, D.C. 20301; the office phone number is (202) 695-0221. The Department of Defense will then determine whether the product can be exempted and will inform the manufacturer in writing as to whether the exemption is authorized.

-/S/-

_____
Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health
Policy Statement #15

# Attachment 5

## Response letter to George W. Siebert, Director of Safety and Occupational Health Policy, Office of the Assistant Secretary of Defense from Mr. John Villforth, Director Center for Devices and Radiological Health regarding the elimination of annual report requirement

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville, MD 20857

Mar 18 1986

George W. Siebert
Director of Safety and
Occupational Health Policy
Office of the Assistant Secretary of Defense
Washington, D.C. 20301-4000 Ref. Doc.: 76EL-0IDoD

Dear Mr Siebert:

This letter is in response to your January 6, 1986 request for amendment of exemption 76EL-01DoD to eliminate the requirement for an annual report. Under this exemption, laser products which are intended to be used in combat or in training for combat were exempted, as necessary, from the performance standard for laser products as provided in 21 CFR 1010.5. These products were also exempted from the reporting requirements of 21 CFR 1002.10 and 1002.12 under the authority provided in 1002.51.

At the time this exemption was granted, the performance standard for laser products was not yet in effect, and the Agency could not reasonably anticipate the type or magnitude of problems which would be encountered, or the efficacy of the various mechanisms provided in the standard in addressing these problems. The Agency elected at that time to maintain what was considered the minimal regulatory position consistent with its responsibility for Public Health, and, therefore, the annual reporting requirements was retained. Now the Center has almost ten years of experience in administering these Regulations, and has received nine annual reports from your department. At this point in time, it is my judgment that these reports on exempted products are no longer needed as a monitoring tool.

Therefore, as provided by 21 CFR 1010.5(e) (2), the Department of Defense (DoD) exemption is hereby amended to revoke the requirement for an annual report. The effective date of this amendment is September 1, 1985. Please note that while DoD will no longer need to submit the subject annual reports, it will still be expected to maintain the types of records on which this report was based. This information may be requested when we need to confirm a manufacturer's claim that he is producing laser products for DoD procurement and that his products are indeed subject to exemption. Your continued close cooperation in providing pertinent information upon request is recognized and appreciated, and, of course, such requests will be limited to information which does not impact on national security.

I trust that this resolution of the issues satisfactorily addresses your concerns.

Sincerely yours,

/S/

John C. Villforth
Director
Center for Devices and
Radiological Health

# Attachment 6

## Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products (Laser Notice No. 52)

***This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.***

**Purpose**
This guidance clarifies and updates the conditions of FDA exemption no. 76EL-01DOD granted in 1976 to the U.S. Department of Defense (DOD) for laser products procured for combat or combat training or that are classified for reasons of national security. This guidance supplements Laser Notice Nos. 9 and 15 and identifies the current resources in the military services for the administration of this exemption.

**Issue**
The U.S. Department of Defense established a joint services group, the Laser Systems Safety Working Group (LSSWG), to coordinate laser safety issues within the DOD. The LSSWG requested FDA to reissue its earlier guidance to industry on the subject of the DOD exemption. The LSSWG request was based on a concern that laser products not in compliance with the FDA standard are offered to various DOD purchasing authorities and
procured without appropriate control measures implemented to assure the safest possible use.

**Background**
Laser products sold in or imported into the United States must comply with the Federal Performance Standard for Laser Products issued by the Food and Drug Ad ministration (FDA), Center for Devices and Radiological Health (CDRH), in Title 21, Code of Federal Regulations, Subchapter J, Parts 1040.10 and 1040.11[1]. The Federal Laser Standards require laser products to incorporate certain safety features, which may include warning lights, warning labels, and housing interlocks.

In 1976, the FDA Commissioner allowed the Department of Defense (DOD) or its components to exempt certain military laser products from the provisions of the Federal Laser Standard and associated reporting and recordkeeping requirements. This exemption applies to DOD lasers used for actual combat or combat training or those

[1] See 21 CFR 1040.10 (a) for details on the applicability of the FDA standard and exceptions from applicability.

classified in the interest of national security. The exemption was granted with the following provisions:

- Laser product specifications must include, to the extent practicable, the safety features required by the FDA standard;

- Laser product specifications will be supplemented with safety controls specified by DOD; and

- DOD exempted laser products will be clearly identified through labeling.

An example of how the DOD exemption may be applied is to exempt a military laser product from the FDA requirements for laser radiation emission indicators and warning labels. These visible or audible emission indicators and brightly-colored labeling are inappropriate for products intended for use in a combat environment where camouflage and concealment are necessary.

**The Least Burdensome Approach**

The issues identified in this guidance document represent those we believe need to be addressed before your product can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

**Guidance**

The manufacturer must obtain an exemption letter from an authorized DOD procuring agency to allow the use of the DOD exemption for a specific product. The manufacturer must obtain the DOD exemption letter prior to sale and retain it for subsequent sales to any DOD agency. Any subsequent modification to a "military exempt" laser product by the manufacturer requires a new DOD exemption letter. The DOD exemption letter may specify a number of units, an armed service, and/or a period of time. A manufacturer violates Federal law if it sells a laser system not in compliance with the FDA standard to the DOD or falsely labels a laser product as exempt without a written DOD exemption letter. Several laser system manufacturers market laser products that are labeled as "military exempt." Many of these systems lack written documentation of DOD exemption. An appropriate DOD laser safety representative must evaluate all "military exempt" laser products to determine compliance with relevant military or Federal requirements. Manufacturers of "military exempt" laser products should not assume the DOD exemption applies to its product unless DOD provides an exemption letter.
Once the DOD exemption is applied to a specific laser system, the system cannot be sold, surplused, or distributed to organizations outside the DOD, unless the laser system is

brought into full compliance with the FDA standard, certified, and reported in accordance with FDA regulations.

For further information on this process, contact an appropriate DOD laser safety representative.

US Army Center for Health Promotion and Preventive Medicine
ATTN: MCHB DC-OLO
Aberdeen Proving Ground, Maryland 21010-5422
Commercial (410) 436 3932

Naval Surface Warfare Center, Dahlgren Division
Code G73
17320 Dahlgren Road, Dahlgren, VA 22448-5100
Commercial (540) 653-1060/1149

Air Force Research Laboratory
Human Effectiveness Directorate; Optical Radiation Branch
Brooks City-Base, Texas 78235 5128
Commercial (210) 536 4784
Email: laser.safety@brooks.af.mil

**Getting More Information**
You can get more information about our requirements for lasers from our electronic product radiation control web page at http://www.fda.gov/cdrh/radhlth/.
If you have questions about this guidance, contact Jerome Dennis, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, FAX 301-594-4672, or e-mail jxd@cdrh.fda.gov.
Sincerely yours,
Phillip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and Radiological Health

# Attachment 7

## FDA Notices to the Laser Industry No. 25

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

SEP 14 1979

TO: ALL LASER PRODUCT MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption of Certain Laser Products Used Exclusively by the Department of Energy or Its Contractors, and by the National Oceanic and Atmospheric Administration, U.S. Department of Commerce

The purpose of this memorandum is to notify all laser product manufacturers of exemptions granted for laser products intended for U.S. Government use (21 CFR 1010.5). These laser products may not be the same as models that are certified and sold or leased commercially. They are to be used exclusively by (1) the National Oceanic and Atmospheric Administration, U.S. Department of Commerce or by (2) the Department of Energy or by its contractors at DOE designated, government-owned contractor-operated (GOCO) facilities in unique research applications or as components in larger research and development systems. The exemption is from the FDA performance standard for laser products, 21 CFR 1040.10 and 1040.11, and the associated reporting and recordkeeping requirements, 21 CFR Part 1002, except for paragraph 1002.20 relating to accidental radiation occurrences.

The exemptions were approved by the Director, Bureau of Radiological Health, by letters dated May 26, 1978, to Mr. James Liverman, Acting Assistant Secretary for Environment, Department of Energy and June 4, 1979 to Mr. Ferris Webster, Assistant Administrator for Research and Development, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

The exemptions apply to all Department of Energy and to all National Oceanic and Atmospheric Administration, U.S. Department of Commerce, contracts and sub-contracts. However, DOE and NOAA procurement specifications will prescribe compliance with the FDA standard to the extent practicable and will be supplemented with safety controls and procedures utilized by DOE and NOAA.

All exempted products are to be clearly identified by labels permanently affixed to or inscribed on each such product so as to be legible and readily accessible to view when each product is fully assembled for

Laser Policy Statement 25

operation. The labels shall contain the wordings set forth below for DOE and for NOAA respectively:

Department of Energy

CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchaper J, pursuant to Exemption No. 78EL-01DOE issued on May 26, 1978. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

National Oceanic & Atmospheric Administration:

CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, under Exemption No. 79EL-01 NOAA issued on June 4, 1979. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

In addition DOE and NOAA will report annually to FDA on the type of devices procured under the exemption, and their manufacturers.

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and these agencies are not adhered to, or if other information becomes available indicating that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to these exemptions.

Correspondence concerning the DOE exemption should be directed to Mr. Kenneth R. Baker, United States Department of Energy, MS E301 Washington, D.C. 20545; the office phone number is (202) 353-5615. Correspondence concerning the NOAA exemption should be directed to Dr. Freeman Hall, Chief of Coherent Lidar and Wave Propagation Laboratory, Environmental Research Laboratories, Boulder, Colorado 80303; the office phone number is (303) 499-1000 X6359.

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

# Attachment 8

## Federal Food, Drug, and Cosmetic Act
## Chapter V: Drugs and Devices; Sections 534(a)(5) and 538(b)

**SEC 534 [21 USC §360kk] Performance Standards for Electronic Products**

(a)(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

**SEC. 538. [21 USC §360oo] Prohibited Acts**

(a) It shall be unlawful—

> (1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 534;
>
> (2) for any person to fail to furnish any notification or other material or information required by section 535 or 537; or to fail to comply with the requirements of section 535(f);
>
> (3) for any person to fail or to refuse to establish or maintain records required by this subchapter or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 537;
>
> (4) for any person to fail or to refuse to make any report required pursuant to section 537(b) or to furnish or preserve any information required pursuant to section 537(f); or
>
> (5) for any person (A) to fail to issue a certification as required by section 534(h), or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a), upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

# Laser Safety

# Fundamentals, Concepts, & Standards

## ANSI Z136.6 – Safe Use of Lasers Outdoors

Robert Aldrich, LSS

# Uses of Lasers

- Engineers are always finding new ways of using lasers. Here is a list of just some of the uses:

| | | |
|---|---|---|
| Range Finder | Bomb Designator | Laser Radar (LIDAR) |
| CD Players | Surgery | Communication Systems |
| Welding | Anti-Missile Defense | Combat Simulation |
| Light Shows | Target Illumination | Non lethal weapons |

# Hazards from Lasers

- Lasers can transmit large amounts of energy great distances without the need of wires or other mediums
- Because laser energy is collimated, the eye can focus this energy to a small spot on the retina causing severe eye damage or even permanent blinding
- Lasers of sufficient energy or power can burn skin, start fires, or even destroy missiles.
- Even laser energy below the damage threshold can cause temporary effects that could be devastating (i.e. crash jet while attempting to land)

# Introduction

- Performing laser hazard calculations requires a high level of training and experience
- The scope of this topic is well beyond the capabilities of any 1-day lecture or workshop
- The purpose of these slides
  - Provide an understanding of hazard classification and hazard evaluation calculations
  - Explain principals involved in these calculations
  - Provide a reference for specialized study of these topics

# ANSI Z136.1 Standard

- American National Standard for the Safe Use of Lasers
- Maximum Permissible Exposure (MPE) limits for Hazard Classification & Evaluation
- Consensus Standard –

  Many Authors, Many Points of View
- Latest revision – Z136.1-2007

# Laser Safety Calculations

- Hazard Classification
  - Used to generalize the need for standard control measures
  - Based on the ability of the laser system
  - Determined by comparing accessible output of the laser to appropriate Accessible Emission Limits (AELs)
- Hazard Evaluation
  - Used to determine or mitigate the potential of laser hazards
  - Based on exposure potential

# Hazard Classification

- Range from Class 1 (not hazardous) to Class 4 (most hazardous)
- Lower-class lasers (< 3B) based on the potential to produce eye injury from direct viewing
- Class 3B & 4 lasers may also pose diffuse reflection hazards, produce skin hazards, or even start fires

# Class 1 Lasers

- Cannot exceed the Class 1 AEL for any expected exposure condition
- Poses no risk to eyes or skin
- Does not usually include Class 1M

# Class 1M Lasers

- Can only exceed the Class 1 AEL when viewed with optical aids
- Cannot exceed the Class 3B AEL when viewed with optical aids
- Poses no risk of injury to the skin or unaided eye
- May pose a risk of injury from an intrabeam viewing when viewed with optical aids
- "M" refers to magnifying optics

# Class 2 & Class 2M Lasers

- Limited to wavelengths that create the brightest visual response to the viewer ($0.4 \leq \lambda < 0.7\ \mu m$)
- Have the same restrictions and risks as Class 1 & 1M except they rely on the natural aversion of the eye to bright light
- Class 2 based on an exposure duration of no longer than 0.25 s
- Does not usually include Class 2M

# Class 3R Lasers

- Exceed applicable Class 1 or Class 2 AEL by no more than a factor of 5
- Do not pose skin hazard
- May pose small hazard to the eye for direct, intrabeam viewing
- Mitigation of the hazard is usually achieved via administrative control measures
- "R" refers to reduced requirements

# Class 3B Lasers

- Exceed the limits of lower hazard Classes
- Do NOT exceed the Class 3B AEL criteria
- Inherently hazardous for direct viewing, but unlikely to start fires, cause skin damage, or pose diffuse reflection hazards
- Definition similar to Class 3b in ANSI Z136.1-2000
- Lasers previously Class 3b are now Class 1M or 2M if they do not exceed the Class 1 or 2 AEL for unaided viewing)

# Class 4 Lasers

- Exceed the limits for all other hazard classes
- Pose significant hazards to both eye and skin
- May cause diffuse reflection hazards
- May start fires
- No upper limit (no Class 4 AEL)

# Limiting Aperture

- Limiting aperture diameter, $D_f$
  - Maximum diameter of a circle over which irradiance or radiant exposure can be averaged
  - Aperture values in Tables 8 and 9 of ANSI Z136.1
- Example – Retinal hazard ($0.4 \leq \lambda < 1.4\ \mu m$)
  - Conservative estimate of pupil is 0.7 cm
  - All power/energy entering pupil is focused onto retina
  - If beam size less than pupil, no additional hazard exists
- Logic – All beams smaller than $D_f$ pose same hazard, regardless of beam size (biologically equivalent)

# "Accessible"

- Used for hazard evaluation and hazard classification
- In this context, simply means "relevant"
- Maximum Permissible Exposure (MPE) levels are averaged over appropriate apertures to determine the relevant safety limits
- These limits are compared to the accessible laser output to determine relevant hazard potential
- Accessible laser output may consider the effects of transmission loss when using viewing aids

# Accessible Emission Limit (AEL)

- Used in Hazard Classification determination
- To determine AELs, the MPE is averaged over a limiting aperture
- Compared to the power or energy passing through this aperture at a specific measurement range from the laser
- Comparison usually done for unaided and telescopic viewing conditions

# AEL and MPE Determination

- Class 1, 2, and 3R AELs – based on the ability to produce injury (based on MPE)
- Maximum Permissible Exposure (MPE) is the safety exposure limit
- MPE – Irradiance ($W \cdot cm^{-2}$) or radiant exposure ($J \cdot cm^{-2}$)
- MPE determination based on tables and methods described in ANSI Z136.1-2007
- MPE is averaged over an aperture to determine AEL
- AEL – Power (W) or Energy (J)

# MPE Parameters

- Source Size
  - Ocular exposure for $0.4 \leq \lambda < 1.4$ µm (retinal hazard region only)
- Wavelength
- Exposure duration – dependant on:
  - Temporal profile of laser (pulse timing)
  - Length of exposure

# MPE – Ocular vs. Skin Exposure

- Largest difference between ocular and skin exposure
  - $0.4 \leq \lambda < 1.4$ µm (retinal hazard region)
- Ocular Exposure
  - Tables 5a and 5b of ANSI Z136.1
- Skin Exposure
  - Table 7 of ANSI Z136.1
- Exposure Considerations for MPEs
  - Section 8 of ANSI Z136.1

# Total Exposure Duration, $T_{max}$

- Limited by design or intended use (how long a person could be in the beam path)
- Single pulse lasers – $T_{max}$ equal to the pulse duration
- UV exposures – additive over hours or even days
- Non-UV, unintentional exposure – *typical assumptions*
  - $T_{max}$ = 0.25 s for $0.4 \leq \lambda < 0.7$ µm – ocular exposure
  - $T_{max}$ = 10 s for $\lambda < 0.7$ µm – ocular exposure
  - $T_{max}$ = 10 s for all skin exposures
- Lasers designed for intentional exposure or having an extended source may require larger values of $T_{MAX}$

# MPE – ANSI Rules

- "The MPE" is not an accurate term for many lasers
- To accommodate for different damage mechanisms, 3 MPE Rules were developed
- These Rules allow a laser to have several MPEs – depending on the time base of a potential exposure
- Example – A laser cannot be safe for a 0.25 s exposure if it is hazardous for a 10 ns exposure

# AEL – Class 1, 2, & 3R

## $AEL_1$, $AEL_2$, & $AEL_{3R}$ – Based on MPE limits

*Visible (0.4 ≤ λ < 0.7 μm) only!*

$$AEL_1 = MPE_{T_{\max}} \cdot \frac{D_f^{\,2} \cdot \pi}{4}$$

$$AEL_2 = MPE_{0.25s} \cdot \frac{D_f^{\,2} \cdot \pi}{4}$$

*Visible (0.4 ≤ λ < 0.7 μm) only!*

$$AEL_{3R} = 5 \times AEL_1 \quad or \quad AEL_{3R} = 5 \times AEL_2$$

# AEL – Class 3B

- Not based on MPE
- Dual limits - pulsed and CW criteria
- CW criteria
  - 500 mW averaged over 0.25 s
- Pulsed criteria
  - 125 mJ delivered in 0.25 s (same as 500 mW)
  - 30 x $C_A$ mJ per pulse ($0.40 \leq \lambda < 1.40$ µm only)

# Classification vs. Evaluation

- Hazard Classification based on laser output (ability to injure)
- Hazard Evaluation based on exposure potential (probability to injure)
- Both consider power or energy through a limiting aperture (accessible power or energy)
  - Also called effective power, $\Phi_f$, or effective energy, $Q_f$

# Effective Power or Energy

Effective Power or Effective Energy is simply the amount of Power or Energy that would pass through a limiting aperture, such as the pupil of the eye.

# Optical Density, $OD_\lambda$

- Within the NHZ, viewing of the laser while wearing laser eye protection (LEP) can mitigate the risk of injury
- $OD_\lambda$ is the minimum measure of eye protection necessary for safe viewing of a laser beam
- Base 10 logarithm of the ratio of the expected exposure compared to the appropriate safety limit
- $\Phi_{MPE}$ or $Q_{MPE}$ (based on $T_{max}$) is compared to effective power, $\Phi_f$, or effective energy, $Q_f$ to find $OD_\lambda$
- With the calculated $OD_\lambda$ of protection, exposure would be to that of a Class 1 (or Class 2) laser

# Optical Density, $OD_\lambda$

- Use of viewing aids changes effective power or energy, therefore not directly seen in equation for $OD_\lambda$
- $OD_{\lambda\text{-}max}$ assumes a condition where all power or energy is collected into the limiting aperture with no transmission loss
- $OD_\lambda$ can never be greater than $OD_{\lambda\text{-}max}$

# Atmospheric Attenuation, $\mu$

- Function of both atmospheric conditions and $\lambda$
- Assuming $\mu = 0$
  - Worst case for safety
  - Simplifies hazard distance calculations
  - Good assumption for r < 1 km at most common wavelengths or for high-altitude lasing at any range
- Common values used (horizontally) as exceptionally clear day
  - $\mu = 1\times10^{-6}$ cm$^{-1}$ for $0.4 \leq \lambda < 0.7$ µm
  - $\mu = 5\times10^{-7}$ cm$^{-1}$ for $0.7 \leq \lambda < 2.8$ µm
- See ANSI Z136.6, Tables C-1 & C-2 for more information

# Nominal Hazard Distance

- Nominal hazard distance is the maximum distance to which a person could be exposed at or above the MPE
  - For eyes – NOHD (Nominal Ocular HD)
  - For skin – NSHD (Nominal Skin HD)
- NOHD calculated for unaided and aided viewing conditions
- Determined by using $Q_{MPE}$ or $\Phi_{MPE}$ for the eye or skin

# Diffuse Hazards

- Diffuse reflections are non-directional, thereby making hazard distances relatively short
- Diffuse reflections can produce extended sources, making the hazardous diffuse viewing distance even shorter
- Lambert's Law shows that irradiance, *E*, or radiant exposure, *H*, at a given range, $r_1$, from a diffuse reflection (ignoring the size of the diffuse image) is found by:

$$H = \frac{\rho_\lambda \cdot Q \cdot cos(\theta_v)}{\pi \cdot r_1^2}$$

$$E = \frac{\rho_\lambda \cdot \Phi \cdot cos(\theta_v)}{\pi \cdot r_1^2}$$

**Worst case:**

$\rho_\lambda = 1$ (100%)

$\cos(\theta_v) = 1$ ($\theta_v = 0$)

where $\rho_\lambda$ is the normalized reflectance of the diffuse material and $\theta_v$ is the viewing angle.

# ANSI Z136.6 - Vision

- Revision to a well-established and well-recognized standard
- Build on the strengths of the document
- Focus on improving usability and consistency
- Update technical considerations
- Clarify topics of hazard classification, FAA & LCH coordination, visual interference zones, etc.
- Add definitions and index
- Minimize Manufacturer-Specific Control Measures

# Changes

- Single Column Format & Index
  - ANSI Z136 new Standard Practice
  - Improves Readability and Searchability
- Definition of "Control Measure"
  - Brings Consistency of Understanding
  - Explanation of Preferred Categories
- Control Measures
  - Recreated entire section – removing most Manufacturer-Specific requirements
  - Expanded Military-Specific section to be stand-alone.
    - Clearly explain Military Exemption requirements

# Changes (continued)

- Visual Interference [illegible] d Airports
  - Added Text Definitions for these Zones
- Standardizing Units
  - Wavelengths all in nm
  - All Units in Metric
  - SAE Units Provided When Helpful
    - "6.2 miles" now "10 km (6.2 miles)"
- FAA Coordination Requirements Clarified
  - FAA Non-Objection – SHALL – for FLPPS Variances
  - FAA Contact – SHOULD – for other Outdoor Use
- Laser Clearinghouse Coordination Clarified
  - Removed Threshold values and incorporated general guidance

# Changes (continued)

- Visual Interference Levels (general)
  - Allows Designation Related to Critical Tasks, not just Airspace Considerations
  - Treats as Generic Terms - Based on Associated Visual Interference Levels
  - When Considering Navigable Airspace, "Flight" Added to Term (e.g., "Critical Zone" Becomes "Critical Flight Zone")
- Philosophical Change to Term "Personnel"
  - "Personnel" Defined as Employees
  - "People" Used for General Term
- Figures Updated
  - Color Added where needed
  - IEC symbology incorporated

# Changes (continued)

- Laser Hazard Classification
  - Practical explanation Hazard Classes
  - Refers to ANSI Z136.1 for Definitions of Classes
  - Explains Purpose of Hazard Classification
    - Application of Common Control Measures
  - Added Classification Comparison Table
    - ANSI Z136.1-2000 verses ANSI Z136.1-2007
  - Allows Engineering Design to be Used to Determine Class (i.e., feedback interlocks)
- Clarified "Operator Controlled Laser"
- Clarified "Higher-Power Class 3B Laser"

# Changes (continued)

- Atmospheric Considerations
  - Attenuation as a Function of Elevation Angle
  - Scintillation Effects Considered
- Removed Old Sections 6 (Medical Exams & Surveillance) and 9 (Measurements and Instrumentation), defined "Military Specific" lasers and moved them to new Section 6.

# Schedule

- **Past Meetings**
  - 12 meetings in 4 years — Apr 2007 – current
- **Future**
  - SCDV — Apr 2011
  - Publish Third Edition — Dec 2012

# Optical radiation - An Overview of Biological Effects and Exposure Limits

David H Sliney, Ph.D.
Consulting Medical Physicist
Fallston, MD USA



## Two Types of Optical Sources

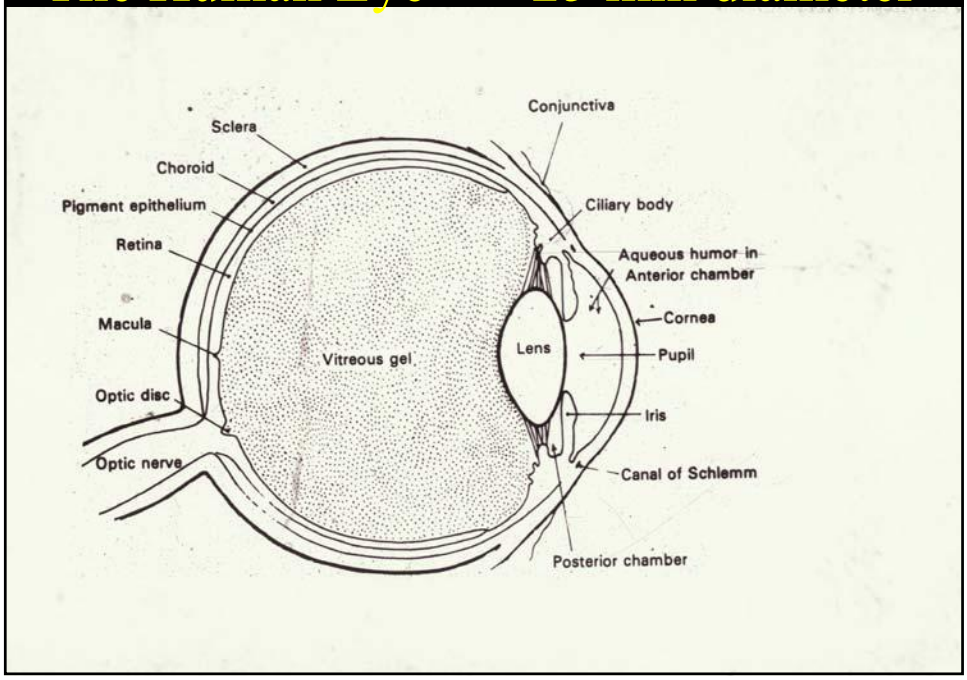
**Incoherent (Broad-Band) Sun, Lamps and Open Arcs**

- The sun—the environmental source for which humans have adapted
- Incandescent lamps and molten metals
- Gas discharge lamps (UV)
- Arc lamps
- Fluorescent lamps
- Broad-band, uncollimated
- Concern: lengthy exposure to ultraviolet or blue light

**Laser Sources (High Radiance)**

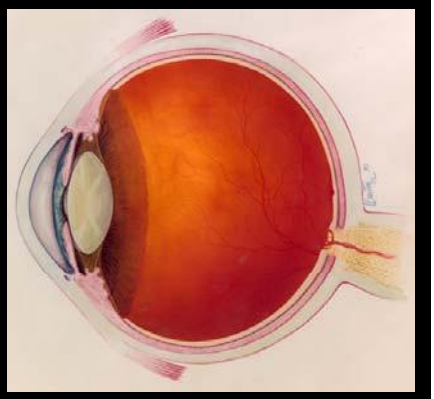
- Lasers—developed only a half-century ago (1960)
- Very high radiance—brighter than the sun or arcs
- Generally, highly collimated—energy at a distance a concern
- Sophisticated safety standards developed before lamp safety standards.
- Concern: pulsed laser thermal injuries.

# The Human Eye ~25 mm diameter




# The Ocular Media

- The transparent ocular media:
  - the cornea
  - the aqueous humor (water)
  - the crystalline lens
  - the vitreous humor (a gel)
- Largely non-scattering
- Transparent to light and IR-A
- Lens absorbs UV-A



2007 David.Sliney@att.net

# Why is a laser so hazardous?

- From optical physics, the answer is: "radiance"
  - …but what is that?
- Radiance is the physical quantity we know as "brightness"
- Even a 1-mW laser pointer is 10X brighter than the surface of the sun!
- It can therefore be focussed to an exquisitely small spot (as for surgery)…or within the eye!

