

Colorado Radiation Advisory Committee (RAC)
March 31, 2016 Meeting Minutes

I. CALL TO ORDER	RAC Chair Tom Johnson called the regular meeting to order on March 31, 2016 at 1:10p.m., in Conference Room C1C, Building C, at the Colorado Department of Public Health and Environment (CDPHE) main campus.
Agenda	The agenda emailed March 18, 2016 was used.
Introductions	<p>Radiation Advisory Committee (RAC) members and Radiation Control Program staff introduced themselves.</p> <p>RAC members in attendance: Jim Burkhart, Tom Johnson, Phillip Koo, Vicki LaRue, Vinod Ravindran, and Jennifer Stickel.</p> <p>The members present constituted a quorum.</p> <p>RAC member(s) absent: Steve Brown (excused), Craig Little (excused), and Riad Safadi (excused).</p> <p>Radiation Control Program staff in attendance: James Grice, Cheri Hall, James Jarvis, Chrys Kelley, Jennifer Opila, Phill Peterson, and Brian Vamvakias.</p>

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<p>II. SELECTION OF CHAIR / VICE-CHAIR</p>	<p>The RAC voted by written ballot and re-elected current Chair Tom Johnson to serve as Chair of the RAC through the end of 2016.</p> <p>The written ballot vote for the Vice-Chair resulted in a tie between members Jim Burkhart and Jennifer Stickel. By a show of hands vote, the quorum of RAC members present voted to defer a re-election for the Vice-Chair until the next RAC meeting when more RAC members are expected to be present.</p>
<p>III. PRESENTATION</p>	<p>RAC Member Vinod Ravindran gave a presentation on Moisture Density Gauges.</p>
<p>IV. Program Updates</p>	
<p>A. Radiation Program update</p>	<p>Jennifer Opila provided updates on the Radiation Program.</p> <p>Jennifer discussed:</p> <ul style="list-style-type: none"> - The proposed Radon bill mentioned during the January RAC meeting continues to move forward through the legislature; - Questionnaires have been sent to a portion of our regulated community to seek feedback on our program and processes. The RAC will be updated when the results of the surveys have been received; - The program continues to develop improvements to help streamline work processes, and in the x-ray program in particular. The addition of the new x-ray database, a shift to electronic recordkeeping and other ongoing enhancements is expected to continue to improve this program; - The position in the uranium program left vacant by a staff retirement will be shifted to the x-ray program since there is not an expected increase in the uranium projects workload in the near future. <p>No written program update was available for the meeting.</p>
<p>B. Radioactive Materials (RAM) Unit update</p>	<p>Jim Grice provided an update on the activities of the Radioactive Materials Unit along with annual updates on the licensing activities by Cheri Hall and the compliance activities as provided by Phill Peterson.</p> <p>Jim discussed:</p> <ul style="list-style-type: none"> - A former veterinary licensee who willfully abandoned their facility and radioactive material was issued an order for a significant monetary penalty. This incident

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has been in process for many months as it was somewhat difficult to locate the former owner of the facility who had moved out of state. In addition to a proposed monetary penalty the individual will be prohibited from working with radioactive material in Colorado for 3 years. The prohibition will also be shared with NRC and Agreement States.

RAC Chair Tom Johnson inquired whether the monetary penalty would be less if there had not been abandoned radioactive material involved?

Staff responded that the proposed penalty would likely have been less had radioactive materials not been abandoned.

Jim continued with the update:

- Plans are continuing with the hiring process for the two openings in the program. The recent application period and screening process did not yield adequate candidates and therefore the position announcements will be reposted in the near future;
- As discussed during the January RAC meeting, an allegation sent to the Department indicated that an out of state industrial radiography licensee had been working in Colorado without reciprocity. When contacted, the licensee denied working in Colorado, but then when presented with evidence to the contrary, the licensee modified their response. In addition to non-authorized reciprocity, this licensee was also not performing work in accordance with safety requirements. A notice of violation is in process;
- The decommissioning of a facility performing smoke detector cleaning activities was recently completed. The department is awaiting review of the final surveys and data;
- A recent inspection indicated a medical facility performing (Iodine-131) therapy activities did not have an authorized user physician signing off on the written directive.

RAC Chair Tom Johnson inquired whether any patients were in danger as a result of the lack of sign off by an appropriate authorized user?

Staff indicated that while this is an apparent violation of regulatory requirements, patient safety was not impacted as a result of these actions.

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Cheri Hall provided a presentation on the status of and statistics relating to licensing activities over the past year and prior.

- A topic discussed during the presentation involved the turnover time - typically 8-10 weeks - for licensing actions.

RAC Chair Tom Johnson asked whether this was a long time period for such activities.

