

Licensing and Registration of Radiation Sources

**Presentation for an Ionizing Radiation Committee
Round Table 244
on Radiation Safety Program Challenges for IHs**

May 26, 2016

American Industrial Hygiene Association

**Annual Meeting
Baltimore, MD**

**Ray Johnson, MS, PSE, PE, DAAHP, FHPS, CHP
Director, Radiation Safety Counseling Institute
Rockville, MD 20853**

ray@radiationcounseling.org

Licensing and Registration of Radiation Sources

A 30-minute Presentation for an Ionizing Radiation Committee Round Table 244
on Radiation Safety Program Challenges for IHs
At the Annual Meeting, AIHce, Baltimore, MD May 26, 2016

Ray Johnson, MS, PSE, PE, DAAHP, FHPS, CHP
Director, Radiation Safety Counseling Institute
Rockville, MD 20853
ray@radiationcounseling.org

Except for some sources of radiation which are specifically exempted (for very small quantities), all sources of radioactive materials require licensing by a State or the Nuclear Regulatory Commission and radiation producing devices require a State registration. Forms (usually one or two pages) for licensing or registration may be obtained on NRC or State websites. Thirty seven states have agreements with the NRC to grant radioactive material licenses and have issued about 19,000 licenses. A license or registration is a contract to assure compliance with regulatory requirements. There are two broad categories of licenses – General and Specific. A general license grants authority to a person for certain activities involving radioactive material and is effective without the filing of an application or the issuance of a licensing document to a particular person. Under a general license the manufacturer can send you whatever you order (such as a nuclear density gauge). The conditions for a general license are given in 10 CFR 30, 31, 40, and 70 and included by the manufacturer in the owner's manual. Radioactive sources requiring a specific license cannot be purchased until the manufacturer has a copy of your license. Requirements for specific licenses are given in 10 CFR 30, 32, and 33. Very good guidance is available for licensing in NUREG 1556 Vol. 1 – 21 (a volume for each type of license).



Raymond H. Johnson, MS, PSE, PE, FHPS, DAAHP, CHP

Director, Radiation Safety Counseling Institute 301-370-8573

- BS - Civil Engineering, University of Vermont (1961)
- MS - Sanitary Engineering, Massachusetts Institute of Technology (MIT) (1963)
- PSE - Professional Sanitary Engineer Degree, MIT and Harvard University (1963)
- PE - Licensed Professional Engineer, Vermont (1965 - present)
- PhD Studies, Radio and Nuclear Chemistry, Rensselaer Polytechnic Institute (1966-1972)
- Greater Washington Institute for Transactional Analysis - Counseling (1977-1980)
- CHP - Certified Health Physicist, American Board of Health Physics (1983-present)
- Johns Hopkins Fellow, Organizational Systems and Communications (1984-1985)
- FHPS - Fellow of the Health Physics Society and Past President (2000)
- DAAHP - Diplomate and Past President, American Academy of Health Physics (2015)
- Commissioned Stephen Minister - Counselor, United Methodist Church (2003-present)