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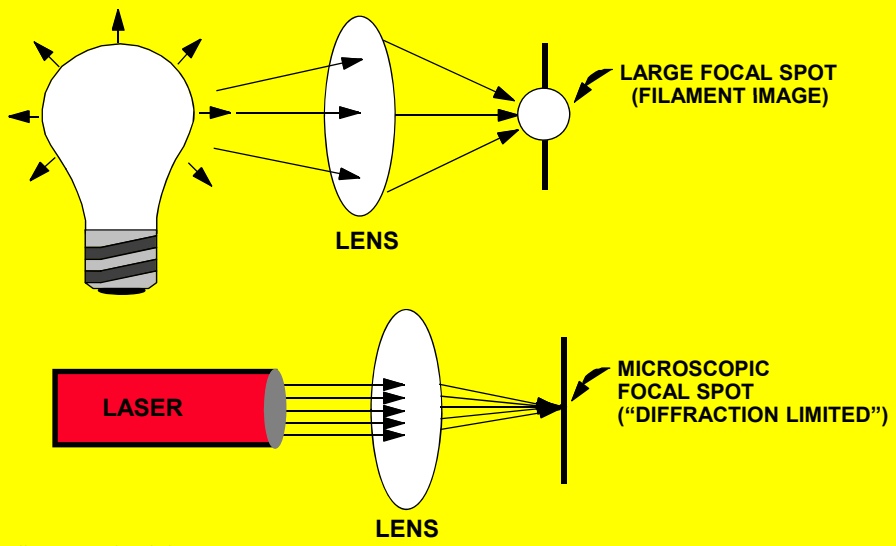
# Laser Brightness (Radiance)




From Sliney DH and Trokel, S, 1993

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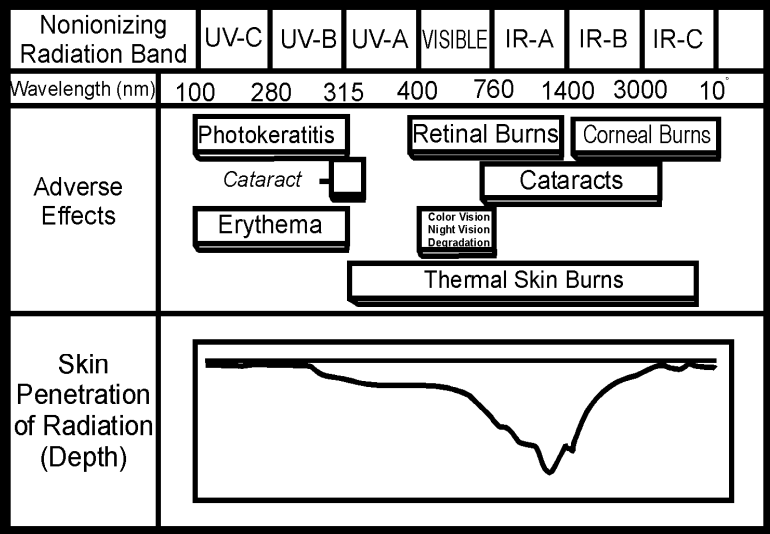
# The CIE Photobiological Spectral Bands

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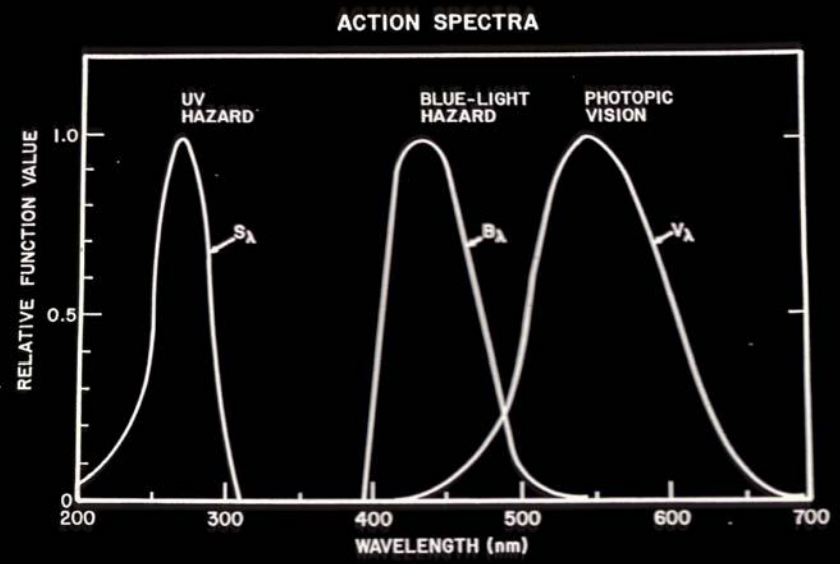
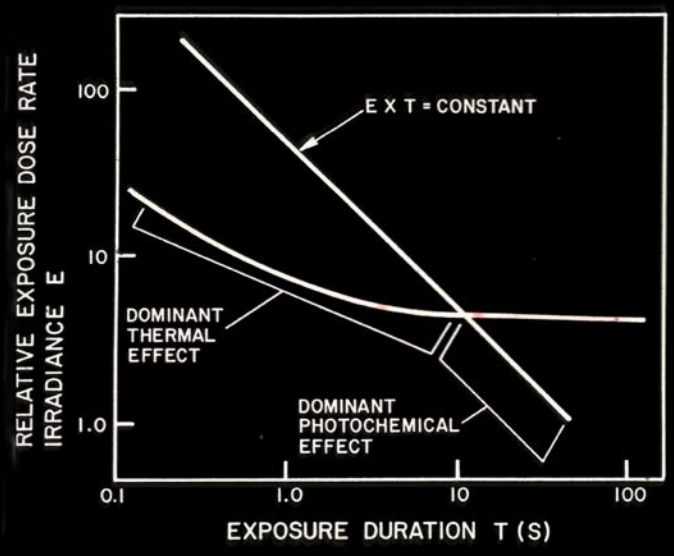
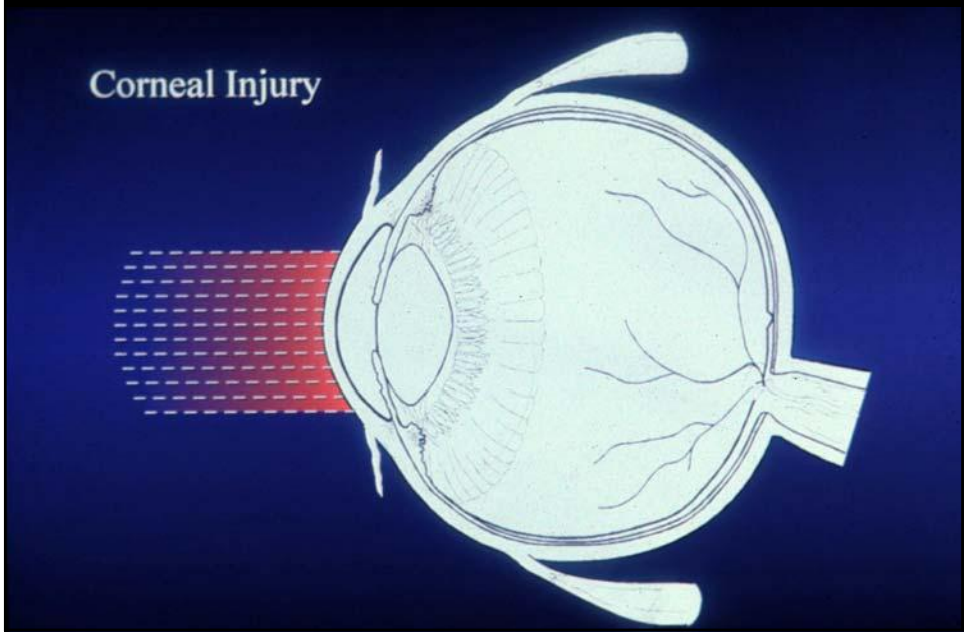
# Photochemical Damage Mechanisms

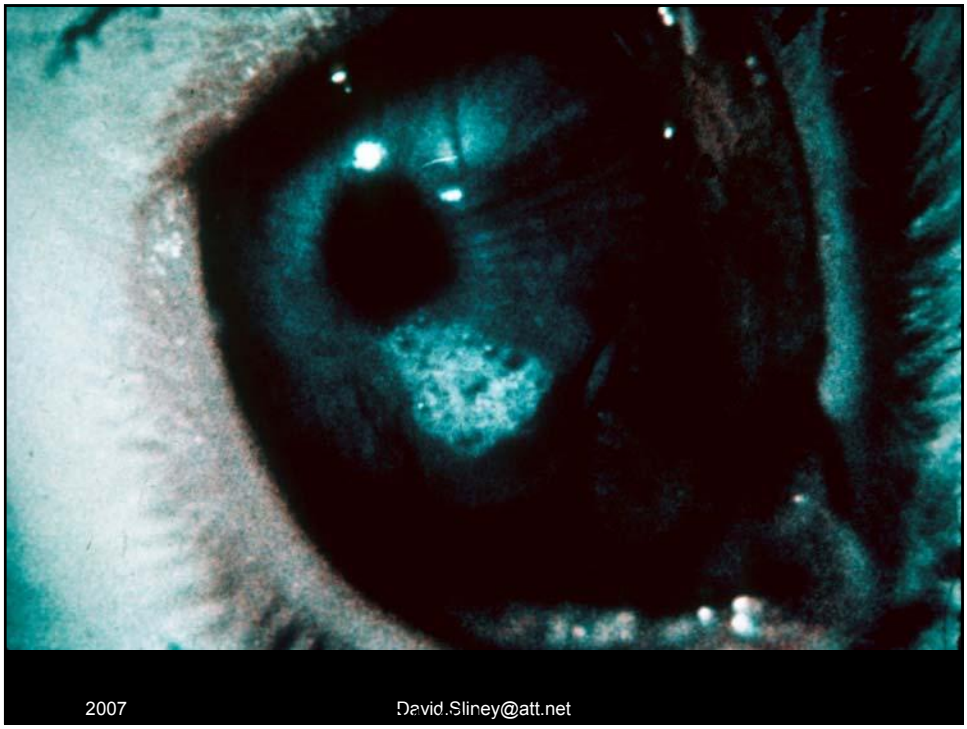


# Thermal and Photochemical Mechanisms




# Corneal Hazards: UV-B/C, IR-B, IR-C

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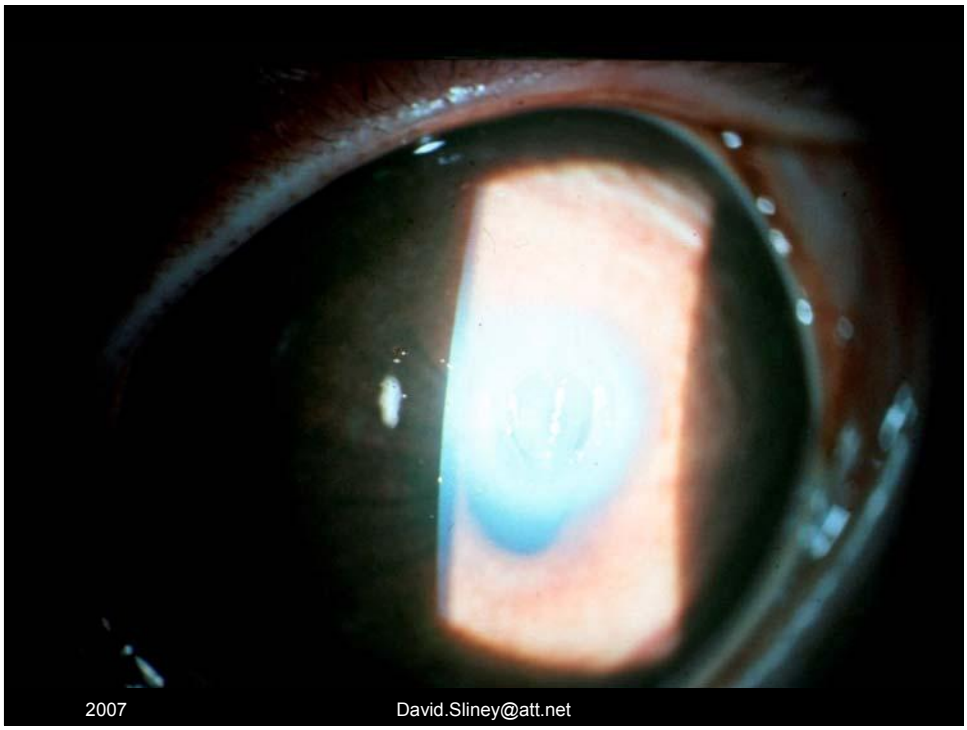
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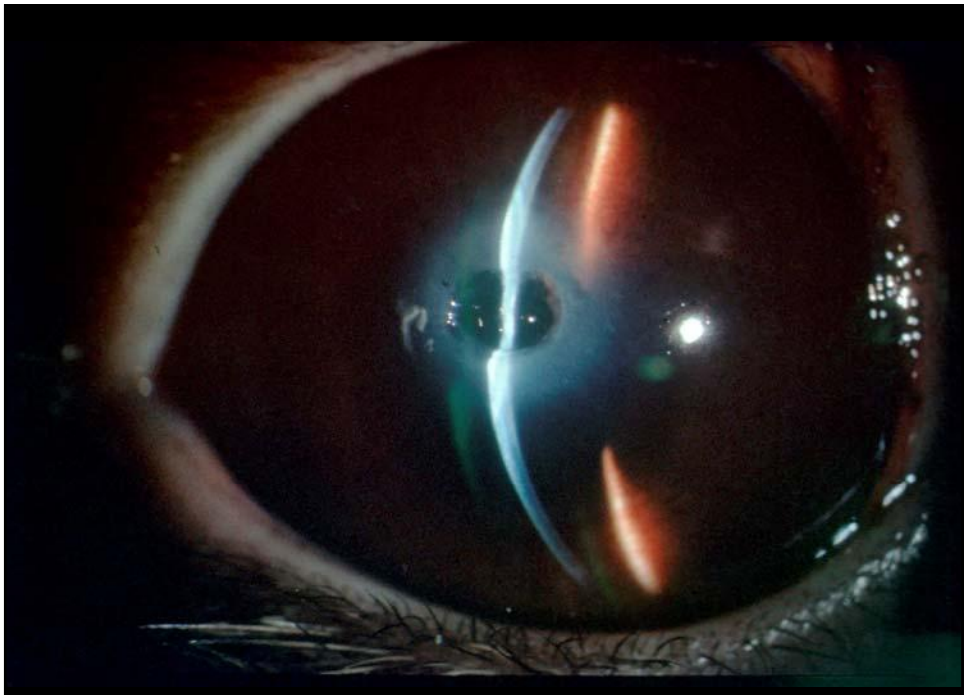
David.Sliney@att.net



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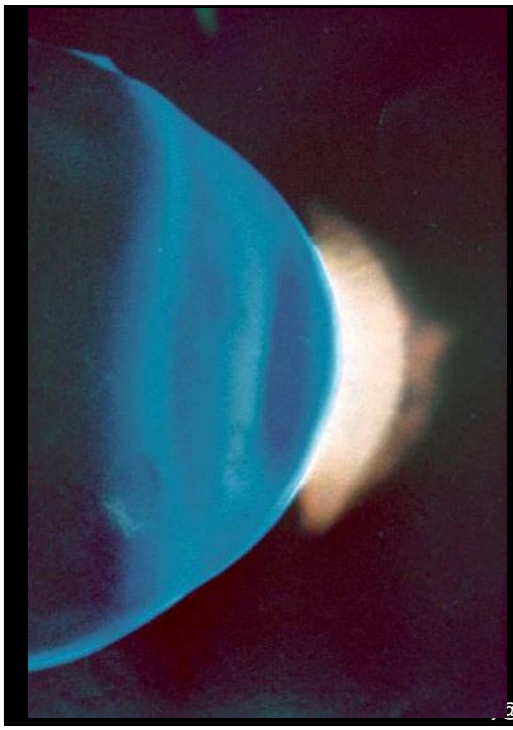
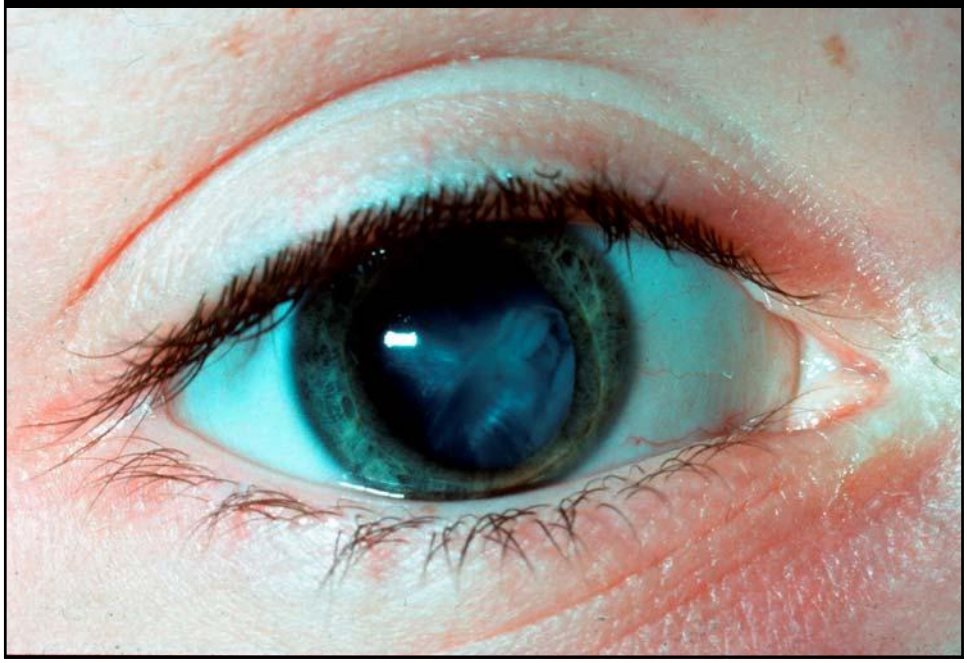


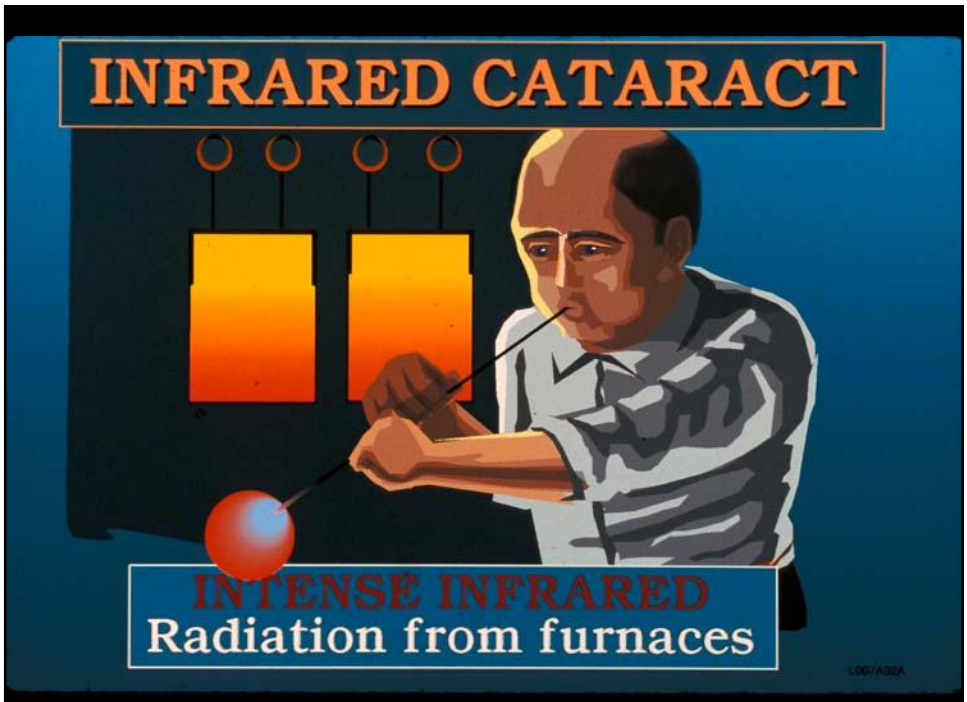
# Corneal Ablation

- Thermo-acoustic ablation is possible from pulsed far-infrared lasers
- Thermally assisted photochemical ablation at 193 nm is used in refractive surgery

@att.net

Cataract - More than 1 million cases in the USA / year



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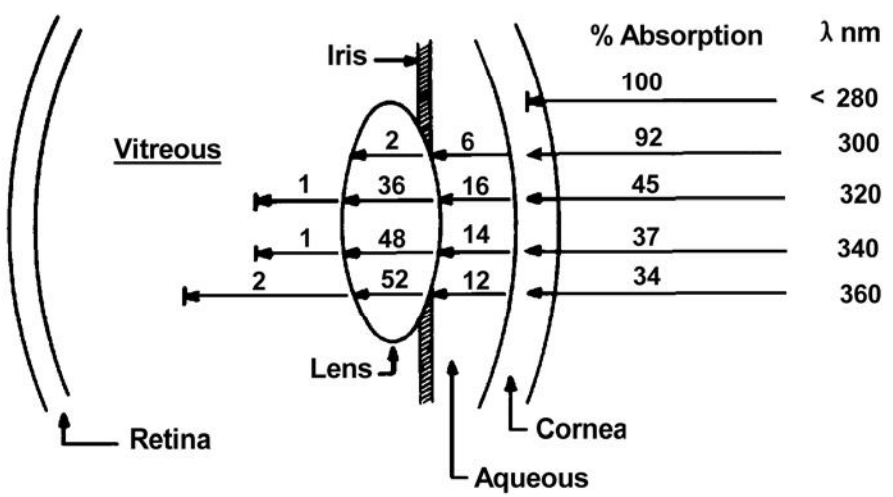
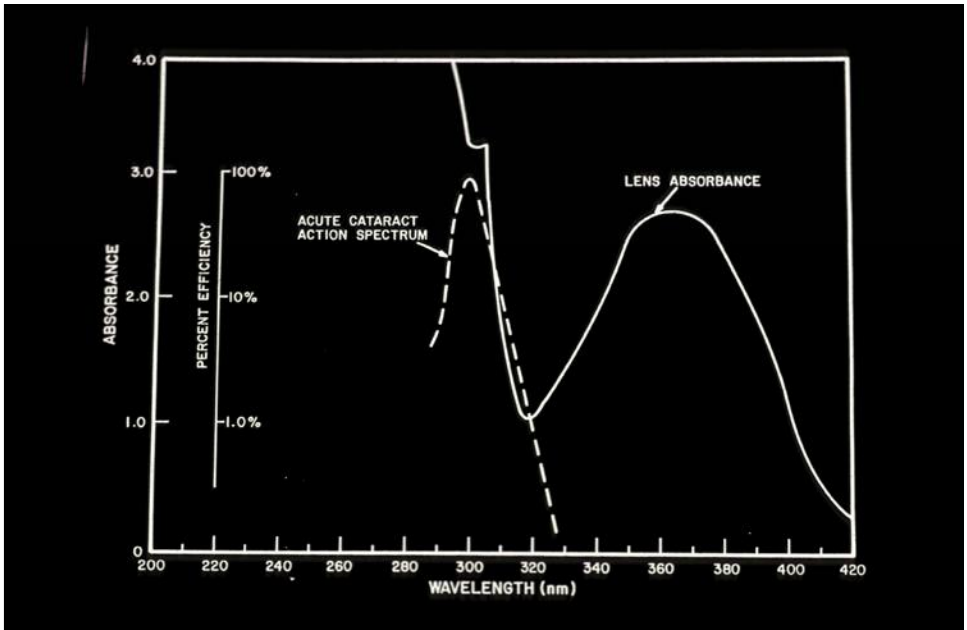
# Infrared Cataract

- IR-A and IR- B (780 nm - 3,000 nm)
- "Glassblower's Cataract" with exfoliation of the lens is now quite rare
- Work conditions were far more severe in 1800-1930 in hot industries
- Dr. Eva Lydahl (1984) showed a higher incidence of early onset of cataract in Swedish glass workers but not steel workers

2007 David.Sliney@att.net

# UV Spectral Absorption in Ocular Tissue






Action spectrum for cataract in an animal model--a 10 nm bandwidth

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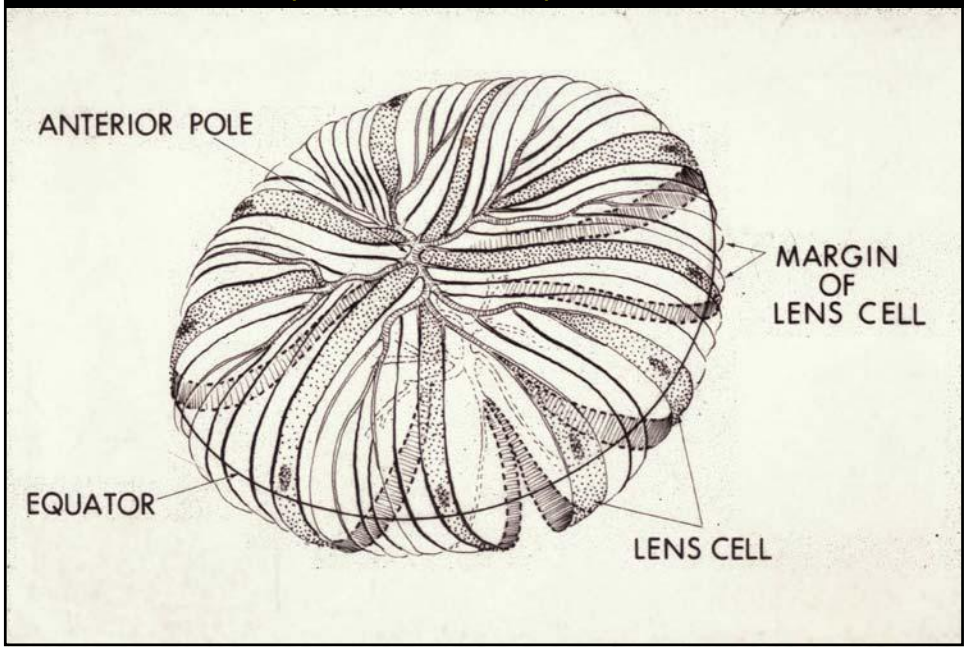
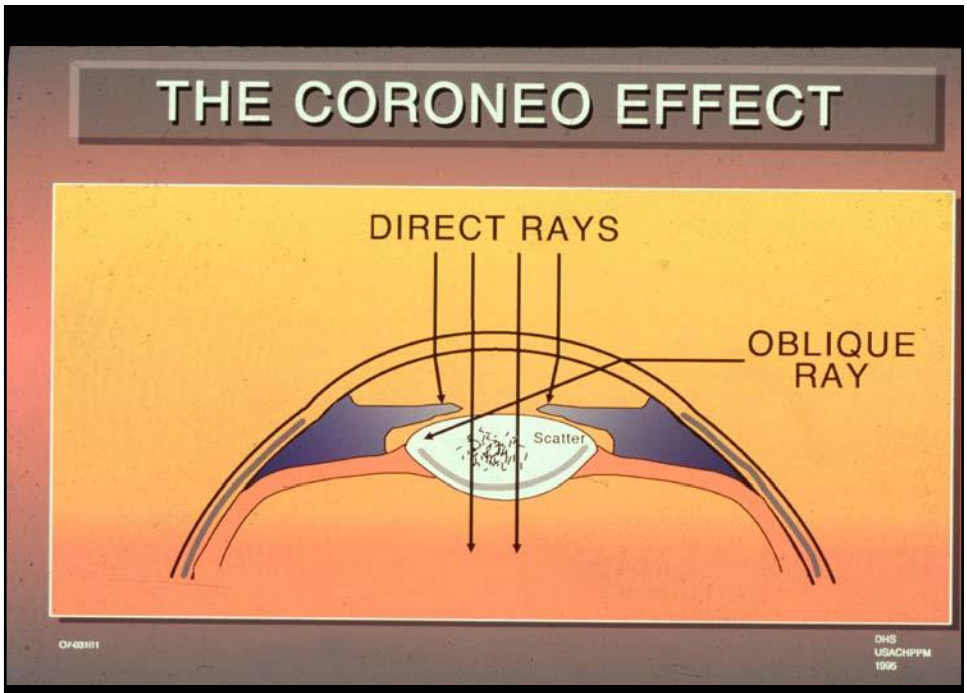
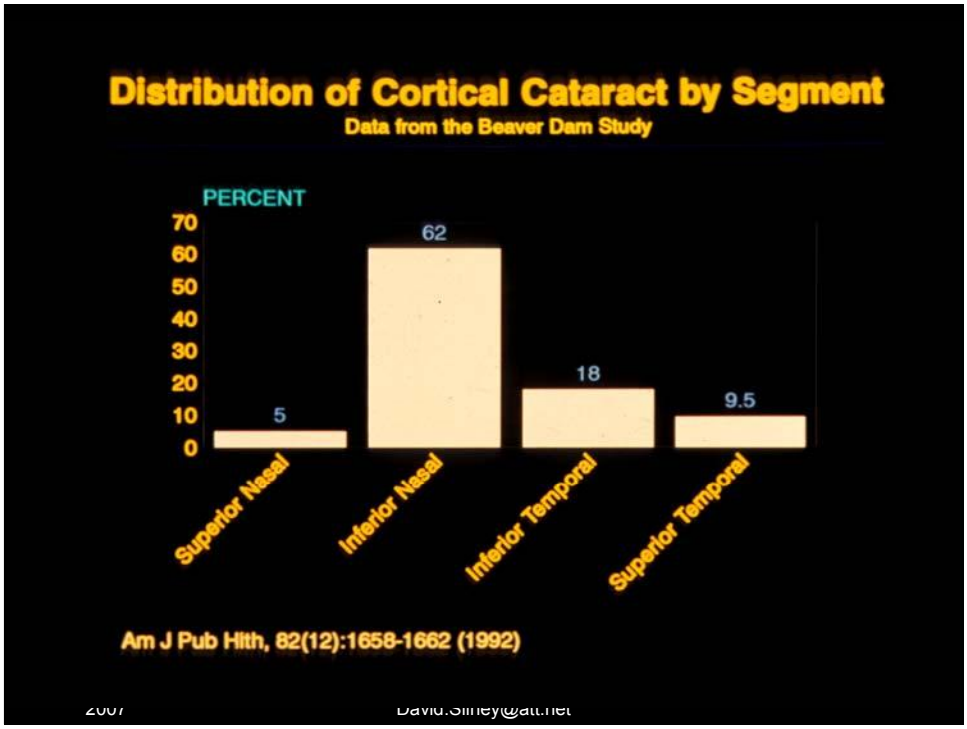
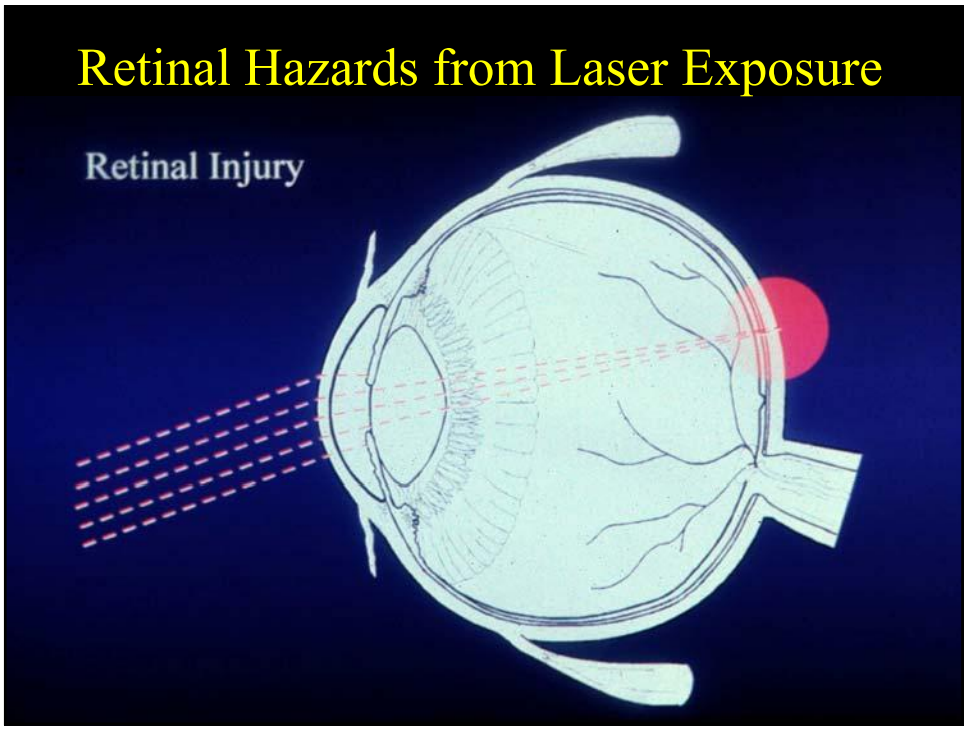
Anterior Segment of the Eye—The Protective Role of the Iris Melanin

# Anatomy of the Crystalline Lens

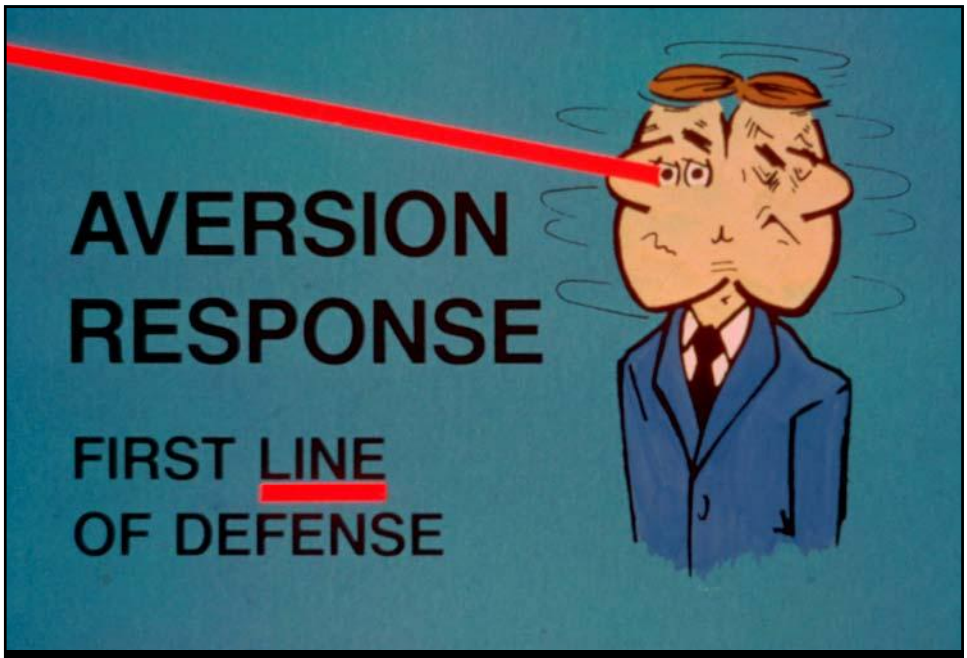


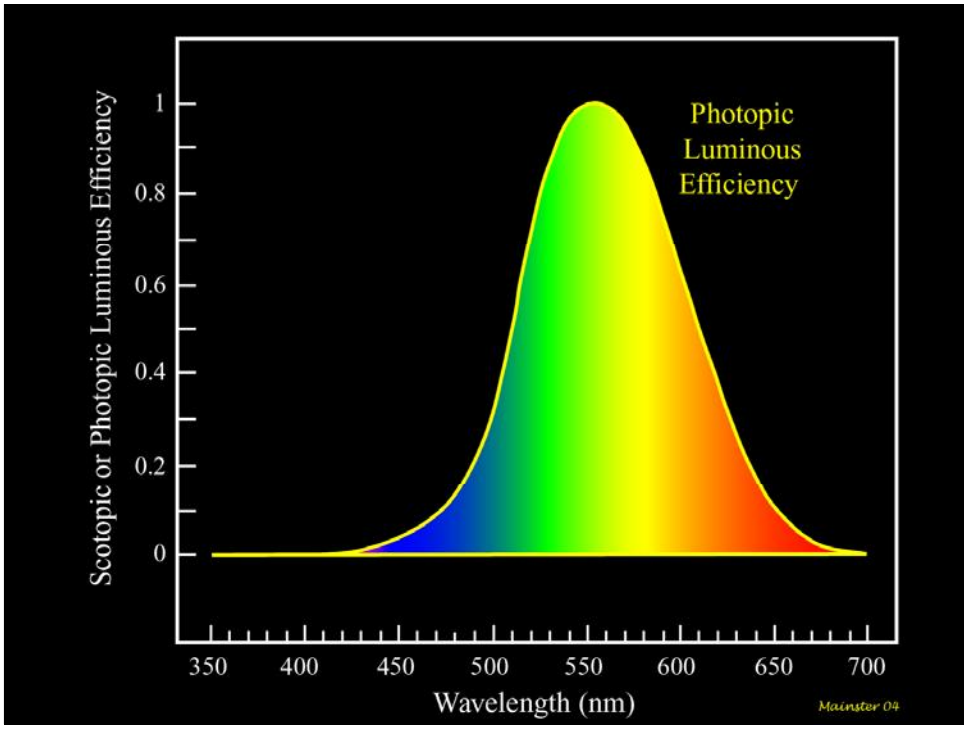

Distribution of Cortical Cataract by Segment
Data from the Beaver Dam Study
PERCENT
70
60
50
40
30
20
10
0
5
62
18
9.5
Superior Nasal
Inferior Nasal
Inferior Temporal
Superior Temporal
Am J Pub Hlth, 82(12):1658-1662 (1992)
2007
David.Sliney@att.net