Cheri Hall responded by indicating that this timeframe is an average and some may be shorter while others may be longer. The timeframe also includes additional actions such as correspondence to and from the licensees for additional requests for information (RFI's) from the licensee. To a degree, the turnaround time will also depend upon the scope of the amendment and whether it is a simple change or involves additional complexities. The radioactive materials unit is in the process of improving its "milestone" tracking activities to better identify turnaround times and effort.

It was asked whether there is a policy on abandonment when a licensee fails to provide the needed information?

Cheri Hall responded that yes, there is an abandonment procedure in place when licensees fail to respond to requests for additional information.

Phill Peterson provided a presentation on the status of and statistics relating to compliance (inspection) activities for radioactive materials licensees over the past several years.

RAC Chair Tom Johnson asked - is there is a "consultation process" during inspections such that a licensee can learn to avoid mistakes or potential violations in the future?

Phill Peterson indicated that while our primary purpose is to evaluate licensees against the regulatory and licensing requirements we do provide information to licensees and make an effort to educate them. This is particularly the case for new licensees who might be on a learning curve. An apparent notice of violation would still be issued where

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	<p>violations exist, but we would also educate the new licensee on how other licensees may have handled a particular issue or situation regarding compliance.</p> <p>Further details may be found on the attached radioactive materials unit summary and the annual licensing and compliance presentations.</p>
C. X-Ray Certification Unit update	<p>Brian Vamvakias provided a summary of the x-ray certification unit statistics and activities.</p> <p>The x-ray certification unit currently has ~5,200 registered facilities and approximately 15,000 radiation machines. The primary machine facilities can be categorized as follows:</p> <ul style="list-style-type: none">- ~50% (~2,600 facilities) are dental- ~2% (~85 facilities) are hospital- ~9 % (~500 facilities) are used by chiropractors- ~8 % (~400 facilities) are used for industrial purposes;- The remaining facilities are made up of veterinary, private practices/clinics and podiatry. <ul style="list-style-type: none">- There is an average of 2 machines per facility;- Machine registrations typically increase by ~2% per year accounting for losses due to facility closures, machine disposals, etc.;- On average, ~300 machines are overdue for inspection each month. The machines have inspection cycles varying from 1-3 years; <p>The x-ray unit is hoping to increase staffing and plans to enhance its efforts with regard to compliance activities by having staff doing more focused inspections. Areas of focus in the future may be on pain centers and those facilities using fluoroscopy.</p> <p><i>RAC Chair Tom Johnson asked - do chiropractors use fluoroscopy?</i></p> <p>Brian, responded that no, chiropractors do not typically use fluoroscopy.</p> <p>Brian continued the discussion indicating that the more common compliance issues with x-ray involve overdue machine inspections and non-registered service provider companies. Some of the overdue machine inspection problems may be due to confusion over the registration process.</p>

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	<p><i>Chrys Kelley asked whether the x-ray unit has considered developing some type of informational video to help registrants better understand the process for registrations and inspections?</i></p> <p>Brian indicated that they have not used videos as an education tool in the past but could consider that for the future.</p> <p>No written update was available for the meeting.</p>
D. Radon Program	<p>Chrys Kelley provided an update and summary on the activities of the Radon program.</p> <p>Chrys discussed:</p> <ul style="list-style-type: none">- The fact that no State Indoor Radon Grant (SIRG) monies were available this cycle due to continuing federal budget issues and timing with the federal budget. We are continuing to communicate with our federal partners to remind them of the interest and need for these grant funds. Should the radon legislation that Jennifer Opila mentioned earlier be finalized, we would expect to have more SIRG grant funding available to distribute to local grantees pending federal availability;- Prior/potential SIRG grantees continue to call the department seeking funds, but again no monies are available for this year's SIRG grant cycle;- Chrys continues to be involved with a number of committees and activities including the CRCPD* E-25 committee, the departments CCPD* grant committee, and national speaking engagements;- Boulder County received a CCPD grant to fund a 3 year study on policy advancement surrounding radon mitigation systems in new construction. The study seeks to obtain feedback on this topic from builders, realtors, homeowners, politicians and others. The study will include a 4 county area;- The program is continuing to work with radon testing companies on a data agreement to obtain more detail on radon test results in the state. Currently, only 3 of the 8 test companies are giving the full radon test data - such as address, whether the tests are pre or post mitigation, etc. The companies have some concerns over releasing address data.