Experience

- 2010 - pres. Director, Radiation Safety Counseling Institute. Workshops, training, and counseling for individuals, companies, universities, or government agencies with concerns or questions about radiation and x-ray safety. Specialist in helping people understand radiation, what is safe, risk communication, worker counseling, psychology of radiation safety, and dealing with fears of radiation and nuclear terrorism for homeland security.
- 2007 - pres. VP, Training Programs and consultant to Dade Moeller Radiation Safety Academy, training and consulting in x-ray and radiation safety, safety program audits, radiation instruments, NORM, and regulatory requirements.
- 1984 - 2007 Director, Radiation Safety Academy. Providing x-ray and radiation safety training, audits, and consulting to industry (nuclear gauges and x-ray), universities, research facilities, and professional organizations.
- 1988 - 2006 Manager and Contractor to National Institutes of Health (NIH) for radiation safety audits of 3,500 research laboratories and 2,500 instrument calibrations a year, along with environmental monitoring, hot lab and analytic lab operations, and inspections of three accelerators and over 100 x-ray machines.
- 1990 - 2005 President of Key Technology, Inc. a manufacturer and primary laboratory for radon analyses with over 1,500,000 measurements since 1985. Primary instructor at Rutgers University for radon, radon measurements, radiation risks, radiation instruments, and radon risk communication courses (1990-1998).
- 1986 - 1988 Laboratory Director, RSO, Inc. Directed analytical programs and Quality Assurance for samples from NIH, Aberdeen Proving Ground, radiopharmaceutical companies, and the nuclear industry.
- 1970 - 1985 EPA program manager and Chief, Radiation Surveillance Branch, EPA, Office of Radiation Programs. Directed studies of radiation exposures from all sources of radiation in the US, coordinated 7 Federal agencies for nuclear fallout events, QA officer 8 years. Head of US delegations to I.A.E.A and N.E.A. on radioactive waste disposal. ANSI N-13 delegate (1975-1985). Retired as PHS Commissioned Officer (0-6) in 1985 with 29 years of service.
- 1963 - 1970 U.S.P.H.S. Directed development of radiation monitoring techniques at DOE National Labs, nuclear plants, and shipyards in the US and Chalk River Nuclear Laboratory in Canada. Conducted doctoral research.

Health Physics and Professional Activities

Health Physics Society (HPS) plenary member 1966; President-elect, President, Past President (1998-2001), Fellow (2000), Treasurer (1995-1998); Secretary (1992-1995); Executive Cmte. (1992-2001), Chair, Finance Cmte. (1996-1998); Head of U.S. delegation to IRPA X (2000). RSO Section Founder and Secretary/Treasurer (1997-2000); Co-founder and President, Radon Section (1995-1996). Co-Chair Local Arrangements Cmte. Annual Meeting in DC (1991); Summer School Co-Chair (2004); Chair, President's Emeritus, Cmte (2006); Chair, Awards Cmte (2002); Chair, History Cmte (2005-2012); Historian (2012-Pres.) Continuing Education Cmte. (2005-2012). Chair, Professional Development School Cmte (2014-Pres.), Academic Dean for HPS Professional Development School on Radiation Risk Communication (2010) and Radiation Instruments School (2014). PEP, CEL and Journal Reviewer. AAHP Instructor; Treasurer, AAHP (2009 - 2012). AAHP President-elect, President, Past President (2012-2015). Baltimore-Washington Chapter: President (1990-1991) and Honorary Life Member; Newsletter Editor (1983-2005); Public Info. Chair (1983-1989), Science Teacher Workshop Leader (1995 - Pres.). New England Chapter HPS, Newsletter Editor, Board of Directors, Education Chair (1968-1972). President, American Association of Radon Scientists and Technologists (1995-1998) and Honorary Life Member, Charter Member; Board of Directors; Newsletter Editor (1990-1993). Founder and first President, National Radon Safety Board (NRSB) (1997-1999). Member of American Industrial Hygiene Association (1997-Pres.) (Secretary, Vice Chair, Chair, Ionizing Radiation Committee, 2009-2012), Conference of Radiation Control Program Directors (1997-Pres.), Taught 3,500 RSO students since 1985. Studied H.P. communication styles and presented Myers-Briggs seminars to over 4,000 H.P.s since 1984. Over 35 professional society awards. Licensed Professional Engineer since 1965. Certified Health Physicist since 1983.

Publications

Authored over 600 book chapters, articles, professional papers, training manuals, technical reports, and presentations on radiation safety. Author of monthly column, "Insights in Communication" HPS Newsletter 1984 - 1989, 1994 -2001, and 2012- 2013.

Contact at: 301-990-6006, ray@radiationcounseling.org, 301-370-8573, www.radiationcounseling.org

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AIHce2016 Inner Harbor, Baltimore

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Ionizing Radiation Committee
Round Table - May 26, 2016

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Director, Radiation Safety Counseling Institute
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What Do You Work With?