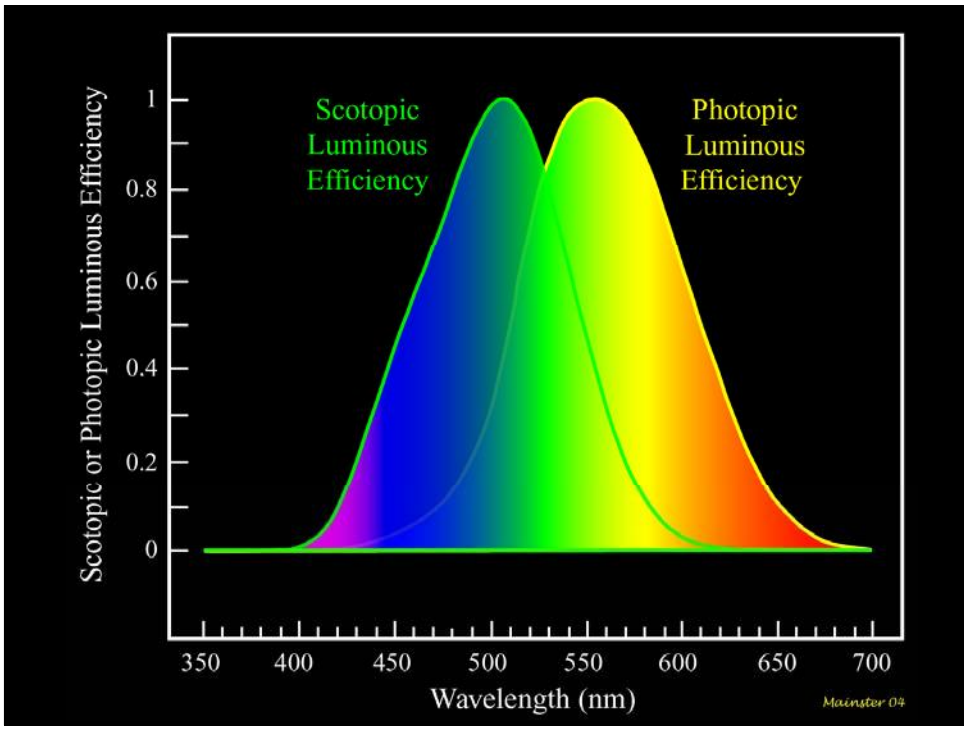

Retinal Hazards from Laser Exposure
Retinal Injury

# Intrabeam Viewing—The Minimal Image



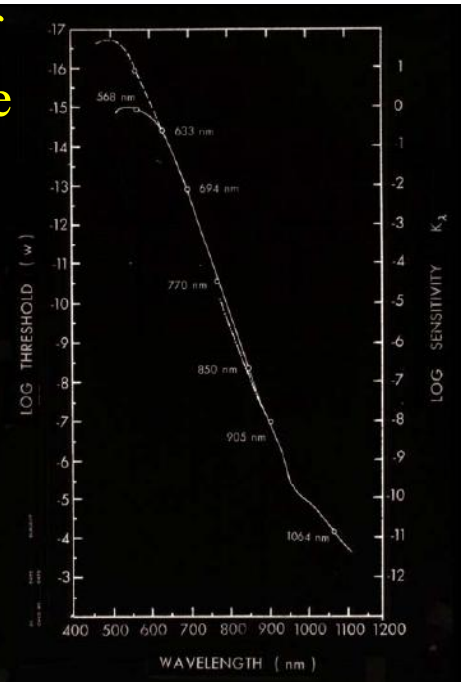

Aversion Response—eye movement, lid movement, head movement


Photopic
Luminous
Efficiency
Scotopic or Photopic Luminous Efficiency
1
0.8
0.6
0.4
0.2
0
350
400
450
500
550
600
650
700
Wavelength (nm)
Mainster 04


Scotopic
Luminous
Efficiency
Photopic
Luminous
Efficiency
Scotopic or Photopic Luminous Efficiency
1
0.8
0.6
0.4
0.2
0
350
400
450
500
550
600
650
700
Wavelength (nm)
Mainster 04

# Spectral Response of Daylight Vision—The CIE V(λ) function

- Logarithmic plot shows spectral dependences of photopic (cone) threshold over 14 orders of magnitude
- Even the 1064-nm Nd:YAG laser wavelength can be seen—but at levels close to the exposure limit

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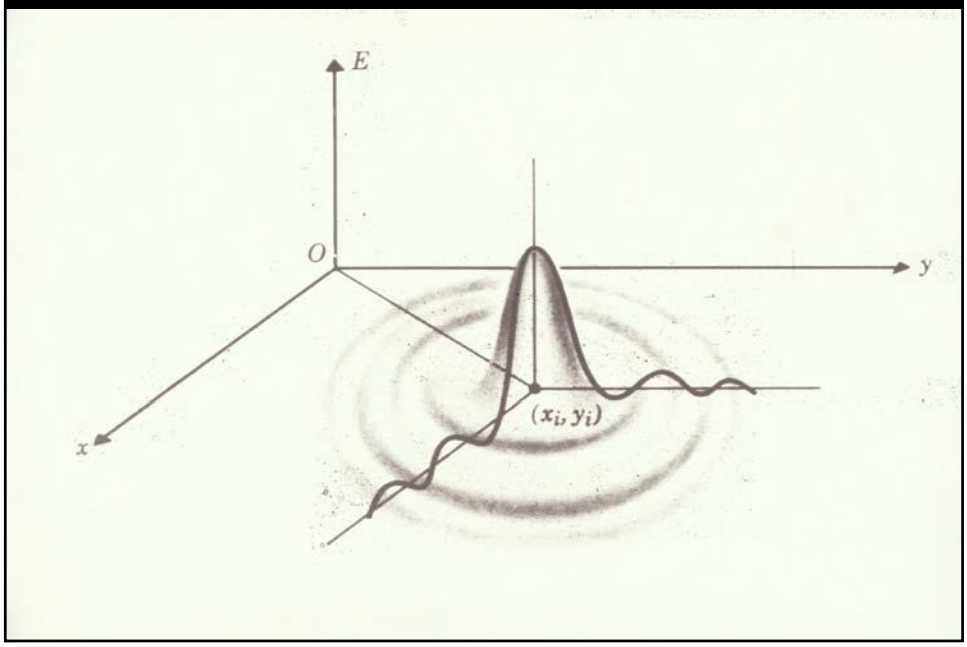
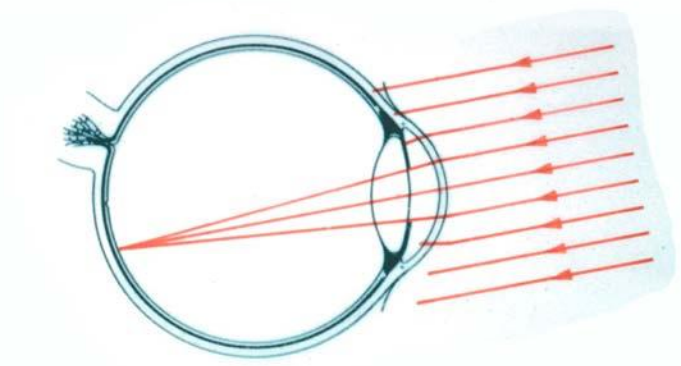
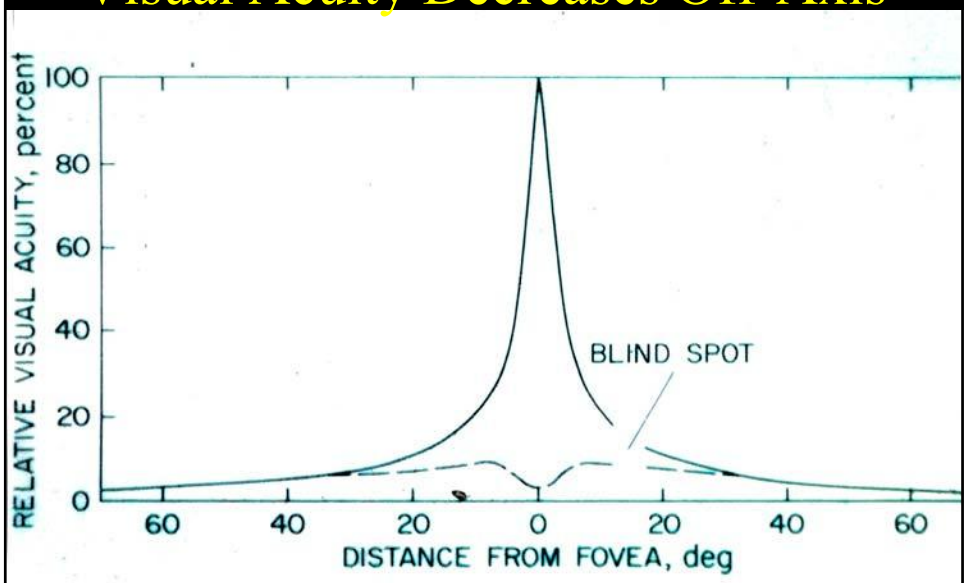
# Minimal Image Size: Diffraction Pattern



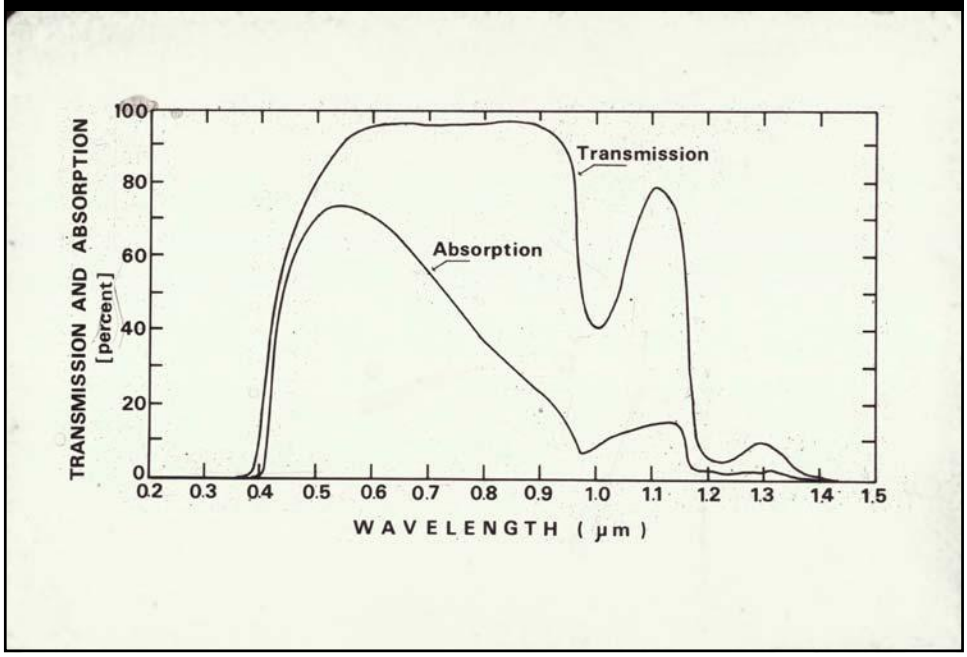
# Off-Axis Retinal Exposure



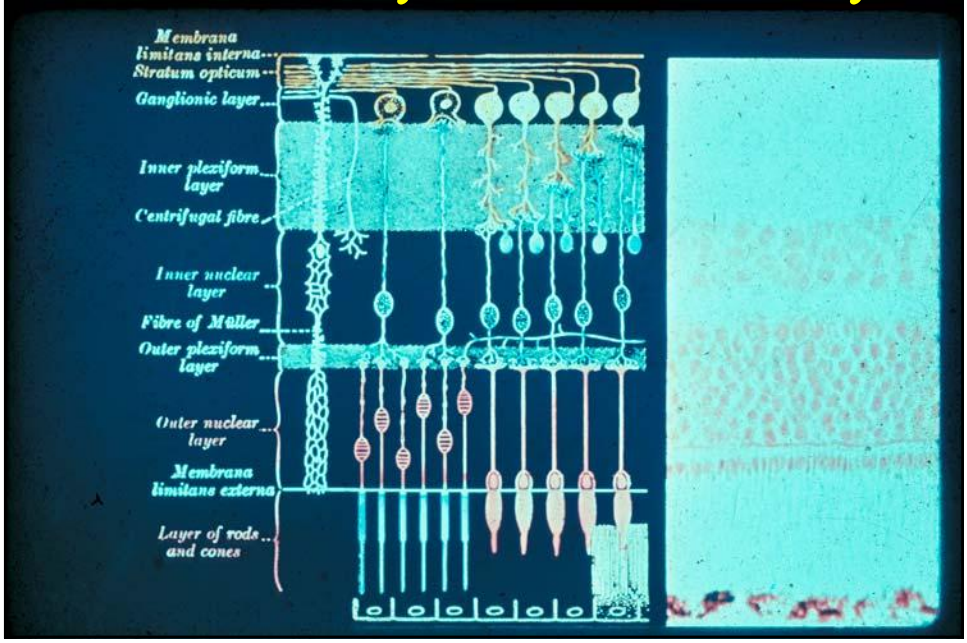
# Visual Acuity Decreases Off-Axis



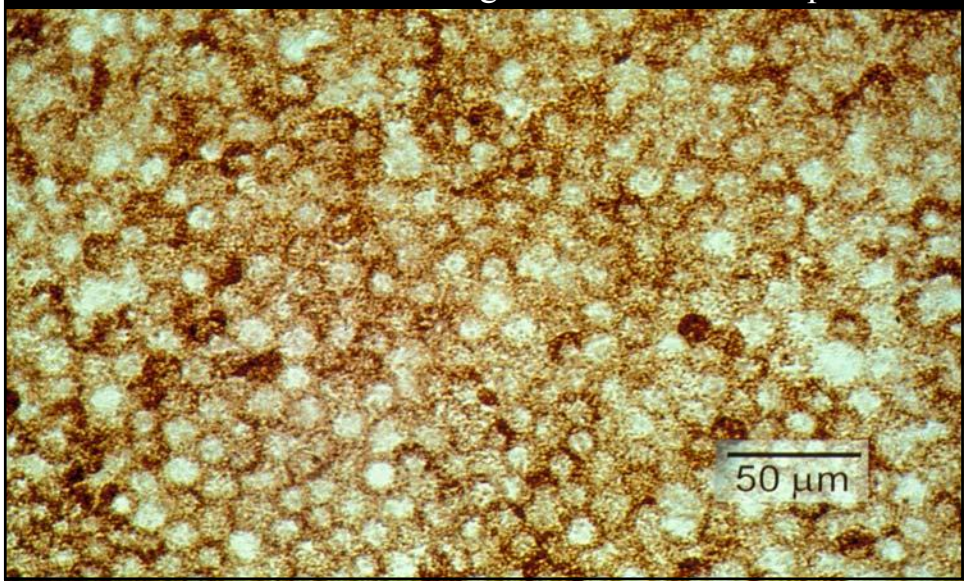
## The Retinal Hazard Region" ~ 400 to 1400 nm



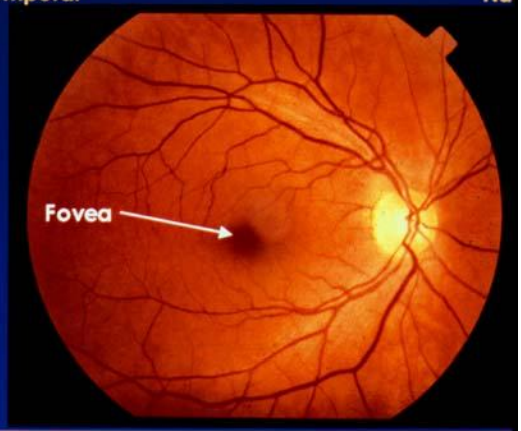

## Retinal Anatomy — 17 Distinct Layers



The melanin granules of the retinal pigment epithelium (RPE) experience the highest temperatures. Mathematica models of thermal damage calculate these temperatures




## The Normal Human Eye




When an eye-care specialists examines the retina, most attention is paid to a small part of the retina—the macula, and the center of the macula—the fovea

LPA 4

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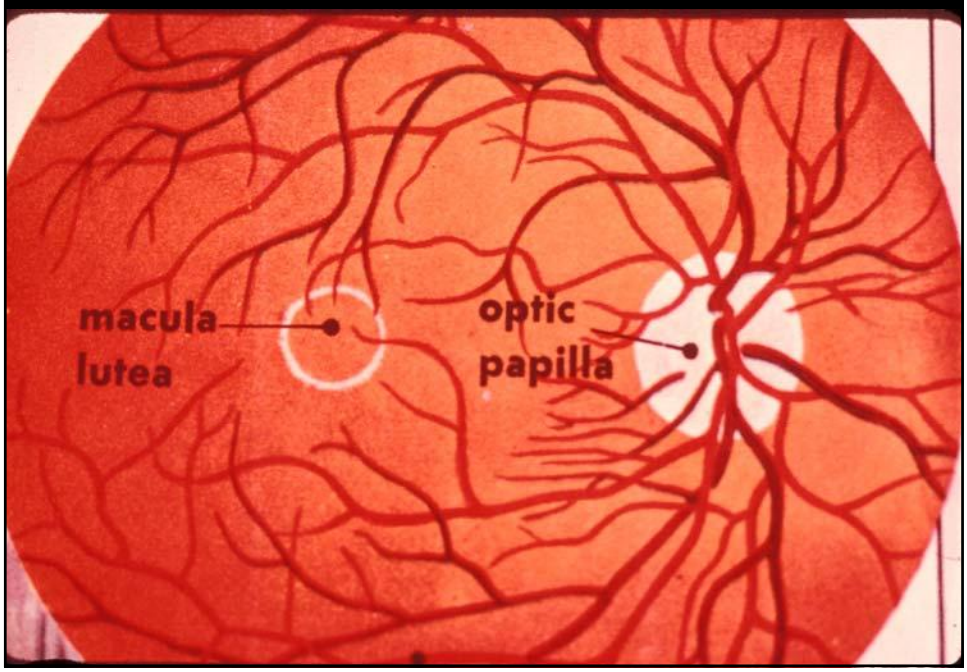
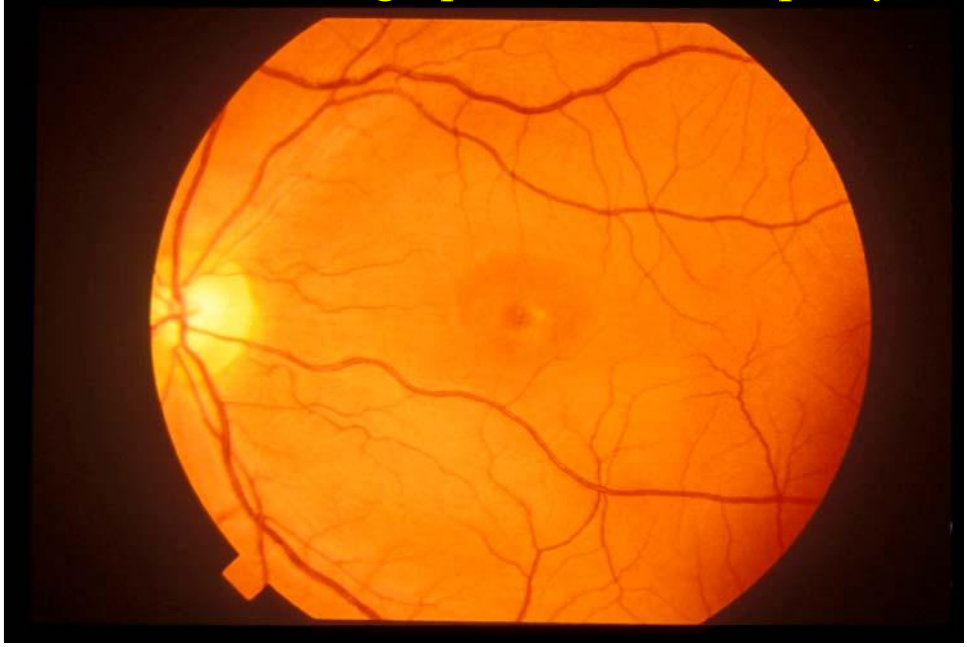
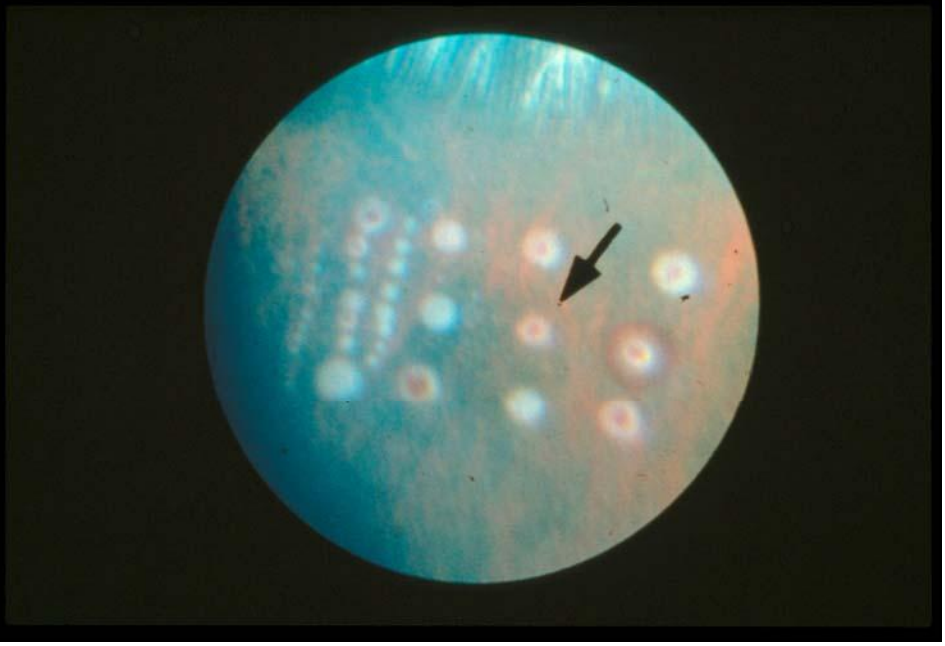
# The Ocular Fundus



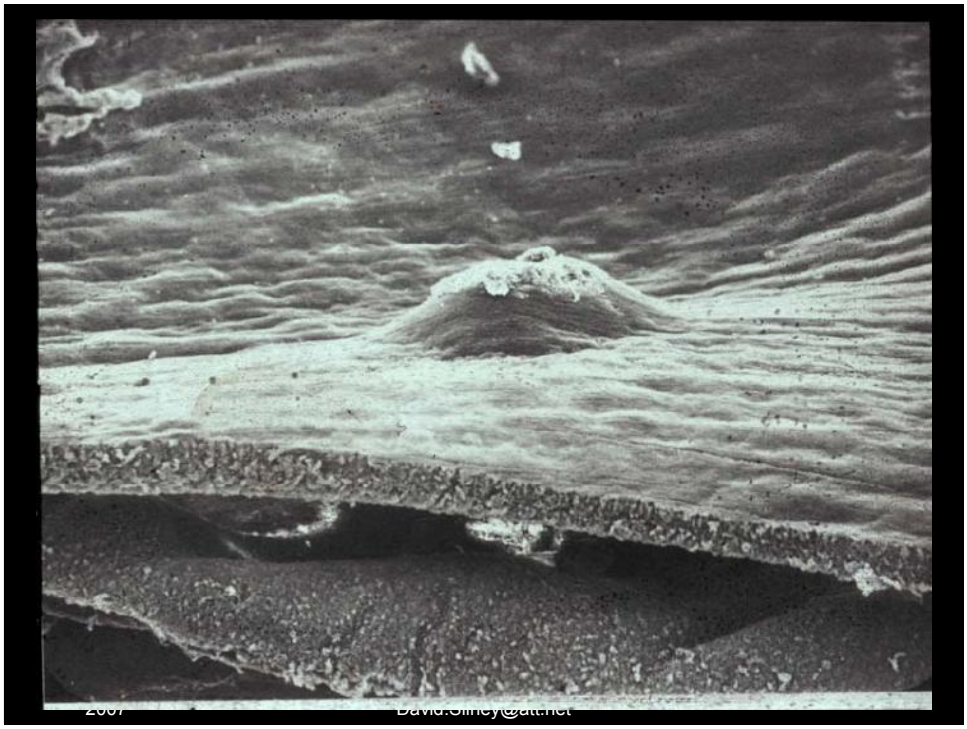

# Fundus Photograph--Photoretinopathy



## Retinal Lesion Appearance and Pulse Duration



## Fluorescein Angiography

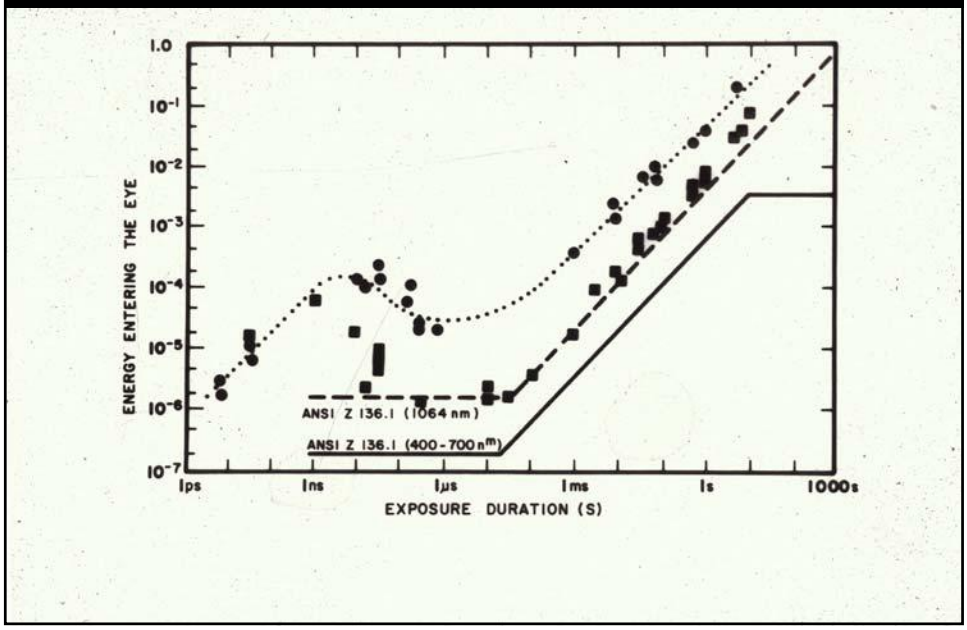




## *Energy Levels Known to Produce Retinal Injury*

- Ruby 649.3 nm
  - Visible Lesion
    - 10 μJ into eye
  - Suprathreshold Lesion
    - 240 μJ into eye
- Neodymium: YAG 1064 nm
  - Visible Lesion
    - 28 μJ into eye
  - Suprathreshold Lesion
    - 1 mJ into eye

# Retinal Injury Thresholds as Energy



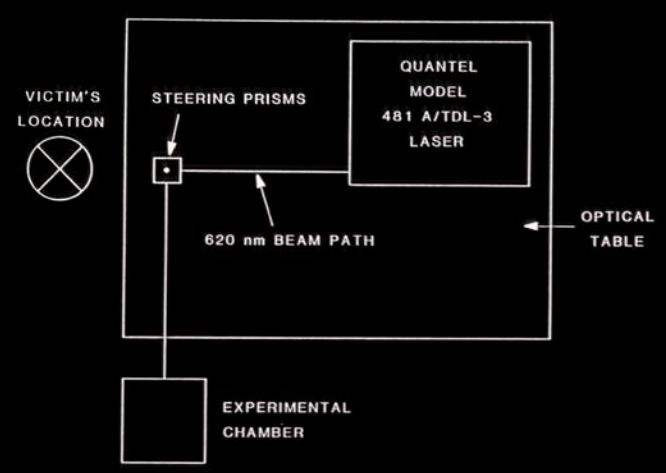

# Laboratory Accidents

- Most eye injuries have occurred in research and engineering laboratories. Why?
- Open beams
  - During alignment
  - For flexibility in calibration procedures
  - Experimental changes in setup
- "I know where the beam is!" (Famous last words)

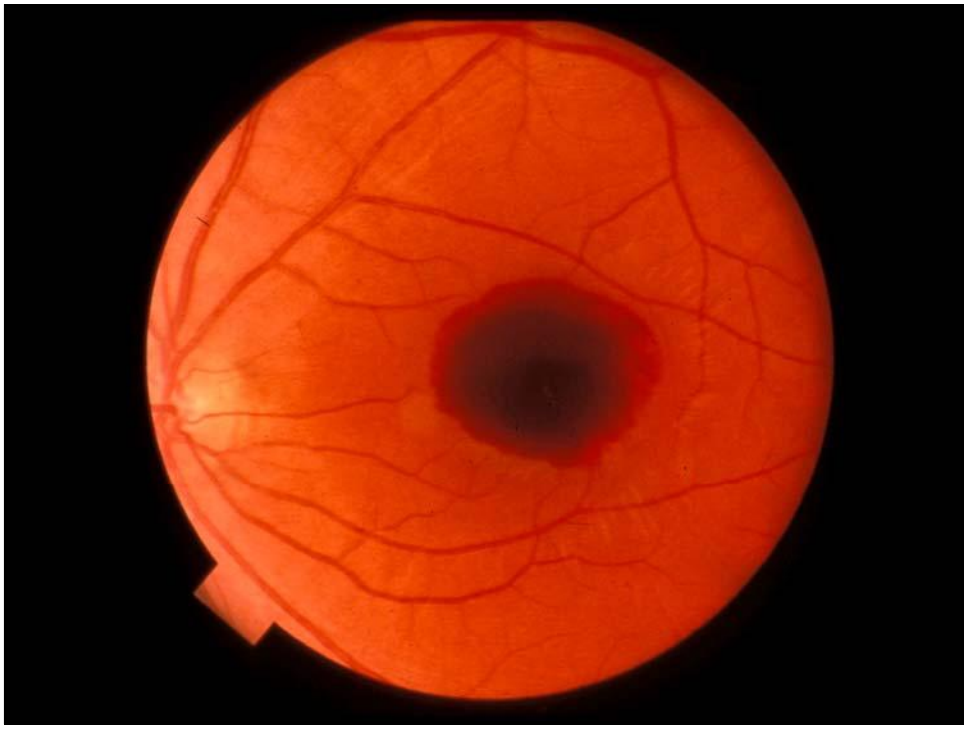
# Laser-Induced Ocular Injuries

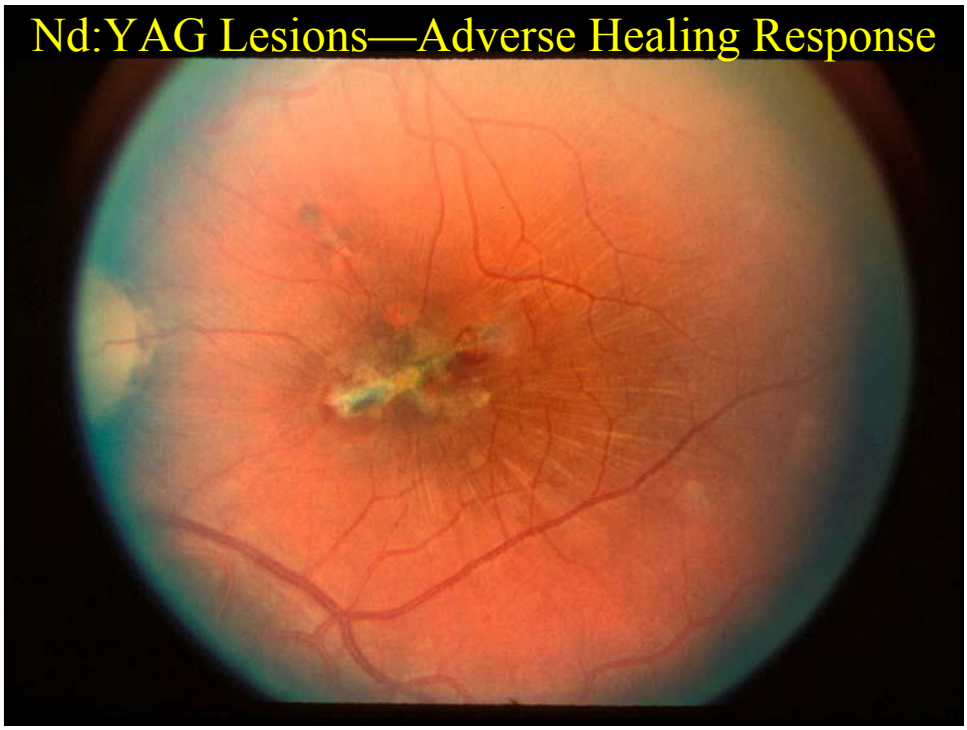
- Most common in R&D laboratories.
- Common elements:
  - Small, upward beam from Brewster-angle window or beam deflector
  - Q-switched or mode-locked ultra-short pulse
  - Small energy in beam (microjoules)
  - Victim fails to wear eye protection



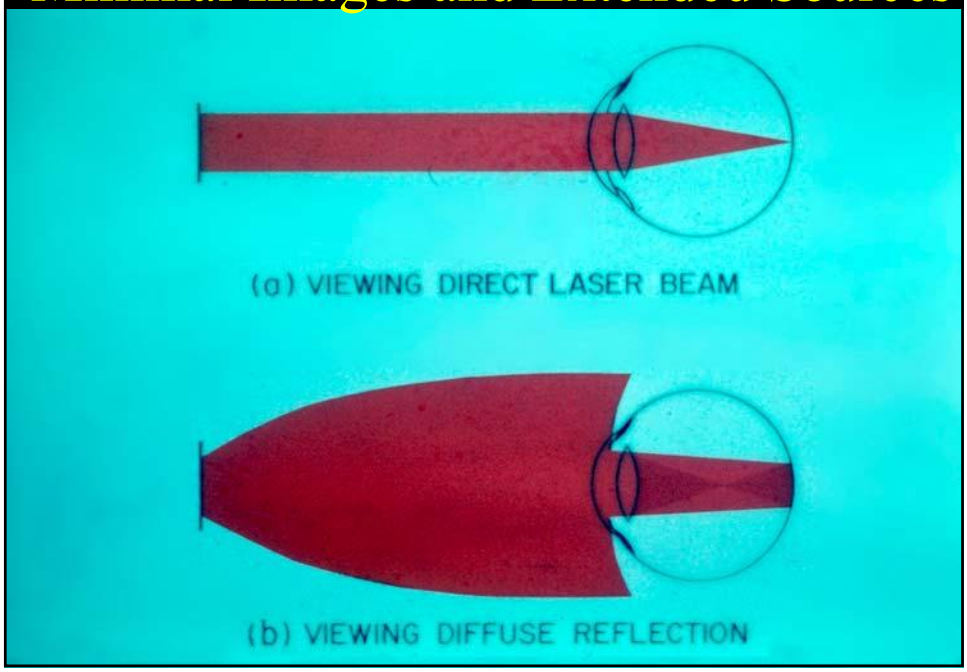



SCHEMATIC OVERVIEW SHOWING BEAM PATHS AND THE VICTIM'S LOCATION. AT THE STEERING PRISM THE BEAM COMES UP OUT OF THE ILLUSTRATION, THEN PARALLEL TO THE OPTICAL TABLE INTO THE EXPERIMENTAL CHAMBER.

