Commonwealth of Virginia Radiation Protection Regulatory Guide



Guidance for Fixed Gauge Devices

ORH-720 C

Virginia Department of Health Radioactive Materials Program 109 Governor Street, Room 730 Richmond, VA 23219 Phone: (804) 864-8150

Revision 3 March 9, 2016

EXECUTIVE SUMMARY

Virginia Regulatory Guides (VAREGS) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of 12VAC5-481 'Virginia Radiation Protection Regulations', to delineate techniques used by the staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants or licensees. VAREGS are not substitutes for 12VAC5-481 'Virginia Radiation Protection Regulations'; therefore, compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Virginia Department of Health (VDH), Radioactive Materials Program, to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this VAREG are encouraged at all times and it will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Comments should be sent to Virginia Department of Health, Radioactive Materials Program, 109

Governor Street, Room 730, Richmond, VA 23219.

Requests for single copies of this guide (which may be reproduced) can be made in writing to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

This guide is available on our website: <a href="http://www.vdh.virginia.gov/radiological-health/radiologi

This VAREG, 'Guidance for Fixed Gauge Devices' has been developed to streamline the application process for a Fixed Gauge License. A copy of the VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' is located in **Appendix A** of this guide.

Appendix C through O provides examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12VAC5-490**.

Revision 3 March 9, 2016

In summary, the applicant will need to do the following to submit an application for a Fixed Gauge license:

- Use this regulatory guide to prepare the VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**).
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**). See "Contents of Application" of the guide for additional information.
- Include any additional attachments.

All supplemental pages should be submitted on 8 ½" x 11" paper.

Please identify all attachments with the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary. If submitted, proprietary
 information and other sensitive information should be clearly identified and a request made to
 withhold from public disclosure.
- Submit an original signed application along with attachments (if any). This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Submit the application fee (for new licenses only).
- Retain one copy of the license application and attachments (if any) for your future reference. You will
 need this information because the license will require that radioactive material be possessed and used
 in accordance with statements, representation, and procedures provided in the application and
 supporting documentation.

If you have any questions about the application process, please contact this office at (804) 864-8150.

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ABBREVIATIONS

ALARA as low as is reasonably achievable

ALI annual limit on intake

bkg background Bq Becquerel

CFR Code of Federal Regulations

Ci Curie

cc centimeter cubed cm² centimeter squared cpm counts per minute

DOT United States Department of Transportation

dpm disintegrations per minute

GM Geiger-Mueller IN Information Notice

mCi millicurie
mR milliroentgen
mrem millirem
mSv millisievert

NIST National Institute of Standards and Technology NRC United States Nuclear Regulatory Commission

NVLAP National Voluntary Laboratory Accreditation Program

OSL optically stimulated luminescence dosimeters

RG Regulatory Guide RSO Radiation Safety Officer

SI International System of Units (abbreviated SI from the French Le Système Internationale

d'Unites)

SSDR Sealed Source and Device Registration

Sv Sievert

TEDE total effective dose equivalent
TLD thermoluminescent dosimeters
VDH Virginia Department of Health

μCi microcurie % percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for a Fixed Gauge License. It also provides guidance on VDH's criteria for evaluating a Fixed Gauge license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices. Various designs of fixed gauges are based in part on their intended use and the location of the radioactive source within the gauge. Typically gauges are used for process control (e.g., to measure the thickness of paper, the density of coal, the level of material in vessels and tanks, and volumetric flow rate). Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety considerations.

This guide describes the information needed to complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**).

The format for each item number in this guide is as follows:

- Rule references the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' applicable to the item;
- **Criteria** outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** provides additional information on the topic sufficient to meet the needs of most readers.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application.

12VAC5-481 'Virginia Radiation Protection Regulations' requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. The appendices describe radiation protection procedures. Each applicant should read the rule and procedures carefully and then decide if the procedure addresses specific radiation protection program needs at the applicant's facility. Applicants may adopt a procedure included in this VAREG or they may develop their own procedures to comply with the applicable rule.

In this guide, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in the **12VAC5-481-10**. Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because **12VAC5-481 'Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation',** sets dose limits in terms of rem, not rad or roentgen. Furthermore, radioactive materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

This VAREG provides the latest guidance, shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'**, and provides a user-friendly format to assist with the preparation of a license application.

LICENSE

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**). VDH expects licensees to provide requested information on specific aspects of their proposed radiation protection program in attachments to the application. When necessary, VDH may ask the applicant for additional information to gain reasonable assurance that an adequate radiation protection program has been established.

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with VDH;
- Terms and conditions of the license; and
- 12VAC5-481 'Virginia Radiation Protection Regulations'.

THE 'AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)' CONCEPT

12VAC5-481-630, Radiation protection programs, states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities" and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA." This section also requires that licensees review the content of the radiation protection program and its implementation annually.

Information directly related to radiation protection standards in 12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation', is contained in:

 NRC's NUREG-1736, 'Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation.'

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

WHO REGULATES FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

In the special situation of work at federally controlled sites in the Commonwealth of Virginia, it is necessary to know the jurisdictional status of the land to determine whether the Nuclear Regulatory Commission (NRC) or VDH has regulatory authority. The NRC has regulatory authority over land determined to be under "exclusive federal jurisdiction," while VDH has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. VDH recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with VDH or NRC regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates the Activity?

| Applicant and Proposed Location of Work | Regulatory Agency |
|--|-------------------|
| Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12]) | NRC |
| Non-federal entity in non-Agreement State, U.S. territory, or possession | NRC |
| Non-federal entity in Virginia at non-federally controlled site | VDH |
| Non-federal entity in Virginia at federally-controlled site not subject to exclusive federal jurisdiction | VDH |
| Non-federal entity in Virginia at federally-controlled site subject to exclusive federal jurisdiction | NRC |

Note: A current list of Agreement States (states that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), including names, addresses, and telephone numbers of responsible officials are maintained by the NRC Office of Federal and State Materials and Environmental Management Programs and is available on their website: http://nrc-stp.ornl.gov/.

MANAGEMENT RESPONSIBILITIES

VDH endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with VDH regulatory requirements.

"Management" refers to the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities or that person's delegate or delegates.

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation protection, security, and control of radioactive materials, and compliance with rule;
- Knowledge about the contents of the license application;
- Compliance with current VDH and United States Department of Transportation (DOT)
 regulations and the licensee's operating and emergency procedures;
- Provision of adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;

Management may delegate individuals (i.e., an RSO or other designated individual) to submit amendment requests to VDH. A correspondence delegation letter must be completed, signed by management and submitted to VDH. A sample letter has been included in **Appendix E**.

SAFETY CULTURE

Nuclear safety culture is defined as 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. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). **Table 2** show traits of a positive nuclear safety culture.

Table 2: Traits of a Positive Nuclear Safety Culture

| Trait | Result |
|---------------------------------------|---|
| Leadership: Safety Values and Actions | Leaders demonstrate a commitment to safety in |
| | their decisions and behaviors |
| Problem Identification and Resolution | Issues potentially impacting safety are promptly |
| | identified, fully evaluated, and promptly addressed |
| | and corrected commensurate with their significance |
| Personal Accountability | All individuals take personal responsibility for |
| | safety |
| Evaluating Work Processes | The process of planning and controlling work |
| | activities is implemented so that safety is |
| | maintained |
| Continuous Learning | Opportunities to learn about ways to ensure safety |
| | are sought out and implemented |
| Environment for Raising Concerns | 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 | Communications maintain a focus on safety |
| Respectful Work Environment | Trust and respect permeate the organization |
| Questioning Attitude | Individuals avoid complacency and continually |
| | challenge existing conditions and activities in order |
| | to identify discrepancies that might result in error or |
| | inappropriate action |

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, holders of quality assurance programs approvals, vendors, and suppliers of safety-related components, and applicants for a license or quality assurance program approval, subject to VDH authority. More information relating to safety culture can be found at: http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read, and follow 12VAC5-481 'Virginia Radiation Protection Regulations'.

The following parts of **12VAC5-481** 'Virginia Radiation Protection Regulations' contain requirements applicable to Fixed Gauge licensees:

| • | Part I | 'General Provisions' |
|---|----------|--|
| • | Part III | 'Licensing of Radioactive Material' |
| • | Part IV | 'Standards for Protection Against Radiation' |

• Part X 'Notices, Instructions and Reports to Workers;

Inspections'

• Part XIII 'Transportation of Radioactive Material'

Requests for single copies of the above documents (which may be reproduced) can be made in writing to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219 or for an electronic copy go to our web site at:

http://www.vdh.virginia.gov/radiological-health/radiological-health/materials/12vac5-481-virginia-radiation-protection-regulations/.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original, signed application. This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this VAREG or submission of alternative procedures will require a more detailed review.

Note: Personal employee information (i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information) should not be submitted unless specifically requested by the agency.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in the Commonwealth of Virginia are subject to the requirements of **12VAC5-481** 'Virginia Radiation Protection Regulations' and must file a license application with:

Virginia Department of Health Radioactive Materials Program 109 Governor Street, Room 730 Richmond, VA 23219

LICENSE FEES

The appropriate fee must accompany each application. Refer to **12VAC5-490** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to 12VAC5-490.

Direct all questions about VDH's fees or completion of **Item 11** of VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**) to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219** or (804) 864-8150.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

Obtain the correct application form for either a new license or a renewal, check the appropriate box and, if appropriate, list the license number for a renewal.

This guide is written to instruct a new licensee in the process of applying for a radioactive material license. Not all discussions will be appropriate to a licensee renewing an existing license.

Item 2: Applicant's Name and Mailing Address

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material. A division or department within a legal entity may not be a licensee. An individual may be designated, as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify the agency of changes in mailing address.

The licensee must also provide sufficient information for the agency to ensure the proposed corporation or controlling legal entity is a valid entity. Verification of this identity can be accomplished by submitting a copy of the company's license from the NRC or another Agreement State or a government contract or certification, etc.

Note: The agency must be notified in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Timely Notification of Change of Ownership or Control

Rule: 12VAC5-481-330, 12VAC5-481-500

Criteria: Licensees must provide full information and obtain the agency's **written consent prior** to transferring ownership or control of the license (commonly referred to as 'transferring the license').

Discussion: Transfer of control may be the results of mergers, buyouts, or majority stock transfers. Although it is not VDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior VDH written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid licenses issued by VDH;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the possessed material; and

Public health and safety are not compromised by the use of such materials.

Appendix C identifies the information to be provided about changes of ownership or control.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: 12VAC5-481-500 states: "Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: 1. The licensee 2. An entity (as that term is defined in 11 USC §101 (15)) controlling the licensee or listing the licensee or licensee as property of the estate; or 3. An affiliate (as that term is defined in 11 USC §101 (2)) of the licensee" and "...shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of filing of the petition".