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	<p><i>RAC Chair Tom Johnson asked - would we would be able to look at or compare cancer data and radon levels?</i></p> <p>Chrys Kelley responded that is a possibility, but we will need to keep the requirements of HIPAA^{***} in mind regarding such data.</p> <p>No written update was available for the meeting.</p> <p><small>* CRCPD is the Conference of Radiation Control Program Directors, Inc. **CCPD is the Cancer, Cardiovascular and Chronic Pulmonary Disease ***HIPAA is the Health Insurance Portability and Accountability Act</small></p>
<p>E. Regulations / Special Projects update</p>	<p>James Jarvis provided an update and summary on the activities and status of regulatory activities.</p> <p>James discussed:</p> <ul style="list-style-type: none"> - The final Parts 1, 3, and 18 regulations went into effect on February 14; - The comment period for Parts 16 (well logging), and Part 19 (irradiators) remains open until April 10. Thus far, only one written comment has been received regarding Part 16 and was generally in support of the propose changes with a few technical change recommendations; - The Part 6 rule drafting/development is continuing with internal meetings being held several times per month with x-ray staff heavily involved. The Part 6 changes are based upon the CRCPD[*] 2015 Part F state model regulations updates and involve some significant changes. (James provided highlights of the proposed changes - refer to the presentation for further details). <p>Refer to the regulatory update presentation and attachments for further details and information.</p> <p><small>* CRCPD is the Conference of Radiation Control Program Directors, Inc.</small></p>
<p>F. Subjects for future discussion</p>	<p>The following items were tabled for future discussion:</p> <ul style="list-style-type: none"> - A 2nd election for the RAC Vice-Chair; - Making minor amendments to the bylaws; and - A presentation on the generally licensed device program.
<p>G. Adjourn</p>	<p>The meeting adjourned at approximately 3:55 p.m.</p>

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Next RAC Meetings:	Remaining 2016 RAC meeting dates: June 2, 2016 July 28, 2016 September 29, 2016 December 1, 2016

Attachments:

1. Colorado Radiation Advisory Committee Agenda for March 31, 2016, as emailed March 18, 2016 (1 page)
2. Presentation on moisture density gauges (14 pages)
3. Radioactive Materials Unit update (1 page);
4. Presentation on the radioactive materials unit licensing activities (7 pages)
5. Presentation on the radioactive materials unit compliance activities (4 pages)
6. Radiation regulations update (12 pages)

Following any requested changes, the Radiation Advisory Committee meeting minutes for March 31, 2016, were approved via email by a quorum of members between June 8, 2016 and June 15, 2016.



COLORADO

Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

**COLORADO RADIATION ADVISORY COMMITTEE
MEETING AGENDA**

Thursday, March 31, 2016 1:00 P.M., CDPHE - Building C
Conference Room C1C

REGULAR MEETING

1:00 PM	I. CALL TO ORDER, INTRODUCTIONS, AGENDA ADDITIONS / CHANGES
1:05 PM	II. Selection of new RAC Chair and Vice-Chair for 2016 - postponed from 01/28/16 Meeting (10 minutes)
1:15 PM	III. PRESENTATION on Moisture Density Gauges - RAC Member Vinod Ravindran (15 minutes)
	IV. PROGRAM UPDATES
1:30 PM	A. Radiation Program update - Jennifer Opila (20 minutes)
1:50 PM	B. Radioactive Materials Unit update - Jim Grice (15 minutes) 1. Licensing - annual update - Cheri Hall (10 min) 2. Compliance - annual update - Phill Peterson (10 min)
2:25 PM	C. X-Ray Certification Unit update - Brian Vamvakias (15 minutes) 1. Annual update on X-Ray Unit activities
2:45 PM	D. Radon Program update - Chrys Kelley (15 minutes)
3:00 PM	E. Regulations/Special Projects update - James Jarvis (30 minutes) 1. Proposed updates to RAC Bylaws 2. Preliminary highlights - Part 6 changes (X-ray in the healing arts)
3:30 PM	F. Subjects for future discussion
~3:35 PM	G. ADJOURN
	2016 RAC Meetings: - June 2, 2016 - July 28, 2016 - September 29, 2016 - December 1, 2016

NOTE: all times, topics, and future meeting dates are subject to change



Portable Nuclear Density Gauge



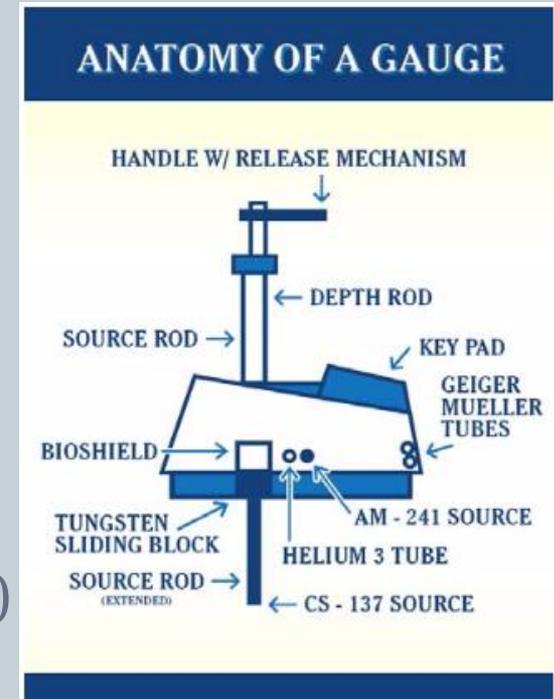


- A portable nuclear density gauge as the name implies measures density and moisture content of soil and other substrates.
- Applications
 - Compaction Testing of soils
 - Compaction Testing of Asphalt
 - Concrete density and rooftop moisture (uncommon)

