

How long to keep records

- Most records should be kept for 3 years or from the last state inspection
- Exceptions are
 - Geometry test on dose calibrator should be kept until it needs to be done again
 - All information related to your RML and correspondence with the state
 - Dosimetry records should be kept for life

Final comments

- Use your computer system to its full potential
 - Log all results there and have it set up with the proper action levels and it will tell you if there is a problem.
 - Don't ignore the results if they are out of spec. It is useless to do a test if you aren't going to do anything with the results.
 - Know how to pull up reports or test results when the inspectors are there.
- Keep documentation in an organized system
 - Makes it easier to find what they are looking for and makes it easier for you to see what you are missing as you get ready for the inspection
- Ask questions if you don't know what or why you are doing things.

Questions?



Part O: Determination of Dose

- All doses received need to be recorded in a log.
- Doses should be assayed in the dose calibrator within 30 minutes of injection and recorded.
- Manufacturers information on dose may be used if decay corrected to calibration time and recorded.
- Injected dose should be within 20% of the prescribed dose for that procedure / patient
- Issues found with state inspections:
 - Dose measured more than 30 minutes prior to injection
 - Not keeping a log of the dose injected on each patient
 - Injected doses more than 20% different from the prescribed dose

Part P: Patient Release

- Patient can be release if they won't expose another person to more than 5 mSv.
- Written and oral instructions are required if they may expose a person to more than 1 mSv
- Women who are breast feeding must be given instructions on the interruption or discontinuation of breast feeding and the consequences of not following the recommendations
- Release of all patients must be approved by an AU
- State recently clarified their requirements for patient release after diagnostic procedures
 - Give each patient an informational handout that indicate the basis for release and is signed by the AU (photocopy or stamps are fine)
 - Have a department policy for the basis of release that is reviewed and signed by the AU annually
 - All therapy patients require written and oral instructions and a copy to be kept with the patient record
- Where there can be lapses:
 - Not having a basis for release for all procedures
 - Not maintaining the basis for release in the patient record for all therapy patients.
 - Not identifying pregnant or breast feeding women

Other areas of concern

- Well counter and thyroid probe
 - Should be checked each day prior to use with a standard source.
 - Should be checked annual with a Chi square test for repeatability and efficiency (well counter)
- Problems found
 - Not having records of daily checks
 - Not having action limits on the daily checks
 - Not performing the chi square tests or noting the efficiency of the well counter

Signs and Postings

- Colorado Notice to Employees
- Sign indicating where license and regulations are kept
 - Regulations can be bookmarked on a web browser as long as it is accessible to all employees
- Emergency contact listing
 - RSO
 - Lead Technologist
 - Other facility contact
 - 24/7 CDPHE Phone Number
- Put a radioactive sticker / label on the trash in the hot lab

Part K: Procedures for Administrations requiring a written directive

- Written Directive is required for I-131 greater than 30 uCi and any other therapy radiopharmaceutical
- Written Directive must contain patient name, name of drug, dose, route of administration, AU name and signature
 - Know which physicians at your facility are AUs for therapy doses
- Patient's identity must be positively verified prior to dosing
- Release instruction need to be provided to each patient and may need to be customized depending on dose level
- Lots can be found missing here:
 - No records of release instruction or basis for release
 - Written directive is missing some piece of information required
 - Need to have access to these records at the time of inspection
 - Physician not listed as AU at time of signature (keep old licenses)

Part L: QC of Diagnostic Equipment

- Daily camera QC done as recommended by manufacturer
 - At least daily flood check of uniformity
- Weekly / monthly testing as recommended by manufacturer
 - At minimum should include checking COR
- Make sure you document the results somewhere as well as the acceptable limits
 - If it falls outside the limits, document what action was taken with dates and initials

Part M: Dose Calibrator tests

- Constancy
 - Done daily prior to patients
- Linearity
 - Done once a quarter
 - Start with the highest dose that you would ever measure (bulk dose) and go down to 10 uCi
 - Measure at least once a half life
 - Errors at each point of less than 10% of expected value
- Accuracy
 - Done yearly
 - Errors of less than 5% for each isotopes selection
- Geometry
 - Done at installation, after repair or if you move the dose calibration
 - Ensure that your standard dose containers (syringes and vials) and standard volumes read consistently
 - If large errors are found, a correction factor is posted for the dose calibrator
- Where things are found lacking?
 - Not having records for daily constancy, especially on the weekends
 - Not having records of the linearity each quarter or the accuracy yearly or geometry at all
 - Having errors outside the acceptable limits and not noting any action taken
 - Not using the cali-check sleeves appropriately for linearity measurements

Part N: Calibration of Survey Instruments

- Survey meters should be calibrated at least annually
- Sticker should be on the meter indicated the calibration date and when it is due again
- Record of the results of the calibration should be kept
- Inspection problems found:
 - No record of calibration annually
 - Having an out of date meter in use at the time of inspection
 - Not updating survey records with the loaner survey meter information when main meter is out for calibration