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. VDH needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). VDH shares the results of its determinations with other entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

Licensee must notify VDH immediately of the filing of a bankruptcy petition.

Item 3: Person to Be Contacted Regarding Application

Criteria: Identify the individual who can answer questions about the application and include his or her telephone number.

Discussion: This is typically the proposed radiation safety officer, unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

Notify the agency if the contact person or his or her telephone number changes so that agency can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment.

Item 4: Address(es) Where Radioactive Material Will Be Used or Possessed

Rule: 12VAC5-481-450, 12VAC5-481-500

Criteria: Most applicants need to provide two types of information in response to **Item 4**:

- Description of storage and use locations
- Specification of whether they intend to use the fixed gauge at temporary job sites.

Discussion: Specify the street address, city and state or other descriptive address (such as on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19, Anytown, VA, Zip) for each Revision 2

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permanent facility used as a location of storage or use. The descriptive address should be sufficient to allow a VDH inspector to find the use/storage location. A Post Office Box address is not acceptable.

Being granted a VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., local zoning requirements for storage locations).

A VDH license amendment is required before locating a gauge at an address not already listed on the license, whether that gauge is an additional unit or a relocation of an existing unit.

For information on conducting operations at temporary job sites (i.e., locations where work is conducted for limited periods of time), refer to the section in this report called 'Fixed Gauges Used at Temporary Job Sites'. That section offers examples of operations where fixed gauges might be used at temporary job sites and gives information that should be provided to the agency to support a request for these operations.

Note: As discussed later in the section 'Financial Assurance and Record Keeping for Decommissioning', licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For fixed gauge licensees, acceptable records are sketches or written descriptions of specific locations where each gauge was used or stored and any information relevant to damaged devices or leaking radiation sources.

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450, 12VAC5-481-630

Criteria: Radiation Safety Officers (RSOs) must have adequate training and experience. Successful completion of training of one of the following is evidence of adequate training and experience:

- Fixed gauge manufacturer's or distributor's course for users or for RSO's
- Equivalent course that meets **Appendix G** criteria

Additional training is required for RSOs of programs that perform non-routine operations. This includes repairs involving or potentially affecting components related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding) and any other activities during which personnel could receive radiation doses exceeding VDH limits (e.g., installation, initial radiation survey, gauge relocation, and removal of the gauge from service). See 'Radiation Safety Program – Maintenance' in this report and **Appendix N**.

Discussion: The person responsible for the radiation protection program is called the Radiation Safety Officer (RSO). The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. RSO duties are described in **Appendix F**. The agency requires the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

Note:

• It is important to notify the agency as soon as possible, of changes in the designation of the RSO. Alternative responses will be evaluated using the criteria listed above.

Item 6: Authorized Users - Training for Individuals Working In or Frequenting Restricted Areas

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2310

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of one of the following is evidence of adequate training and experience:

- Fixed gauge manufacturer's or distributors course for users
- Equivalent course that meets **Appendix G** criteria

Applicants requesting to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service, must provide additional training. See the section in this report entitled 'Radiation Safety Program – Maintenance' and **Appendix N**.

Discussion: An AU is a person whose training and experience meet the agency's criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must ensure the proper use, security, and routine maintenance of fixed gauges containing licensed material. AUs must attend the training and instruction given at the time of installation or receive equivalent training and instruction.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Note: Records of training should be maintained. Alternative responses will be evaluated against the criteria listed above.

Item 7: Radioactive Material and Item 8: Chemical and Physical Form

Part 1: Sealed Sources and Devices

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-720

Criteria: Applicants must provide the manufacturer's or distributor's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by the NRC or another Agreement State.

Discussion: A maximum possession limit, per isotope, is required to be requested; this should reflect the total number of sealed sources and devices containing a particular isotope (i.e., Cesium-137) that would ever be possessed at any one time, including inactive sources being held for storage and devices awaiting shipment. This should also include sources and devices expected to be purchased at in the future. This limit is isotope specific (i.e., one limit for Cesium-137 and another for Americium-241) and not allowed

to be exceeded; that is, the total of all sources and devices in the licensee's possession cannot exceed this limit. An amendment request must be made and an amended license received prior to obtaining more sources and devices.

Possession limits can be obtained from information provided by the manufacturer; specifically, the activity provided by the manufacturer on the sources and devices the licensee anticipates acquiring. This information will list each isotope with the activity for the source and device. A simple calculation can be performed with this information by totaling the number of each source and device, per isotope, that the licensee expects to possess at any one time. For example; a licensee anticipates possessing three gauges containing Cesium-137 and two containing Americium-241. The manufacturer states that each gauge has a maximum quality of 20 mCi of Cesium-137 or 50 mCi of Americium-241. The licensee is able to perform the simple calculation (20 multiplied by 3 and 50 multiplied by 2) to request a 60 mCi maximum possession limit for Cesium-137 and a 100 mCi maximum possession limit of Americium-241.

Licensees are also required to maintain a limit per device. This is separate from the maximum possession limit; this limit is applied to each source and device itself and is typically determined by the manufacturer's Sealed Source and Device Registration Certificate.

NRC or another Agreement State performs a safety evaluation of fixed gauges before authorizing a manufacturer or distributor to distribute the gauges to specific licensees. The safety evaluation is documented in a Sealed Source and Device Registration (SSDR) Certificate. Before the SSDR process was formalized, some older gauges may not have been evaluated in a separate document, but were specifically approved on a license. Licensees can continue to use these gauges that are specifically listed on their licenses.

Consult with the proposed manufacturer or distributor to ensure that sources and devices conform to the sealed source and device designations registered with NRC or another Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining the agency's prior permission in a license amendment. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSDR Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions are specified. Except as specifically approved by VDH, licensees are required to use gauges according to their respective SSDR Certificates. Applicants should obtain a copy of the certificate and review it with the manufacturer, distributor or with the agency, to ensure that they understand and comply with the requirements of the SSD.

Note: SSDR certificates include reviews by the NRC and other Agreement States. Contact the agency at (804) 864-8150 for assistance with locating specific SSDR certificates.

Part 2: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 12VAC5-481-450 C must meet the requirements for decommissioning financial assurance. All licensees are required to maintain, in an identified location, records of information important to decommissioning of the facility until the site, or any area, is released for unrestricted use. Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 12VAC5-481-500 or to VDH before the license is terminated.

Discussion: VDH wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to the rule: financial assurance that applies to SOME licensees, and recordkeeping that applies to ALL licensees. The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most fixed gauge applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the thresholds in **12VAC5-481-450 C.** The thresholds for typical radionuclides used for fixed gauge sealed sources are shown in **Table 3**.

Table 3. Examples of Minimum Inventory Quantities Requiring Financial Assurance

| Radionuclide (Sealed Sources) | Activity in Gigabecquerels | Activity in Curies |
|-------------------------------|----------------------------|--------------------|
| Co-60 | 3.7×10^5 | 10,000 |
| Kr-85 | 3.7×10^7 | 1,000,000 |
| Sr-90 | 3.7×10^4 | 1,000 |
| Cs-137 | 3.7×10^6 | 100,000 |
| Am-241 | 3.7×10^3 | 100 |
| Ra-226 | 3.7×10^3 | 100 |
| Cf-252 | 3.7×10^3 | 100 |

A licensee would need to possess hundreds of gauges before the financial assurance requirements would apply. Since the standard gauge license does not specify the maximum number of gauges that a licensee may possess (allowing flexibility in obtaining additional gauges specifically authorized by the license as needed without amending its license), it contains a condition requiring the licensee to limit its possession of fixed gauges to quantities not requiring financial assurance. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide possessed, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring financial assurance, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds 1 (i.e., 'unity'), then applicants must submit evidence of financial assurance for decommissioning.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All fixed gauge licensees need to maintain records of structures and equipment where each gauge was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where gauges were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g. employee recollections). In addition, if fixed gauge licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to

maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For fixed gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored.

Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 12VAC5-481-500 B or to the agency before the license is terminated.

Reference: NRC Regulatory Guide 3.66 "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72", is available from the agency upon request.

Part 3: Purpose(s) for Which Licensed Material Will Be Used

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-500 C

Criteria: Proposed activity is authorized by **12VAC5-481 'Virginia Radiation Protection Regulations'.** Gauges should be used only for the purposes for which they were designed, according to the manufacturer's or distributor's recommendations and instructions, as specified in an approved SSDR Certificate, and as authorized on a VDH license.

Discussion: Uses other than those listed in the SSDR Certificate require review and approval by the agency, the NRC or another Agreement State. Requests to use fixed gauges for purposes not listed in the SSDR Certificate will be reviewed on a case-by-case basis. Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. The agency will evaluate the radiation safety program for each type and use of gauge requested.

Note:

- A VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations.
- Allowed uses of fixed gauges normally include process control methods such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc.
- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.
- If the applicant wishes to be authorized for fixed gauge use at temporary jobsites (see **Item 10.12**) indicate in purpose of use.

Item 9: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880

Criteria: Facilities and equipment must be adequate to protect health and to minimize danger to life or property. This may be demonstrated by the following:

- The location of the gauge is compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSDR Certificate
- The fixed gauge is secured to prevent unauthorized removal or access (e.g., located in a locked room, permanently mounted, or chained and locked to a storage rack).

Discussion: Fixed gauges incorporate many engineering features to protect the user from unnecessary radiation exposure in a wide variety of environments. Fixed gauges may be located in harsh environments involving variables such as pressure, vibration, mounting height/method, temperature, humidity, air quality, corrosive atmospheres, corrosive chemicals including process materials and cleaning agents, possible impact or puncture conditions, and fire, explosion, and flooding potentials. Applicants need to consult the sections on the SSDR Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" to determine the appropriate gauge for a location. In those instances when a proposed location is not consistent with the SSDR Certificate, the applicant may ask the source or device manufacturer or distributor to request an amendment to modify the SSDR Certificate to include the new conditions. If the manufacturer or distributor does not request an amendment, the applicant must provide the agency with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

12VAC5-481-450 A states that an application will be approved if, among other things, the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the public's health and safety. **12VAC5-481-840** states that (1) sources of radiation shall be secured against unauthorized removal from the place of storage and (2) sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

You should keep in mind that the device needs to be in storage or physically watched by authorized users at all times. It is not acceptable for a device to be chained to a post or left lying unattended at the place of use during lunch or breaks, because the device would then be accessible to unauthorized persons.

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used;
- Location, room numbers, and principal use of each room or area where radioactive material is used or stored;
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below; and,
- If multiple locations of storage, indicate address on diagram.

Note:

- Any deviations from an SSDR Certificate will require specific agency approval.
- Alternative responses will be evaluated using the criteria listed above.