CONSTRUCTION



- Plastic Construction
- Source Housing
 - Stainless Steel (Encapsulated)
- Shielding
 - Lead and Tungsten
- Typical Sources
 - Neutron Source Am-241 (40mCi/1.48GBq)
 - Gamma Source Cs-137 (8mCi/0.3GBq)



THEORY OF OPERATION



- **Density**
 - The gauge uses gamma ray photons to measure density
 - Gamma ray photons emitted by Cs-137 is allowed to pass through the soils and detected using Geiger tubes.
 - As the soil/ asphalt is rolled and compacted, density of the material increases. As the material becomes denser, it absorbs more photons, preventing the photons from reaching the Geiger tube.
 - The amount of gamma ray photons detected is fed in to the on board computer and the density of the material is calculated.

THEORY OF OPERATION

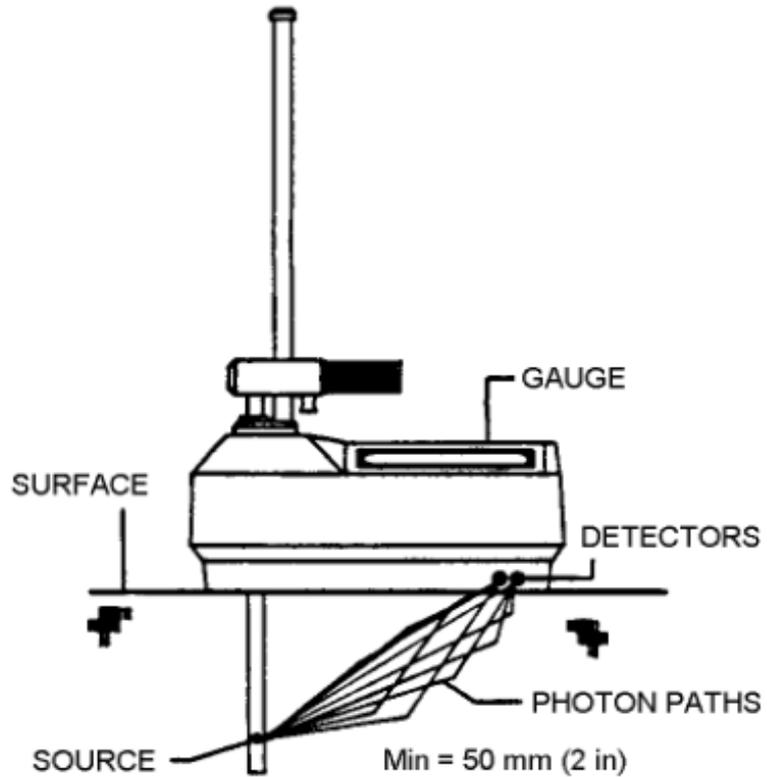


Figure A-1. Direct Transmission Geometry

THEORY OF OPERATION



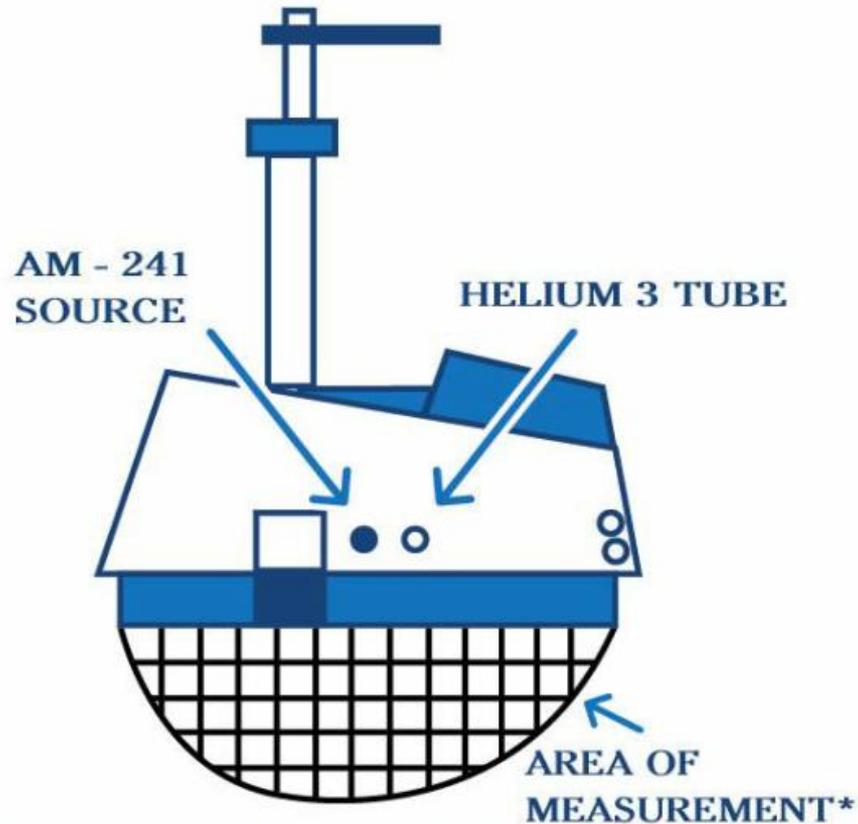
- **Moisture**

- The gauge uses neutron radiation to measure Moisture
- Am-241:Be produces neutron radiation to measure moisture in soils.
- Fast neutrons are slowed down due to thermalization process when the neutron collides with a nucleus equivalent to its mass, in this case – Hydrogen atom in water
- Helium 3 detector tube is used to count the thermalized neutrons, which are proportional to the amount of water molecules present

THEORY OF OPERATION



Moisture Measurement



*Depends on Hydrogen Content

Maintenance



- **Leak Tests**
 - Every Six Months
- **Calibration**
 - Every year

TRANSPORTATION



- Type A Package
- Labeling
 - Hazardous material
 - Radioactive II
 - Transportation index (0.3-0.7)
- Paperwork
 - Bill of Lading
 - Emergency procedures
 - User Manual



HAZARDS



- Leaving unattended at jobsite
- Automobile accidents