Part G: Training and Instruction to Workers

- Radiation workers need to be trained at the start of the job and annually thereafter.
 - Includes regulation changes, areas of use, radiation safety, specific facility rules, RSO contact information, locations where regulations and license are kept
 - Records need to be maintained for 3 years including name of those trained, who did the training, topics covered and date of training
- Problems found:
 - Not keeping records - defined by what your policy says
 - Not keeping DOT training up to date

Part H: Dosimetry Program

- Radiation monitors are required for all nuclear medicine technologists - both body and ring
 - Wear them properly - body badge at the location indicated on the badge and ring badge with the active area toward your palm
 - Keep them at work
 - Return them on time
 - If pregnant, you can get a fetal badge that is followed more closely
- Problems here...
 - Not having ring or body badge on when using radioactive materials
 - Not requesting prior badge records for new employees



Part I: Radiation Protection Program, ALARA Provisions and Annual program audit

- Management must commit to ALARA policy
 - Annual review of radiation safety program and use of radioactive materials according to license and policies
 - Frequent monitoring of dosimetry results and proper follow up on "high" badge readings
 - No eating, drinking, smoking or makeup application in hot lab or other areas where radioactive materials are used
 - Use gloves and monitor your hands if you suspect anything got on them
 - No mouth pipetting
 - Label all syringes and containers properly
- What gets cited here?
 - Not having written records of the annual program audit with managements signature
 - Repeated problems identified in audit but not corrected
 - Proof of food or drink in the hot lab trash
 - Unlabeled lead pigs or syringes - may lead to "mis-administration"

Part J: Authority, Duties and Responsibilities of the RSO

- Review of badge records and annual program review
- Ensure proper working training and education
- Working with management and technologists when a problem / error / deficiency is found
- Available to answer questions
- Make sure you have a signed agreement with the RSO and management giving them this authority.

Part D: Radioactive Waste Disposal

- Decay-in-storage method
 - Must keep for a minimum of 10 half lives of longest lived isotope in bin
 - Label each bag with the date of closure and potential date of disposal.
 - After 10 half lives, monitor exposure rate of bag (should be at background) and remove or deface all radioactive symbols
 - Dispose of with normal trash
 - Log disposal including date, meter used, background level, waste bag level, initials of person
- What goes wrong?
 - Not labeling each bag
 - Not noting each bag in log or computer (vent kits especially)
 - Not logging each disposal and survey results

Part D: Radioactive Waste Disposal

- Transfer Material to Disposal Service
 - Get return paperwork or other approval to send sources back
 - Follow instructions from vendor or RSO on packing sources and proper labeling of packages
- What can get cited?
 - Not having up to date DOT training
 - Not keeping a copy of the shipping papers and proof from company that sources were received

Part E: Spills and Emergency Procedures

- Minor Spill (single patient dose or less)
 - Let everyone in the area know what happened
 - Clean it up
 - Report it to RSO and your supervisor
- Major Spill (more than a single patient dose or any therapy dose)
 - Vacate the room / area of all non-involved persons
 - Determine extent of spill / persons contaminated
 - Notify RSO and supervisor immediately
 - Follow RSO instructions for clean up / decon
- What does the state want to see?
 - That you have these procedures posted where everyone can find them
 - That all spills are reported and documented

Part F: Leak Testing Sealed Sources

- Each sealed source needs to be inventoried and leak tested every 6 months
- For leak testing:
 - Each source is wiped with an alcohol pad. If sources are in storage / decay, a single wipe of the decay box works.
 - The pads are counted (as well as the background and a standard source) in a well counter with a sensitivity to detect 5 nCi of contamination
 - The counts for each sources are converted to an activity and verified to have less than 5 nCi
- What gets missed?
 - Not accounting for all sources on the inventory in the leak tests
 - Not hitting the 6 month time frame
 - Not having sufficient data on the leak test results to show the sensitivity of the well counter and the calculation for each source