References: Information Notices are available in the "*Reference Library*" on NRC's Home Page at http://www.nrc.gov./ SSDR certificates include reviews by the NRC and other Agreement States. If necessary, contact the agency for assistance with locating specific SSDR certificates.

Item 10: Radiation Safety Program

Item 10.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-980, 12VAC5-481-990

Criteria: Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure the following:

- Compliance with VDH and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (12VAC5-481-630); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix H contains a suggested audit program that is specific to the use of fixed gauges and is acceptable to the agency. All areas indicated in **Appendix H** may not be applicable to every licensee and all items may not need to be addressed during each audit. For example, licensees do not need to address areas, which do not apply to their activities, and activities, which have not occurred since the last audit need not be reviewed at the next audit. Currently the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of fixed gauge users to determine if, for example, operating and emergency procedures are available and are being followed, etc.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject. The agency will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the agency will normally exercise discretion and may elect not to cite a violation. The agency's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. The agency has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

References: Information Notices (i.e., IN 96-28) are available in the "*Reference Library*" on NRC's Home Page at http://www.nrc.gov.

Item 10.2: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: Pursuant to the rule requirements described above, the licensee must do the following:

- Notify the agency, in writing, within 60 days of:
 - Expiration of the license;
 - Decision to permanently cease licensed activities at the entire site or in any separate building or outdoor area that contains residual radioactivity making them unsuitable for release according to VDH requirements;
 - No principal activities having been conducted at the entire site under the license for a period of 24 months;

- No principal activities having been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity making them unsuitable for release according to VDH requirements;
- Submit decommissioning plan, if required by 12VAC5-481-510;
- Conduct decommissioning, as required by 12VAC5-481-510 & 12VAC5-481-1161;
- Submit to the agency a completed VDH Form, 'Certificate for Disposition of Material' (Appendix B) and demonstrate that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the agency as required by 12VAC5-481-571. If licensed activities are transferred or assigned in accordance with 12VAC5-481-500 B, transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in above, before a licensee can decide whether it must notify the agency, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to VDH requirements. A licensee's determination that a facility is not contaminated is subject to verification by an agency inspection.

For guidance on the disposition of radioactive material, see the section on 'Waste Management -Gauge Disposal or Transfer'. For guidance on decommissioning records, see the section on 'Radioactive Materials – Financial Assurance and Record Keeping for Decommissioning'.

Licensees must use the VDH Form, 'Certificate of Disposition of Materials' (**Appendix B**) when submitting for termination of a license.

Item 10.3: Survey Instruments and Instrument Calibration

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-1000

Criteria: Licensees must possess, or have access to, radiation monitoring instruments which are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Usually it is not necessary for fixed gauge licensees to possess a survey meter. However, surveys according to **12VAC5-481-750** will be required if an applicant plans to conduct non-routine operations. This includes installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source, and non-routine maintenance and repair of components related to the radiological safety of the gauge. Because some of these operations may increase the risk of radiation exposure, individuals performing these operations should be carefully monitored with a survey meter. Such survey meters should be properly calibrated. Proper calibration is particularly important for initial surveys since the results can be used as a basis for public dose estimates. For those licensees requesting authorization to calibrate their own survey instruments, **Appendix I** contains calibration procedures acceptable to the agency. Licensees who perform surveys pursuant **12VAC5-481-750** must possess a survey meter that:

- Measures at least 0.3 through 200 mR per hour (50 microcoulombs per kilogram)
- Is capable of measuring the radiation being emitted from the gauge's sealed source

- Is checked for functionality with a source of radiation at the beginning of each day of use (e.g., with the gauge or a check source)
- Is calibrated:
 - At intervals not to exceed 12 months
 - Using a source of radiation similar to those found in the gauges
 - To ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than \pm 20% on each scale
 - After any servicing or repair (other than a simple battery exchange)
 - By the instrument manufacturer or person specifically authorized by VDH, the NRC or an Agreement State.

Since many fixed gauge licensees are not required to possess a survey meter, applicants should preplan how they will obtain assistance in performing a radiation survey in the event of an emergency (e.g., obtain a survey instrument from hospitals, universities, other VDH, NRC or another Agreement State licensees, or local emergency response organization). It is important to determine as soon as possible after an incident, by the use of a radiation survey meter, whether the shielding and source are intact.

For those licensees using gauges containing only beta, neutron or alpha-emitting radionuclides, specialized survey instruments may be required.

Note:

- Surveys according to 12VAC5-481-750 will be performed by a person specifically authorized by VDH, the NRC or another Agreement State to perform these surveys.
- Alternative responses will be reviewed against the criteria listed above.
- The VDH license will state that the instrument manufacturer will perform survey meter calibrations or a person specifically authorized by VDH, the NRC or another Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See **Appendix I** for more information.
- Regardless of whether an applicant is authorized to calibrate survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records for at least 3 years.

Item 10.4: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1090, 12VAC5-481-3091, 12VAC5-481-3100

Criteria: Licensees must do the following: Maintain records of receipt, transfer, and disposal of fixed gauges and conduct physical inventories at intervals not to exceed 6 months, or some other interval justified by the applicant and approved by the agency, to account for all sealed sources.

Discussion: Radioactive materials must be tracked from 'cradle to grave' in order to ensure gauge accountability, identify when gauges could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded and the licensee complies with financial assurance requirements in **12VAC5-481-450** C. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories. Significant problems can arise from failure to ensure the accountability of gauges. See Information Notice 88-02, "Lost or Stolen Gauges", dated February 2, 1988.

'Cradle to Grave' accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization through performing the physical inventories (ensuring the material's location, etc) until it leaves your organization (through transfer, return to manufacturer/distributor, or disposal to properly licensed facility).

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 4**. Maintain inventory records that contain the following types of information:

- Radionuclide and amount (in units of Bq or curies) of radioactive material in each sealed source:
- Manufacturer's name, model number, and serial number of each sealed source;
- Manufacturer's name, model number, and serial number of each device containing depleted uranium or radioactive material;
- Location of each sealed source and device;
- Date of the inventory; and
- Name of individual performing inventory; and
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, serial number).

| Table 4. Record Maintenance | | |
|------------------------------|--|--|
| Type of Record | Type of Record How Long Record Must be Maintained | |
| Doggint | For as long as the material is possessed until 3 years after transfer or | |
| Receipt | disposal | |
| Transfer | For 3 years after transfer | |
| Disposal | Until VDH terminates the license | |
| Important to decommissioning | Until the site is released for unrestricted use | |

Table 4. Record Maintenance

Note: Information about locations where licensed material is used or stored are among the records important to decommissioning and required by **12VAC5-481-450 C**. See the section on 'Financial Assurance and Record Keeping for Decommissioning' for additional information.

References: Information Notices (i.e. IN 88-02) are available on the NRC's Home Page at http://www.nrc.gov

Item 10.5: Occupational Dosimetry

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2280

Criteria: Applicants must do either of the following:

• Maintain, for inspection by the agency, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits (5 Rem TEDE) pursuant to **12VAC5-481-640**.

OR

 Provide dosimetry processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor that is exchanged at a frequency recommended by the processor. **Discussion:** Under conditions of routine use, the typical fixed gauge user does not require a personnel monitoring device (dosimetry). A gauge user also does not require dosimetry when proper emergency procedures are used. **Appendix J** provides guidance on performing a prospective evaluation demonstrating that fixed gauge users are not likely to exceed 10% of the limits as shown in **Table 5** and thus, are not required to have personnel dosimetry.

Individuals who perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service are more likely to exceed 10% of the limits as shown in **Table 5**. Applicants may be required to provide dosimetry (whole body and perhaps extremity monitors) to individuals performing such services or must perform a prospective evaluation demonstrating that unmonitored individuals performing such non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Table 5**.

 Occupational Dose Limits for Adults (12VAC5-481-640)

 Body Location
 Dose (Annual)

 Total Effective Dose Equivalent (TEDE)
 0.05 Sv (5 Rem)

 Dose to the skin of the whole body or any extremity*
 0.5 Sv (50 Rem)

 Dose to lens of the eyes
 0.15 Sv (15 Rem)

 *Extremities includes the arms below the elbows and the legs below the knees

Table 5. Occupational Dose Limits For Adults

When personnel monitoring is needed, most licensees use either film badges or Optically Stimulated Luminescence (OSLs) that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Note:

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with VDH requirements (e.g., to respond to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, "*National Voluntary Laboratory Accreditation Program Directory*", is published annually and is available electronically at http://ts.nist.gov/nvlap. NIST Publication 810 can be purchased from GPO, whose URL is http://www.gpo.gov. ANSI N322 may be ordered electronically at http://www.ansi.org or by writing to ANSI, 1430 Broadway, New York, NY 10018.

Item 10.6: Public Dose

Rule: 12VAC5-481-10, 12VAC5-5481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-3070, 12VAC5-481-3080

Criteria: Licensees must do the following:

- Ensure that fixed gauges will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv [100 mrem] in one year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations.
- Prevent unauthorized access, removal, or use of fixed gauges.

Discussion: Public dose is defined in **12VAC5-481-10** as "the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant or to any other source of radiation under the control of licensee or registrant". Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of fixed gauges, members of the public include persons who live, work, or may be near locations where fixed gauges are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges are used or stored. Since a fixed gauge presents a radiation field, the applicant must use methods to limit the public dose such that the radiation level in an unrestricted area (e.g., a nearby walkway or area near the gauge that requires frequent maintenance) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour.

Because fixed gauges are generally permanently mounted (e.g., chained and locked to a storage rack), they may not need to be in a locked area to prevent loss, theft, or unauthorized removal. Operating and emergency procedures regarding security and lock-out procedures specified in this document should be sufficient to limit the exposure to the public during use or storage and after accidents. IN 81-37, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices", dated December 15, 1981, provides information about two events that resulted or may have resulted in unnecessary radiation exposure to members of the public and to maintenance workers. IN 88-02, "Lost or Stolen Gauges", dated February 2, 1988, provides information about several events where fixed gauges were lost or stolen.

Public dose is also affected by the location of the gauge. Use the concepts of time, distance, and shielding when developing a method to limit public dose. Decreasing the time spent near a gauge, increasing the distance from the gauge, and using shielding will reduce the radiation exposure. The most effective way to limit public dose is to prevent members of the public from entering areas where gauges are used or stored. This may be accomplished by administrative or engineering controls.

Administrative controls include training and warning signs. In cases where gauges are located in hostile environments (e.g., high temperatures, caustic chemicals, etc.), warning signs may be difficult to maintain so mandatory training programs may be necessary to caution employees.

Engineering controls reduce radiation levels in areas that are accessible to the public. Shielding the gauge with a protective barrier (e.g., using brick, concrete, lead, or other solid walls) or placing the gauge within an enclosure to prevent access to higher radiation levels are examples of engineering controls (**Table 6**).