- Theft or vandalism



DAMAGES



DAMAGES



DAMAGES



QUESTIONS



?

Radioactive Materials Unit
Project Status 03/31/2016

Staffing:

- Two Openings for EPSI licensing and inspection staff: this position was reposted in February in order to acquire a larger applicant pool, HR currently reviewing the applications that were received during the posted period for adequacy.

Licensing/Compliance

- March 19 marked the date in which full implementation of Part 22 is required for all licensees who are subject to Part 22: Physical protection of Category 1 and Category 2 quantities of material. The old Increased Controls have been replaced by this new regulatory structure.
 - All licensees previously subject to the old IC requirements have received administratively amended licenses and now include the Part 22 items, with the exception of a handful that are in the process of amendment or renewal. These will be issued in the near future.

Escalated Enforcement

- Medical licensee had multiple therapies performed at the direction of unauthorized physicians
- Peak Veterinary – Revocation of license and immediate reply from licensee. In excess of \$2,000,000 in draft proposed penalty calculation.
- Annual report

Incidents, emergencies, etc.

- Received an allegation of an out of state radiographer working in the state without approval.
 - Notice of Apparent Violation was issued and we will be pursuing a compliance order
 - They were previously authorized to work in a different part of the state but that authorization has been temporarily suspended pending completion of the enforcement action
- Smoke Detector Servicing Facility Update:
 - A service provider has been authorized to begin initial site characterization to prepare for decommissioning.