- **Radioactive Materials (RAM) (States and NRC)**
 - Sealed Sources, nuclear gauges, etc
 - Unsealed Sources - liquids, gases, powders
- **Radiation Producing Devices (States)**
 - X-ray Devices
 - X-rays Created "Incidental to Process"
 - Accelerators (Operation – States) (RAM – NRC)
- **NORM or NARM**
 - Discrete sources (Ra-226) NRC
 - TENORM - States

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Licenses and Registrations

- **Exempt:**
 - Smoke detectors, self-luminous devices, radiation instrument check or calibration sources
- **General License:**
 - Fixed or portable nuclear gauges, static eliminators, exit signs, in-vitro testing (RIA kits), LSCs, gas chromatographs
- **Specific License of Limited Scope:**
 - Irradiators, nuclear gauges, gamma radiography, medical uses of RAM, accelerator (RAM), R&D labs
- **Specific License of Broad Scope (Type A, B, C):**
 - Universities and hospitals
- **Registration (by States only)**
 - Radiation Producing Devices (i.e. x-ray machines)

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General vs. Specific Licenses

10 CFR 30, 31

- **General License (for devices, gauges, LSC)**
 - No application filed by user – requirements specified by manufacturer – 10 CFR 31.5
 - Anyone can buy sources under a general license
 - State may require "Registration" of these sources
- **Specific License**
 - Apply for license (on required form), show purpose, qualifications, training, safety plan, etc.
 - Cannot buy source until license received by distributor

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Who Regulates What?

- **Radioactive Byproduct Materials (from a reactor)**
 - Nuclear Regulatory Commission (NRC)
 - Agreement States (37)
 - Agreed to assume responsibility for enforcing NRC radiation protection regulations at the State level
- **X-ray Equipment**
 - **Manufacturers regulated by:**
 - FDA Center for Devices and Radiological Health (CDRH)
 - Manufacture, installation, assembly, and maintenance
 - **Machine Users Regulated by:**
 - State Health or Radiation Protection Departments
- **Accelerators**
 - Operation regulated by States, RAM by NRC

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NRC or Agreement States

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Where to Find Help for Licensing

- **Agreement States:**
 - Conference of Radiation Control Program Directors (CRCPD)
 - State radiation control programs listing [http://www.crcpd.org/Radiation Control Programs](http://www.crcpd.org/Radiation%20Control%20Programs)
- **Nuclear Regulatory Commission**
www.nrc.gov

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Agreement States vs. NRC

- Agreement States Regulate at State Level with NRC Oversight
 - **Must provide as much protection as NRC:**
 - Agreement States usually cover:
 - By-product Use, Transfer, Disposal
 - Accelerators (NRC regulates some RAM)
 - Naturally Occurring Radioactive Materials (NORM) or (TENORM)
 - Electronic Products (x-ray producing devices)
 - Agreement States **Do Not** Regulate:
 - Federal Facilities
 - Nuclear Reactors

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Nuclear Regulatory Commission

- **Regulates**
 - **By-product material** (made radioactive in a reactor and residues from the milling of uranium and thorium)
 - **Source material** (uranium and thorium)
 - **Special nuclear material** (enriched uranium and plutonium, bomb material)
- **Does Not Regulate or Inspect:**
 - Accelerators (Operation)
 - Naturally Occurring Radioactive Materials
 - X-ray Machines

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Exemptions from Licensing

- Exempt Concentrations (10 CFR 30.14):
- Exempt Quantities (10 CFR 30.18):

Radionuclide	µCi	Gas (µCi / ml)	Liquid or Solid (µCi / ml)
C-14	100	1x10 ⁻⁶	8x10 ⁻³
Co-60	1	---	5x10 ⁻⁴
I-131	1	3x10 ⁻⁹	2x10 ⁻⁵
H-3	1,000	5x10 ⁻⁶	3x10 ⁻²

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Generally Licensed Devices (GLDs)

- GLDs are devices containing radioactive material and are typically used to detect, measure, gauge, or control the thickness, density, level, or chemical composition of various items.
- Examples include: gas chromatographs (detector cells), density gauges, fill-level gauges, and static elimination devices

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General Licensees (GLs)

- Subject to NRC 10 CFR 31.5
 - Accountability and control – do not abandon
 - Inventory every six months
 - Routine maintenance – follow manufacturer
 - Leak tests, shutter tests every six months (or 36)
 - Damage or test failure
 - Repair or disposal, report in 30 days
 - Other reporting
 - Transfer or disposal, change of owner, cannot give away

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General License Registration ?