When dose rates in an area are high enough that a member of the public could receive a dose in excess of 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year, licensees must take additional measures to prevent public access to these higher dose rates, such as building enclosures around the gauges.

Public dose can be estimated in areas near the gauge by using radiation levels determined during initial surveys and applying the 'inverse square' law to evaluate the effect of distance on radiation levels and occupancy factors to account for the actual presence of members of the public. See **Appendix K** for an example.

If, after making a public dose estimate, the conditions used to make the evaluation change (e.g., changes the location of gauges, changes the type or frequency of gauge use, adds gauges, changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

Table 6. Methods to Limit Public Dose

| Tuble of Methods to Elimit I done Dose | | |
|--|---|--|
| Limiting Public Dose | | |
| Administrative Controls | Restrict access | |
| | Post Warning signs | |
| | Training | |
| Engineering Controls | Pre-planned storage/shielding | |
| | • Security | |
| | New/additional shielding construction | |
| Radiation Safety Concepts | • Time | |
| | • Distance | |
| | Shielding | |
| | Surveys | |

During agency inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for individual members of the public. See **Appendix K** for examples of methods to demonstrate compliance.

References: IN 81-37, "*Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices*", dated December 15, 1981, and IN 88-02, "*Lost or Stolen Gauges*", dated February 2, 1988 are located on the NRC's webpage at http://www.nrc.gov.

Item 10.7: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-2260, 12VAC5-481-3091

Criteria: Each applicant must develop, implement, and maintain operating and emergency procedures containing the following elements:

• Instructions for operating the gauge

- Instructions for performing routine cleaning and maintenance (e.g., calibration and lubrication) according to the manufacturer's or distributors recommendations and instructions
- Instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSD certificate
- Instructions for lock-out procedures, if applicable, that are adequate to assure that no individual or portion of an individual's body can enter the radiation beam
- Instructions to prevent unauthorized access, removal, or use of fixed gauges
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability (i.e., inventory)
- Instructions to ensure that non-routine operations such as installation, initial radiation survey, repair and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service are performed by the manufacturer, distributor or person specifically authorized by VDH, the NRC or another Agreement State
- Steps to ensure that radiation warning signs are visible and legible.
- Develop, implement, and maintain emergency procedures for gauge malfunction or damage containing the following elements for each type of fixed gauge:
 - Stop use of the gauge.
 - Restrict access to the area.
 - Contact responsible individuals. (Telephone numbers for the RSO, AUs, the gauge manufacturer or distributor, fire department, and the agency should be posted or easily accessible.)
 - Do not attempt repair or authorize others to attempt repair of the gauge except as specifically authorized in a license issued by VDH, the NRC or another Agreement State.
 - Require timely reporting to the agency pursuant to 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110 or 12VAC5-481-1150.
 - Take additional steps, dependent on the specific situations.
- Provide copies of operating and emergency procedures to all gauge users.
- Post copies of operating and emergency procedures at each location of use or if posting procedures
 is not practicable, post a notice which briefly describes the procedures and states where they may
 be examined.

Discussion: The agency will permit an applicant greater flexibility if one or more of the following safety conditions are met. The applicant should clearly indicate which safety conditions are met for each fixed gauge:

- The air gap between the radiation source and detector of the device is less than 45 cm (18 inches)
- The air gap of the device would not allow insertion of a 30 cm (12 inches) diameter sphere into the radiation beam of the device without removal of a barrier
- The radiation dose rate in the radiation beam of the device at 45 cm (18 inches) from the radiation source with the device shutters, if any, in the open position does not exceed 1 mSv/hour (0.1 rem/hour)
- Entry into vessels (e.g., bins, tanks, hoppers, or pipes) with a gauge installed is not necessary under any foreseeable circumstances and is prohibited.

Operating and emergency procedures should be developed, maintained, and implemented to ensure that gauges are used only as they were designed to be used, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA. This can be

accomplished by adopting the procedures listed in **Item 10.7**, 'Operating and Emergency Procedures' Criteria.

Improper operation could lead to the damage or malfunction of a gauge and elevated exposure rates in the gauge's immediate vicinity. Emergency procedures should be developed to address a spectrum of incidents (e.g., fire, explosion, mechanical damage, flood, or earthquake) that could produce the potential for elevated exposure levels. A list of specific items that should be addressed in operating and emergency procedures is contained in **Appendix L.**

The agency considers security of licensed material extremely important and lack of security is a significant violation for which licensees may be fined. Although most fixed gauges are difficult to move, the licensee must prevent unauthorized access, removal, or use of the gauge. Licensees are responsible for ensuring that gauges are secure and accounted for at all times (e.g., during plant modifications, change in ownership, staffing changes, or after termination of activities at a particular location).

The agency must be notified when gauges are lost, stolen, or certain other conditions occur. The RSO must be proactive in evaluating whether agency notification is required. Refer to **Appendix P** and the regulations (12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150) for a description of when and where notifications are required.

When the distance or air gap between the source and detector permits entry of all or a portion of a person's body into the primary radiation beam, licensees must develop lock out procedures. Lock-out procedures encompass locking the on-off or shutter mechanism into the off position or otherwise controlling the radiation beam or using any other means of preventing an individual or a portion of an individual's body from entering the radiation beam during maintenance, repairs, or work in, on, or around the process line (e.g., bin, tank, hopper, pipe, or conveyor belt) where the device is mounted. The on-off or shutter control mechanism should be tagged to indicate that the gauge is locked out. A warning sign should be posted at each entryway to an area where it is possible to be exposed to the primary beam. In addition to providing a warning, the sign should give safety instructions, e.g., "contact the RSO before entering this vessel". Lock-out procedures should specify who is responsible for performing them.

Note: • Alternative procedures will be evaluated using the criteria listed above.

• If fixed gauges are used at Temporary Job Sites, additional procedures for the use of the fixed gauges addressing such issues as security (see **Item 10.12**) must be submitted.

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during normal business hours (8 a.m. - 4:30 p.m.) For immediate notifications after normal business hours, the 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological.

References: The following Information Notices from NRC: IN 81-37, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices", dated December 15, 1981; IN 86-31, "Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges", dated May 5, 1986; IN 88-02, "Lost or Stolen Gauges", dated February 2, 1988; IN 88-90 "Unauthorized Removal of Industrial Nuclear Gauges", dated November 22, 1988; and IN 94-15, "Radiation Exposures during an Event Involving a Fixed Nuclear Gauge", dated March 2, 1994 are located on the NRC's webpage at http://www.nrc.gov.

Item 10.8: Leak Test

Rule: 12VAC5-481-180, 12VAC5-481-740, 12VAC5-481-1010, 12VAC5-481-1150

Criteria: The agency requires testing to determine whether there is any radioactive leakage from the source in the fixed gauge. The agency finds testing to be acceptable if it is conducted by an organization approved by VDH, the NRC or another Agreement State or according to procedures approved by VDH. Records of the test results must be maintained.

Discussion: When issued, a license will require performance of leak tests at intervals approved by VDH, the NRC or another Agreement State as specified in the Registration Certificate. A leak test sample is collected according to the gauge manufacturers and the leak test kit supplier's instructions. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Manufacturers, distributors, consultants, and other organizations may be authorized by VDH, the NRC or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the fixed gauge manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results.

Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. **Appendix M** contains information to support a request to perform leak testing and sample analysis.

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed and, if approved, VDH staff will authorize via a license condition.

References: Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services", dated June 1985 is available on the NRC's webpage at http://www.nrc.gov

Item 10.9: Maintenance

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-980

Criteria: Licensees must routinely clean and maintain gauges according to the manufacturer's or distributor's written recommendations and instructions. Individuals performing routine maintenance must have adequate training and experience. Radiation safety procedures for routine cleaning and maintenance (e.g., removal of exterior residues from the gauge housing, external lubrication of shutter mechanism, calibration, and electronic repairs) must consider ALARA and ensure that the gauge functions as designed and source integrity is not compromised.

Non-routine maintenance or repair (beyond routine cleaning, lubrication, calibration, and electronic repairs) means any maintenance or repair that involves or potentially affects components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source

drive mechanism, shutter, shutter control or shielding) and any other activities during which personnel could receive radiation doses exceeding the agency limits.

Non-routine repair or maintenance must be performed by the fixed gauge manufacturer or distributor or a person specifically authorized by VDH, the NRC or another Agreement State. Licensees need to perform routine maintenance to ensure proper operation of the fixed gauge. For non-routine maintenance, most licensees rely on the gauge manufacturer, distributor or other service companies. Information to support requests for specific authorization to perform non-routine maintenance or repair is addressed in **Appendix N.**

Discussion: VDH permits fixed gauge licensees to perform routine maintenance of the gauges provided that they follow the gauge manufacturer's or distributor's written recommendations and instructions. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- The tasks to be performed
- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- ALARA considerations
- Training and experience of personnel performing the work
- The qualification of parts, components, other materials to be used in the gauge
- The tests (to be performed before the gauge is returned to routine use) to ensure that it functions as designed.

Although manufacturers or distributors may use different terms, 'routine maintenance' includes, but is not limited to, cleaning, lubrication, calibration, and electronic repairs. Routine maintenance does **not** include any activities that involve:

- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding);
- Installation, relocation, or alignment of the gauge;
- Initial radiation surveys;
- Replacement and disposal of sealed sources;
- Removal of a gauge from service;
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding the VDH limits.

Mounting a gauge is unpacking or uncrating the gauge, and fastening, hanging, or affixing the gauge into position before using. Mounting does not include electrical connection, activation, or operation of the gauge. Installing a gauge includes mounting, electrical connection, activation, and first use of the device. Specific VDH, NRC or another Agreement State authorization is required to install a gauge. However, a licensee may initially mount a gauge, without specific VDH, NRC or another Agreement State authorization, if the gauge's SSDR Certificate explicitly permits it and under the following guidelines:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor
- The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by the NRC or another Agreement State

- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded
- The gauge must be received in good condition (package was not damaged)
- The gauge must not require any modification to fit in the proposed location.

The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by VDH, the NRC or another Agreement State to perform such operations.

A condition in the VDH license will state that operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service shall be performed only by the manufacturer, distributor or other persons specifically licensed by VDH, the NRC or another Agreement State to perform such services. Most licensees do not perform non-routine operations. Rather, these licensees rely upon persons specifically licensed by VDH, the NRC or another Agreement State who have the specialized equipment and technical expertise needed to perform these activities. Applicants seeking authorization to perform non-routine operations must submit specific procedures for review. See **Appendix N** for more information.

Note:

- Alternative procedures for performing routine maintenance will be evaluated using the criteria listed above.
- Information requested in **Appendix N** will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine operations.