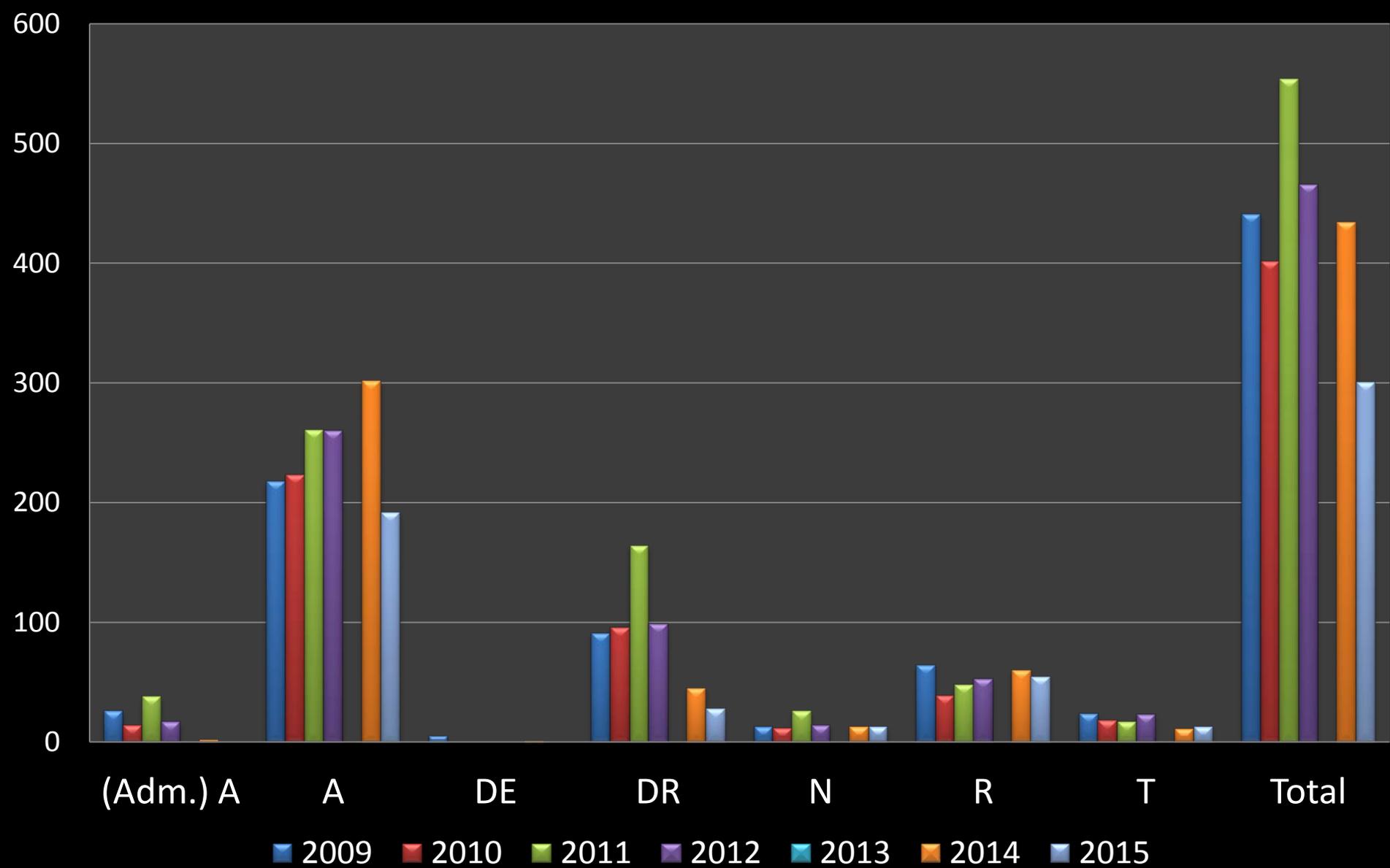
Radioactive Materials Licensing

2015 Year End Review

Current Licensee Data

Primary Licensed Activity	Fee Category	Current Licensee's	Percentage
Portable and Fixed Gauge	3P	109	33%
Medical/Vet	7C	84	26%
Catch All	3Q	33	10%
Service Provider	3N	17	5%
Basic Research	3M	15	5%
Provisional/ Covenants	Prov	14	4%
Industrial Radiography	3O	12	4%
Well Logging	5A	11	3%
Manufacturing and Distribution	3B	7	2%
Radiopharmacies	3C	7	2%
Licenses in Decommissioning	14A	4	1%
Source Material	2C	3	1%
Research Broad Scope	3L	2	1%
Closed Cell Irradiators	3E	2	1%
Uranium Recovery	2A2	1	0%
Panoramic Irradiators	3F	1	0%
Waste Disposal	4A	1	0%
Medical Sealed Sources	7A	1	0%
Cyclotron	3S	1	0%
Medical Broad Scope	7B	1	0%
TOTAL		326	

Past Year Trends



Past Years: By The Numbers

2010	
(Adm.)	
A	14
A	223
DE	0
DR	96
N	12
R	39
T	18
Total	402

2011	
(Adm.)	
A	38
A	261
DE	0
DR	164
N	26
R	48
T	17
Total	554

2012	
(Adm.)	
A	17
A	260
DE	0
DR	99
N	14
R	53
T	23
Total	466

2014	
(Adm.)	
A	2
A	302
DE	1
DR	45
N	13
R	60
T	11
Total	434

2015	
(Adm.)	
A	0
A	192
DE	0
DR	28
N	13
R	55
T	13
Total	301

- 2015: Decline in amendment received and issued
- Consistent numbers in new, renewal, and terminating licensees
- Significant reduction once again in Document Reviews as a result of less Uranium program activity
- We no longer capture administrative amendment information
- All other action types consistent with five year trends

Licensing Trend Breakdown

- 13 terminations, 13 new licensees
- Highest number of terminations were in the portable gauges category but there was a fairly even distribution across the categories
- Majority of new licenses were provisional licenses

License Type	Terminations	New Licenses
3.N	1	
3.B	1	
3.O	1	2
3.P	6	2
3.Q		3
5.A	1	
7.C	2	1
PROV	1	5
Total	13	13

Current Interests

- Part 22 Implementation
 - Administrative Amendments for licensees not in renewal or amendment process
 - New procedural requirements in licensing
 - Adjustment for both us and the licensees
- Ongoing refinement of the materials available to licensees to help communicate expectations
- Continually finding new ways to utilize and optimize the NRC Web-based Licensing database
- New Licensing Lead and will hire and train two new staff this year. We seem to constantly be working our way through the learning curve while continuing to meet goals.