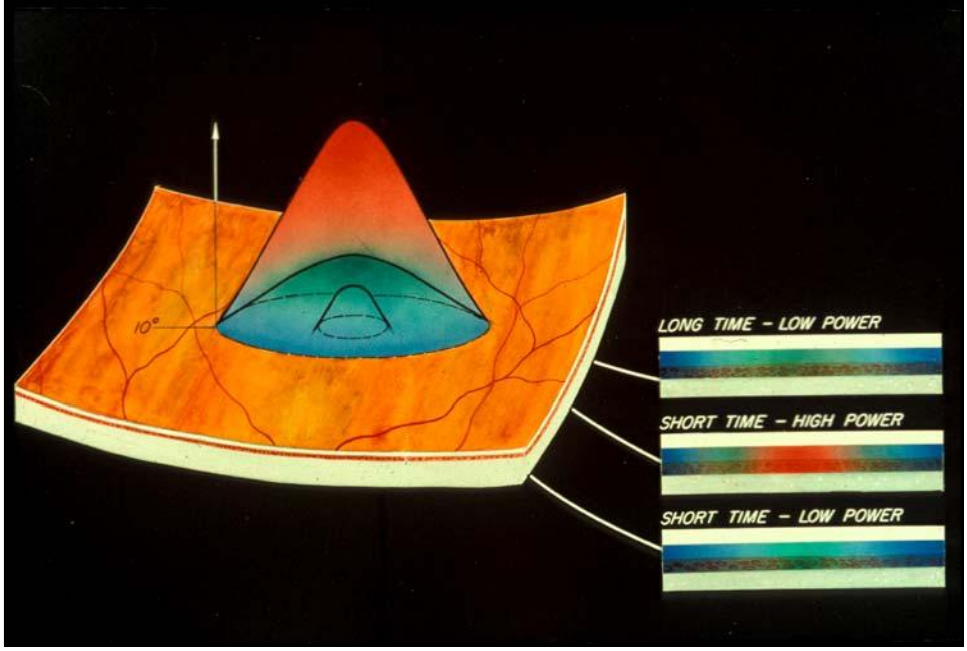



Nd:YAG Lesions—Adverse Healing Response

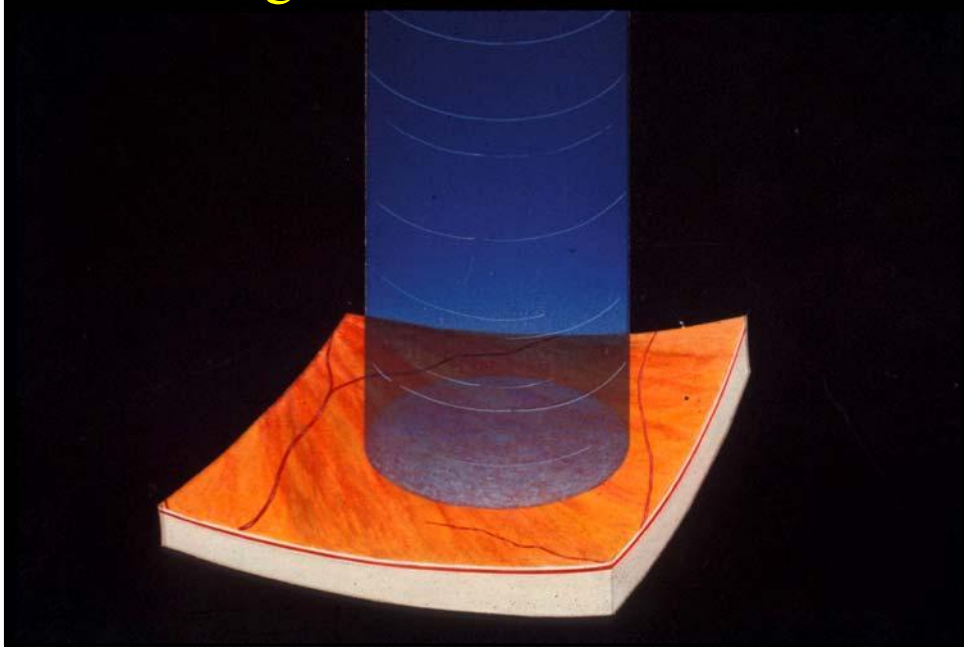
# Minimal Images and Extended Sources




## Spot-Size Dependence of Thermal Injury -- Radial Heat Flow



# Blue-Light Hazard: Photoretinitis



# Optical Safety Exposure Limits

- Several National and International Standards bodies have recommended the same set of ocular exposure limits (ELs)
- International Commission on Non-Ionizing Radiation Protection (ICNIRP)
- International Electrotechnical Commission (IEC) follows ICNIRP
- In the UK, BSI Standards and in USA: ACGIH and ANSI Z136.1 standard

## Guidelines for Human Exposure

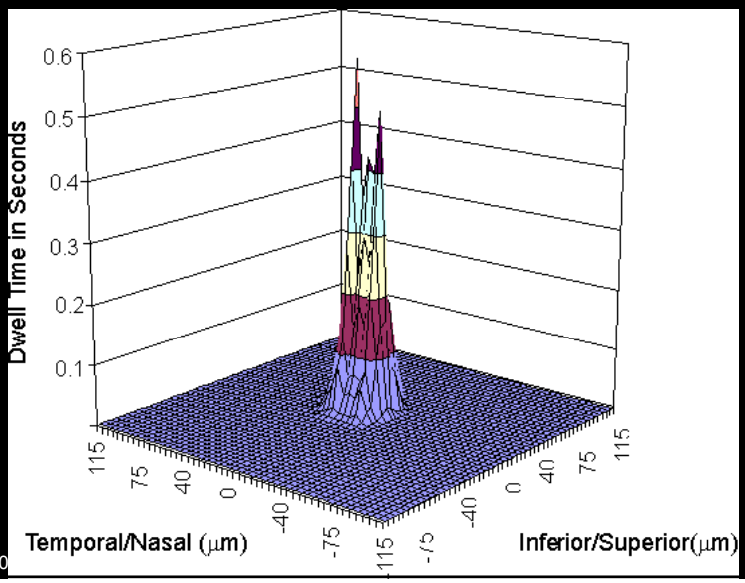
- American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs)
- ICNIRP Guidelines for human exposure to laser radiation (2001)
- ANSI Z136.1-2007, paragraph 8
- All the exposure limits are generally the same (minor differences for CW lasers)



## Biological Basis of Laser Safety Exposure Limits

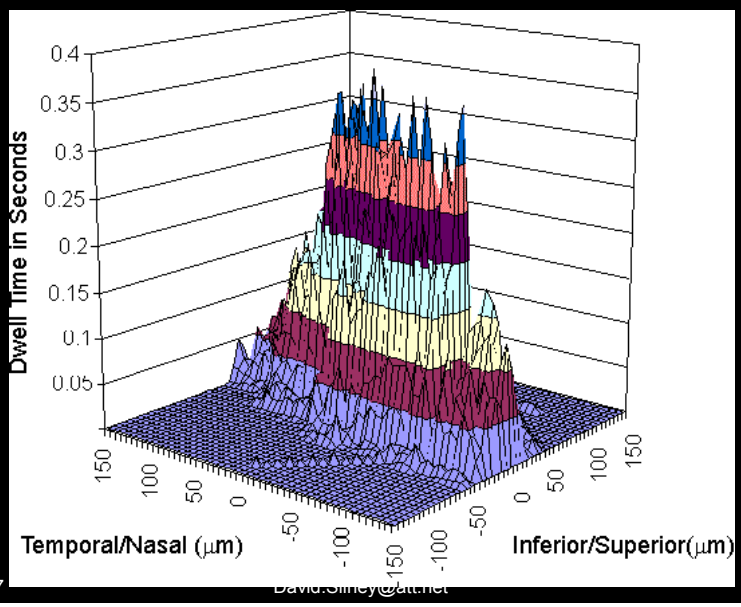
- Based upon a large data base of experimental retinal injury thresholds as evaluated by select task groups of biophysicists and eye specialists
- Mathematical models of biological injury were used to extrapolate to conditions not studied and safety factors applied
- Eye movements critical for CW exposures

# Eye Movements: 1-second Fixation




200

# Eye Movements: 100-second Fixation

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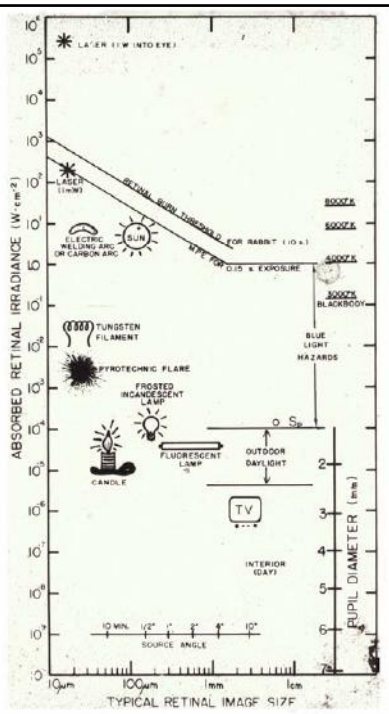
# Retinal Illumination

- The ambient outdoor illumination of the retina is of the order of 0.02-0.1 mW/cm2 and these levels are just comfortable to view
- The sun's image is a million times greater






# Laser Safety Standards

Two types of standards

- Manufacturer standards – *regulates emission*
  - *Example:* FDA/CDRH *Federal Laser Performance Standard*
  - *International:* IEC 60825-1.2-2001
- User Safety Standards – *regulates exposure*
  - *Example: ANSI Z136.1-2008 Safe Use of Lasers*
- Both use the same hazard (risk) classification scheme: Classes 1 through 4

## But what about chronic, low-level, life-long exposure?

What we know from studies of occupational exposures in industry and environmental exposure to sunlight…



## Environmental Sunlight Exposure and Ocular Health

- Photokeratitis or "snowblindness" (acute)
- Pterygium--strong association
- Cataract--strongly dependent upon latitude
- Labrador keratitis (droplet keratopathy or "spheroidal degeneration of the cornea"): association
- Retinal Effects (?): possible, but only weak association (if any) shown by epidemiology

# Pterygium—Common in Sunny Open Climates

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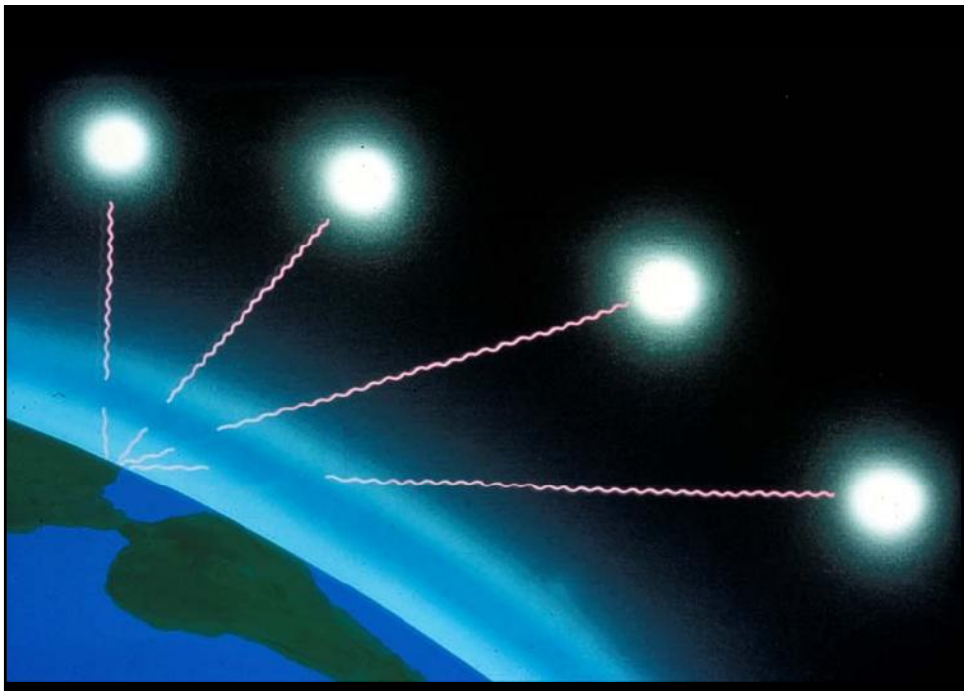

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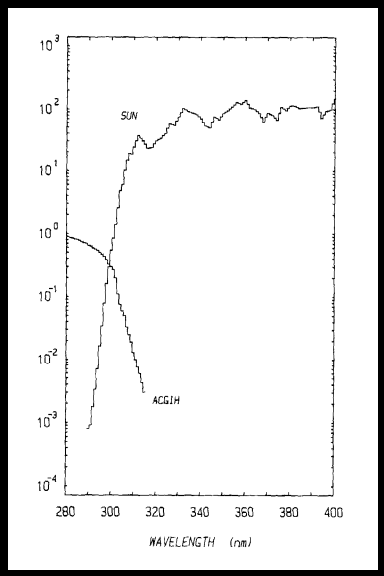


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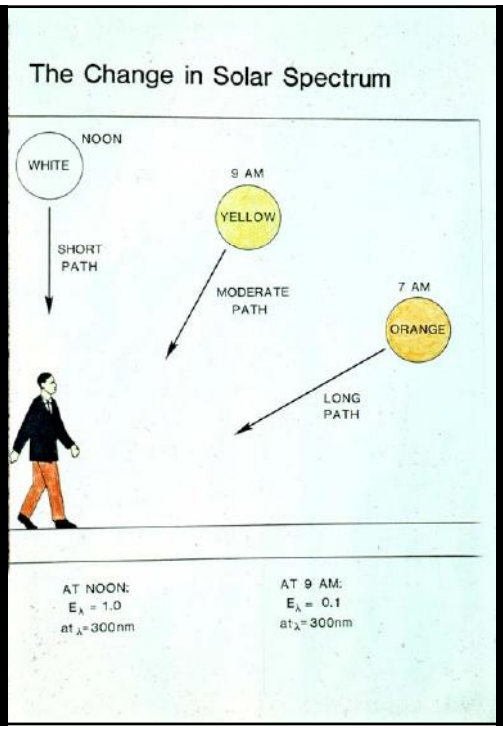


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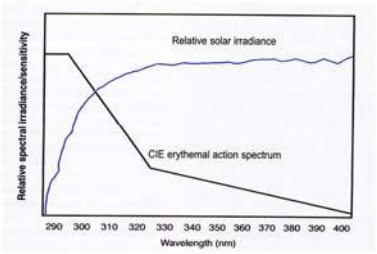
# Skin Cancer—the real risk of UV

—A major risk for outdoor workers but very difficult to control. UV limit reached in five minutes in summer sunlight!



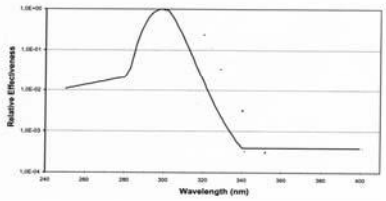




Fig. 1. Action spectrum for photocarcinogenesis. Non-Melanoma skin cancer.

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## Dimension of the epidemic (sources: IARC, WHO)

| | 1985 – 1990 | 2000 – 2004 |
|---|---|---|
| Non-Melanoma Skin Cancer (NMSC) | 2,750,000 | 3,000,000 |
| Cutaneous Malignant Melanoma (CMM) | 106,000 | 132,000 |

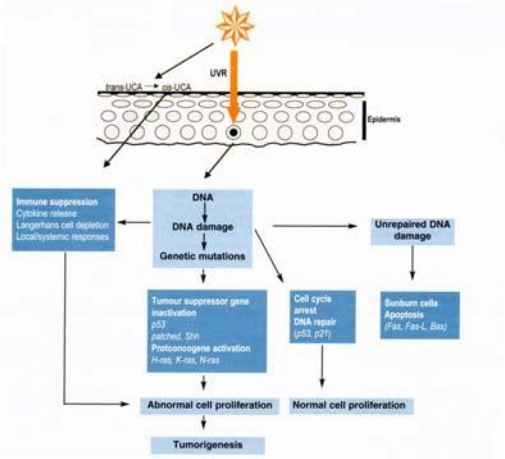
In USA, Australia, Canada, skin cancers incidence increased by 200% between 1960 and 1980

CMM is 5% of skin cancers but responsible for 80% of all skin cancer deaths. In Australia, life time risk of CMM is 1 in 27

*Skin cancers represent a considerable burden on health systems*

# UV photocarcinogenesis takes time

Generally there are years of delay before appearance—an age-related disease

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NIVA 2011

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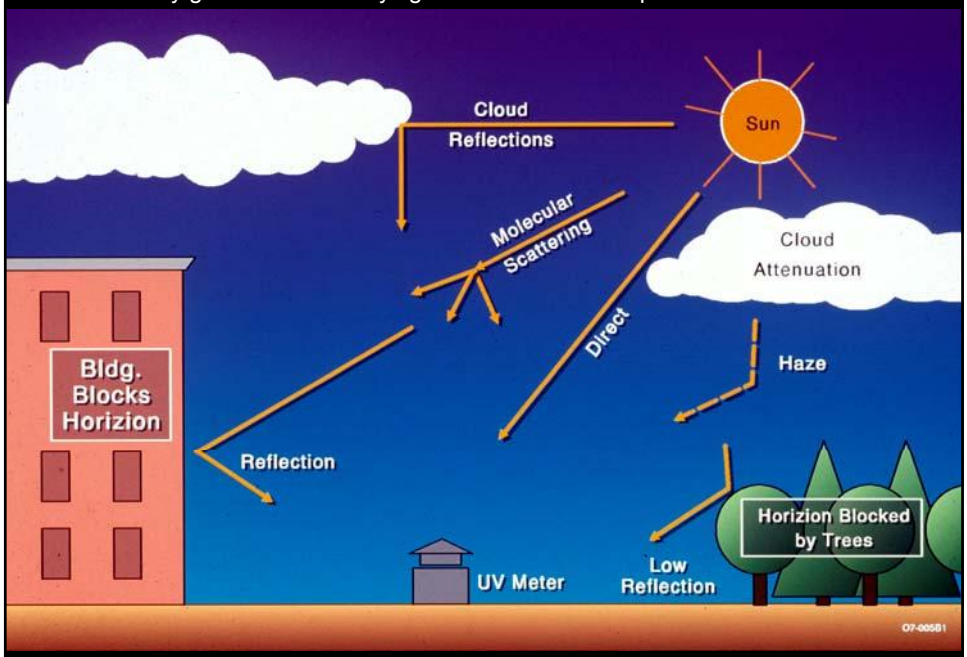
There are many geometrical modifying factors for ocular exposure to ultraviolet radiation

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# Reflections from Water

## —the Fresnel Laws of Specular Reflection

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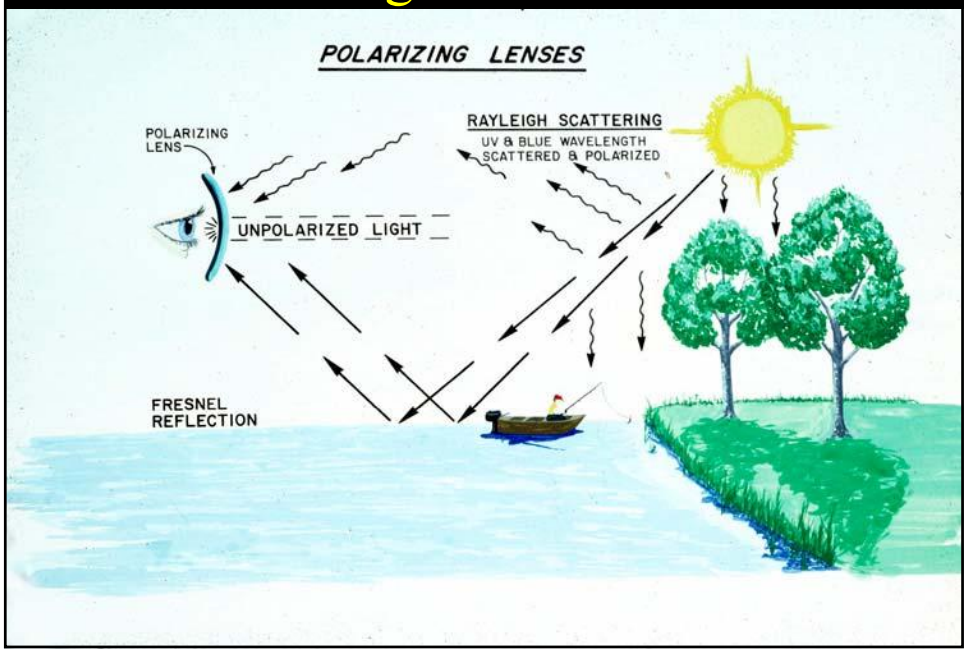
# Combating Reflective Glare



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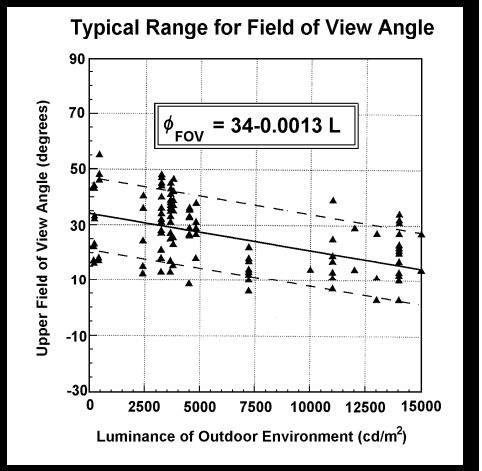
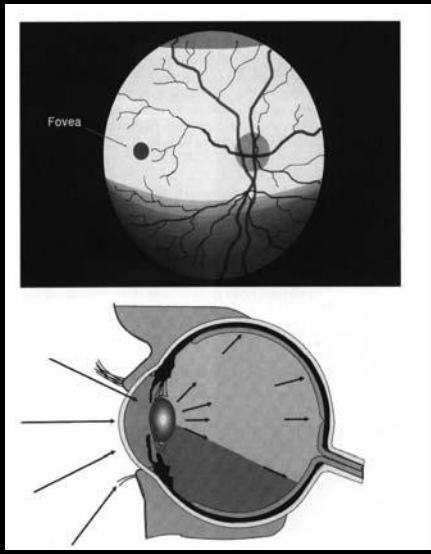
# USACHPPM Studies of Lid Opening




CHPPM Studies David.Sliney@att.net

# Retinal Exposure

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The importance of exposure geometry

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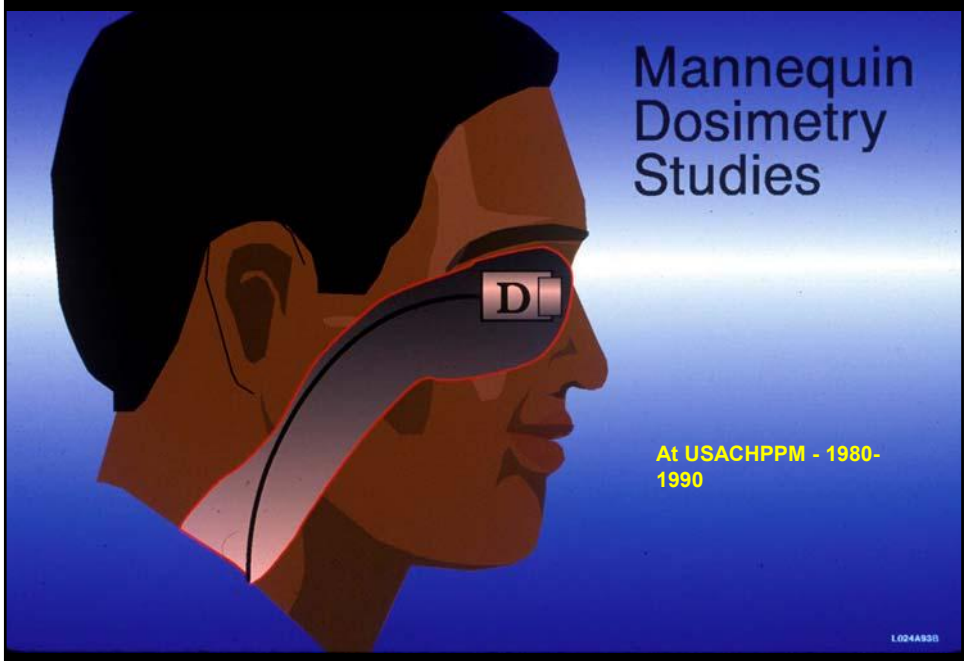


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The Winner! Ten-fold better protection than ordinary sunglasses!
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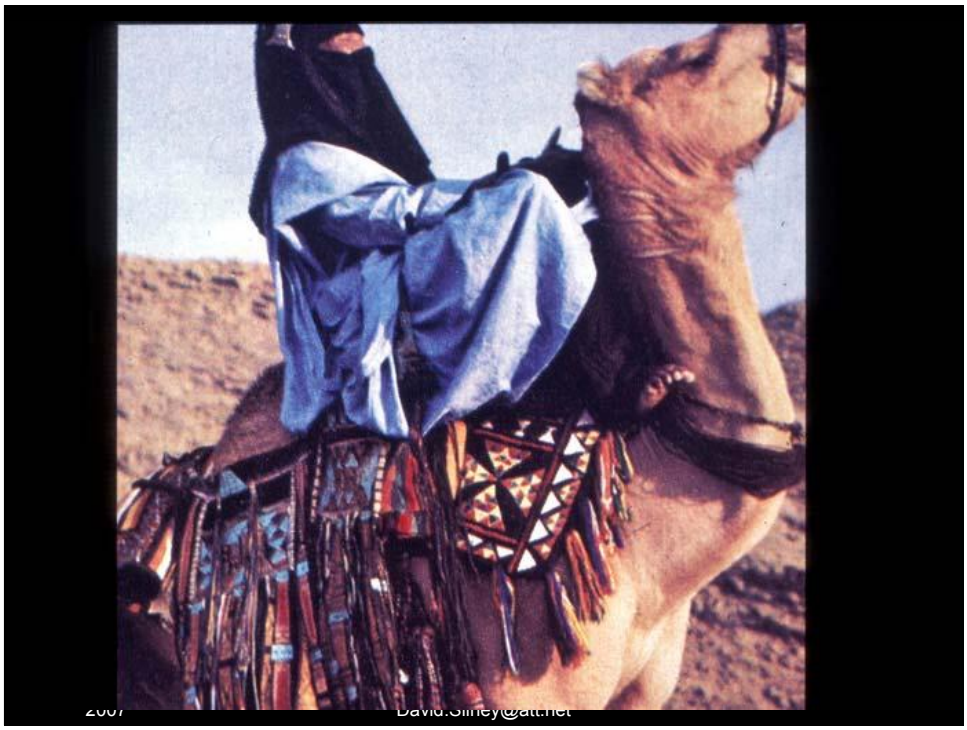
David.Sliney@att.net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David.Sinney@att.net

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2007
David.Sliney@att.net

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# Optical Radiation Exposure Limits

- The MPEs (also termed TLVs, ELs, guidelines) for both lasers and incoherent sources are based upon the same biological database.
- Presentation differs because of different exposure geometry
- Uncertainty level ("safety factor") differs for lasers
- Lasers generally monochromatic
- Broadband sources require evaluation of ultraviolet (UV), visible and infrared.
- Different radiometric quantities applied.

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# *Similar, but different MPEs*

- For a laser, only the hazards at a wavelength of interest are reflected in the MPE, and competing hazard mechanisms lead to, at most, *two limits, or "dual limits."*
- With broad-band lamp sources, at least *five* different potential hazards must be assessed.

## Contrasting Laser & Broad-Band Limits

- Attempts to compare and plot laser MPEs to contrast with broad-band limits show apparent differences and disconnects that can be quite puzzling at first sight.
- This was a particular concern of those trying to assess the optical risks of viewing bright LEDs.
- The rationale behind the two sets of exposure limits necessarily differ:
  - The default source size for lasers is a "point" source defined by alpha-min; whereas,
  - the default source size for incoherent sources is a large source and alpha-max.