Item 10.10: Fixed Gauge Disposal and Transfer

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-2980, 12VAC5-481-3100

Criteria: Licensed materials must be disposed of in accordance with VDH requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of fixed gauges, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer or distributor of the device, a commercial firm licensed by VDH, the NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the radioactive material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in **12VAC5-481-570 D**. In addition, all packages containing radioactive sources must be prepared and shipped in accordance with the VDH and DOT regulations. Records of the transfer must be maintained as required by **12VAC5-481-100** and **12VAC5-481-571**.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Significant problems can arise from improper gauge transfer or failure to dispose of gauges in a proper and timely manner. See Information Notice 86-31, "Unauthorized Transfer and Loss of

Control of Industrial Nuclear Gauges", dated May 5, 1986, and IN 88-02, "Lost or Stolen Gauges", dated February 2, 1988.

References: NRC IN 86-31, "*Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges*", dated May 5, 1986 and NRC IN 88-02, "*Lost or Stolen Gauges*", dated February 2, 1988 are available at the NRC's webpage http://www.nrc.gov.

Item 10.11: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481-3110, 49 CFR Parts 171-178

Criteria: Applicants must either:

• Arrange for transportation of a gauge by the manufacturer, distributor or other person specifically licensed to transport gauges by VDH, the NRC or another Agreement State.

OR

• Develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT regulations.

Discussion: Some fixed gauge licensees have the manufacturer, distributor or other person specifically licensed to transport gauges by VDH, the NRC or another Agreement State arrange for preparing and shipping licensed material. If licensees decide to transport their own gauges, they are responsible for compliance with DOT regulations which require, in part, specific labeling and surveying of the package before shipping. To appropriately survey the package the surveyor must use instruments that can measure radiation exposure rates around the package and detect contamination on the package. **Appendix O** lists major DOT regulations and provides an example of a shipping paper. During an inspection, the agency uses the provisions of **12VAC5-481-2980** to examine and enforce transportation requirements applicable to gauge licensees.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

Item 10.12: Fixed Gauges Used at Temporary Job Sites

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-590, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-2980, 12VAC5-481-3100

Criteria: Each applicant requesting authorization to perform work with fixed gauges at temporary job sites should develop, implement, maintain, and distribute operating and emergency procedures containing the following elements:

• Instructions for transporting radioactive material to ensure compliance with DOT regulations

- Instructions for using gauges at temporary job sites and performing routine maintenance according to the manufacturer's or distributor's recommendations and instructions
- Instructions for maintaining security during storage and transportation
- Instructions to keep gauges under control and immediate surveillance or secured to prevent unauthorized use or access.
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability during use
- Steps to control access to a potentially damaged gauge
- Steps to take, and who to contact, when a gauge has been lost or damaged (e.g., local officials, RSO, etc.)
- If gauges are to be installed at temporary job sites, the operating and emergency procedures should contain instructions on using personal dosimetry and survey instruments and conducting surveys
- Provide copies of operating and emergency procedures to all gauge users and at each job site.

Discussion: A temporary job site is a location where work with licensed materials is conducted for a limited period of time. Temporary job sites are not specifically listed on a license. A gauge user may be dispatched to work at several temporary job sites in one day. A location is not considered a temporary job site if it is used to store and dispatch radioactive material. The agency considers such a location to be a field office. Licensees must apply for and receive a license amendment specifically listing each field office location. Licensee personnel implement emergency procedures when a traffic accident results in a damaged gauge and potentially elevated exposure levels.

There are two categories of fixed gauges used at temporary job sites: Gauges that are permanently mounted to vehicles or trailers, and gauges that are transported to plants or refineries and temporarily installed on process equipment to conduct short-term QA/QC studies.

Applicants must develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT regulations. During an inspection, the agency will use the provisions of **12VAC5-481-2980** to examine and enforce transportation requirements applicable to fixed gauge licensees. **Appendix O** lists major DOT regulations and provides examples of shipping documents, placards, and labels.

When working at a temporary job site, licensees generally have to follow the rules and procedures of the organization that owns or controls the site. Thus, licensees may not be able restrict access to areas in the same manner that they could at their own facilities. Furthermore, non-licensee personnel may not be familiar with fixed gauges or radioactive material. Therefore, to avoid lost or stolen gauges and to prevent unnecessary radiation exposures to members of the public, licensees must keep gauges under constant surveillance, or secured against unauthorized use or removal.

While installing gauges, personnel could receive radiation doses exceeding VDH limits if proper radiation safety principles are not followed. Licensee personnel performing installations should be assigned and wear personal dosimetry and use a survey meter to monitor radiological conditions.

After installing a gauge at a temporary job site, a radiation survey should be conducted to ensure that dose rates in unrestricted areas will not exceed 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year. If surveys indicate that a member of the public (e.g., client personnel) could receive a dose exceeding these limits, licensees would need to adopt additional security measures to prevent public access such as maintaining constant surveillance or erecting physical barriers.

Item 11: License Fees

For a listing of application fees, please see **12VAC5-481-490**. On VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**) enter the fee category and the amount.

Item 12: Certification

Individuals acting in a private capacity are required to sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**). Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices' (**Appendix A**). **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** The agency will return all unsigned applications for proper signature.

Note:

- It is a violation of **12VAC5-481-30** to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Appendix A

VDH Form

'Application for Radioactive Material License Authorizing the Use of Fixed Gauge Devices'

The Form is located at: http://www.vdh.virginia.gov/radiological-health/materials/forms-postings/

Attachment A Fixed Gauge Applicant's Checklist

| Yes | No | Item | Material Needed | |
|-----|----|-------------|---|--|
| | | Application | Used the correct form (New for new licensees or Renewal for renewing | |
| | | | licensees) | |
| | | Application | Checked at least one box and filled in all the required information, as | |
| | | | needed, for all Items | |
| | | Item 5 | Attached training information, as needed | |
| | | Item 6 | Attached training information, as needed | |
| | | Item 9 | Attached facility diagram | |
| | | Item 10.3 | Checked box or attached alternate procedures | |
| | | Item 10.4 | Checked box or attached alternate procedures | |
| | | Item 10.7 | Checked box or attached alternate procedures | |
| | | Item 10.8 | Checked at least one box and, if needed, attached alternate procedures | |
| | | | including analysis instrumentation information | |
| | | Item 10.9 | Routine: checked box or attached alternate procedure | |
| | | Item 10.9 | Non-Routine: checked box or attached information contains all the | |
| | | | requirements of Appendix G | |
| | | Item 10.12 | Checked box or attached procedures | |

Appendix B

VDH Form 'Certificate of Disposition of Materials'



CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-500**. Failure to provide information will result in this request for termination of a specific license not being processed.

Instructions – Complete all items. Retain one copy and submit original to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

| CONTA | CONTACT INFORMATION | | | | | | |
|-----------|---|--|--|--|--|--|--|
| Item 1 N | Name and Mailing Address of Applicant: | Item 2 Virginia Radioactive Material License Number | | | | | |
| | | | | | | | |
| | | Item 3 Contact Person – Name | | | | | |
| | | | | | | | |
| | | Contact Person - Telephone Number (Include area code) | | | | | |
| , | - | () - x | | | | | |
| TERMI | NATION AND DISPOSITION INFORMATI | ON | | | | | |
| The follo | wing information is provided in accordance with 12 V | AC 5-481-510. (Check all that apply) | | | | | |
| | Item 4 All use of radioactive material authorized under the above referenced license has been terminated. | | | | | | |
| | Item 5 Radioactive contamination has been removed to the levels outlined in 12VAC5-481-1161 B. | | | | | | |
| | Item 6 All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply) | | | | | | |
| | Transferred to: Name | Address | | | | | |
| | | | | | | | |
| | | | | | | | |
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| | | | | | | | |
| | | | | | | | |
| | Who is (are) authorized to possess su | ch material under Licensed Number: | | | | | |
| | Issued by (Licensing Agency): | | | | | | |
| | Decayed, surveyed and disposed of as non-radioactive waste. | | | | | | |
| | No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license. | | | | | | |
| | Other (Attach additional pages) | | | | | | |
| | Item 7 Attached are radiation surveys or equivalent and certify that each instrument is properly calibrate | t as specified in 12VAC5-481-510 L. Specify the survey instrument(s) used as required in 12VAC5-481-510 K. | | | | | |

| Certificate of Disposition of Materials Page 2 of 2 | | | | | |
|--|----------------------|--|--|--|--|
| Item 8 Records required to be maintained for the license termination requested are availa location(s): | ble at the following | | | | |
| Name: | | | | | |
| Address: | | | | | |
| Contact Person Telephone Number: () - X | | | | | |
| Additional remarks (Attach additional pages if necessary.) | | | | | |
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| CERTIFICATION (To be completed by an individual authorized to make hinding commitments on behalf of | of the applicant) | | | | |
| CERTIFICATION (To be completed by an individual authorized to make binding commitments on behalf of the applicant.) Item 10. | | | | | |
| The undersigned, on behalf of the licensee, hereby certifies that licensable quantities of radioactive material under the jurisdiction of the Virginia Department of Health are not possessed by the licensee. It is therefore requested that the above referenced radioactive material license be terminated. | | | | | |
| SIGNATURE - Applicant or Authorized Individual | Date signed | | | | |
| Print Name and Title of above signatory | | | | | |

Appendix C

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain VDH's **prior written consent** before transferring ownership or control of the license; some licensees refer to this as 'transferring the license'. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of a VDH-licensed operation.

Transferor: A transferor is a VDH licensee selling or otherwise giving up control of a licensed operation.

- 1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who the agency may contact if more information is needed.
- 2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
- 3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
- 4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
- 5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to VDH, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
- 6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

References: The information above is derived from NRC Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*", which is available at the NRC's webpage at http://www.nrc.gov.

Appendix D

Reserved

Appendix E

Model Delegation of Authority (RSO)

Subject: Delegation of Authority You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Virginia Department of Health, Radioactive Materials Program at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities. Signature of Management Representative I accept the above responsibilities, Signature of Radiation Safety Officer cc: Affected department heads.