- Certain general licensees must register their GLDs with NRC or States – pay fee

Activity	
Isotope	(mCi)
Cesium-137	10
Strontium-90	0.1
Cobalt-60	1
Radium-226	0.1
Americium-241	1
Any other transuranic	1

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Application Form for a Specific License

- NRC - Form 313
 - www.nrc.gov/reading-rm/doc-collections/forms_1 page, 13 questions
- Agreement States
 - www.crcpd.org/Map/default.aspx
 - From each State's website
 - Usually 1 or 2 pages

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Licensing Guidance, NUREG 1556

- Consolidated Guidance About Materials Licenses
- 21 volumes of detailed information and procedures – very readable
 - Vol. 1, Portable Gauges (suggested for XRF)
 - Vol. 4, Fixed Gauges (suggested for industrial x-ray)
 - Vol. 7, Academic, Research and Development, and Other Licenses of Limited Scope
 - Vol. 11, Broad Scope
 - Other Programs

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The NRC Form 313 Application: Item 1

- New application
- Amendment (usually just a letter)
- Renewal

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Item 2

- Should be corporation or other institutional entity
- Name and mailing address
- Rarely a private individual
- State in which mailing address is located is used to determine license number

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Item 3

- Addresses where licensed material will be used or possessed
- PO Box is NOT acceptable here
- Should list street address or descriptive address for each proposed location
- Can request temporary job sites and field studies, and provide description of supporting program in items 9, 10, and 11 or as separate attachment

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Item 4 – Contact Person

- Can be consultant
 - Such as a CHP
- Does not have to be RSO, but must be someone who will respond to regulator.

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Item 5 – Radioactive Material

➔ Type, form, and maximum quantities of radionuclides request

- Maximum limit for each nuclide where appropriate
- Don't forget to include storage and wastes

Radionuclide	Form	Activity
H-3	Any, non-volatile	1 Ci
C-14	Any	500 mCi
Cs-137	Sealed Source	3000 Ci
Ni-63	Sealed Source model XXX-YYY	15 mCi
P-32	Any	25 mCi

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Item 5 – Radioactive Material

- Must be appropriate for requested use and for license expertise;
- List on attached paper;
- Specify maximum limit:
 - Per source, and total quantity of each source;
- Make sure to include provisions for multiple, or unknown isotopes;
- Sealed sources – include make and model – reference SSD registration certificate, or provide information in 10 CFR 30.32(g)(3).

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Item 6 – Purpose

- Purposes must be specified, e.g.:
 - Labeling of compounds;
 - Measurement of moisture in soil;
 - Human Use for imaging and localization;
- Must be appropriate for uses according to licensee expertise;
- Must not be frivolous
 - No approval for “nice-to-have” nuclides.

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Item 7 – Individual Responsible

- Name of RSO will be listed in license
- Information re: competency and qualifications of staff and management
- MUST have authorized user for each radionuclide use requested

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Item 7 – Individual Responsible

- Authorized Users must have appropriate training and experience
 - Varies with the proposed RAM and uses
 - CV or resume usually not sufficient
 - Need details on training and experience specific to use of RAM in this license
 - quantities and types of RAM used
- A 40 hour class is considered good for small, limited licenses, NOT adequate for broad scope
 - Helpful if you have handled RAM before
 - May hire consultant in interim while gaining experience

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Licensing and Registration of Radiation Sources

RSO Responsibilities

- Authorize purchases and use of RAM, X-rays, Accelerators...
 - Use in proper facilities with appropriate signs
 - Training
- Shielding design and assessment
- Availability, use, maintenance, and calibration of survey instrumentation
- Program documentation and accountability
 - Inventories
- Annual Program Audits
- Regulatory agency interface and inspections

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RSO Responsibilities

- Periodic surveys of Use Areas
 - Contamination Surveys
- Radiation dosimetry and surveillance
- Work with the Committee on disciplinary matters
- Emergency response and interface
 - Investigation and corrective action
- Waste management and disposal
- Shipping/Receiving radioactive materials

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Radiation Safety Committee (for Broad Scope Type A Licenses, optional for others)

- Provide guidance and information on radiation safety program
 - For senior management
 - For user community
- Enforce the program requirements
- Assist RSO in program development, implementation, and maintenance
- Ensure adequate resources are available to administer the program


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Item 8 – Training

- Training for anyone likely to receive more than 100 millirem in one year (10 CFR 19.12).
- Regulatory agency may expect written program for worker training.
- Made part of the license by “tie-down” condition.
- Should include topics above and beyond 10 CFR 19.12 to ensure safe use.