DHS 87

*Background:*

## Optical Radiation Hazards

- IEC TC76 attempted to treat solid-state lamps (LEDs) as if "lasers" in IEC 60825-1 Edn.1 from 1993 until 2007—*unique to IEC*
- ANSI Z136 and IESNA/ANSI RP-27 series and CIE S009 always treated all lamps under lamp-safety standards (except OFCS)
- Why? Source Size!
  - Lamps — *large source size is default condition*
  - Lasers — *point source size is default condition*

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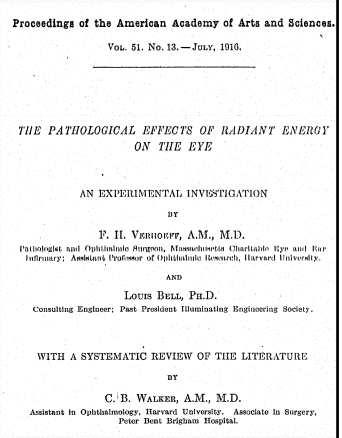
# Lasers and Lamps are Different!

| Source Type/ Characteristic | Lasers | Lamps |
|---|---|---|
| Radiance | Very High! | Limited |
| Hazard at Distance | Yes, unless focused or divergent beam | Even a searchlight has a very limited hazard distance |
| Spectrum | Monochromatic (although multiple emission lines possible) | Normally broad-band, with potential spectral extending into UV & IR |
| Hazards to Evaluate | Normally just one hazard based upon wavelength, or dual limits for competing mechanisms | UV under S(λ), total UV, Retinal Photochemical (Blue-Light), Retinal Thermal, Infrared -Cornea |
| Default condition for Retinal Hazard Evaluation | "Point-Source" Intrabeam Viewing—Irradiance MPE Power in Aperture AEL | Large-Source Default Condition—Radiance for MPE and AEL |



# Optical Safety of Lamps– not New!

- Optical safety was an issue in 1900:
- Widmark, 1889; Birch-Hirschfeld, 1912; Verhoef & Bell, 1916
- Lamp envelope size
- Minimize thermal-burn hazard
- UV photokeratitis risks (arcs)
- Verhoeff and Bell, 1916 (185pages)
  - "…no more dangerous than steam radiators"


Proceedings of the American Academy of Arts and Sciences.

Vol. 51. No. 13.—July, 1916.

THE PATHOLOGICAL EFFECTS OF RADIANT ENERGY ON THE EYE

AN EXPERIMENTAL INVESTIGATION

BY

F. H. Verhoeff, A.M., M.D.

Pathologist and Ophthalmic Surgeon, Massachusetts Charitable Eye and Ear Infirmary; Assistant Professor of Ophthalmic Research, Harvard University.

AND

Louis Bell, Ph.D.

Consulting Engineer; Past President Illuminating Engineering Society.

WITH A SYSTEMATIC REVIEW OF THE LITERATURE

BY

C. B. Walker, A.M., M.D.

Assistant in Ophthalmology, Harvard University. Associate in Surgery, Peter Bent Brigham Hospital.

D Sliney 2006

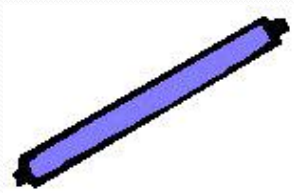
# F. H. Verhoeff and Louis Bell, 1916

THE fundamental purpose of this investigation has been to discover what if any pathological effects can be produced upon the structure of the eye by exposure to artificial or natural sources of light. That such action may occur under sufficiently powerful exposure to radiant energy is certain, but the essential fact is the discovery of the quantitative relations between the amount of incident energy and the effects. These relations have generally been left quite out of the reckoning in discussing the subject, with the result of leading to vague and often quite unwarranted conclusions as irrelevant as if one should condemn steam heating as dangerous because one can burn his finger upon a radiator.

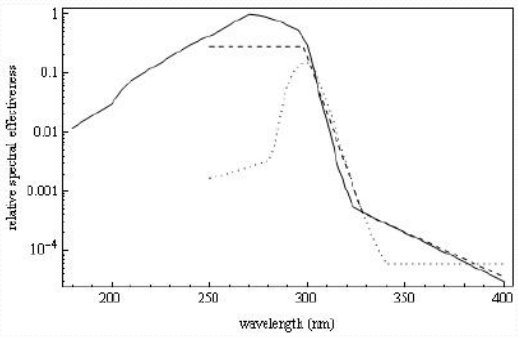
*Quoted in: Sliney & Wolbarsht, Safety with Lasers and Other Optical Sources—a Comprehensive Handbook, New York, Plenum, 1980, 1000 pages*

# Ultraviolet hazards to the eye

- The eye has evolved under a constant bath of ultraviolet rays from the sun—but the eye is well adapted because of geometry and the avoidance of bright light
- Effect from a single, acute exposure: UV photokeratitis ("snow blindness")
- Effects from chronic exposure:
  - Cataract
  - Pterygium and pinguecula



# UV Action Spectra Applied in Risk Analyses

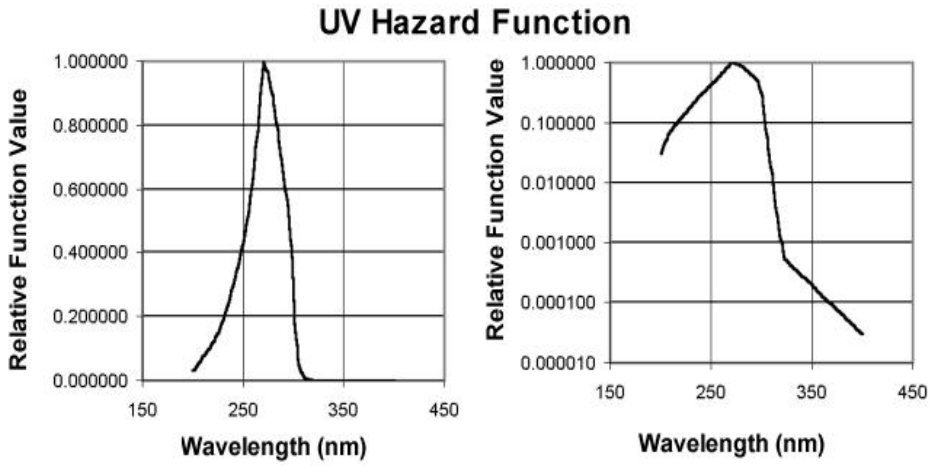



The importance of recognizing that all biologically relate at λ ~300 nm

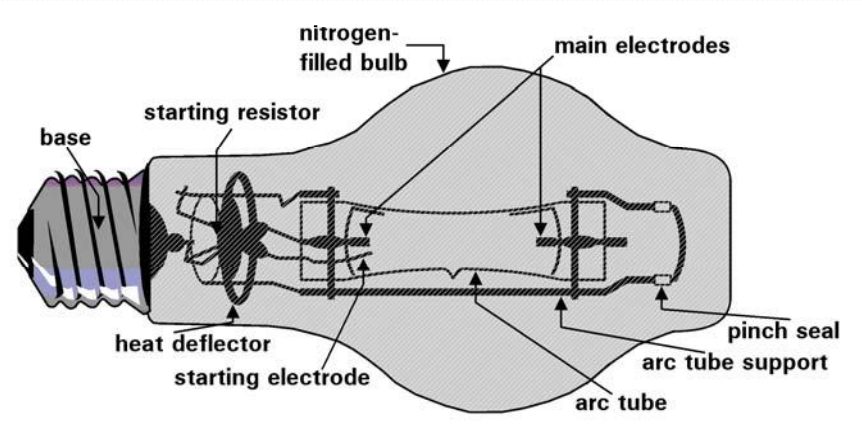
- 3 UV Action spectra—different at λ < 300 nm:
  - ACGIH/ICNIRP UV S(λ) hazard function, applied in CIE lamp safety stnd. S009
  - CIE standardized erythemal A.S. applied in UV index
  - CIE standardized A.S. for photocarcinogenesis—note low value at 254 nm (UVGI)

# How to Plot an Action Spectrum

## Example: ICNIRP/ACGIH UV Hazard Function



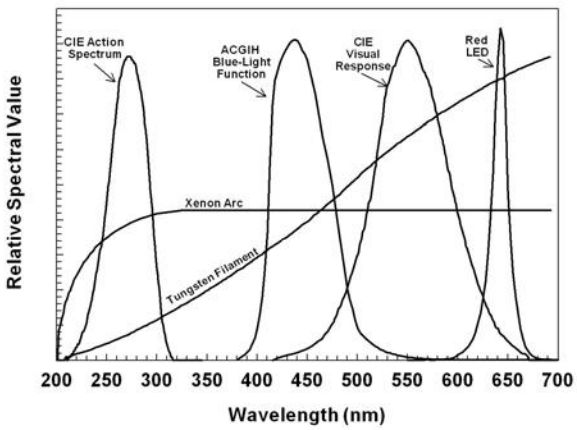
## *A Common Lamp Safety Problem:*
## The HID Fluorescent—broken envelope





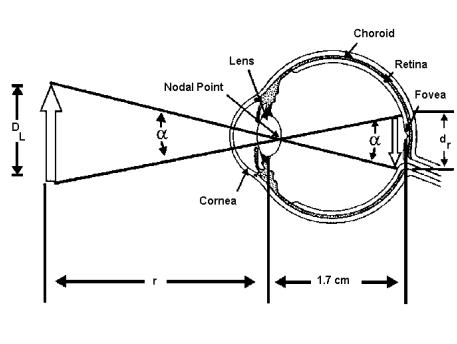

## Spectral Weighting
## —the visible light (e.g., CIE lux) does not predict the relative photobiological effectiveness

- LEDs have a very limited spectral emission
- Other lamps have very specific spectral distributions
- Lamp envelope may block UV



## Calculating Retinal Irradiance —for extended sources: Radiance L

- The retinal irradiance $E_r$ is:
- $E_r = 0.27\ L \cdot \tau \cdot d_e^{\,2}$
  - where L is the radiance of the source viewed – in units of $W \cdot cm^{-2} \cdot sr^{-1}$
  - $\tau$ is the transmittance of the ocular media
  - $d_e$ is the pupillary diameter in cm
- Retinal Irradiance depends upon Source RADIANCE




DHS 97

## Lamp Safety Standards (Manufacturer—Product Safety

- The CIE: ***Commission Internationale de l'Eclairage*** (International Commission on Illumination), Vienna
- First Issued **CIE S009** *Photobiological Safety of Lamps and Lamp Systems* (2002) in three languages, English, German and French.
- But CIE S009 was only finally adopted adopted as a dual-logo standard in 2006, now referenced as IEC62471/CIE S009. I**EC 62471**:2006 is identical to the earlier S009
- The original basis for the above standards was the US recommended practice standard, the **ANSI/IESNA RP 27.1-1993 and RP27.3** (1996), now updated in 2nd Edns.

## Sources of
# Technical Standards of Interest

- CIE Division 6—Photochemistry and Photobiology
  - International Lighting Vocabulary (ILV) and Measurement TRs
  - CIE standard action spectra (erythema, NMSC, B(λ) etc)
  - CIE S009 Photobiological Safety of Lamps & Lamp Systems
- IEC TC76, Lasers, established in 1976
  - IEC 62471 –IEC edition of CIE S009
  - IEC 60601-61 –Medical laser standard in medical equipment series
- ISO TC 172 Optical Instruments SC6 Ophthalmic Instruments
  - ISO 15004-2 Ophthalmic Instrument Exposure
- ISO TC94 (PPE)/SC6 on eye protection (industrial and sunglasses)



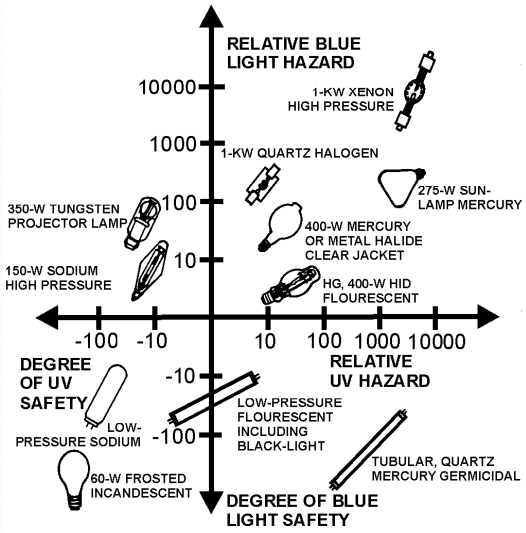
# Emission Limits for Risk Groups of Continuous Wave Lamps

| Risk | Action Spectrum | Symbol | Emission Limits | | | Units |
|---|---|---|---|---|---|---|
| | | | Exempt | Low Risk | Mod Risk | |
| Actinic UV | S(λ) | $E_s$ | 0.001 | 0.003 | 0.03 | $W/m^2$ |
| Near UV | | $E_{UVA}$ | 10 | 33 | 100 | $W/m^2$ |
| Blue Light | B(λ) | $L_B$ | 100 | 10000 | 4000000 | $W/(m^2 \cdot sr)$ |
| Blue Light, small source | B(λ) | $E_B$ | 1.0* | 1.0 | 400 | $W/m^2$ |
| Retinal Thermal | R(λ) | $L_R$ | 28000/α | 28000/α | 71000/α | $W/(m^2 \cdot sr)$ |
| Retinal Thermal, weak visual stimulus** | R(λ) | $L_{IR}$ | 6000/α | 6000/α | 6000/α | $W/(m^2 \cdot sr)$ |
| IR Radiation, Eye | | $E_{IR}$ | 100 | 570 | 3200 | $W/m^2$ |

* Small source defined as one with a < 0.011 radian. Averaging field of view at 10000 s is 0.1 radian.

** Involves evaluation of non-GLS source

# UV and Blue-Light Hazards

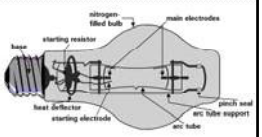



From Sliney, 1980

# „Lamps“ and „Lamp System“

„Lamp“:

- Not only for lighting, also „UV-Lamp“, LED,...



„Lamp System“: **Final product** (Lamp fixture, housing)

- When used for <u>lighting</u>: **„Luminaire“**
- For <u>non-lighting</u>:
  - Medical devices (Intense Pulsed Light, PUVA)
  - Photocuring, hardening
  - Insect Traps (UV-A), germicidal (UV-C)
  - Radiant heaters

# Lamp System (Luminaire or projector) can change risk

**Generally Decreased Hazard**

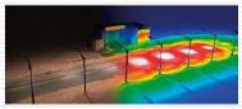
- Protective housing (Photocuring)
- Diffused cover blocks UV-B, reflects IR
- Reduced UV in GLS from low reflectance

**Increased Hazard**

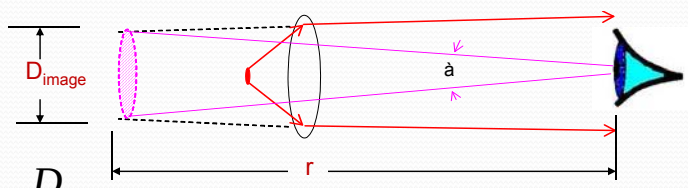
- Several lamps in one lamp system
- Reflectors, projection optics
  - Photochemical retinal hazard—the spatially averaged radiance can be increased if source is smaller than 2.2 mm
  - Of course the true radiance cannot be increased by optics)

# *solid-state lamps: LEDs—miniature lamps*

- General Lighting Service—only beginning (glare problems)
- – Escape lighting LEDs
- – Embedded LED luminaires
- – Roadway Lighting with solar cell power
- –Courtyard Lighting
- – Miner's helmet LED lamps
- – Emergency lighting
- Indicator lamps, lighting -motor vehicles



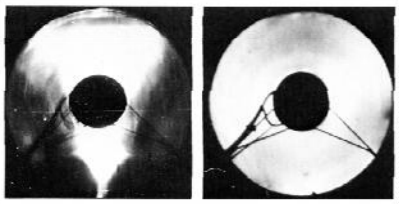
# Apparent Angular Source Size

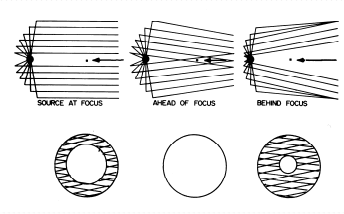



$$\alpha = \frac{D_{image}}{r} \text{ where r = distance to image}$$

- Apparent angular source size for diode emitter
  - $D_{image}$ = image of diode =apparent source for eye

# Searchlight Source Images





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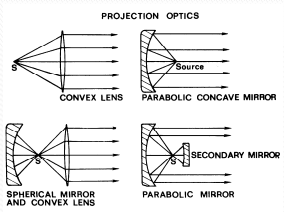
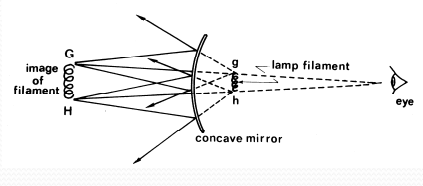
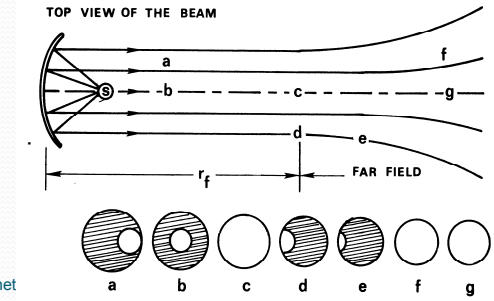
## Searchlights and Projectors

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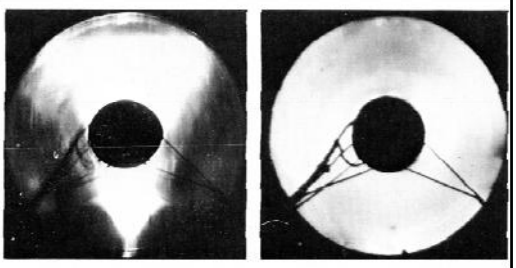
## Retinal Thermal Hazards—

### only from lasers or projected arcs

- Retinal thermal hazards are a major issue for laser, but not for lamp products
  - Xenon-arc searchlights
  - Ophthalmic Xe-arc photocoagulators
  - Ophthalmic flashlamps



*D Sliney 2006*

## *Tabulating the Limit Guidelines*

- Laser limits are expressed as irradiance ($W \cdot cm^{-2}$) and radiant exposure ($J \cdot cm^{-2}$), and broad-band limits as radiance ($W \cdot cm^{-2} \cdot sr^{-1}$) limits to protect the retina.
- Some laser limits may be easier to apply to a non-laser, monochromatic point-source, such as super-luminescent diodes and OFCS fiber tips, and incoherent source limits to some large-source laser displays.

DHS 109

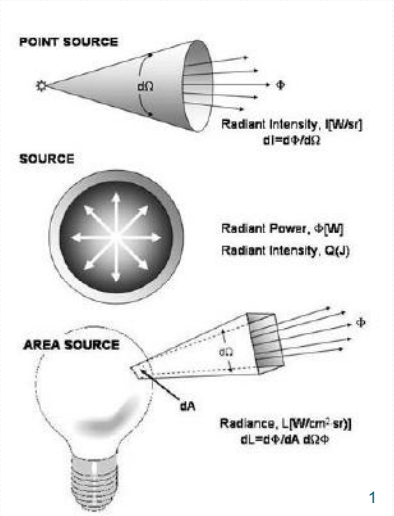
## The Aversion Response: the reactive pupil

- A rapidly closing pupil is dealt with differently in the two different sets of limits, leading to what appear to be "discontinuities" between pulsed and CW for broad-band retinal hazard limits
- Laser safety standards emphasize "smooth" functions and employ Class 2

DHS 110

## CIE Standardized Radiometric Terms for Lamp Output

- Provided in the CIE International Lighting Vocabulary and ISO and IEC standards
- Radiometric quantities, units and symbols are standardized.
- Retinal irradiance is directly proportional to *radiance*

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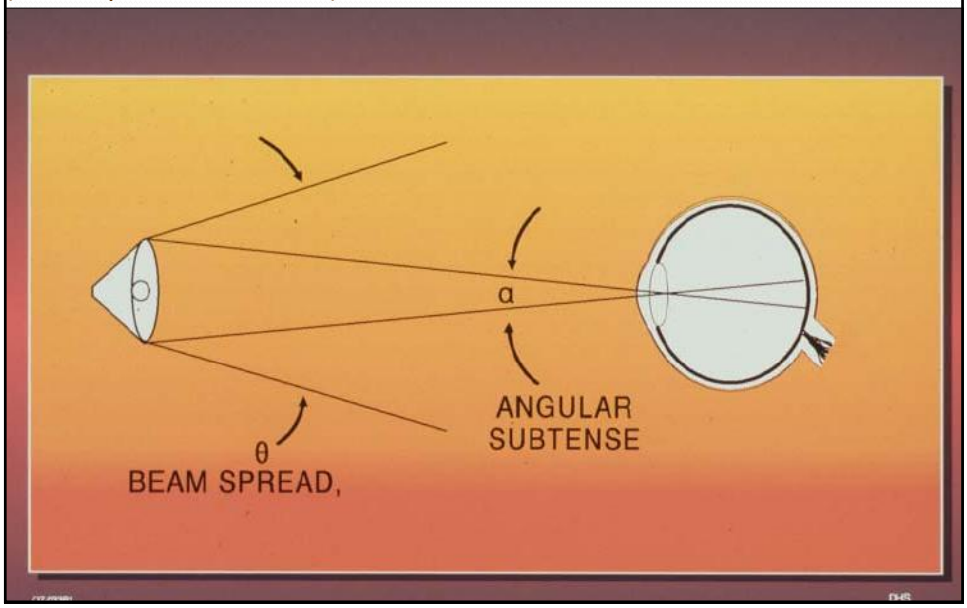
## Radiance

- Calculated at viewer's location
  - Corneal irradiance
  - Angular subtense

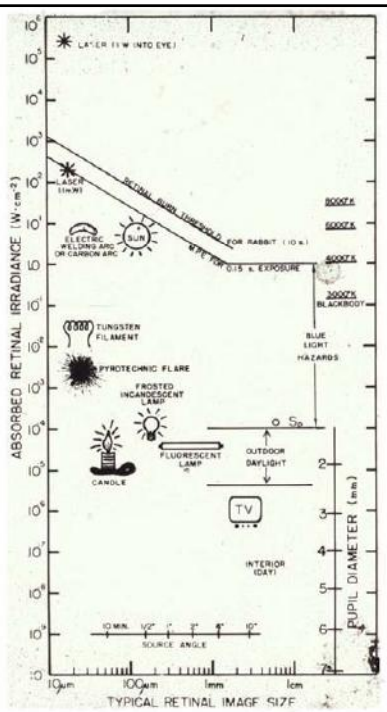
$$L_e = \frac{E_{viewer}}{\Omega_{source}}$$

Angular subtense of the source is important for retial hazard evaluations. (Beam spread is different)




## Retinal Illumination

- Retinal illumination from outdoor ambient outdoor of the is of the order of 0.02-0.1 mW/cm² and these levels are just comfortable to view
- The sun's image is a million times greater
- An LED chip cannot produce a retinal level above that of the filament




DHS 114

## *Revisions Underway in Both Sets of MPEs (ELs) ICNIRP and ACGIH –20 11*

- Planned Revisions in the Laser Exposure Limits
  - Raising MPEs for extended-sources—by varying $\alpha_{max}$ with the greatest increase in MPEs for pulse durations less than 0.6 ms.
  - Change in laser ELs in the 1200-1400 nm spectral region
  - Reduction in MPEs for point sources at t < 30 ns (?)
  - Other minor updates
- Planned Revisions in Broad-band Exposure Limits
  - Revised retinal thermal hazard function R(λ): removes "blue hump"
  - Revision of extended-source retinal thermal hazard ELs for shorter pulses. Limits will be closer to the ACGIH TLV values prior to 1990.
  - ACGIH has already made all of these changes; ICNIRP plans to.

DHS 115

## Required Measurement Data

- Initially: broad-band measurements to assure that rigorous, spectroradiometric measurements are not required, or…
- Spectroradiometric Information
  - Spectral Radiant Power Distribution
  - Spectral Irradiance
  - Spectral Radiance
- Source Size

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## Commercial Spectroradiometers to Measure Small-Source Areas—Examples

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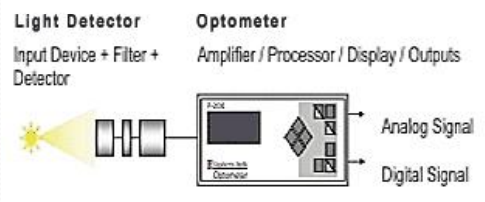
## Commercial Broad-Band Meters with Safety Spectral Response Functions

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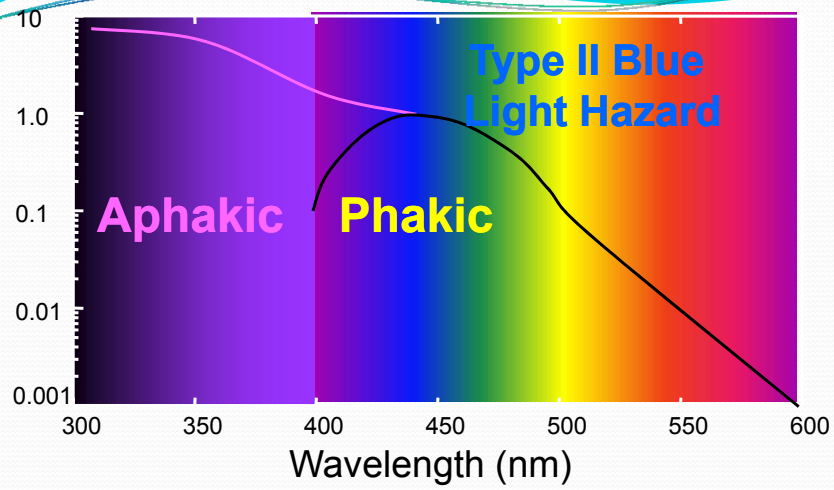
# Photoretinitis Hazard Functions




The retina is six times more sensitive to 350 and 325 nm than to Blue light (441nm)

Ham et al, Amer.J.Ophthalmol. 93: 299-306 (1982)

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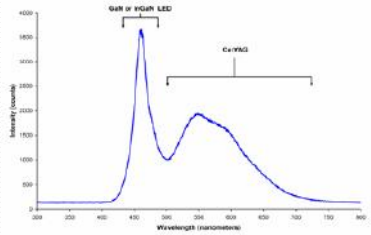
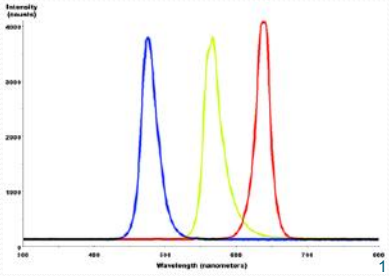
# What about "White" Light-Emitting Diodes (LEDs)?





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## ICNIRP Statement on LED Safety (2000) from Expert Task Group

- The International Commission on Non-Ionizing Radiation (ICNIRP) convened a task-group of experts on solid-state diode emitters and retinal biophysics in Regensburg, Germany in 1999.
- These experts concluded that LEDs without gain (e.g., all surface emitters) were intrinsically limited in radiance ***below the retinal hazard level*** *(Health Physics,* 78(6): 744-752, 2000).
- ***This conclusion was based on the fact that LEDs are* radiance limited and continuous staring at blue LEDs was unrealistic (aversion)**

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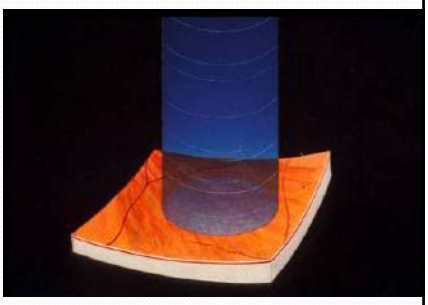
## But *are* there any LED hazards?

- ICNIRP Statement (2000)—No! Not under realistic use and viewing conditions
- Today—two blue-light effects may be of interest and should be re-addressed:
- Photomaculopathy
  - Retinal injury
- Neuro-endocrine effects
  - Sleep disturbances
  - Altered melatonin levels?
    - Immunology—cancer???



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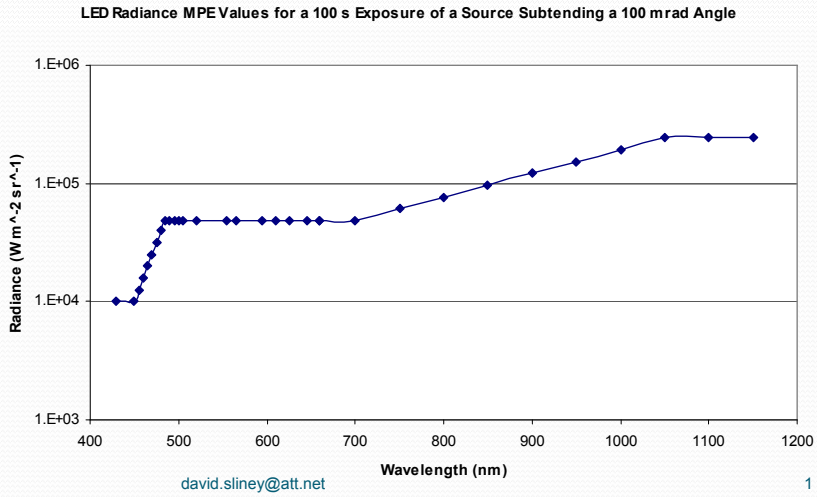
# Light Emitting Diodes (LEDs)

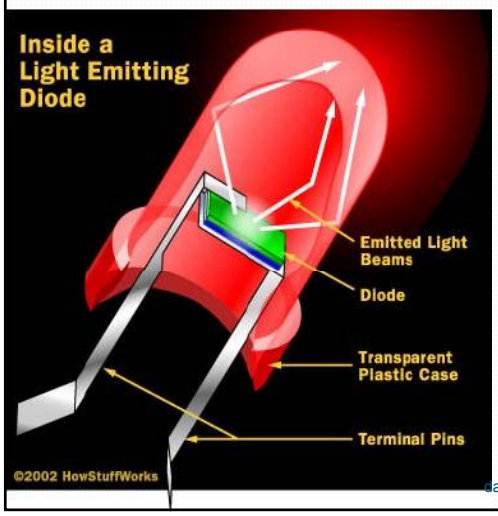
- Conventional, surface-emitting LEDs are radiance limited and do not have gain.
- Radiance limited to approximately 4 $W \cdot cm^{-2} \cdot sr^{-1}$
- Optical collimators, projection lenses cannot increase the radiance
- Conservation of Radiance (the brightness theorem).