Memo to: Radiation Safety Officer

From: Chief Executive Officer

Appendix F

Duties and Responsibilities of the Radiation Safety Officer

Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with both VDH regulations and the conditions of the license. The RSO's duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Development, maintenance, distribution, and implementation of up-to-date operating and emergency procedures
- Individuals that use fixed gauges are properly trained
- Possession, installation, relocation, use, storage, routine maintenance and non-routine operations
 of fixed gauges are consistent with the limitations in the license, the SSDR Certificate(s),
 manufacturer's or distributor's recommendations and instructions
- Safety consequences of non-routine operations are analyzed before conducting any such activities that have not been previously analyzed
- Non-routine operations are performed by the manufacturer, distributor or person specifically authorized by VDH, the NRC or another Agreement State
- Prospective evaluations are performed demonstrating that unmonitored individuals are not likely
 to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel
 monitoring devices are provided
- Personnel monitoring devices, if required, are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in 12VAC5-481-720.
- Fixed gauges are properly secured
- Notification of proper authorities of incidents such as damage to or malfunction of fixed gauges, fire, loss, or theft
- Investigation of unusual occurrences involving the fixed gauge (e.g., malfunctions or damage), identification of cause(s), implement of appropriate and timely corrective action(s)
- Radiation safety program audits are performed at intervals not to exceed 12 months and should include development, implementation, and documentation of timely corrective actions
- Radioactive material is transported according to all applicable DOT requirements
- Radioactive material is disposed of properly
- Appropriate records are maintained

- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner
- Posting of documents required by **12VAC5-481-2260** (license documents, operating procedures, VDH Form, 'Notice to Employees').

Appendix G

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

Course Content

Classroom training may be in the form of lecture, online, videotape, or self-study emphasizing practical subjects important to safe use of the gauge.

Radiation Safety:

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Location of sealed source within the gauge

Regulatory Requirements:

- Applicable regulations
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Recordkeeping
- Prior events involving fixed gauges
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by VDH
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct

Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee:

- Operating and emergency procedures
- Routine vs. non-Routine maintenance
- Lock-out procedures

On-the-job training must be done under the supervision of an Authorized User or Radiation Safety Officer:

- Supervised Hands-on Experience Performing:
 - Operating procedures
 - Test runs of emergency procedures
 - Routine maintenance
 - Lock-out procedures

Training Assessment

Management will ensure that proposed Authorized Users are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed Radiation Safety Officer's are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges to be possessed by the applicant. This may be demonstrated by written or oral examination or by observation.

Course Instructor Qualifications

Instructor should have:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of an 8 hour radiation safety course; and
- 8 hours hands-on experience with fixed gauges

OR

- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of 40 hour radiation safety course; and
- 30 hours of hands-on experience with fixed gauges.

OR

• The applicant may submit a description of alternative training and experience for the course instructor.

Note: Additional training is required for those applicants intending to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See **Appendix N**.

Appendix H

Suggested Fixed Gauge Audit Checklist

Suggested Fixed Gauge Audit Checklist

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

| Licensee's name: | License No.: |
|-----------------------|---------------------|
| Date of this Audit: | Date of Last Audit: |
| Auditor Signature: | Date: |
| Management Signature: | Date: |

Audit History

- A. Last audit of this location conducted on (date)
- B. Were previous audits conducted at intervals not to exceed 12 months? (12VAC5-481-630)
- C. Were records of previous audits maintained? (12VAC5-481-990)
- D. Were any deficiencies identified during last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies)

Organization and Scope of Program

- A. If the mailing address or places of use changed, was the license amended?
- B. If ownership changed or bankruptcy filed, was VDH's prior consent obtained or was the agency notified?
- C. Radiation Safety Officer:
 - 1. If the RSO was changed, was license amended?
 - 2. Does new RSO meet VDH requirements?
 - 3. Is RSO fulfilling his or her duties?
 - 4. To whom does the RSO report?
- D. If the designated contact person for the agency changed, was the agency notified?
- E. Sealed Sources and Devices
 - 1. Does the license authorize all of VDH's regulated radionuclides contained in gauges?
 - 2. Are the gauges as described in the Sealed Source and Device Registration (SSDR) Certificate?
 - 3. Have copies of (or access to) SSDR Certificates?
 - 4. Have manufacturers' or distributor's manuals for operation and maintenance?
 - 5. Are the actual uses of gauges consistent with the authorized uses listed on the license?
 - 6. Are the locations of the gauges compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSDR Certificates?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed or exceed 1 mSv (100 mrem) in a year instructed per 12VAC5-481-2270? Annual training provided, as needed 12VAC5-481-2270? Records maintained?
- B. Did each Authorized User (AU) receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges?
- C. Are training records maintaining for each AU?
- D. Did individuals who perform non-routine operations receive training before performing these operations?
- E. Did interviews with AUs reveal that they know the emergency procedures?

- F. Did this audit include observations of AUs using the gauge?
- G. Did this audit include observations of workers performing routine cleaning and lubrication on the gauge?
- H. HAZMAT training provided, if required? [49 CFR 172.700; 172.701; 172.702; 172.703; 172.704]

Radiation Survey Instruments

- A. If the licensee is required to possess a survey meter, does it meet the agency's criteria? (12VAC5-481-750)
- B. Are calibration records maintained? (12VAC5-481-1000)

Gauge Inventory

- A. Is a record kept showing the receipt of each gauge? (12VAC5-481-100, 12VAC5-481-571)
- B. Are all gauges physically inventoried every six months?
- C. Are records of inventory results with appropriate information maintained?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program? (12VAC5-481-630)
- B. Were prospective evaluations performed showing that unmonitored individuals receive less than or equal to 10% of the limit? (12VAC5-481-640, 12VAC5-481-760)
- C. Did unmonitored individuals' activities change during the year which could put the over 10% of the limit?
- D. If yes to C. above, was a new evaluation performed?
- E. Is external dosimetry required (individuals likely to receive >10% of limit)? And is dosimetry provided to those individuals?
 - 1. Is the dosimetry supplier NVLAP approved? (12VAC5-481-750)
 - 2. Are the dosimeters exchanged at the appropriate frequency (for example monthly for film badges)?
 - 3. Are dosimetry reports reviewed by the RSO when they are received?
 - 4. Are the records VDH forms or equivalent? (12VAC5-481-1000, 12VAC5-481-1040, 12VAC5-481-1080)
 - a. VDH Form, 'Cumulative Occupational Exposure History' completed?
 - b. VDH Form, 'Occupational Exposure Record for a Monitoring Period' completed?
 - 5. Declared pregnant worker/embryo/fetus
 - a. If a worker declared her pregnancy, did licensee comply with 12VAC5-481-710?
 - b. Were records kept of embryo/fetus dose 12VAC5-481-1040?
 - 6. Are annual exposure reports given to employees who receive greater than 100 mrem per year? (12VAC5-481-2280)
- F. Are records of exposures, surveys, monitoring, and evaluations maintained? (12VAC5-481, Part IV, Article 12)

Public Dose

A. Is public access to gauges controlled in a manner to keep doses below 1mSv (100 mrem) in a year? (12VAC5-481-720, 12VAC5-481-730)

- B. Has a survey or evaluation been performed per **12VAC5-481-730**? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- C. Do unrestricted area radiation levels exceed 0.02mSv (2mrem) in any one hour? (12VAC5-481-720)
- D. Is gauge access controlled in a manner that would prevent unauthorized use or removal? (12VAC5-481-840)
- E. Records maintained? (12VAC5-481-1050)

Operating and Emergency Procedures

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required elements?
- C. Dose each individual working with the gauges have a current copy of the operating and emergency procedures (including lock-out procedures and emergency telephone numbers)?
- D. Is a lock-out warning sign posted at each entryway to an area where it is possible to be exposed to the beam?
- E. Did any emergencies occur?
 - 1. If so, were they handled properly?
 - 2. Were appropriate corrective actions taken?
 - 3. Was agency notification or reporting required? (12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150)

Leak Tests

- A. Was each sealed source leak tested every 6 months or at other prescribed intervals?
- B. Was the leak test performed according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was the agency notified?

Maintenance of Gauges

- A. Are manufacturer's or distributor's procedures followed for routine cleaning and lubrication of gauge?
- B. Was each on-off mechanism tested for proper operation every 6 months or at other prescribed intervals?
- C. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor or person specifically authorized by VDH, the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 12VAC5-481-640 limits)?
- D. Are labels, signs, and postings identifying gauges containing radioactive material, radiation areas, and lock-out procedures/warnings clean and legible?

Transportation

(Note: This section will not apply if you have not transported gauges during the period covered by this audit.)

- A. DOT-7A or other authorized package used? (49 CFR 173.415; 173.416(b))
- B. Package performance test records on file if licensee performs shipment?
- C. Special form sources documentation? (49 CFR 173.476(a))

- D. Package has two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? (49 CFR 172.403; 173.441)
- E. Package properly marked? (49 CFR 172.301; 172.304; 172.310; 172.324)
- F. Package closed and sealed during transport? (49 CFR 173.475(f))
- G. Shipping papers prepared and used? (49 CFR 172.200(a))
- H. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} (49 CFR 172.200; 172.201; 172.202; 172.203; 172.204; 172.604)
- I. Shipping papers within drivers reach and readily accessible during transport? (49 CFR 177.817(e))
- J. Package secured against movement? (49 CFR 177.834)
- K. Placards on vehicle, if needed? (49 CFR 172.504)
- L. Proper overpacks, if needed? (49 CFR 173.25)
- M. Any incidents reported to DOT or the agency? (49 CFR 171.15; 171.16)

Auditor's Independent Survey Measurements (if made)

A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits?

Notification and Reports

- A. Was any radioactive material lost or stolen? Were reports made? (12VAC5-481-1090)
- B. Did any reportable incidents occur? Were reports made? (12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150)
- C. Did any overexposures or high radiation levels occur? Reported? (12VAC5-481-1100, 12VAC5-481-1110)
- D. If any events (as described in items a through c above) did occur, what was the root cause? Were corrective actions appropriate?
- E. Is the management/RSO/shift foreman licensee aware of the telephone number for the agency? (During business hours: (804) 864-8150 or 24 hour emergency number (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological).

Posting and Labeling

- A. VDH Form, 'Notice to Employees' posted? (12VAC5-481-2260 C)
- B. The VDH rule, license documents posted or a notice posted? (12VAC5-481-2260 A)
- C. Other postings and labelings? (12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-2260)

Record Keeping for Decommissioning

- A. Records kept of information important to decommissioning? (12VAC5-481-450 C)
- B. Records include all information outlined in 12VAC5-481-450 C?

Bulletins and Information Notices

- A. VDH bulletins, Information Notices, NRC Information Notices, NMSS Newsletters, received?
- B. Appropriate training and action taken in response?

Special License Conditions or Issues

A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

Deficiencies Identified in Audit; Corrective Actions

- A. Summarize problems/deficiencies identified during audit.
- B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.

Evaluation of Other Factors

- A. Senior licensee management is appropriately involved with the radiation protection program and/or RSO oversight?
- B. RSO has sufficient time to perform his or her radiation safety duties?
- C. Licensee has sufficient staff to support the radiation protection program?