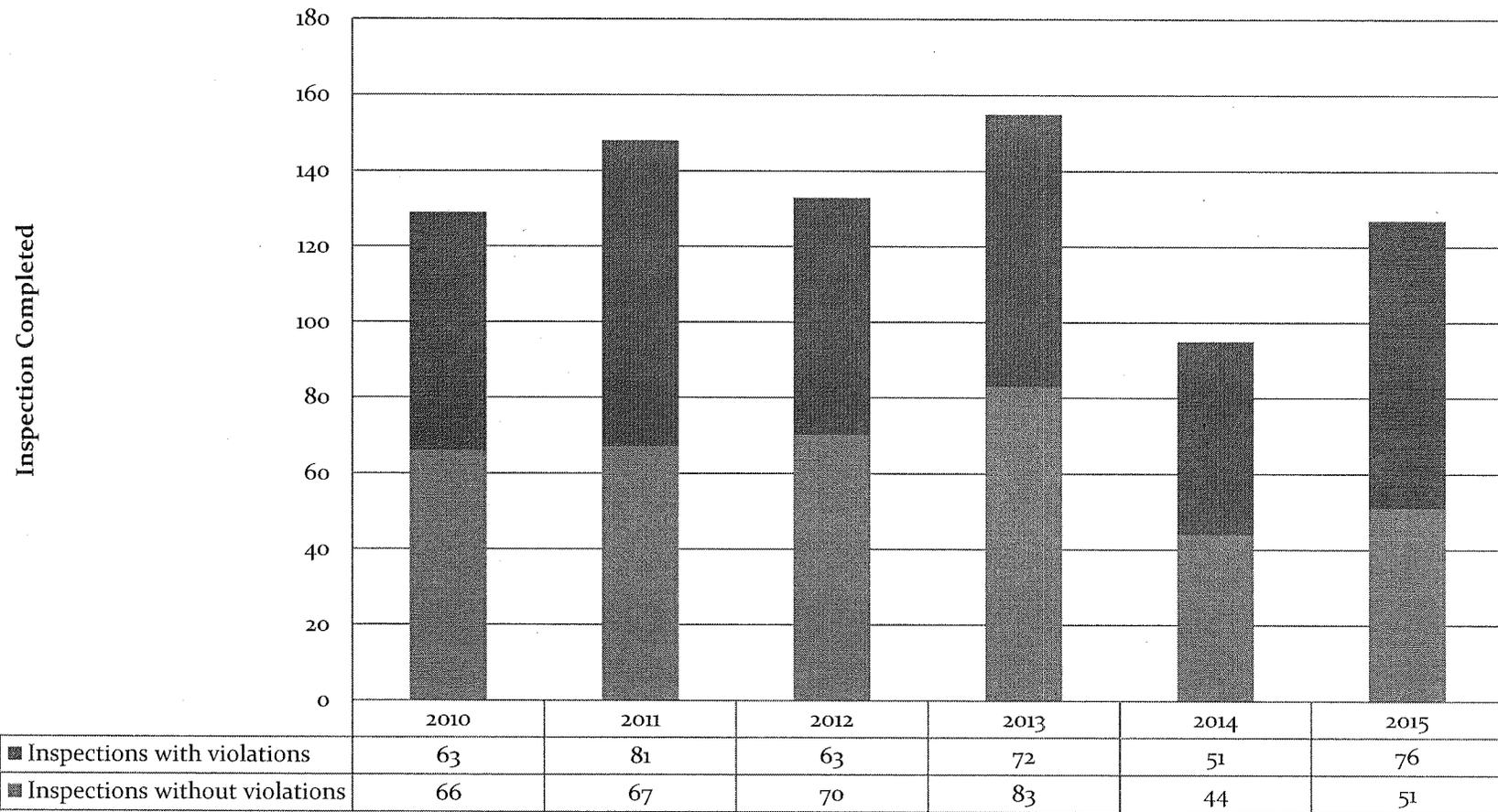
Questions?

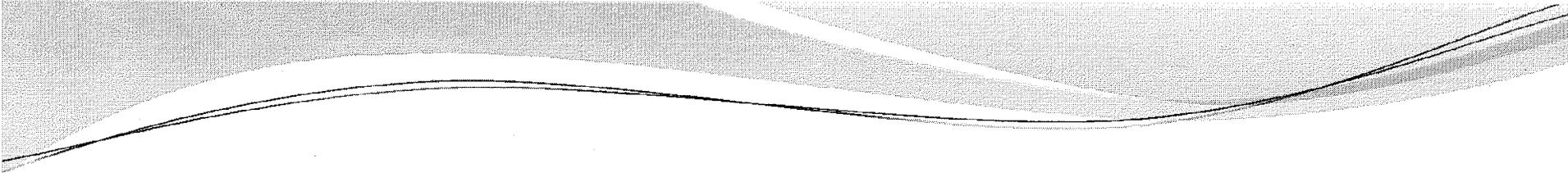
Radioactive Materials Unit

2015 Inspection Summary

- 107 initial and routine inspections were completed
- 58.5% of those inspections resulted in a Notice of Apparent Violation
- 3 Compliance Orders were completed in 2015
- 8 special or reactive inspections at licensed facilities
- 13 incidents/allegations at non-licensed facilities that required a field response
- 12 reciprocity inspections were completed. The total percentage of completed NRC eligible inspections was 39% (NRC goal is 20%)