# Laser MPE Radiance Values as a Function of Laser Wavelength



# Surface-Emitting LEDs




- Estimating the radiance:
- Radiant power P = 40 mW
- Chip size: A =1 x 1 mm
- Radiant intensity I = W/sr
- Step 1: Calculate radiance if a Lambertian chip:
  - $M = P/A = .04\ W/(0.1\ cm)^2$
  - $L = M/\pi = 1.3\ W \cdot cm^{-2} \cdot sr^{-1}$
- Step 2: Compare with MPE

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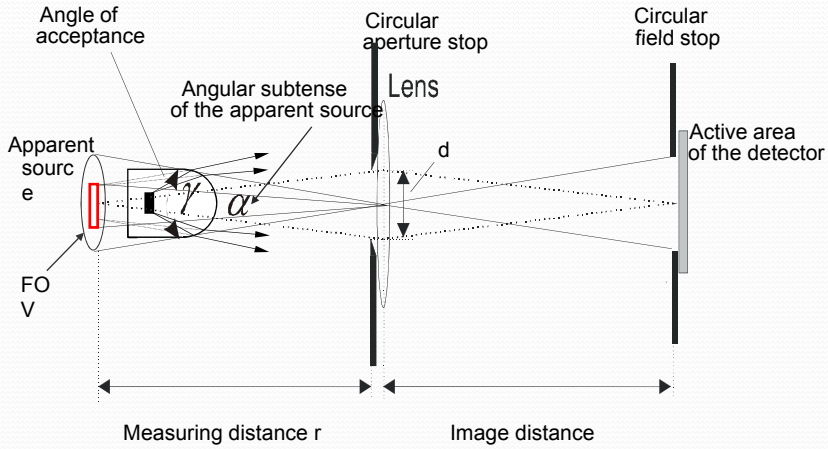
# Lamps with integrated/attached beam-shaping optics LEDs

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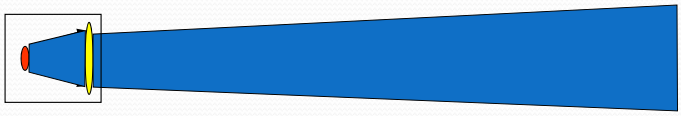
# Diode Projection System

- Lens concentrates (projects) the emission from the LED source into a beam
- Attempt is usually to produce the greatest collimation as possible (within reason)



- Diode projector optics cannot increase the final radiance ("brightness"), only change $\alpha$

# LED and lamp limitations

- If the input (pump) energy of a laser is increased, output energy continues to increase and may increase by orders of magnitude before thermal failure.
- If current to an LED or incandescent filament is increased, the radiance may slightly increase, but the chip or filament burns up momentarily and the risk is nil

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## Quick Measurement of Radiance:
## *my preferred method*

- Materials and equipment
  - Irradiance meter
  - 2.2-mm aperture and mm ruler > 200 mm
  - Digital camera with manual focus and adjustable f/#, plus neutral-density D4-5 filter (Note: It is important to find a digital camera that sees IR-A)
- Method: Darken the room, photograph the source size with light on and with rule
- Measure irradiance at 200 mm with 2.2-mm aperture in front of the source

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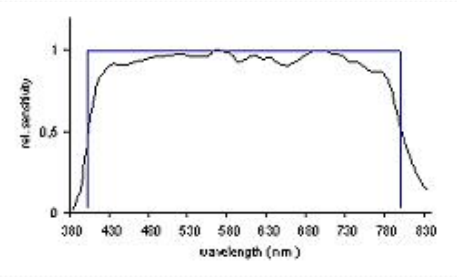
## CAUTION:
## Spectral Response of Broad-band Radiometer

- A number of filter, silicon-based broad-band radiometers are commercially available.
- Most are direct-reading from approximately 400 nm to 750-900 nm

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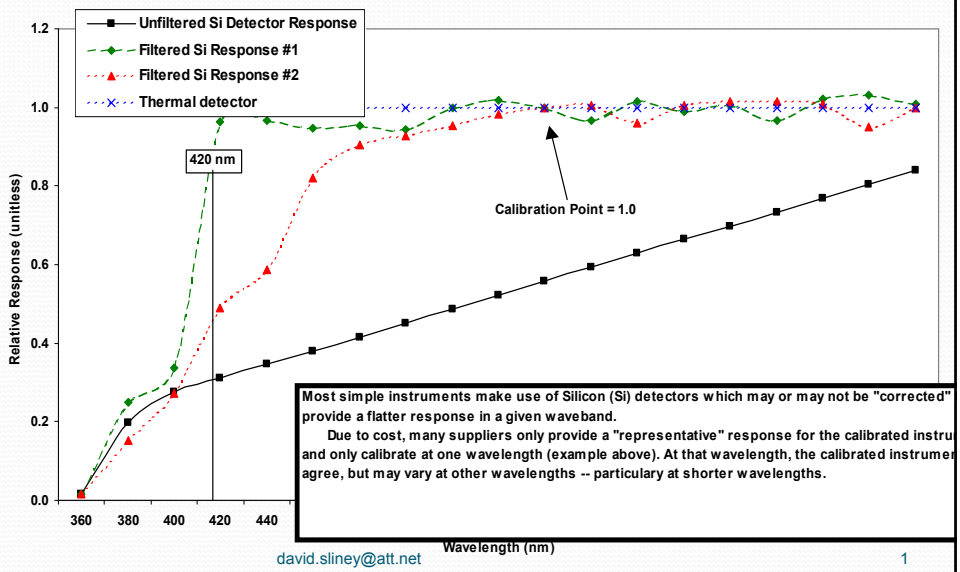
# Spectral Response Problem




Most simple instruments make use of Silicon (Si) detectors which may or may not be "corrected" provide a flatter response in a given waveband.

Due to cost, many suppliers only provide a "representative" response for the calibrated instru and only calibrate at one wavelength (example above). At that wavelength, the calibrated instrumer agree, but may vary at other wavelengths -- particulary at shorter wavelengths.

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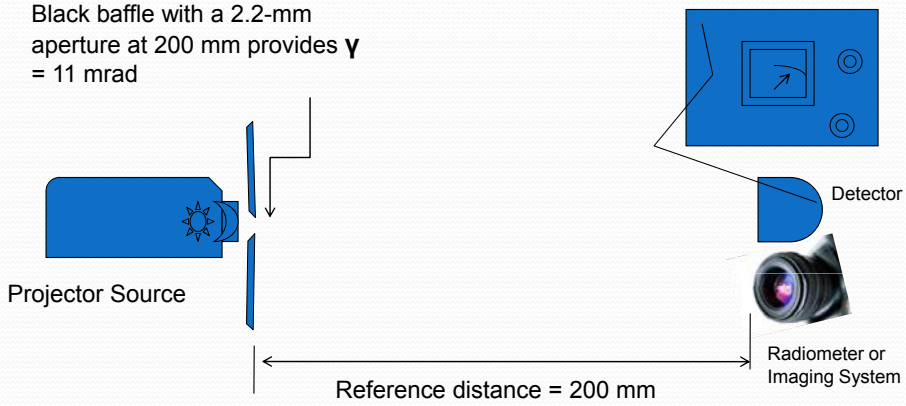
# Measurement Set-Up for Source Radiance—an example for conventional and digital light projectors

Black baffle with a 2.2-mm aperture at 200 mm provides γ = 11 mrad




Irradiance measurements should be made at a range of distances r

# Some Projectors Types Evaluated

35-mm Slide Projector

DLP Projector

High Intensity DLP

Overhead Projectors

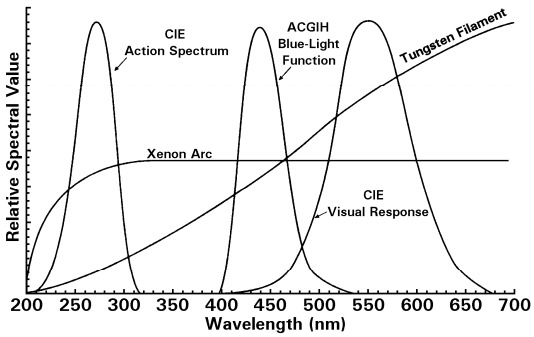
DLP Projector

Bicycle Lights, Flashlights



# IEC/CIE 62471/S009:2006 Criteria for Assessment

- Ultraviolet S(λ)
- Ultraviolet UV-A
- Retinal Blue-Light Hazard B(λ)
- Retinal Thermal Hazard R(λ)
- Infrared Cornea/Lens
- Retinal Thermal w/ Low-Visual Stimulus

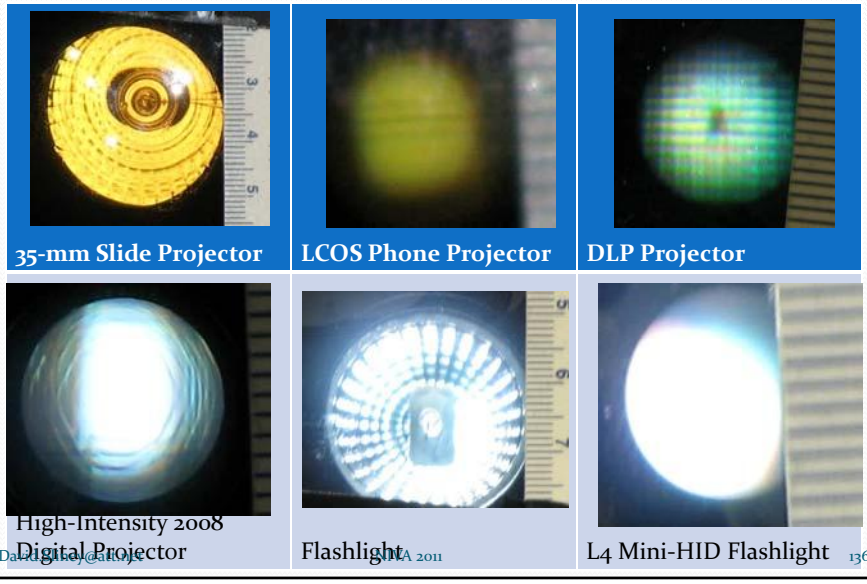


# Emission Limits for Risk Groups — Continuous Wave Lamps

| Risk | Action Spectrum | Radi-ometric Quantityl | Emission Limits | | | Units |
|---|---|---|---|---|---|---|
| | | | Exempt | RG-1 Low Risk | RG-2 Mod Risk | |
| Actinic UV | S(λ) | $E_s$ | 0.001 | 0.003 | 0.03 | $W/m^2$ |
| Near UV | | $E_{UVA}$ | 10 | 33 | 100 | $W/m^2$ |
| Blue Light | B(λ) | $L_B$ | 100 | 10000 | 4000000 | $W/(m^2 \cdot sr)$ |
| Blue Light, small source | B(λ) | $E_B$ | 1.0* | 1.0 | 400 | $W/m^2$ |
| Retinal Thermal | R(λ) | $L_R$ | 28000/α | 28000/α | 71000/α | $W/(m^2 \cdot sr)$ |
| Retinal Thermal, weak visual sti-mulus** | R(λ) | $L_{IR}$ | 6000/α | 6000/α | 6000/α | $W/(m^2 \cdot sr)$ |
| IR Radiation, Eye | | $E_{IR}$ | 100 | 570 | 3200 | $W/m^2$ |

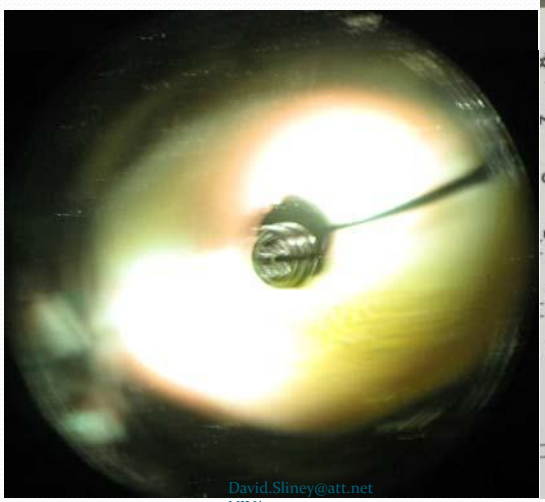


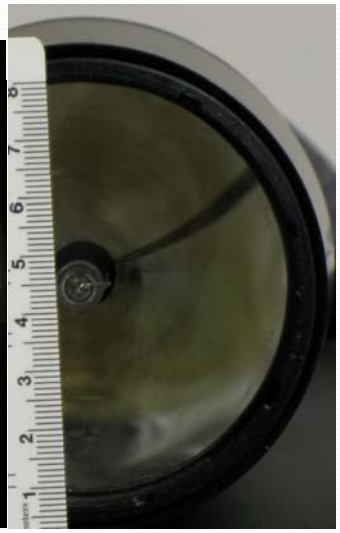
# Intrabeam Radiance Images



# Polarion Police Hand-held Spotlight

*arc discharge*







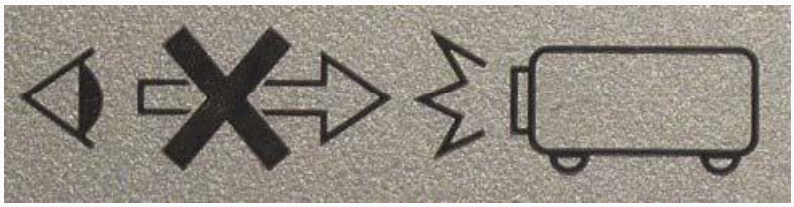
# Summary of Projector Systems

- Essentially all DLP projectors, such as the one used in this room are RG-2—analogous in risk to Class 2 laser products. The old 35-mm slide projectors were also RG2. This is because the source size is relatively large compared to lasers
- Some low-wattage overhead projectors were even RG-1
- Some pocket-sized projectors were RG-1

- Can guidance be provided to TC 108 with regard to appropriate Risk-Group/Laser Class for different applications? Joint meeting for WG-1 and WG-9

# What does this label mean?

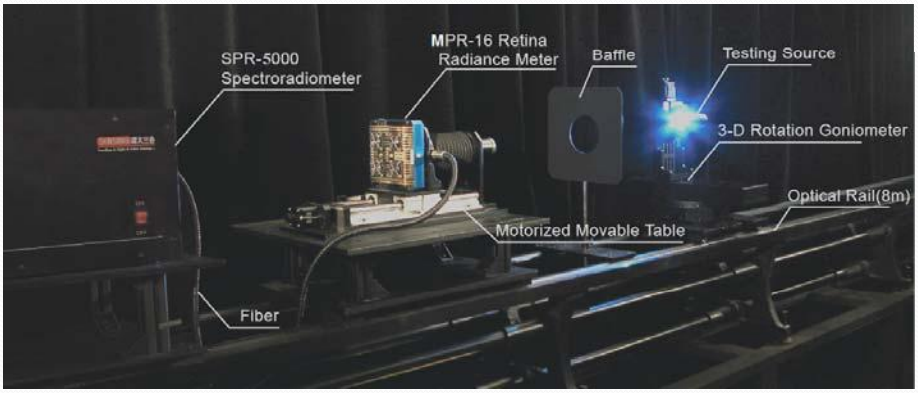
- It was on almost all newer projectors that were measured!





# One had Label with Words Added

# Measurement system for photobiological safety




**Sensing, Ltd. assessment of optical radiation safety for LEDs**

# LED Measurement Problems

- Both the laser and lamp extended-source techniques effectively measure radiance
- Radiance profile can be imaged, but the apparent source typically varies along the z-axis as well as the x- and y- axes.
- Angular distribution of Radiant Intensity is the most common LED specification and is the least relevant to retinal hazards.

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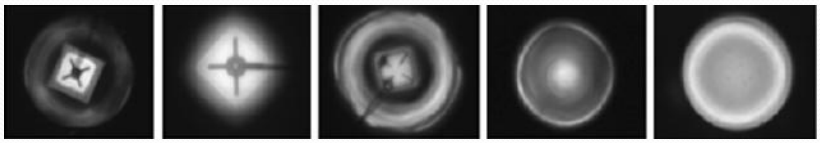
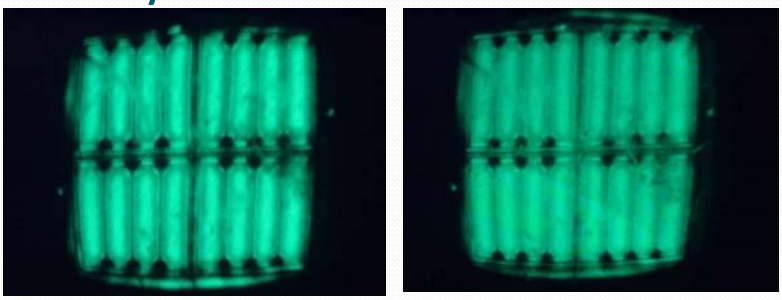
# Single LEDs—the simple case

- Most individual LEDs are very simple to test.
- Typical LED diameters are ~ 3 – 5 mm mounting
- A 2.2-mm diameter mask in front of the LED provides the spatially averaged radiance required at 20 cm. Move the aperture to maximize irradiance measured.
- The radiance is then simply: $L_{11} = E/(10^{-4}\ \mathrm{sr})$





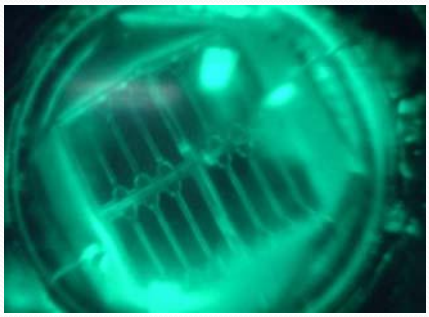
# Radiance Distribution of a Lumileds LED array



Photographs of a 5-watt cyan LED using a digital camera and a computer or an oscilloscope display

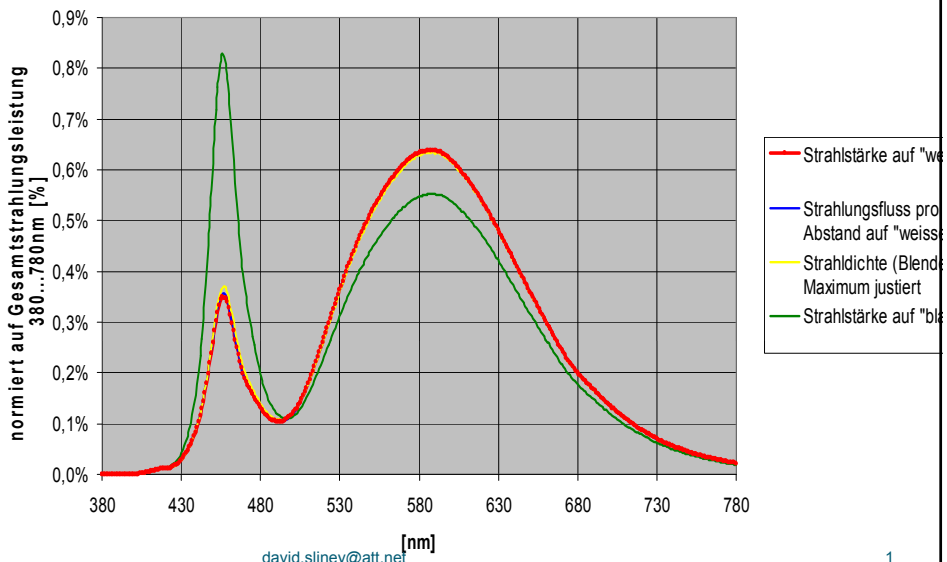
# Examing the Chip Emitters

- Digital photograph with the room lights on and the LED off to show the chip arrangement for this surface-emitting LED array.





# "White" LEDs -- Blue Peak



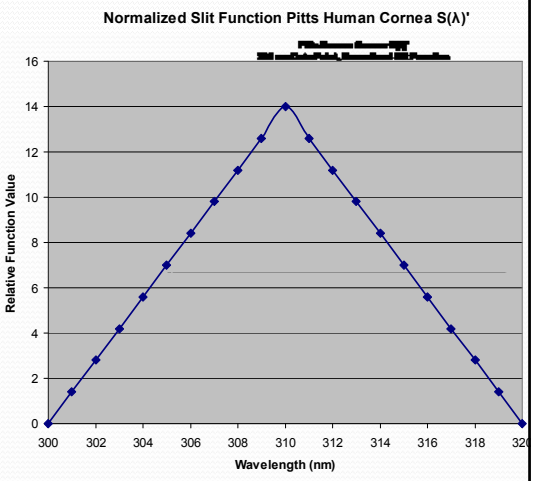
## The Weighted Lamp Spectrum with the Action Spectrum

- The choice of spectral bandwidth for a monochromator depends upon the spectral region
- Ten-nanometer bandwidths may be fine in the infrared, but provide a large error in the ultraviolet region—particularly in the region between 290-320 nm
- Example--Consider the bands at 310 and 320 nm.

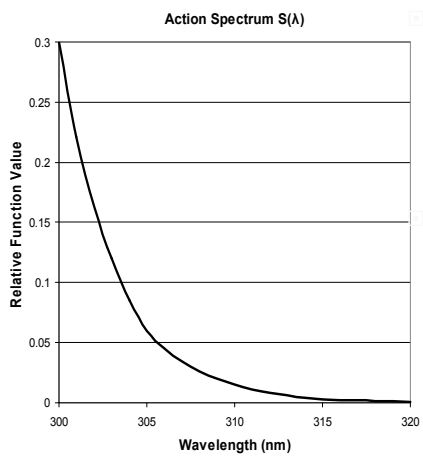


## Monochromator Slit Function

- For a spectral bandwidth of 10 nm Full-Width-at-Half-Maximum (FWHM), the approximate spectral power distribution for that one experimental exposure is:



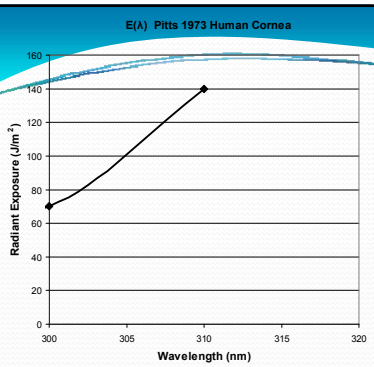
# The "actual" action spectrum within this spectral band

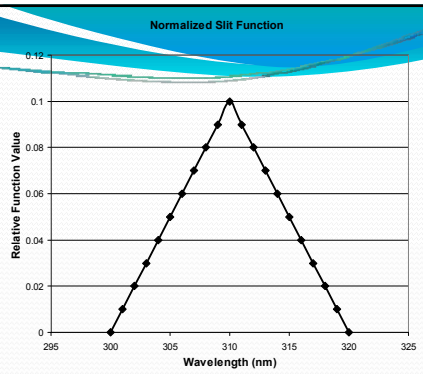


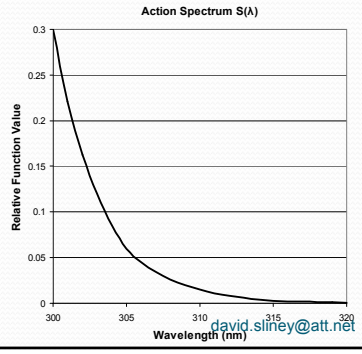

The actual change in the sensitivity of the cornea varies by a factor of 10-fold in just 7 nm!

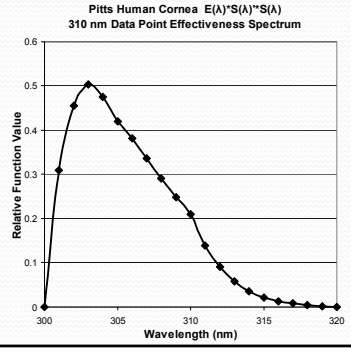
Therefore, wavelengths at the beginning of the slit function are dominant





## Digital Radiometers—A Caution!

- Many relatively inexpensive CCD spectrometers are available today
- Dynamic range is quite limited.
- Useful for visible and IR-A LEDs
- Generally not useful for ultraviolet sources
  - Stray light problems
  - Insufficient dynamic range



## Conclusion: Simple tests first!

- A little knowledge about characteristic spectra of sources is important.
  - You can obtain the spectral power distribution from most manufacturers
  - Use spectral weighting only if source fails test
- A good understanding of projection optics and the Conservation of Radiance is important
  - You can measure radiance with a 2.2-mm aperture in opaque baffle and irradiance meter
  - Incorporate digital photography or beam profiler cam.

# Table of Comparisons

| OPTICAL SOURCE → | LAMPS AND LAMP SYSTEMS | LASERS AND LASER PRODUCTS |
|---|---|---|
| Underlying Philosophy | *Most lamps are safe.* Only rarely do lamps pose a realistic hazard | *Most lasers are dangerous.* The threshold for laser action is normally above safety limits. |
| Spatial Characteristic of Emission | *Omni-directional* or broad-beam ("highly collimated" is a few degrees and < 100 mrad). Hazards only at close distances | *Collimated* and highly directional beam of typical 1-mrad divergence. Hazard can exist to distances of kilometers for collimated beams |
| Source Radiance | *Radiance Limited.* Almost all sources have radiance less than sun (~1 $kW \cdot cm^{-2} \cdot sr^{-1}$) Applications depend on emitted power. | *Radiance is unlimited.* Laser pointers are brighter than the sun. Most applications depend on the laser's enormous radiance |
| Exposure Conditions &Probability of exposure | *Highly likely, intended:* Exposure is expected and generally lengthy and not to be avoided. Widest applications are for illumination in general lighting service (GLS) | *Unlikely and unintended:* Exposure of the body to collimated beam (particularly the eye) is unlikely and generally to be avoided. Exposures are generally incidental or accidental and not lengthy |
| Initial hazard of typical basic source | Very low hazard or non-hazardous emitter. Many lamps used as final products instead of product components | Hazardous from direct exposure to raw beam. Most laser emitters are incorporated into a product or modified by beam-delivery system. |
| Source Viewing Conditions | Extended source, viewing is frequently intended (displays, indicator lights, lamp fixtures). Lengthy viewing is typical | Point source where viewing is not intended, momentary and highly uncomfortable if a visible laser. Viewing of diffuse beam spot. |

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# Table of Comparisons (cont.)

| Optical Source → | Lamp Products | Laser Products |
|---|---|---|
| Traditional safety approach | Unwritten "safety standards" evolved over a century ago with lamp envelopes to block UVR and limit skin-burn hazard at a touch; formal standards issued in 1990's | Highly formal written user standards evolved with the development of the first lasers since the 1960s, with product safety standards in the 1970s. Hazards were widely recognized. |
| Radiometric Measurements of Product for Retinal Hazards | Spectroradiometric measurement of source radiance averaged over an angular subtense of 0.011 (~0.6°) to 0.1 radian (~6°) (CW) and as small as 0.0017 radian (i.e., 1.7 milliradians, when pulsed) at a distance of at least 20 cm. Source size (angular subtense $\alpha$) also must be measured unless default 100-mrad source assumed (most typical). | Radiometric measurement of radiant power through a 7-mm aperture (spatially averaged irradiance) at 1.4 - 10 cm for hazard classifications against an Accessible Emission Limit (AEL). Source size (angular subtense $\alpha$) also must be measured unless default 1.5-mrad source assumed (most typical). |
| Limiting Hazard | Typically UVR $S(\lambda)$-weighted irradiance (fluorescent lamps) or blue light (LEDs) | Typically retinal thermal hazard or total radiant power (higher classes) |
| Product Safety Standards | US: FDA/CDRH Sunlamp standard and US-user only ANSI-RP27., .2, .3 etc. International: CIES009/IEC62471 | US: FDA/CDRH - 21CFR1040 ANSI user-safety standards Z136.1, .2, .3, etc. International: IEC 60825-1, -2, etc. |
| Risk/Hazard Classification | Exempt, RG-1 (risk in rare applications); RG-2 (low risk for momentary viewing); RG-3 (moderate to high risk, even for momentary viewing, e.g., xenon-arc lamps) | Class-1 (safe under reasonably foreseeable exposure); Class-2 (low risk for momentary viewing); Class 3 (ocular risk, even for momentary viewing); Class 4 (high risk, to include skin hazards, fire hazards, etc. |
| Use in home electronics | Exempt group or RG-1; e.g., LED indicator lights and displays | Class 1 by protective housing; e.g. CD players |

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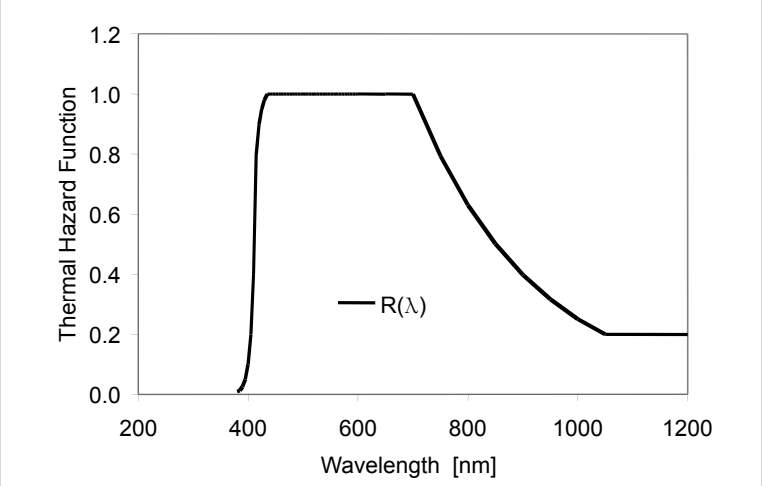
# Revisions Underway in ELs

- Revision of retinal thermal hazard function R(λ) issued by ACGIH, but ICNIRP behind
- ACGIH revised extended-source retinal thermal hazard ELs for shorter pulses
- Changing laser ELs in the 1200-1400 nm spectral region
- Other minor updates



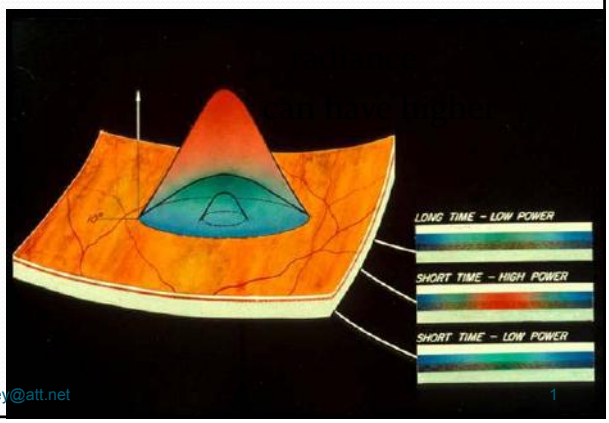
# Retinal Thermal Hazard Function R(λ)

Is this a realistic concern for lamps?



## Heat-flow geometry limits chip radiance and the corresponding retinal image irradiance

- The geometry of heat flow from an LED chip limits chip radiance and retinal irradiance
- Smaller chips can have higher
- Smaller images irradiance






# WHAT IS GLS—and Why?

- Many lamps are used quite independently of fixtures, and these are used in general lighting service (GLS).
- We know the UVR is strongly reduced by luminaires (lighting fixtures)
- Most materials do not reflect UVR well
- GLS lamps are not intended for lengthy fixation (staring).

# General Lighting Service (GLS)

- In CIE S009 all lamps are measured at one distance, but the RG determination is based upon converting to a 500 lux illumination (as average daily exposure)
- Use µW/lm for each of the seven hazards, etc.

Lamp frosting and tube diameter traditionally was chosen to reduce luminance to < 1 cd/cm$^2$

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# Luminaires—the impact of fixtures: Can hazards be increased?

- Remember that GLS lamps are assessed at 500 lx
- Fixtures are designed to optimize the visible light
- UV and IR transmission/ reflectance always reduce fraction, RG still valid!
- Source size can be magnified, but still reduced as one goes out to 500 lx

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## GLS Risk Group Determination: It sounds too simple!

- Because the GLS risk group determination is based upon 500 lx and does require UV or IR or radiance measurement at 20 cm, some have questioned whether it can be valid
- However, the conservation of radiance (brightness) theorem requires that the apparent source size will increase if the irradiance increases and vice-versa. Thus lens luminaires will increase LED angular subtense, but illuminance must increase proportionally above 500 lx

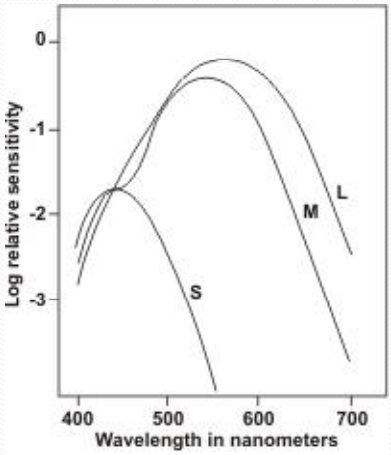


## Is there a Red-Green Light Hazard? *"Light damage of the first kind"*

- One study on a potential green-red light hazard to the retina was published in 2008 and deserves attention
- Morgan, JIW, JJ Hunter, BM, R Wolfe, DC Gray, WH Merigan, FC Delori, DR Williams, Light-induced retinal changes observed using high-resolution autofluorescence imaging of the retinal pigment epithelium, *Invest Ophthalmol Vis Sci.* **49**(8):3715-3729 (2008).

# The Red-Green Light Hazard

- Morgan et al., *Invest Ophthalmol Vis Res* (2008) reported on 568-nm retinal injury thresholds that were far lower than predicted by the Blue-Light Hazard limits (laser & non-coherent limits.
- Questions raised!
- Light damage of the first kind (known since 1966).