Appendix I

Model Survey Instrument Calibration Program

Model Survey Instrument Calibration Program

Training

Before independently calibrating survey instruments, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:
 - Principles and practices of radiation protection
 - Radioactivity measurements, monitoring techniques, and the use of instruments
 - Mathematics and calculations basic to using and measuring radioactivity
 - Biological effects of radiation.
- On-the-job training will be considered complete if the individual has:
 - Observed authorized personnel performing survey instrument calibration; and
 - Conducted survey meter calibrations under the supervision, and in the physical presence of an individual already authorized to perform calibrations.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present
- Individuals conducting calibrations will wear assigned dosimetry
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

- A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within \pm 5% accuracy by National Institutes of Standards and Technology (NIST)
 - Contain a radionuclide which emits radiation of identical or similar type and energy as the sealed sources that the instrument will measure
 - Be strong enough to emit a radiation field that is representative of the field being emitted by the gauge. For calibration of instruments intended to measure gamma radiation, the exposure rate should be at least 30 mR/hour (7.7 microcoulomb/kilogram per hour) at 100 cm [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of Co-60].
- Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration.
- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$.
- There are three kinds of scales frequently used on radiation survey meters. They are calibrated either as described in ANSI N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration Portable Survey Instruments", or as follows:

- Meters on which the user selects a linear scale must be calibrated at not fewer that two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
- Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.
- Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
- Readings above 200 mR/hour (50 microcoulomb/kilogram per hour) need not be calibrated. However, higher scales should be checked for operation and approximately correct response.
- Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include:
 - The owner or user of the instrument
 - A description of the instrument that includes the manufacturer's name, model number, serial number, and type of detector
 - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the 'battery check' mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
 - For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
 - The exposure rate from a check source, if used
 - The signature of the individual who performed the calibration and the date on which the calibration was performed.
- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration -Portable Survey Instruments". Copies may be ordered electronically at http://www.ansi.org or by writing to ANSI, 1430 Broadway, New York, NY 10018. NRC RG FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments", dated June 1985.

Appendix J

Guidance for Demonstrating that Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in **12VAC5-481-640**. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the gauge. However, for most gauges even these activities result in the individual receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

One gauge manufacturer has estimated the doses to the extremities and whole body of a person replacing the assay plate on one of its series of gauges. Each gauge in the series is authorized to contain up to 7.4 gigabecquerels (200 millicuries) of Cs-137. The manufacturer based its estimate on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer had the following types of information:

- Time needed to perform the entire procedure (e.g., 15 minutes)
- Expected dose rate received by the whole body of the individual, associated with the shielded source and determined using measured or manufacturer-determined data (e.g., 0.02 mSv/hr [2 mrem/hr] at 46 cm [18.1 in] from the shield)
- Time the hands were exposed to the shielded source (e.g., 6 min)
- Expected dose rate received by the extremities of the individual, associated with the shielded source and determined using measured or manufacturer-determined data on contact with the shield (e.g., 0.15 mSv/hr [15 mrem/hr])

From this information, the manufacturer estimated that the individual performing each routine cleaning and lubrication could receive the following:

- Less than 0.005 mSv (0.5 mrem) TEDE (whole body) and
- 0.015 mSv (1.5 mrem) to the hands.

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 millirems) per year. If one routine maintenance procedure delivers 0.005 mSv (0.5 mrem), then an individual could perform 1,000 of these procedures each year and remain within 10% of the applicable limit. The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 millirems) per year. If one of routine maintenance procedure delivers 0.015 mSv (1.5 mrem), then an individual could perform 3,333 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,000 routine maintenance procedures per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are not required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may not be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of gauge(s) they intend to use; this information is generally available from the gauge manufacturer or the SSDR Certificate maintained by VDH, the NRC and other Agreement States. **Table 7** may be helpful in performing a prospective evaluation.

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new gauges containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table 7. Dosimetry Evaluation Dosimetry Evaluation for Model Gauge Time needed to perform the entire routine Α. maintenance procedure. minutes/60 hour B. Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the gauge while the sealed source is in the shielded position. mrem/hr C. Time the hands were exposed to the shielded source. minutes/60 hour D. Expected extremity dose rate received by the individual, determined using measured or manufacturer-provided data for the shielded source at the typical distance from the hands to the shielded source. mrem/hr Formula: (__# hours in Row A) x (_____mrem/hr in Row B) = (___ mrem per routine # of routine maintenance procedures each year) = procedure) x (_ mrem* Whole Body Dose Formula: (# hours in Row C) x (mrem/hr in Row D) = (mrem per routine _# of routine maintenance procedures each year) = _ mrem ** Extremity Dose procedure) x (* Expected whole Body Dose Less Than 500 mrem requires no dosimetry ** Expected Extremity Dose Less Than 5000mrem requires no dosimetry

Appendix K

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

1. The radiation dose received by individual members of the public does not exceed 1 millisievert (1 mSv) [100 millirems (100 mrem)] in one calendar year resulting from the licensee's possession and/or use of radioactive materials.

Members of the public include persons who live, work, or may be near locations where fixed gauges are used or stored and employees whose assigned duties do not include the use of radioactive materials and who work in the vicinity where gauges are used or stored.

2. The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Unrestricted areas may include offices, shops, laboratories, a nearby walkway, an area near the gauge that requires frequent maintenance, areas outside buildings, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both 1 and 2 above. Calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculation Method

For ease of use by most fixed gauge licensees, the examples in this appendix use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.

The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications:

- each gauge is a point source;
- typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source & Device Registration (SSDR) Certificate or the manufacturer's literature; and
- No credit is taken for any shielding found between the gauges and the unrestricted areas.

Part 1 of the calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the portion of time that both the gauge and the affected member of the public are present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculation method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1

To better understand the calculation method, we will look at ABC Bottling, Inc., a fixed gauge licensee. Yesterday, while on a walk-through during product changeover, the company's president noted that three new gauges will be very close to a bottling control panel where a quality control supervisor, a worker who does not work with fixed gauges, works. The company's president asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with the VDH rule.

Joe measures the distances from each gauge to the bottling control panel and looks up in the manufacturer's literature the radiation levels individuals would encounter for each gauge. **Figure 1** is Joe's sketch of the areas in question, and **Table 8** summarizes the information Joe has on each gauge.

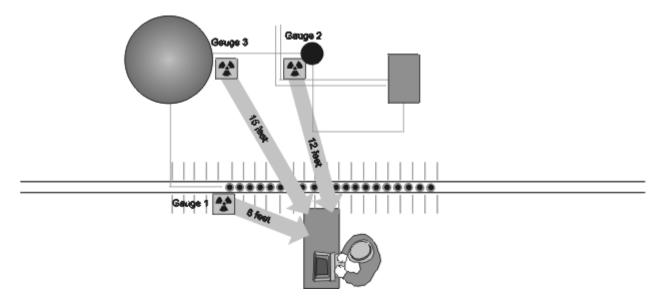


Figure 1. Diagram of Bottling Line and Fixed Gauges

Table 8. Information Known about Each Gauge

| Description of Known Information | Gauge 1 | Gauge 2 | Gauge 3 |
|---|------------------------|-------------------------|-------------------|
| Where gauge is located | Gauge on bottling line | Gauge on main feed line | Gauge on tank |
| Dose rate in mrem/hr encountered at specified distance from the gauge (from manufacturers literature) | 2 mrem/hr at 1 ft | 8 mrem/hr at 1 ft | 2 mrem/hr at 3 ft |
| Distance in ft to bottling control panel | 8 ft | 12 ft | 15 ft |

Example 1: Part 1

Joe's first thought is that the distance between the gauges and the bottling control panel may be sufficient to show compliance with **12VAC5-481-720**. So, taking a worst case approach, he assumes: 1) the gauges are constantly present (i.e., 24 hr/d), 2) all three gauges are on (i.e., shutters are open), and 3) a quality control (QC) supervisor, a worker who does not work with the fixed gauges, is constantly sitting at the control panel (i.e., 24 hr/d). Joe proceeds to calculate the dose the QC supervisor might receive hourly and yearly from each gauge as shown in **Tables 9, 10, and 11** below.

Table 9. Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 1

| Gau | | | | |
|----------|---|--|---------|--|
| Step No. | Description | Input Data | Results | |
| 1 | Dose received in an hour at known distance from gauge | | | |
| | (e.g., from manufacturer's data), in mrem/hr | 2 | 2 | |
| 2 | Square of the distance (ft) at which the Step 1 rate was | | | |
| | measured, in square feet | $(1)^2$ | 1 | |
| 3 | Square of the distance (ft) from the gauge to the bottling | | | |
| | control panel in an unrestricted area, in square feet | $(8)^2$ | 64 | |
| 4 | Multiply the results of Step 1 by the results of Step 2 (| | | |
| | this is an intermediate result) | $2 \times 1 = 2$ | | |
| 5 | Divide the result of Step 4 by the result of Step 3 to | | | |
| | calculate the dose received by the worker at the bottling | 2/64 = 0.031 | | |
| | control panel, HOURLY DOSE RECEIVED FROM | | | |
| | GAUGE 1, in mrem in an hour | | | |
| 6 | Multiply the result of Step 5 by 24 hr/d x 365 d/yr = $\frac{1}{2}$ | | | |
| | MAXIMUM ANNUAL DOSE RECEIVED FROM | $0.031 \times 24 \times 365 = 0.031 \times 8760 = 272$ | | |
| | GAUGE 1, in mrem in a year. | | | |

Table 10. Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 2

| | e 10. Curculation Nacinou, I are 1. Hourry and Allina | | Gauge 2 | |
|----------|---|--|---------|--|
| Step No. | Description | Input Data | Results | |
| 1 | Dose received in an hour at known distance from gauge | | | |
| | (e.g., from manufacturer's data), in mrem/hr | 8 | 8 | |
| 2 | Square of the distance (ft) at which the Step 1 rate was | | | |
| | measured, in square feet | $(1)^2$ | 1 | |
| 3 | Square of the distance (ft) from the gauge to the bottling | | | |
| | control panel in an unrestricted area, in square feet | $(12)^{2}$ | 144 | |
| 4 | Multiply the results of Step 1 by the results of Step 2 (| | | |
| | this is an intermediate result) | $2 \times 1 = 2$ | | |
| 5 | Divide the result of Step 4 by the result of Step 3 to | | | |
| | calculate the dose received by the worker at the bottling | 8/144 = 0.56 | | |
| | control panel, HOURLY DOSE RECEIVED FROM | | | |
| | GAUGE 2, in mrem in an hour | | | |
| 6 | Multiply the result of Step 5 by 24 hr/d x 365 d/yr = $\frac{1}{2}$ | | | |
| | MAXIMUM ANNUAL DOSE RECEIVED FROM | $0.056 \times 24 \times 365 = 0.056 \times 8760 = 491$ | | |
| | GAUGE 2, in mrem in a year. | | | |

Table 11. Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 3

| | | | Gauge 3 |
|----------|-------------|------------|---------|
| Step No. | Description | Input Data | Results |
| D | 1 (2016 | | 72 |

| 1 | Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr | 2 2 | |
|---|---|-----------------------------------|------------------------|
| 2 | Square of the distance (ft) at which the Step 1 rate was measured, in square feet | (3) 2 9 | |
| 3 | Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet | (15) 2 225 | |
| 4 | Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result) | $2 \times 9 = 18$ | |
| 5 | Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 3 , in mrem in an hour | 18/225 = 0.08 | |
| 6 | Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 3, in mrem in a year. | $0.08 \times 24 \times 365 = 0.0$ | 08 x 8760 = 701 |

To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables.