Radiation Safety Portions in Colorado RML

- | | |
|--|---|
| <input type="checkbox"/> 16. Operating Procedures and Provisions for the Radiation Protection Program | <input type="checkbox"/> K. ____ Procedures for Administrations Requiring a Written Directive (7.12) |
| <input type="checkbox"/> Attach a copy of your written operating procedures and provisions addressing each of the applicable items. If an item is not applicable to your program, indicate with N/A in the blank provided. | <input type="checkbox"/> L. ____ Quality Control of Diagnostic Equipment (7.15) |
| <input type="checkbox"/> A. ____ Receipt of Radioactive Materials and Opening Packages (4.32) | <input type="checkbox"/> M. ____ Dose Calibrator tests of constancy, linearity, accuracy and geometry dependence (7.16) |
| <input type="checkbox"/> B. ____ Storage of Radioactive Materials and Material Security (3.9.2) | <input type="checkbox"/> N. ____ Calibration of Survey Instruments (7.17) |
| <input type="checkbox"/> C. ____ Routine Surveys for Contamination (4.15.1, 4.17 and 7.25) | <input type="checkbox"/> O. ____ Determination of Dosages of Radioactive Material for Medical Use (7.18) |
| <input type="checkbox"/> D. ____ Radioactive Waste Disposal (4.33 and 7.29) | <input type="checkbox"/> P. ____ Release of individuals who have been administered radioactive drugs (7.20) |
| <input type="checkbox"/> E. ____ Spills and Emergency Procedures (4.5.2) | <input type="checkbox"/> Q. ____ Mobile Nuclear Medicine Services (7.27) |
| <input type="checkbox"/> F. ____ Leak Testing Sealed Sources (4.16, 7.20) | <input type="checkbox"/> R. ____ Safety Procedures and Instructions for a Pharmacy Administering Unit, Teletherapy Unit, or Gamma Stereotactic Radiotherapy Unit (7.34) |
| <input type="checkbox"/> G. ____ Training and Instruction to Workers (3.9.1, 4.5.2, 7.10, and 10.3) | <input type="checkbox"/> S. ____ Procedures and Instructions for Spot Checks of Primary Administrator Units (7.36) |
| <input type="checkbox"/> H. ____ Dosimetry Program (4.18) | <input type="checkbox"/> T. ____ Procedures and Instructions for Spot Checks of Teletherapy Unit (7.38) |
| <input type="checkbox"/> I. ____ Radiation Protection Program, ALARA Provisions, Annual Program Audit (4.5, 7.7) | <input type="checkbox"/> U. ____ Procedures and Instructions for Spot Checks of Stereotactic Radiotherapy Unit (7.44) |

Part A: Receipt of Radioactive Material and Opening Packages


- What do you do when you receive a package with radioactive materials (from pharmacy or other shipper)?
 - Visual inspection
 - Wipe and survey outside of package
 - Open package and remove packing slip, verify contents, visual inspection of contents
 - Wipe inside of container
 - Log results - either in computer system or on paper
- What can go wrong - or what can you get cited for at an inspection
 - No log of results of wipes or surveys
 - Not knowing what your levels are on the wipe test for contamination
 - Most wipe counters report in CPM and you need to know how to convert to DPM (contamination is DPM/2000)
 - Having results that are made up (i.e. all zeros)

Part B: Storage of Radioactive Materials and Materials Security

- Doses should be stored in shielded, labeled containers
- Wastes should be stored in shielded, labeled containers for decay
- Syringe shields and carriers should be available and used as appropriate
- Hot lab, decay room, and any other location where materials are kept should be locked at all times someone is not in view of it.
- All sources should be kept in hot lab or other locked area
- Need to have a policy for delivery of radioactive materials during normal hours and when a technologist is not present
 - Does the pharmacy have direct access to the delivery location (hot lab) or do they need to be escorted by security?
- What here is cited?
 - Not labeling waste properly - especially vent kits.
 - Keeping the flood sources in an unlocked camera room
 - Not locking the door to the hot lab or department when you walk away for a minute
 - Not using syringe shields or carriers

Part C: Routine Surveys for Contamination

- Includes area monitoring as well as shipping surveys
 - Shipping packages must have surface and 1m survey readings and wipe tests prior to pickup
 - Area surveys must be done at the end of each day in areas where written directive material was used (i.e. I-131) and at least once each week in all areas where material or waste is stored.
 - Need a detailed map (not to scale) of the location of survey
 - Wipe tests must be done on each day a generator or bulk dose is used or if contamination is found or suspected. They are also done each week in all areas of use.
- Where do problems arise?
 - Not indicating the background reading for each survey
 - Not indicating the survey meter ID used (or not updating the ID when a meter is off for calibration)
 - Not keeping log of results (using bulk dose on weekend)
 - Need to know your action level and what to do



Requirements of Colorado State Radioactive Materials Licenses

Jennifer R Strickel, Ph.D. DABR
Colorado Associates in Medical Physics
RMNMTA Meeting - September 18, 2011

Outline

- 1.) Review radiation safety agreements that are part of Colorado State Radioactive Materials Licenses
- 2.) Review QC requirements that are part of Colorado State Radioactive Materials Licenses
- 3.) Discussion of recent inspection finding at a variety of locations including violations and corrective actions
- 4.) Question period for individual concerns on radiation safety in nuclear medicine departments

Disclosure

- The RSO at your facility has the final say on requirements / rules pertaining to your use of radioactive materials.
 - If I am your RSO, all that I say applies
 - If I am not your RSO, what I say applies in general but may be implemented differently at your institution or clinic. Check with your RSO if in doubt.

Radiation Safety Portions in Colorado RML

- Colorado is an NRC agreement state so state is responsible for implementing rules and inspections
 - Part 7 of the state regulations lists the rules for radioactive materials
- When you apply for or renew a Radioactive Materials License (RML), you are required to submit your policies and procedures for a variety of situations.
- These are what the state is going to approve and hold you responsible for at inspection time.
- Make sure you know what is being sent in so that you can follow those requirements (frequency of tests to be done, documentation required)