The Three Cone Spectral Responses

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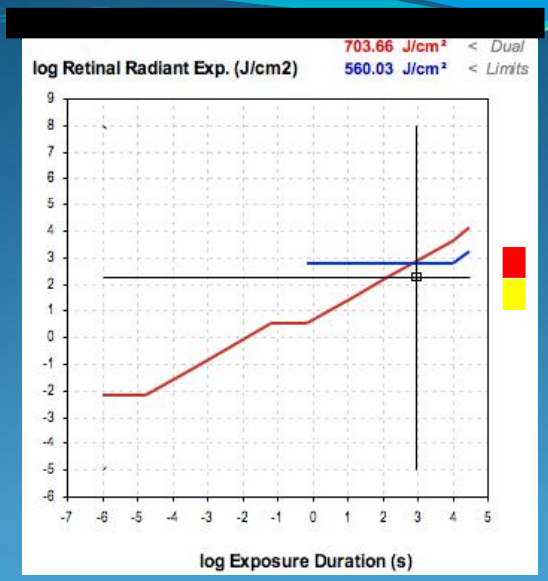
NIVA 2009



0.5° x 0.5°. λ=568 nm




Damage
Dimming

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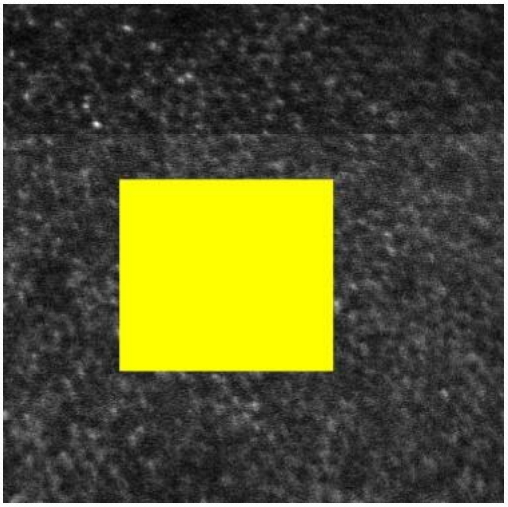
NIVA 2009

## Location 2a: RPE pre-exposure image with exposure location



150μW exposure over .5 deg imaging field for 15 minutes

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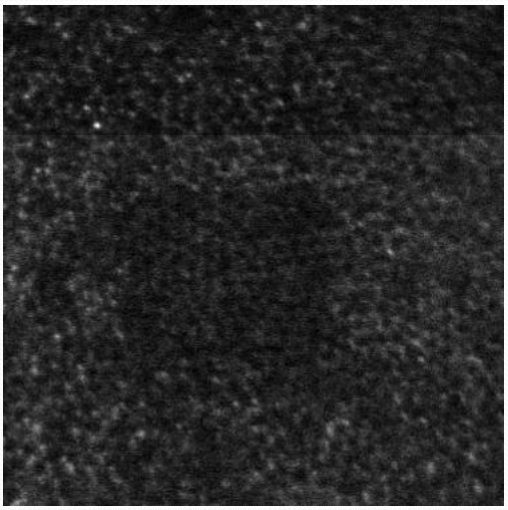
NIVA 2009



## Location 2a: RPE immediately post-exposure image



V24 102706, decrease in autofluorescence in exposure area

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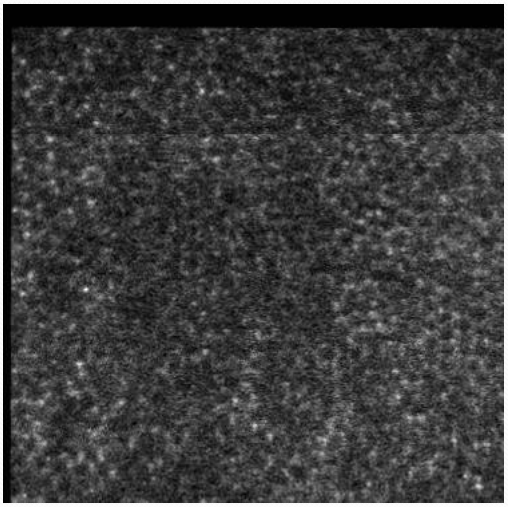
NIVA 2009

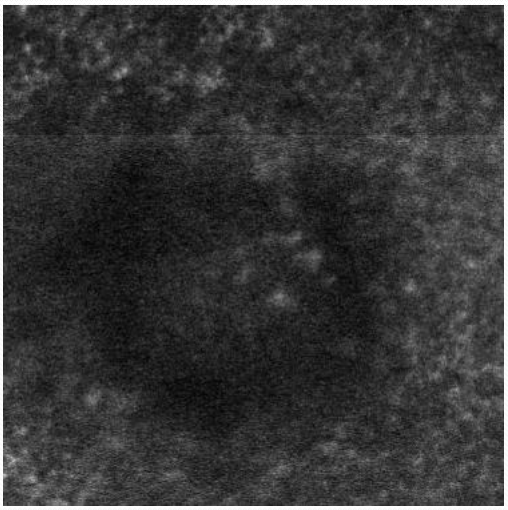
## Location 2a: RPE ~1.5 hours post-exposure image



V50 102706, decreased autofluorescence from initial image, but partially recovered in comparison to immediately after exposure.

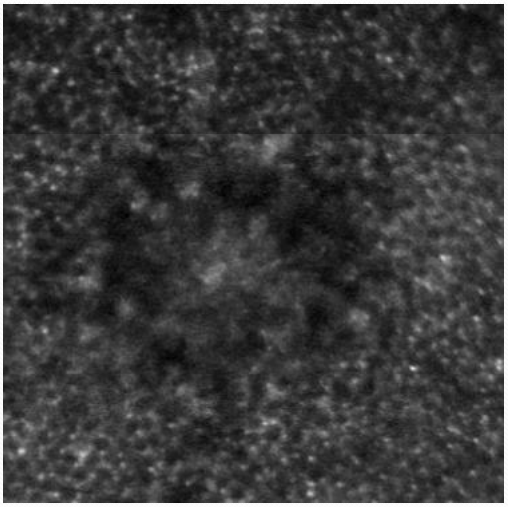


## Location 2a: RPE 11 days post-exposure image



V29 110706, RPE structural change observed 11 days later.

## Location 2a: RPE 26 days post-exposure image



V25 112206, RPE structural change observed 26 days later.



# The Red-Green Light Hazard

- The Morgan study showed potential retinal injury in the primate retina from 247 $J \cdot cm^{-2}$ (at the retina) which corresponds to a time-integrated radiance $L \cdot t = 2.54 \times 10^4$ $J \cdot cm^{-2} \cdot sr^{-1}$ for a 2-mm pupil, which would greatly stress the retina and interfere with the normal rhodopsin and cone-opsin cycles.
- The "bleached" rod-rhodopsin or cone-opsin is regenerated in the adjacent cells of the retinal pigment epithelium (RPE), and re-transported back into the photoreceptor cells. In that process, there are a number of intermediate products. Some, such as retinal, are toxic in their own right. This is "Type I" light-induced injury.

# Ophthalmic Instruments

- So what is the impact of:
  - Standards Activities
  - Changing Exposure Guidelines
  - New light sources such as LEDs

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# The Patient

- Will generally be cooperative, and not object to viewing an intense light source
- The head may be stabilized (e.g., in a chin rest)
- The pupils may be dilated
- During surgery, eye movements may be reduced, or virtually eliminated
- The aversion response to bright light is absent under anesthesia

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# Background

- ICNIRP Guidelines for human exposure to optical radiation are based upon the underlying assumption that the person exposed is awake and task-oriented, which includes normal eye movements
- Ophthalmic examination and diagnostic tests alter these assumptions:
  - The eye may be stabilized
  - The pupil may be dilated



# ISO TC 172/SC7/WG6 Activities

- The International Standards Organization (ISO) Technical Committee TC 172/SC7/WG6, Ophthalmic Instruments developed a performance standard for optical radiation safety of ophthalmic instruments.
- ISO TC 172 requested ICNIRP to provide specific, scientifically based guidelines for limiting exposure.
- ICNIRP Task Group formed under Sub-committee IV (Optical Radiation) –Sliney
- ISO Standard 15004-2-2007 was based upon the guidelines with certain assumptions of use.

# ISO 172/SC7/WG6

- ISO 15004-2007 now up for revision
- New efforts to amend the Operating Microscope Standard and remove requirement for measurement, but the manufacturer must provide a worst-case safe exposure duration
- ISO 15752 Endoilluminators issued



# *ISO TC94 Personal Protective Equipment SC6 – Eye Protection (all types)*

- Items Discussed for draft standards:
- Frames, head-shapes, etc.
- Welding filter shade #s
- Laser protection
  - Optical density measure
  - Filter stability testing
  - US proposal for default tests (some object!)
- Testing methods
- Glare tests (scatter)

# Reiteration of FAA Policy Regarding Notification Requirements

Federal Aviation Administration

Presented to: Triennial NASA Health Physics Training

By: Kelly Neubecker

Date: April 21, 2011

# Reiteration of FAA Policy Regarding Notification Requirements

- www.FAA.gov
- Regulations and Policies
- Policy and Guidance
- Outdoor Laser Operations

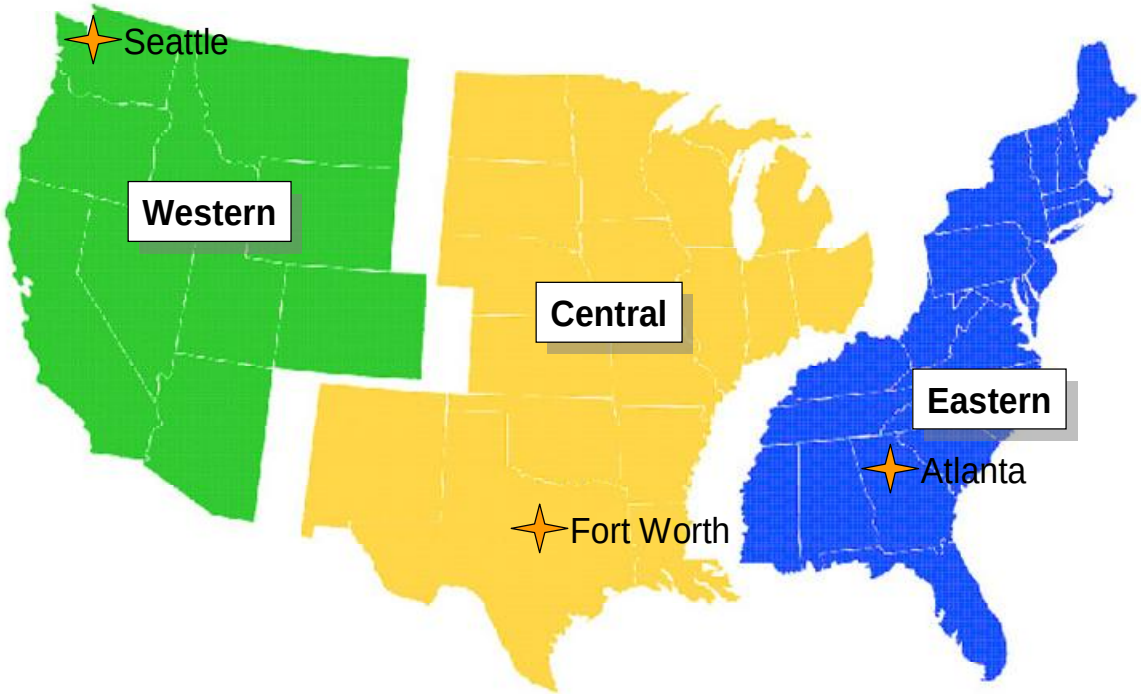
# TITLE 49 U.S.C.

- The U.S. Government has exclusive sovereignty of airspace of the U.S.
- A citizen of the U.S. has a public right of transit through the navigable airspace.
- The FAA Administrator shall:
  - develop plans and policy for the use of the navigable airspace
  - assign by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace.

# Airspace Authority, Title 49, U.S. Code

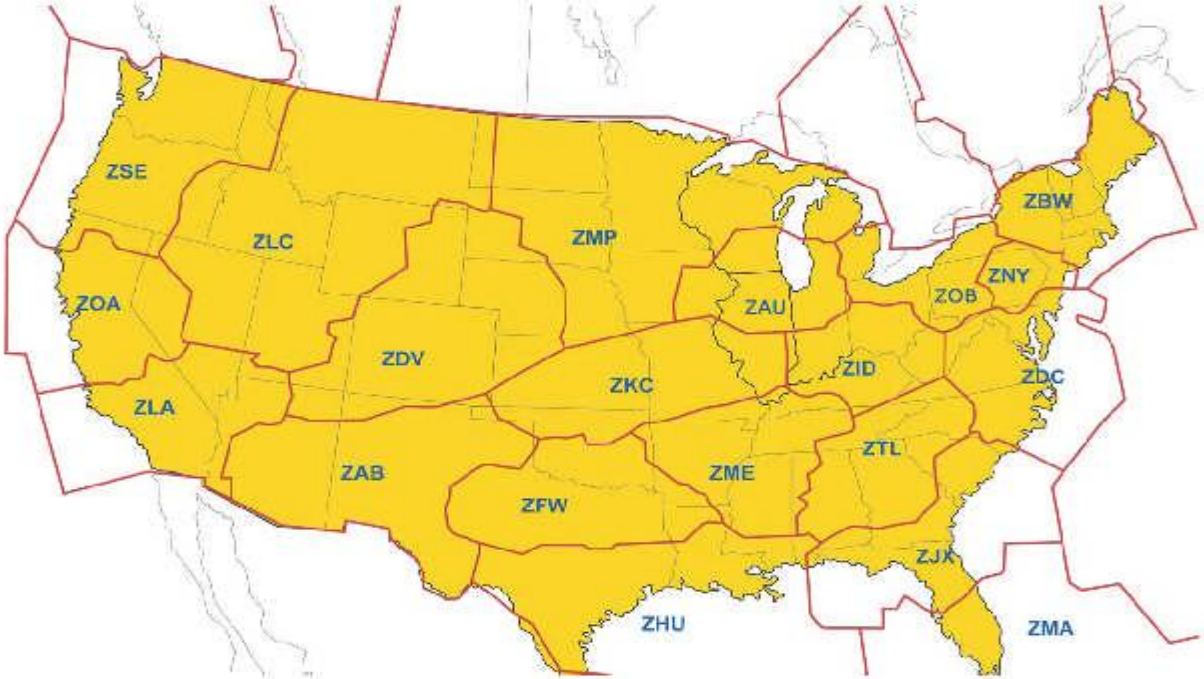
- **Section 40103(a)(1), governs the sovereignty and use of airspace within the U.S.**
- **Section 40103(b)(1), grants the FAA Administrator the authority to "develop plans and policies for the use of the navigable airspace.....to ensure the safety of aircraft and the efficient use of the airspace**
- **Section 44701(a)(5), Congress authorizes the FAA to promulgate safety rules to protect civil aircraft and air commerce**

# FAA ATO Service Areas

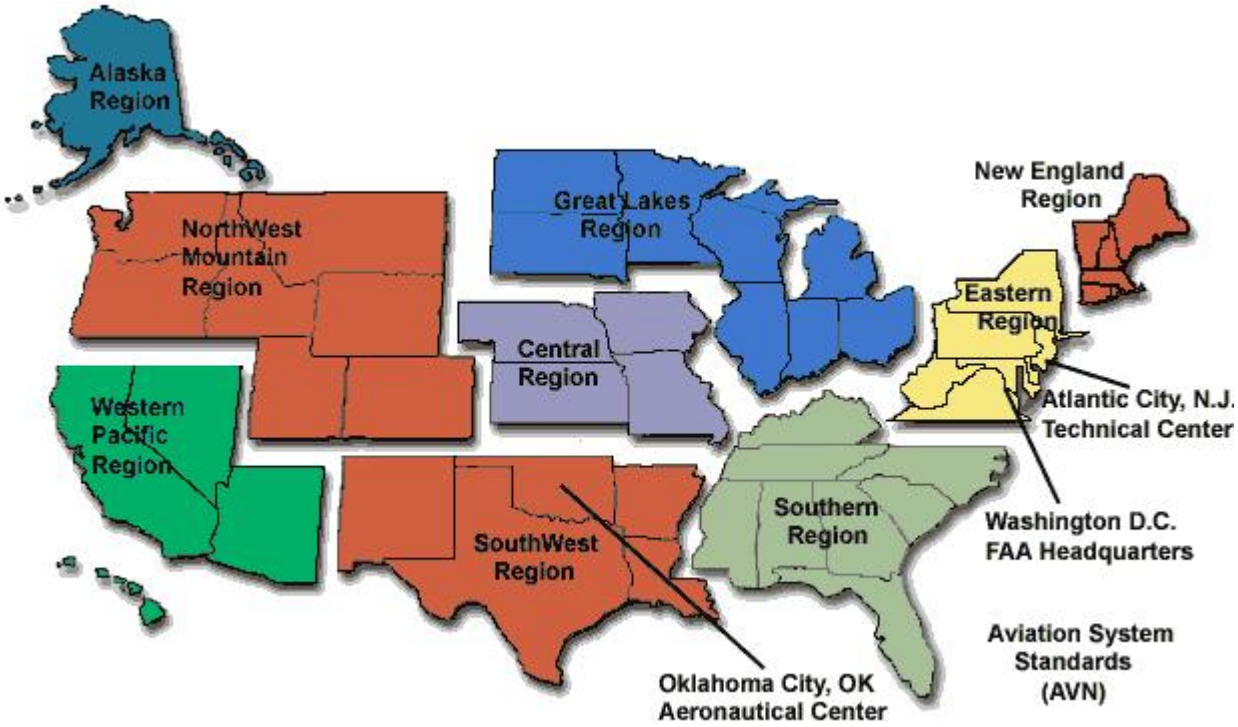


FAA
Air Traffic Organization

## The National Airspace - Air Route Traffic Control Center Boundaries

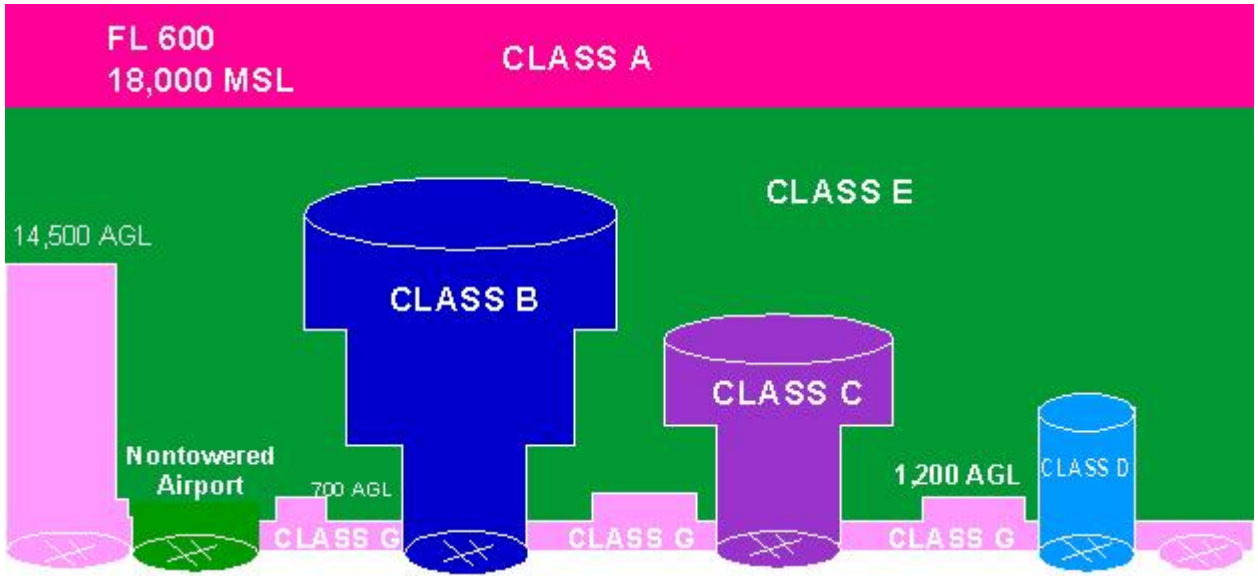


# FAA Regional Offices



# U.S. AIRSPACE CLASSES

ABOVE FL 600:  CLASS E



# Reiteration of FAA Policy Regarding Notification Requirements

- **Laser Light Shows/Demonstrations**
- **An outdoor laser light show/demonstration is considered to be a laser product by the Food and Drug Administration's Center for Devices and Radiological Health (CDRH) and, if the irradiance is greater than 5 miliwatts per square centimeter, the demonstration requires a variance to Title 21, Code of Federal Regulations, Section 1040.11c. The variance (issued by the CDRH) requires the laser user to notify the Federal Aviation Administration (FAA) of the proposed laser operation and resolve any objections that the FAA may have.**

# Reiteration of FAA Policy Regarding Notification Requirements

- **Scientific/Research Lasers**
- **However, title 49, United States Code (49 USC), section 40103 (a)(1), governs the sovereignty and use of airspace within the United States. Section 40103 (b)(1) grants the Administrator of the FAA the authority to "develop plans and policies for the use of the navigable airspace and assign by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace." Moreover, 49 USC, section 44701 (a)(5), Congress authorized the FAA to promulgate safety rules to protect civil aircraft and air commerce. Accordingly, the FAA specifically prohibits interference with crewmembers under 14 CFR, section 91.11. Federal criminal law also prohibits the interference with pilots of an aircraft under 18 USC, section 1993. See also, 18 USC section 32(a)(3), (5).**

# Reiteration of FAA Policy Regarding Notification Requirements

- **Scientific/Research Lasers**
- **The FAA's safety rules and the criminal law provisions outlining interference with crewmembers are independent of any rules promulgated by the FDA. Therefore, before conducting any outdoor laser operation, a researcher must ensure all physical, procedural, and automated control measures are used to ensure no aircraft will be exposed to levels of illumination greater than the respective maximum irradiance levels established for the various protection zones. This includes any laser that is in a building but may exit the building through an opening.**

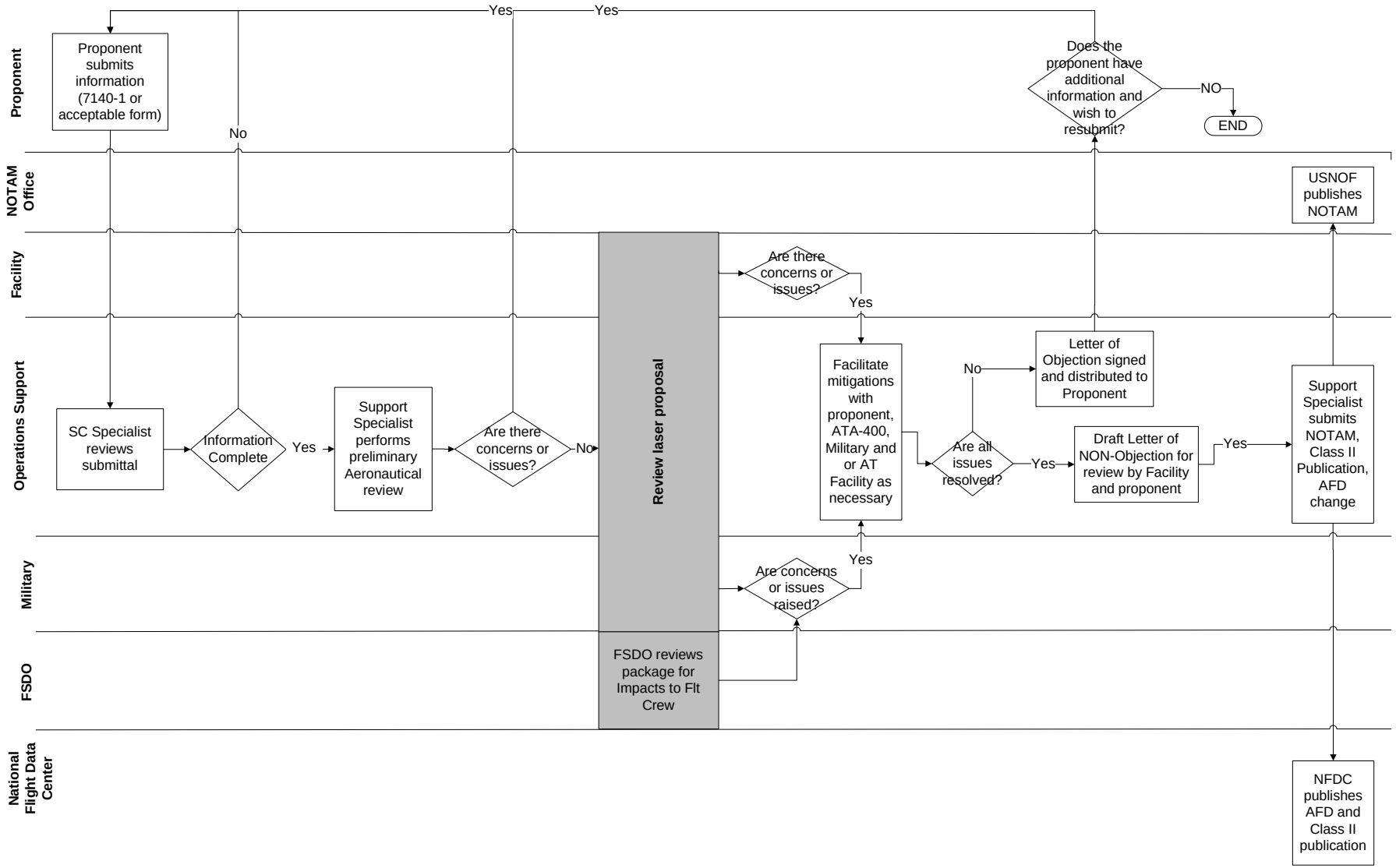
# Reiteration of FAA Policy Regarding Notification Requirements

- **4. When should I send the notice to the FAA?**
- **Scientific/Research Lasers**
- **The FAA evaluation of new outdoor scientific/research laser operation is more complex than for a laser light show/demonstration and may require a comprehensive safety risk assessment. Because this analysis may take an extended period of time to complete, we recommend that you send the notice to us at least 4 months before you plan to conduct any new outdoor scientific/research laser operation. We recommend renewals for recurring operations be submitted at least 45 days in advance of proposed operations.**

# Reiteration of FAA Policy Regarding Notification Requirements

- **2. What will the FAA do when I notify them about a planned outdoor laser operation?**
- **The FAA will evaluate your proposed outdoor laser operation in accordance with procedures detailed in FAA Order 7400.2, Procedures for Handling Airspace Matters, and will issue a letter of determination of objection or no objection.**
- **3. How do I notify the FAA about a planned laser operation?**
- **To notify the FAA, use FAA Form 7140-1, Notice of Proposed Outdoor Laser Operation(s) (PDF). This is a 2-page form. The first page asks for general information. The second page is a Laser Configuration Worksheet that should be completed for each individual laser.**
- **Further information may be found in FAA Advisory Circular AC 70-1, Outdoor Laser Operations**

# Outdoor Laser Proposal Process



# FAA Regional Points of Contact

| Western Svc Center | Central Svc Center | Eastern Svc Center |
|---|---|---|
| ATC | ATC | ATC |
| **Richard Roberts**<br>richard.roberts@faa.gov<br>425-203-4517 | **Angel Cases**<br>angel.cases@faa.gov<br>817-321-7726 | **Pete Acevedo**<br>peter.k.acevedo@faa.gov<br>404-305-5598 |
| **Raul Garza**<br>raul.garza@faa.gov<br>425-203-4541 | **Kathryn Bidinger**<br>kathryn.bidinger@faa.gov<br>817-321-7712 | **Armando Castro**<br>Armando.castro@faa.gov<br>404-305-5590 |
| Send the Notice of Proposed Outdoor Laser Operation(s) to:<br>Federal Aviation Administration<br>ATO, Western Service Center<br>Operations Support Group, AJO2-W<br>1601 Lind Ave<br>Renton, WA 98057 | Send the Notice of Proposed Outdoor Laser Operation(s) to:<br>Federal Aviation Administration<br>ATO, Central Service Center<br>Operations Support Group, AJO2-C<br>2601 Meacham Blvd<br>Fort Worth, TX 76137 | Send the Notice of Proposed Outdoor Laser<br>Operation(s) to:<br>Federal Aviation Administration<br>ATO, Eastern Service Center<br>Operations Support Group, AJO2-E<br>P. O. Box 20636<br>Atlanta, GA 30320 |
| **Mike Werner - AFS** | **Robert Payne - AFS** | **David Porter - AFS** |
| michael.h.werner@faa.gov<br>425-917-6770 | robert.e.payne@faa.gov<br>817-222-5253 | david.r.porter@faa.gov<br>404-305-6050 |

# Reiteration of FAA Policy Regarding Notification Requirements

- **For airborne lasers that cross service area boundaries, send the request to the FAA service center where the flight originates.**
- **FAA Headquarters POC's:**
  **Ellen Crum: 202-493-4562 and Dick Temple: 202-385-4611**

# Flight Profiles

- **Include on the 7140 when submitted**
- **All the potential intended flight tracks for all missions and potential dates**
- **Program Mission Manager responsibility**
- **Gives the appropriate service center the ability to pre-coordinate with all ATV facilities involved**

# NOTAM Information

- ***!FDC x/xxxx (ARTCC id) (state code). SPECIAL NOTICE.. EFFECTIVE FROM (date-time) UTC UNTIL (date-time) UTC, AIRBORNE LASER OPERATIONS WILL BE CONDUCTED BETWEEN (latitude/longitude, fix-radial-distance, and/or other appropriate geographic description) AND (latitude/longitude, fix-radial-distance, and/or other appropriate geographic description) FROM _____ FEET MSL TO _____FEET MSL. THE LASER BEAM MAY BE INJURIOUS TO PILOTS'/AIRCREWS' AND PASSENGERS' EYES FOR A DISTANCE OF 13,700 FEET BELOW THE AIRCRAFT. THIS AREA WILL BE MONITORED BY OBSERVERS AND THE LASER BEAM WILL BE TERMINATED IF NON PARTICIPATING AIRCRAFT ARE DETECTED THAT MAY ENTER THE AFFECTED AREA. THE DOMESTIC EVENTS NETWORK (DEN) AT (202) 493-5107, IS THE FAA COORDINATION FACILITY.***

# Flight Timelines

- **Within 72 hours of the operation – NOTAM submitted**
- **At least 12-24 hours of the operation – specific flight track information**
- **The Program Mission Manager or Scheduler will normally provide this information**

# Legal Interpretation of 14 CFR 91.11

- **Presently states, “Prohibits the interference with crewmembers in that "no person may assault, threaten, intimidate, or interfere with a crewmember in the performance of the crewmember's duties aboard an aircraft being operated”**
- **Will apply to laser incidents, provided evidence exists to prove all elements of the regulation were violated**
- **Will include crew interference from the ground, not just airborne**
- **Will be able to pursue civil penalty action (49 U.S.C. 46318 $27,500)**
- **AGC-200 currently coordinating Legal Interpretation with Air Traffic and Flight Standards**
- **If approved, will disseminate clarification to regional legal counsels, Flight Standards District Offices, etc.**
- **Should coordinate with other Federal agencies to consider "best solutions" to laser events, requirements, responsibilities, etc.**

# Continuing Education

# Board of Laser Safety

*Providing a means for improvement in the practice of laser safety*

Kurt Geber
NASA Occupational Health Program
Dynamic-Life Sciences Support Contract
M/S: DYN-4
Kennedy Space , FL 32899

March 24, 2011

Dear Kurt ,

This letter is to inform you of the status of your request for BLS certification maintenance points. The material you submitted has been reviewed and will be awarded CM points to CLSOs and/ or CMLSOs as follows:

| | |
|---|---|
| **Sponsoring Organization:** | NASA Occupational Health Program |
| **Activity:** | 2011 Health Physics Conference |
| **Duration of Approval:** | April 21, 2011 |
| **CM Points Awarded:** | 1 |
| **BLS CM Number:** | 106-2526 |

BLS does not accredit, certify or endorse any courses, seminars, conferences or educational programs. Please inform CLSOs or CMLSOs who attend your activity of the BLS CM points which were awarded and the BLS CM number.

CM points are accrued by Certified Laser Safety Officers (CLSOs) and Certified Medical Laser Safety Officers (CMLSOs) who are certified by the Board of Laser Safety.

Verification of the activity must include the following: a certificate, letter, attendance roster or some other documentation for the sponsoring organization. Sponsoring organizations are required to distribute verification documentation directly to CLSOs and/or CMLSOs.

Please contact me or Barbara Sams if you have any questions or need further assistance.

Sincerely,

Jennifer Craft
BLS Certification Coordinator

13501 Ingenuity Drive, Suite 128 ♦ Orlando, FL 32826
Phone: 407-380-5833 ♦ Email: bls@lasersafety.org ♦ www.lasersafety.org

## Geber, Kurt R. (KSC-IHA-5000)[Innovative Health Applications LLC]

**From:** Willison, Jim [jim.willison@wsms.com]
**Sent:** Monday, April 11, 2011 3:06 PM
**To:** Geber, Kurt R. (KSC-IHA-5000)[Innovative Health Applications LLC]
**Cc:** Nancy Johnson
**Subject:** AAHP Continuing Education Credits

This is to inform you that the NASA Triennial Health Physics Meeting has been granted 24 CEC and assigned ID number 2011-04-001.