Inspection History





Significant Events 2015

- Peak Veterinary Specialists (CO 1212-01) abandoned their facility. A draft unilateral order is being drafted with a substantial financial penalty.
- Two industrial radiography licensees cited for failure to control materials in excess of Category 2 quantities
- Contaminated crushed car identified in Grand Junction
- Unlicensed facility contaminated with Am-241 (individual was working with smoke detectors)



2016 upcoming events

- Inspections incorporating Part 22
- New employees, continued cross-training for current inspectors

Regulations Current Status

Regulations Status

- Parts 1, 3, 18 went into effect Feb 14
- Part 16 (well logging)
 - Comment period open through April 10
 - 1 stakeholder comment letter received
 - NRC comments received
 - Stakeholder meeting 3/29 - no stakeholders
- Part 19 (panoramic irradiators)
 - Comment period open through April 10

Part 6 (X-Ray Imaging in the Healing Arts)

- Purpose is to align Part 6 with SSRCR “F” (2015)
 - Lots of changes in the 2015 revision
- Changes so far...
 - Deletion of multiple unused definitions

New definitions/concepts

- “Alert value” - a dose index (CTDI) set by user (registrant) to alert a CT operator that standardized protocols are / will be exceeded.
 - Concept is to bring attention to CT scan protocols that are “out of the norm”

CTDI = Computed Tomography Dose Index

New definitions/concepts (cont.)

- “Diagnostic Reference Level” (DRL) - an administrative(?) investigation level used to ID unusually high doses for common procedures.
 - Concept is that a facility will review its procedures to determine if lower doses can be achieved while maintaining quality images.

- “Fluoroscopically-Guided Interventional (FGI) Procedures” - interventional or therapeutic procedure...using fluoroscopy to localize or characterize a lesion/diagnostic site/treatment site to monitor procedure and control and document the therapy

- “Medical event” - an [unplanned] event requiring notification of the Department (including written report, records)
 - criteria includes:
 - unintended skin dose >200 rad (2 Gy);
 - excessive organ or effective dose that also exceeds 5x the facility’s protocol;
 - wrong patient/wrong site and exceeds organ or effective dose limits (50 rad organ; 5 rem effective dose).
 - Not modality specific

● Radiation safety program

- Expansion of current Part 6 and Part 4 requirements, but specific details for x-ray are added
- Requires limiting useful beam to clinical area of interest; use of nationally recognized diagnostic reference levels; use of techniques appropriate to patient size; limitations on holding of x-ray tube housing; methods to verify patient identity, etc.

● Quality Assurance program

- Current Part 6 rule contains QA requirements, but 2015 Part F expands and provides more detail in some areas
 - Designating person to manage QA program
 - Written QA/QC procedures
 - Check images for artifacts / take action as needed
 - Performing repeat / reject analysis of radiographic images quarterly IAW national organizations
 - Preventative maintenance on machines

- Requirement to establish a radiation protocol committee (RPC)
 - Applies to CT or FGI facilities
 - Requires formation of a committee to review CT/FGI protocols periodically to lower dose/improve image quality
 - Requires written protocols
 - Requires establishment of DRL's (Diagnostic Reference Levels), notification values, and alert values for procedures
 - Requires records of radiation output sufficient to estimate radiation dose
 - Establish procedures and training for CT Fluoroscopy
 - Requires annual meeting and review of protocols by committee
 - Requires records of meetings
 - Provides for some exceptions for veterinary CT systems and CT systems used with treatment planning, and Nuc Med PET/SPECT scanning

- Expansion of requirements pertaining to fluoroscopy
 - Added (special activation) requirements for high-level controls
 - Special considerations when fluoro used in sterile fields/special procedures to ensure protection
 - Operator qualifications (licensed practitioner; radiologist assistant; ARRT certification in fluoro; certain students)
 - Expansion/specificity of training for operators/supervising use of fluoro systems
 - 4 hrs minimum training (radiation properties; bio effects, radiation protection; factors affecting fluoro output; dose management)
 - 8 hrs minimum training required for **FGI** procedures
 - 1 hr hands on fluoro training

- Expansion of requirements pertaining to fluoroscopy (cont.)
 - Use methods to monitor dose during use
 - Establish written policy regarding patient dose management
 - Medical physicist evaluation of entrance exposure rates; AKR (air kerma rate); eval of high/low contrast resolution; warning systems and timer
 - Establish RPC for FGI

More to come...

Questions?