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Item 8 – Training

- Should have a retraining program
 - Part of “model procedures” (NUREG 1556);
 - Refresher - Not repeat
- Don’t forget ancillary personnel training
 - Administrative, support, maintenance or security staff who may work near radiation sources.

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Basic Training Outline

- Basic radiation physics and radiation safety principles
- Biological effects (case studies)
- Radiation detection and instrumentation
- Purchase, use, transfer, and disposal of radioactive materials
- Safe work practices and handling techniques for RAM; x-ray; gauges
- Regulations and license conditions
- Enforcement
- Radiation safety plan and emergency procedures


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Item 8 – Training

- There are no time requirements for training, but the training:
 - Must be commensurate with the hazards expected to be encountered.
- Can be simple for non-rad workers:
 - What is rad symbol?
 - What to touch? What not to touch?
 - What to do if RAM is found?

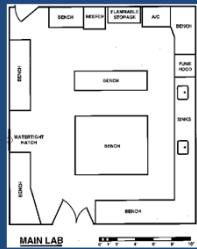


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Item 9 – Facilities

- Facilities and Equipment (Meters)
- Must address all locations
 - May include floor plans
- Other minimum facility and equipment descriptions made part of license by tie-down conditions



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Item 9 – Facilities

- Include all “hardware” used in radiation safety
 - Describe special function equipment, e.g., calibrator
 - Iodination facilities
 - Sinks used for RAM disposal
 - Animal facilities
- Special concern for control of airborne materials



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Item 10 – Radiation Safety Program

(look for Licensee and Registrant Shall)


- Annual audit program,
- Radiation monitoring instruments,
- Material receipt, and accountability,
- Occupational dose,
- Public dose,
- Safe use of RAM, operating and emergency procedures, bioassay, security
- Surveys, leak tests, calibrations
- Transportation,
- Contamination minimization
- Waste disposal

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Item 11 – Wastes

- Waste management and disposal
 - Transfer to authorized recipient
 - Burial, processing, brokers
 - Source return
 - Sewer disposal
 - Decay-in-storage
 - Effluent releases
 - On-site storage




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Item 12


- License fees
- Must be submitted with application
 - For NRC licenses
 - States may collect an annual fee
 - States may also charge for inspections



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Item 13



- Certification
- Must be signed by management representative
 - Usually not RSO!
 - Ideally, the signer will be high up in the organization
- Management's role is to define radiation protection responsibilities and provide an environment in which staff can do their jobs properly

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Amendments

- Can be single page letter
- No form required
- Must supply docket number, license, address, management signature

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License Renewal

- Submit at least 30 days before expiration
- Some regulators require entirely updated plan
- Others simply request changes to make



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Licenses and Registrations

- Exempt:
 - Smoke detectors, self-luminous devices, radiation instrument check or calibration sources
- General License:
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- Specific License of Limited Scope:
 - Irradiators, nuclear gauges, gamma radiography, medical uses of RAM, accelerator (RAM), R&D labs
- Specific License of Broad Scope (Type A, B, C):
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Summary – Tools for Licensing

- You should now be familiar with:
 - How to apply for a license for use of radioactive materials
 - Where to get an application form
 - How to amend and renew your license,
 - The type of information you must provide to regulatory agencies.

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Summary – Tools for Licensing

- License application, 1 – page form
 - From NRC or State websites
- Follow NUREG 1556
- Provide your RSO certificate and other training / experience specific to your license application
- Most of your time will be spent on defining your Radiation Safety Program
 - We generally allow a week

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