As credit was requested for all participants, this assignment will be posted to the AAHP website.

If you have any questions regarding this assignment, please contact us at aahpcec@burkinc.com

Jim Willison
AAHP Continuing Education Committee Chair

Attachment: 2011 Approved CE Courses (05/13/2011)
http://www.hps1.org/aahp/cec/cec11.htm

| | | | | |
|---|---|---|---|---|
| 2011-03-001 | Bridging the Gaps: Public Health and Rad EP Conference | Centers for Disease Control | 03/21-24/2011 | 18 |
| 2011-03-002 | Radiological Triage | Conference of Radiation Control Program Directors | 03/19/2011 | 10 |
| 2011-03-003 | Dosimetry for Medical and Research Facilities | North Carolina HPS | 03/03/2011 | 5 |
| 2011-03-004 | Spring 2011 Meeting | North Carolina HPS | 03/03-04/2011 | 12 |
| 2011-03-005 | Part II Certification Review Course | East Tennessee Chapter HPS | Mar-June 2011 | 4 per session |
| 2011-03-006 | International Laser Safety Conference | ISLC | 03/14-17/2011 | 12+ |
| 2011-03-007 | ILSC Medical/Technical Practical Application Sessions | ISLC | 03/14-17/2011 | 2 each group |
| 2011-03-008 | Armed Forces Public Health Conference | US Army Public Health Command | 03/18-25/2011 | 12+ |
| 2011-03-009 | Workshop of NYC Radiological Reserve Corps | NYC Department of Health | 03/25/2011 | 5 |
| 2011-04-001 | NASA Triennial Health Physics Meeting | NASA | 04/19-21/2011 | 24 |
| 2011-04-002 | 2011 Technical Seminar | Savannah River HPS | 04/15/2011 | 13 |
| 2011-04-003 | Spring 2011 Technical Meeting | Rio Grande Chapter HPS | 04/11/2011 | 4 |
| 2011-04-004 | Midwest HPS Technical Symposium | Midwest Chapter HPS | 04/16/2011 | 7 |
| 2011-04-005 | Nuclear Criticality Safety Training | West Valley Demonstration Project | 2011 | 4 |
| 2011-04-006 | John Horan Memorial Symposium | Great Salt Lake/East Idaho HPS | 04/02/2011 | 5 |
| 2011-05-001 | Spring 2011 Chapter Meeting | North Central Chapter HPS | 05/20/2011 | 5 |
| 2011-05-002 | Emergency Resopnse Planning for Rad Emergencies | MidAmerica Chapter HPS | 05/06/2011 | 3 |
| 2011-05-003 | Spring Chapter Technical Meeting | Missouri River Valley AAPM | 05/07/2011 | 5 |
| 2011-06-001 | International Records and Dosimetry Symposium | Landauer Inc. | 06/06-10/2011 | 28 |
| 2011-07-001 | Radiation Safety 101 for Combined Med/Academic Lic. Facilities | CSHEMA | 07/16/2011 | 4 |
| 2011-08-001 | Advanced Laser Safety Workshop | DOE EFCOG Laser Working Group | 08/02-04/2011 | 18 |
| 2012-01-001 | US Particle Accelerator School | University of Texas | 01/16-20/2012 | 32 |

+ denotes: 2 credits per half day up to a maximum of 12 credits.

National Registry of Radiation
Protection Technologists
P.O. Box 3084
Westerly, RI 02891

## Registration Maintenance Category 9: Continuing Education Courses and Seminars

For courses with ABHP CM points, one-quarter (1/4) point will be given per ABHP CM point.

# ABIH

March 23, 2011

Bart Geyer CIH
Innovative Health Applications
NASA Occupational Health
IHA-400
Kennedy Space Center, FL 32899

In response to your request for ABIH Certification Maintenance (CM) points, ABIH has reviewed the Activity for subject matter content and contact time. CM points are awarded as follows:

| | |
|---|---|
| Sponsor: | NASA |
| Activity: | 2011 Health Physics Triennial Meeting |
| Date: | 4/19/2011 - 4/21/2011 |
| CM Points: | 0.5 point per 0.5 day, 3.0 Industrial Hygiene CM Points |
| Approval#: | 11-1021 |

Results of your recent CM point request are as follows and will soon be available online at http://www.abih.org/members/roster/coursesearch.cfm:

Approved events are assigned either a new CM#, or the CM# was retained for courses unchanged from the previous year (Note: the authorized dates were changed). Granting of CM points does not imply that ABIH accredits, certifies or endorses an Activity, nor does it authorize use of the ABIH logo.

Sponsors have permission to publicize this information. Advertising your event to ABIH's Diplomates can dramatically increase its visibility and maximize your participation rates. A customized ABIH list rental allows you to reach thousands of CIHs, or smaller target audiences. Contact ABIH for additional information.

ABIH Diplomates are responsible to document proof of attendance. Where possible, Sponsors are asked to also provide proof of attendance, e.g., a completion certificate, participation letter, attendance roster, or on-site registration receipt.

For future CM point requests, please be aware that the CM Point Request Form and rules do periodically change. The latest form will be at http://www.abih.org/general/cmpointrequest.html. After January 1, 2011, we no longer honor the older forms.

This email is your official notification from ABIH; you will not receive a postal letter.

# Attendance Roster

TRIENNIAL HP MEETING 4-19-11

| | NAME | SIGNATURE |
|---|---|---|
| 1. | GUY CAMOMILLI | |
| 2. | KURT GEBOZ | |
| 3. | DAN SIMPSON | |
| 4. | RANDY SCOTT | |
| 5. | Charles Patanasiri | |
| 6. | JOHN CARDARELLI | |
| 7. | PATRICK UNDERWOOD | |
| 8. | Stanleigh Phillips | |
| 9. | Eric Packard | |
| 10. | Kim Nemth | |
| 11. | GL WOOD | |
| 12. | Shaun Healy | |
| 13. | Gary Schumann | |
| 14. | Marc Martz | |
| 15. | Gloria Mar | |
| 16. | Ronilla Ernest | |
| 17. | Kathrina Wright | |
| 18. | JONATHAN B. MULLIN | |
| 19. | Philip Brown | |
| 20. | Cheryl Zieschag | CHERIE ZIESCHAG |
| 21. | Ted Simmons | |
| 22. | Bart Geyer | |
| 23. | Linda Cooper | Linda P. Cooper |
| 24. | Edna Tobares | |
| 25. | Doreen Hill | |

TRIENNIAL HP MEETING 4/20/2011

| | NAME | SIGNATURE |
|---|---|---|
| 1. | Shawn Healy | Shawn Healy |
| 2. | Guy Camomicci | [illegible] |
| 3. | Patrick Muldoon | [illegible] |
| 4. | Eric Packard | [illegible] |
| 5. | Stan Phillips | Stan Phillips |
| 6. | Ray DEZA | [illegible] |
| 7. | Kim Merritt | [illegible] |
| 8. | Philip Brown | [illegible] |
| 9. | Gloria Mar | Gloria Mar |
| 10. | Linda Cooper | Linda P. Cooper |
| 11. | Marc Martz | [illegible] |
| 12. | CHERIE ZIESCHANG | Cherie Zieschang |
| 13. | CARLOS DA CRUZ | [illegible] |
| 14. | Ted Simmons | [illegible] |
| 15. | Bart Geyer | [illegible] |
| 16. | Katrina Wright | [illegible] |
| 17. | [illegible] | KURT GEBER |

4/21/2011

TRIENNIAL HP MEETING

| | NAME | SIGNATURE |
|---|---|---|
| 1. | Patrick Hancock | |
| 2. | DAN SIMPSON | |
| 3. | Shawn Healy | |
| 4. | Bart Geyer | |
| 5. | RANDALL SCOTT | |
| 6. | PATRICK MULDOON | |
| 7. | Eric Packard | |
| 8. | Kim Merritt | |
| 9. | CHERIE ZIESCHANG | Cherie Zieschang |
| 10. | Edna Tobares | |
| 11. | Ted Simmons | |
| 12. | CARLOS DA CRUZ | |
| 13. | Katrina Varela | |
| 14. | Marc Martz | |
| 15. | Gloria Mar | |
| 16. | Charles Patanasivi | |
| 17. | Stan Phillips | |
| 18. | Philip Brown | |
| 19. | KURT GEBER | |

# Speaker Biographies

**Radiation Effects Facility Irradiator Upgrades**

Daniel Simpson, Radiation Safety Officer
Goddard Space Flight Center (NASA)

Dan Simpson has been working for NASA-Goddard Space Flight Center (GSFC) since the end of August 2006. Dan got his undergraduate degree in Chemistry from Lipscomb University in Nashville, TN and his graduated degree in Health Physics from the University of Massachusetts in Lowell, MA. He served over 21 years in the United States Navy before coming to NASA. Major highlights during his military career was that he oversaw the Safety programs for the Armed Forces Radiobiological Research Institute (AFRRI), Bethesda, MD, a Tri-Service laboratory, which conducts research in the field of radiobiology and related matters essential to the operational and medical support of the U.S. Department of Defense and the military services; was the Director of Safety for both the Naval Medical Research Center and Walter Reed Army Institute of Research, Silver Spring, MD where he provided guidance to the Facility to ensure research was conducted in a safe and environmentally sound manner, including overseeing a comprehensive Radiation Health, Chemical and Environmental Hygiene and an Occupational Safety and Health Programs. Currently he is GSFC's Radiation Safety Officer (RSO) identified on two Nuclear Regulatory Commission (NRC) radiological licenses. The first license is for a cobalt-60 facility and the second license is a broad scope use of radioisotopes by researchers for various experimental analyses. In addition, he is the Head of the Radiation Protection Office where he oversees all the safety aspects of the ionizing devices (X-Ray generators) and non-ionizing radiation sources or devices (Lasers, RF, UV) used on the Greenbelt and Wallops Island centers.

**Irradiator Project Lessons Learned**

Gloria Mar, Radiation Safety Engineer
Jet Propulsion Laboratory (California Institute of Technology)

Gloria Mar is a Health Physicist (Alternate Radiation Safety Officer) at the Jet Propulsion Laboratory (JPL) in Pasadena, CA. Prior to working in the space science industry, Gloria worked in organic synthesis, specialty converting (including RFID Tags), and optical components. She obtained her graduate and undergraduate studies at the University of Southern California.

**Health Physics Assessments for X-Ray Scanner Devices**

John Cardarelli, PhD, CHP, CIH, PE
Occupational Safety Program Office
U.S. Environmental Protection Agency

CAPT John Cardarelli started at NIOSH in 1992, transferred into the Public Health Service in 1997 and joined the Environmental Protection Agency National Decontamination Team in 2005. He holds a B.S. in Nuclear Engineering, an M.S. in Health Physics and Ph.D. in Industrial Hygiene from the University of Cincinnati. He is board certified as a Professional Engineer (nuclear specialty), an Industrial Hygienist, and as a Health Physicist. He currently serves as a Health Physicist on the EPA National Decontamination Team to provide scientific and technical support within various levels of the government ranging from local to international. His experience includes dose reconstruction on DOE workers in support of epidemiologic studies, conducting health hazard evaluations in the work place, and emergency response. During his tenure at NIOSH he led an effort to characterize potential radiation exposures to Transportation Security Administration workers from baggage-screening technologies. At EPA he leads an effort to develop and implement the ASPECT Gamma Emergency Mapper project, which is its airborne detection and mapping asset. He has received several PHS and non-PHS awards, most notably the EPA, PHS, and Federal Engineer-of-the-Year awards in 2006 and the John C. Villforth Leadership Award in 2009. His presentation will provide an overview of the various screening technologies used for Homeland Security purposes and findings from his efforts during the NIOSH TSA study.

**Health Physics Evaluations for Medical and Analytical X-Ray Devices**

Marcum Martz, CHP, Radiation & Laser Safety Officer
Occupational Safety Program Office
Jet Propulsion Laboratory (California Institute of Technology)

Marcum Martz, CHP, holds a bachelor's degree in geology from Sonoma State University, and was certified by the American Board of Health Physics in 1996. He served as Radiation Safety Officer at Loma Linda University and the Medical College of Wisconsin until joining JPL in September, 2010. He has served as moderator of the Academic and Medical Radiation Safety Officer listserve since 2003, and is president of the Campus Radiation Safety Officers organization.

**GRC Cyclotron Decommissioning**

Gerald Wood, Radiological Engineer
Plum Brook Research Reactor Decommissioning Project (SAIC)

Mr. Wood is a Radiological Engineer with SAIC and has been supporting the Decommissioning of the NASA Plum Brook Reactor Facility since 2004. His experience includes expertise in Final Status Survey design and implementation, Monitoring and verification of soil remediation efforts and compliance with the release criteria, Development and implementation of embedded piping remediation and survey strategies, Radioactive waste shipping, and field supervision of site activities. Gerry will be providing current information on the implementation of the GRC Cyclotron Facility Characterization.

**RF Radiation Safety Training**

Brad J. Roberts, Electronics Engineer
Radio Frequency Program
US Army Institute of Public Health
U.S. Department of Defense

Mr. Brad Roberts is a graduate of the University of Massachusetts (Lowell) and has been an electronics engineer with the DoD for 30 years. The last 25 have been as an electronics engineer with the Radio Frequency Program, U.S. Army Public Health Command (formerly U.S. Army Center for Health Promotion and Preventive Medicine-USACHPPM), Aberdeen Proving Ground, MD. In this position, he has been responsible for establishing RF radiation hazard (RADHAZ) safety programs for systems developed/operated/ or maintained by Department of the Army (DA) personnel. These RADHAZ programs are established primarily by analysis and measurement of the specific RF radiating sources. The RF sources evaluated cover the frequency range of 3 kHz-300 GHz. Major programs he has been involved with include the Active Denial System (ADS), Ground-based Mid-Course Defense (GBMD) system, PATRIOT Air Defense System, Theatre High Altitude Air Defense System (THAAD), and numerous countermeasure systems. Mr. Roberts has been active on personnel RADHAZ standards committees including the IEEE International Committee on Electromagnetic Safety (ICES) and the NATO Standardization Agreement (STANAG) Committee 2345. He is a member of and past chair for the DoD Transmitted Electromagnetic Radiation Protection (TERP) working group. In his position with Army Public Health Command, Mr. Roberts also provides training to DA/DOD personnel on issues related to Hazards of Electromagnetic Radiation to Personnel (HERP).

**Mishap & Close-Call Reporting & Investigation Training**

Gerald Schumann
Office of Safety & Mission Assurance (NASA Headquarters)

Gerry Schumann has served in the Safety profession in the Federal Government for 36 years. Gerry served in the United States Air Force from November 1975 until November 1984 and then in the Air National Guard until April 1987. He has been with NASA for 20 years – 17 of those years with the Launch Vehicle Processing, Safety and Mission Assurance (S&MA) Division as an operations safety professional. He served as the contingency manager in the S&MA Directorate with responsibilities as the senior safety advisor to Kennedy Space Center (KSC) senior management for all aspects of Shuttle processing and contingency operations. Gerry was selected and served as the Processing and Operations Safety Lead for the Constellation Program's Ares I-X program successful test flight. Gerry is now serving as the Agency's Acting Mishap Investigation Program Manager at NASA Headquarters, Washington D.C.

**Major Source Launch Contingency Planning**

Randall Scott, Radiation Protection Officer
Kennedy Space Center (NASA)

Randy's professional career spans 36 years filling civilian Health Physics positions in nuclear fuel fabrication and nuclear power operations, and in U.S. Air Force Health Physics positions dealing with x-ray machine compliance testing, radiation dosimetry, medical center RSO duties, nuclear medicine, radiation therapy, radio frequency radiation safety issues, and laser safety consulting. He served on the Air Force Inspector General staff performing radioactive material license inspections issued under the Air Force Master Material license. He lead the Air Force Radiation Accident Response Team and commanded the Air Force Surgeon General 's Health Physics Laboratory Consulting Services that provided Air Force wide radioanalytical laboratory services, ionizing, laser, and radiofrequency radiation safety consulting services, and TLD dosimetry services. Randy is currently the KSC Radiation Protection Officer overseeing the Center-wide radiation protection program operating under an NRC broad scope license and for major radiological source launches serves as the NASA lead for radiological contingency planning and directs the radiological accident assessment center. Additionally, he represents the Agency Occupational Health Program as a Certified Laser Safety Officer member on the American National Standards Institute Z136.6 and Society of Automotive Engineers G-10 Outdoor Laser Safety committees.

**Interagency Nuclear Safety Review Process (INSRP) - Part 1**

Peter Prassinos
NASA Office of Safety and Mission Assurance (NASA Headquarters)

Mr. Prassinos has expertise and experience in nuclear safety, probabilistic risk assessment (PRA), safety analysis, engineering systems evaluations, transportation safety, and standards development. He has applied PRA methods and techniques to many systems including nuclear power plants, hazardous and explosive facilities, and transportation and security systems. Mr. Peter Prassinos hold a BS degree in Aerospace Engineering and a Masters Degree in Nuclear Engineering. Mr. Peter Prassinos is a member of the Safety and Assurance Requirements Division (SARD) in the Office of Safety and Mission Assurance (OSMA) at the National Aeronautics and Space Administration (NASA). His present responsibilities include applying PRA methods and techniques to space systems. He is also the NASA Member on the Interagency Nuclear Safety Review Panel (INSRP) for the Mars Science Laboratory (MSL) Mission.

**Interagency Nuclear Safety Review Process (INSRP) - Part 2**

John Lyver Ph.D., C.S.P
NASA Office of Safety and Mission Assurance (NASA Headquarters)

Dr. John W. Lyver, IV, is employed by the National Aeronautics and Space Administration (NASA) Headquarters Office of Safety and Mission Assurance as NASA's Nuclear Flight Safety Assurance Manager. He is responsible for the nuclear safety reviews of all NASA space missions that contain radioactive materials. In addition to his nuclear safety assignment, Dr. Lyver serves as the Manager for NASA's Micrometeoroid and Orbital Debris Program and manages the Agency-Level requirements for NASA's Safety and Mission Assurance Technical Authority. His duties with nuclear safety have included being manager of radiological emergency preparedness for launches of NASA's radiological missions, and as NASA's member and Coordinator of the Interagency Nuclear Safety Review Panel (INSRP) (joint panel with Department of Defense, Department of Energy, Nuclear Regulatory Commission and the Environmental Protection Agency supporting the Executive Office of the President's Office of Science and Technology Policy). He served as the senior member of the INSRP's for NASA's Pluto-New Horizons Mission (2006), and Mars Exploration Rover 2003 mission, and member of the INSRPs for the Mars Pathfinder Mission (1996), and the Cassini Mission (Saturn) (1997). Additionally, he was a primary author of the rewrite of the Presidential Directive (PD-25) which governs the nuclear mission Presidential launch approval. Dr. Lyver retired from the U.S. Naval Reserve as an Engineering Duty Officer in 1994. He holds a bachelor's degree from the U.S. Naval Academy in Engineering-Physics in 1978, a Master of Science degree in Computers and Electronic Engineering from George Mason University in 1988, a Master of Science degree in Computational Science in 2008 and a Ph.D. in Computational Science and Informatics at George Mason University in 2010. Additionally, Dr. Lyver graduated from the U.S. Naval Nuclear Power School and Prototype in 1979, and in 1990, Dr. Lyver earned the designation as a licensed Certified Safety Professional (C.S.P.) in Systems Safety.

**Responding to Nuclear Terrorism**

Brooke Buddemeier, CHP
Lawrence Livermore Laboratory
US Department of Energy

Brooke Buddemeier works for the Global Security directorate of Lawrence Livermore National Laboratory supporting radiological and nuclear risk and consequence management activities. Brooke is a council member of the National Council on Radiation Protection and Measurements (NCRP) and an active member of the Health Physics Society's Homeland Security Committee. From 2003 through 2007 he was assigned the Department of Homeland Security's as the WMD emergency response and consequence management program manager for Science and Technology's emergency preparedness and response research and development. He supported FEMA and the Homeland Security Operations Center as a radiological emergency response subject matter expert. Prior to that, he coordinated Lawrence Livermore National Laboratory's involvement in the Radiological Assistance Program (RAP) for California, Nevada, and Hawaii. RAP is a national emergency response resource that assists federal, state and local authorities in the event of a radiological incident. He is Certified Health Physicist who received his Master's in Radiological Health Physics from San Jose State University and his B.S. in Nuclear Engineering from the University of California, Santa Barbara.

**Excellence in Radiation Protection Programs**

Donald Cool, PhD, Senior Advisor, Radiation Safety and International Liaison
Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission

Dr. Donald Cool is currently the Senior Advisor for Radiation Safety and International Liaison in the Office of Federal and State Materials and Environmental Management Programs at the U.S. Nuclear Regulatory Commission. He has been with the NRC for more than 27 years, serving in a variety of positions, including serving as the Director, Division of Industrial and Medical Nuclear Safety, where he was responsible for the materials licensing and inspection programs of the NRC. He is currently the co-chair of the federal Interagency Steering Committee on Radiation Standards, and a member of the International Commission on Radiological Protection's committee on Application of the Recommendations. He holds a B.S. in Biology, and an M.S. and Ph.D in Radiation Biology from the University of Rochester School of Medicine and Dentistry.

**Update on the NRC's Tritium Exit Sign Demand for Information**

Angela McIntosh
Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission

Angela McIntosh joined the Nuclear Regulatory Commission (NRC) in June of 2000, where she was a General Scientist with the Office of Nuclear Materials Safety and Safeguards. As a General Scientist, one of her chief functions was that as the Agency's coordinator of the Advisory Committee on the Medical Uses of Isotopes. After the Office of Federal and State Materials and Environmental Management Programs was formed in 2006, Ms. McIntosh was promoted to Regional Events Coordinator. In this capacity, Ms. McIntosh coordinates with NRC regional and headquarters staff in the processing of reportable materials events for appropriate NRC response, and eventual inclusion in various annual reports that are forwarded to the U.S. Congress. Before joining the NRC, Ms. McIntosh spent several years in the United States Army in the field of health physics, administering the radiation safety program in assignments at facilities with Broad Scope, Type A licenses. Along with applied health physics experience and technical training in health physics and preventive medicine, Ms. McIntosh obtained a Bachelor of Science in Health Care Administration from Southern Illinois University at Carbondale, where she graduated Magna Cum Laude.

**National Institutes of Health Onsite Health Physics Program Review**

Robert Zoon, Director, Division of Radiation Safety
National Institutes of Health
U.S. Department of Health and Human Services

Bob Zoon is the former Radiation Safety Officer at the National Institutes of Health (NIH), Bethesda, Maryland. He has graduate degrees in Nuclear Engineering (1970, New York University) and Computer Science (1987, Johns Hopkins University) and a degree in Physics (1968, Rensselaer Polytechnic Institute). Bob entered the U.S. Public Health Service Commissioned Corps in February, 1970 where he joined the FDA's Bureau of Radiological Health, Training Section. In 1971, he was assimilated into the newly created U.S. Environmental Protection Agency, serving in the Office of Radiation Programs. He joined the NIH in 1976 as a staff health physicist within the NIH Radiation Safety Branch (RSB). In 1978, he became the chief of the Health Physics Section (the field HP group) and in 1985 was made chief of the Data & Analytical Services Section (laboratory & database management). He served as Deputy Chief, RSB during 1992 through September, 1994, when he was appointed Acting Chief, RSB. Bob was appointed as Chief, Radiation Safety Branch and NIH RSO in May, 1995. In October, 2003 The Radiation Safety Branch was elevated to the Division of Radiation Safety (DRS) within a newly reorganized Office of Research Services, where Bob served as the DRS Director. Bob is scheduled to retire from the NIH on April 30$^{th}$.

Nancy Newman, Radiation Safety Officer
Chief, Division of Radiation Safety
National Institutes of Health
U.S. Department of Health and Human Services

Nancy Newman is NIH's new Radiation Safety Officer and takes over the management of the Radiation Safety Program upon Bob Zoon's imminent retirement. In the 26 years that Nancy has been with NIH she has held numerous positions within the Division of Radiation Safety (DRS). She is concurrently the Chief of the Radiation Safety Operations Branch, which contains the DRS's area health physicists. Nancy has degrees from Virginia Tech and Georgetown University and is a graduate of the NIH Senior Leadership Program. The NIH received the official approval of the NRC on February 10, 2011, naming Nancy as the RSO on NIH's four NRC licenses.

**NIST Onsite Health Physics Program Review**

Thomas O'Brien, Radiation Safety Officer
National Institute of Standards and Technology
U. S. Department of Commerce

Mr. O'Brien is a Certified Health Physicist and Radiation Safety Officer at the National Institute of Standards and Technology and has 30 years of operational health physics and radiation safety program management experience with Byproduct Material (broad scope license), Research Reactor, Linear Accelerator, and Pool Irradiator operations in a research laboratory setting. Tom's early health physics career was spent at the Armed Forces Radiobiology Research Institute (AFRRI), Bethesda, MD. During that time he earned an M.S. degree in Radiation Science from Georgetown University. After AFFRI the next five years were spent at the NRC. Then, except for a brief stint as the campus RSO at University of Maryland, College Park, the rest of his successful career has been spent at NIST, first as a reactor health physicist then, most currently, as the Radiation Safety Officer.

**MOBLAS-7 Lessons Learned**

Patrick Hancock , Deputy Division Chief,
Occupational Safety & Health Division
Goddard Space Flight Center (NASA)

Patrick is the Deputy Division Chief of the Occupational Safety & Health Division. He has been with GSFC and NASA for 11 years, starting as an engineer in what was then the Safety, Environmental and Security Office. A few organizational changes later and here we are now. Before coming to NASA Patrick was a civilian safety engineer, Laser Safety Officer, and Radiation Safety Officer for the US Navy. He is currently a member of the ANSI Z136.6 Standards Subcommittee SSC-6 for Outdoor Lasers. Patrick spends all his time away from work with his wife and 7 (soon to be 8) children.

**Laser Lessons Learned**

Kim Merritt, Radiation & Laser Safety Officer
Langley Research Center (Safety & Quality Assurance Alliance)

Kim Merritt is the Radiation and Laser Safety Officer for NASA Langley. He has an associate's degree in radiation safety from Las Positas College and is a graduate of the Naval Nuclear Power Program. He is certified by the board of laser safety and is a member of several ANSI standard subcommittees on laser safety and is the incoming Chair of the AIHA's nonionizing radiation committee.

**OSHA Radiation Protection Program Activities**

Sven Rundman, Senior Industrial Hygienist
Office of Health Enforcement
Occupational Safety and Health Administration
U.S. Department of Labor.

Sven J. Rundman III is a Team Leader and with the U.S. Department of Labor-Occupational Safety and Health Administration (OSHA), Directorate of Enforcement Programs, (OHE), in Washington, DC. Mr. Rundman provides leadership and guidance to the OHE staff in the development of policy and procedures related to the enforcement of OSHA's health-related standards and compliance assistance. This includes the development of interpretation letters, compliance instructions, and compliance assistance tools. Mr. Rundman's areas of expertise include hazardous waste operations and emergency response, bloodborne pathogens, respiratory protection, noise, recordkeeping, and air contaminants. Previously, Mr. Rundman was an industrial hygienist with the Indiana-OSH State Plan program and with the federal OSHA area offices in Cincinnati, OH, and Frankfort, KY. Mr. Rundman also spent over 13 years as a Senior Industrial Hygienist with OSHA's Atlanta Regional Office, Enforcement Programs office. Mr. Rundman is a graduate of Purdue University.

**Exemptions from FDA Laser Regulations**

Patrick Hintz
Center for Devices and Radiological Health
Food and Drug Administration
U.S. Department of Health and Human Services

Mr. Hintz is a degreed Industrial Hygienist working as a Health Promotion Officer for the U. S. FDA. He has a Master of Science degree from Montana College of Mineral Science and Technology in Industrial Hygiene and a B.S in Microbiology/Biology from University of Montana. Patrick was a Research Industrial Hygienist at the CDC/NIOSH Division of Respiratory Disease Studies in Morgantown, WV were he conducted occupational respiratory health research and definition of health hazards in areas of indoor air quality, bioaerosols, respiratory hazards in composting, silica exposure in mining, asthma in insect mass rearing facilities, asthma in wood products plants, diesel exhaust particulate and mine gases. He transferred to the CDC/NIOSH Spokane Research Laboratory serving as a research industrial hygienist in the mining industry for 10 years. He also conducted occupational health research and defined health hazards in the mining industry for areas including heat stress, exposure to diesel exhaust particulate and mine gases, chemical hazards, dermatitis, asbestos exposure, and noise exposure. Mr. Hintz is currently serving as a Health Promotion Officer in the Electronic Products Branch in the FDA Center for Devices and Radiological Health (CDRH) where he is focused on the regulation of laser products entered into US commerce and contributes to guidance document and policy development, safety notifications, and conducts regulatory compliance actions.

**ANSI Z136.6 Outdoor Laser Safety Updates**

Robert Aldrich, Laser Safety Specialist
Lead Naval Technical Laboratory for Laser Safety
U.S. Department of Defense

Robert is an accomplished professional who demonstrates leadership and proficiency in system safety and laser safety concepts, standards development and training. He has an extensive background in laser safety standards and policy development. Robert is an effective communicator with excellent skills of negotiation and consensus building. He has a Bachelor of Science degree in Electrical Engineering from West Virginia University - Institute of Technology. Was granted a patent for the development a “Laser Pulse Counter” in 2007. For the past 18 years Robert has been employed by the Department of Defense as a Laser Safety Expert at the Naval Surface Warfare Center in Dahlgren, Virginia. He is the designated Laser Hazard Evaluator for Department of Navy laser systems and developer and primary instructor for the DoN Laser Safety Specialist (LSS) Certification Course. He develops policy, standards, and guidance for DoN and DoD laser safety, actively liaises and participates in the development of laser safety standards for military, industry, national and international communities, and performs surveys and certifications of DoN laser training ranges. He is the author of many laser safety presentations and multiple laser safety publications. In addition Robert is a member of multiple laser safety professional organizations and committees such as ANSI Z136.6, “Safe Use of Lasers Outdoors” (where he is the committee chairman); ANSI ASC Z136; and a plethora of ANSI Z136 laser safety subcommittees; NATO STANAG 3606, Laser Safety for NATO military training ranges; IEC 60825, International Laser Safety Standard; SAE G10T, Laser safety considerations in airspace (advisory group to FAA); DoD LSSWG, Working group for DoD laser safety considerations; and ICAO committee on laser safety in and around international aerodromes. Robert is a Certified Laser Safety Officer.

**Optical Radiation: An Overview of Biological Effects and Exposure Limits**

David Sliney, PhD
Consulting Physicist

Dr. Sliney received his B.S. in physics from Virginia Polytechnic Institute, his M.S. in physics and radiological health from Emory University, and his Ph.D. in biophysics and medical physics from the University of London, Institute of Ophthalmology. He was the Manager of the Laser/Optical Radiation Program at the US Army Center for Health Promotion and Preventive Medicine for many years until retiring in 2007. His research interests focus on subjects related to UV effects upon the eye, optical hazards from intense light sources and lasers, laser-tissue interactions, laser hazards and laser applications in medicine and surgery. He served as member, advisor and chairman of numerous committees and institutions, which are active in the establishment of safety standards for protection against non-ionizing radiation in particular from lasers and other high-intensity optical sources (ANSI, ISO, ACGIH, IEC, WHO, NCRP, and ICNIRP). He received the Schawlow Award from the LIA in 2005 and the Award for Distinguished Scientific Achievements from the Health Physics Society in 2009. He served as President of the Laser Institute of America in 1992 and as President of the American Society for Photobiology during 2008-2009.

**Agency Outdoor Laser Coordination**

Kelly J. Neubecker
Airspace and Rules
Federal Aviation Administration
U.S. Department of Transportation

Kelly Neubecker, is an Air Traffic Control Specialist at FAA headquarters in Washington D.C. She works in the Airspace, Regulations, and ATC Procedures Division as a principal element within the Air Traffic Airspace Management Program responsible for formulating regulatory policy and standards related to the National Airspace System. She is also the Air Traffic Program Lead on proposed outdoor laser operations.

Kelly is a retired Navy Air Traffic Controller with a B.S. in Professional Aeronautics from Embry Riddle Aeronautical University, and a Juris Doctor from Regent University. She is a prior Public Defender and a member of the Virginia State Bar. Kelly is also a member of the SAE G-10T and ANSI Z136.6 committees.