Table 12. Calculation Method, Part 1: Total Hourly and Annual Dose Received from Gauges 1, 2, and 3

| Step No. | Description | Gauge 1 | Gauge 2 | Gauge 3 | Sum |
|----------|--|---------|---------|---------|----------------------|
| 7 | TOTAL HOURLY DOSE | | | | |
| | RECEIVED from Step 5 of Tables 5, | 0.031 | 0.056 | 0.08 | 0.031 + 0.056 |
| | 6, and 7, in mrem in an hour | | | | +0.08 = 0.167 |
| 8 | TOTAL ANNUAL DOSE | | | | |
| | RECEIVED from Step 6 of Tables 5, | 272 | 491 | 701 | 272 + 491 + |
| | 6, and 7, in mrem in a year | | | | 701 = 1464 |

Note: The Sum in **Step 7** demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the Sum in **Step 8** exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.167 mrem, but notes that an individual could receive a dose of 1,464 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the QC supervisor is not at the bottling control panel 24 hr/d. He decides to make a realistic estimate of the number of hours the QC supervisor would be present at the bottling control panel, keeping his other assumptions constant (i.e., the gauges are constantly present (i.e., 24 hr/d), all three gauges remain on (i.e., shutter is open). He then recalculates the annual dose received.

Table 13. Calculation Method, Part 2: Annual Dose Received from Gauges 1, 2, and 3

| Step No. | Description | Results |
|----------|---|---------|
| 9 | A. Average number of hours per day that individual | |
| | spends in area of concern (e.g., worker present at | 5 |
| | bottling control panel 5 hr/day; the remainder of the | |
| | day the worker is away from the area performing | |
| | other duties that are not in the vicinity of gauges) | |

| | B. Average number of days per week in area (e.g., worker is part time and works 3 days/week) | 3 |
|----|--|------------------------------|
| | C. Average number of weeks per year in area (e.g., worker works all year) | 52 |
| 10 | Multiply the results of Step 9.A. by the results of Step | |
| | 9.B. by the results of Step 9.C. = AVERAGE NUMBER | $5 \times 3 \times 52 = 780$ |
| | OF HOURS IN AREA OF CONCERN PER YEAR | |
| 11 | Multiply the sum in Step 7 by the results of Step 10 = | |
| | ANNUAL DOSE RECEIVED FROM GAUGES | $0.167 \times 780 = 130$ |
| | CONSIDERING REALISTIC ESTIMATE OF TIME | |
| | SPENT IN AREA OF CONCERN, in mrem in a year | |

Note: If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that Gauge 3 will only be used on the process line during product changeovers and Gauge 2 has different radiation levels depending on whether the gauge is in the 'on' or 'off' position (i.e., shutter is open or closed). As he examines the situation, he realizes he must consider each gauge individually.

Table 14. Calculation Method, Part 3: Summary of Information

INFORMATION ON GAUGES:

- **Gauge 1:** operates continuously (24 hrs/day) on the bottling line.
- Gauge 2: operates (in the "on" position) while the tank is being filled, approximately 1 hour during the time the worker is present. When the pipe is not filling the tank, the gauge is in the "off" position. While in the "off" position, the radiation level around the gauge drops to 2 mrem/hr at 1ft, one-fourth of the radiation level as when the gauge is in the "on" position.
- **Gauge 3:** is only used on the process line during product changeovers, 4 weeks per year. While affixed, it operates continuously (24 hrs/day).

INFORMATION FROM EXAMPLE 1, PART 2, ON WHEN THE WORKER IS PRESENT AT THE BOTTLING CONTROL PANEL:

- 5 hours per day
- 3 days per week
- 52 weeks per year

Table 15. Calculation Method, Part 3: Annual Dose Received from Gauges 1, 2, and 3

| Step No. | Description | Gauge 1 | Gauge 2 'On' | Gauge 2 'Off' | Gauge 3 |
|----------|---|---------|-----------------|------------------|---------|
| 12 | Average number of hours per day gauge operates when worker is present at the bottling control panel | 5 | 1 | 4 | 5 |

| 13 | Average number of days per week gauge operates when worker is present at the bottling control panel Average number of weeks per | 3 | 3 | 3 | 3 |
|----|--|-------------------------|-----------------------------|------------------------------------|---|
| 11 | year gauge operates when worker is present at the bottling control panel | 52 | 52 | 52 | 4 |
| 15 | Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = TOTAL HOURS EACH GAUGE OPERATED PER YEAR WHILE WORKER IS PRESENT AT BOTTLING CONTROL PANEL | 5 x 3 x 52 = 780 | 1 x 3 x 52 = 156 | 4 x 3 x 52 = 624 | 5 x 3 x 4 = 60 |
| 16 | Multiply the results of Step 15 by the results of Step 7 (for Gauge 2 in the "off" position, the radiation level drops to 1/4 th , so divide the results of Step 7 by 4) = ANNUAL DOSE RECEIVED FROM EACH GAUGE, in mrem in a year | 780 x 0.031 = 24 | 156 x 0.056 = 8.7 | 624 x (0.056/4) = 8.7 | 60 x 0.08 = 4.8 in mrem in a year |
| 17 | Sum the results of Step 16 for each gauge = TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN AND TIME GAUGE OPERATES, in mrem in a year | 24 + 8.7 + 4.8 = 4 | 46.2 | | |

Note: If the result in **Step 17** is greater than 100 mrem/yr, the licensee must take corrective actions.

Joe is pleased that the result in Step 17 shows compliance with the 100 mrem/yr limit. Had the result in Step 17 been higher than 100 mrem/yr, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy and the time each gauge operates are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding located between the gauges and the bottling control panel -- such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., add shielding, move the bottling control panel) and perform new calculations to demonstrate compliance
- Train the QC supervisor as required by 12VAC5-481-2270.

Note that in the example, Joe evaluated the unrestricted area at the bottling control panel. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., adding a gauge to the process line, changing the QC supervisor's schedule, or changing the estimate of the portion of time spent at the bottling control panel) and to perform additional evaluations, as needed.

RECORD KEEPING: **12VAC5-481-1050** requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement - Calculation Method

This method, which allows the licensee to take credit for shielding between the gauge and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each gauge. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a work year of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs. TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 rem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF2 that are used for environmental monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Example 2

As in Example 1, Joe is the RSO for ABC Bottling, Inc., a fixed gauge licensee. The company has three gauges located near a bottling control panel which is operated by a worker who does not work with the fixed gauges. See **Figure 1** and **Table 8** for information. Joe wants to see if the company complies with the public dose limits at the bottling control panel.

Joe placed an environmental TLD badge at the bottling control panel for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 16. Combination Measurement - Calculation Method

| Step No. | Description | Input Data and Results | | | | |
|----------|---|---------------------------------|--|--|--|--|
| | Part 1 | | | | | |
| 1 | Dose received by TLD, in mrem | 100 | | | | |
| 2 | Total hours TLD exposed | 24 hr/d x 30 d/mo = 720 | | | | |
| 3 | Divide the results of Step 1 by the results of Step 2 to | | | | | |
| | determine HOURLY DOSE RECEIVED , in mrem in an hour | 0.14 | | | | |
| 4 | Multiply the results of Step 3 by 365 d/yr x 24 hr/d = 8760 | | | | | |
| | hours in one year = MAXIMUM ANNUAL DOSE | 365 x 24 x 0.14 = 8760 x 0.14 = | | | | |

RECEIVED FROM GAUGES, in mrem in a year

1226

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100mrem in a year allowed by the regulations.

Part 2

At this point Joe can adjust for a realistic estimate of the time the worker spends at the bottling control panel as he did in Part 2 of Example 1.

Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time spent in the area of concern as in Part 3 of Example 1. (Recall that the TLD measurement was made while all the gauges were operating; i,e., 24 hr/d for the 30 days that the TLD was in place.)

Appendix L

Operating and Emergency Procedures

Operating and Emergency Procedures

Operating Procedures:

- If personnel dosimetry is provided:
 - Always wear your assigned film badge or optically simulated luminescent dosimeter (OSL) when using the gauge.
 - Never wear another person's film badge or OSL.
 - Never store your film badge or OSL near the gauge.
- Use the gauge according to the manufacturer's or distributors instructions and recommendations. Perform routine cleaning and maintenance according to the manufacturer's or distributor's instructions and recommendations.
- Test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSDR certificate.
- Do not touch the unshielded source with your fingers, hands, or any part of your body.
- Do not place hands, fingers, feet, or other body parts in the radiation field from an unshielded source.
- Post a radiation warning sign at each entryway to an area where it is possible to be exposed to the beam.
- Prevent employees from entering the radiation beam during maintenance, repairs, or work in, on, or around the bin, tank, or hopper on which the device is mounted by developing lock-out procedures. These procedures should specify who will be responsible for ensuring that the lock-out procedures are followed.
- Prevent unauthorized access, removal, or use of the gauge.
- After making changes affecting the gauge (e.g., changing the location of gauges, removing shielding, adding gauges, changing the occupancy of adjacent areas), reevaluate compliance with public dose limits and ensure proper security of gauges.
- Conduct a physical inventory every 6 months to account for all sealed sources and devices.

Emergency Procedures:

- If the gauge becomes damaged or if any other emergency or unusual situation arises:
 - Stop use of the gauge.
 - Immediately secure the area and keep people away from the gauge until the situation is assessed and radiation levels are known. However, perform first aid for any injured individuals and remove them from the area only when medically safe to do so.
 - If any equipment is involved, isolate the equipment until it is determined there is no contamination present.
 - Gauge users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
 - Notify the persons in the order listed below of the situation:

| NAME | WORK PHONE NUMBER | HOME PHONE NUMBER |
|------|-------------------|-------------------|
| | | |

• Follow the directions provided by the person contacted above.

Note: Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the RSO, AUs, or other knowledgeable licensee staff, licensee's consultant, gauge manufacturer, distributor or representative, fire department, or other emergency response organization, as appropriate, and the agency) to be contacted in case of emergency.

RSO and Licensee Management:

- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person
 using appropriate radiation detection instrumentation. This person could be a licensee employee
 using a survey meter, a local emergency responder, or a consultant. To accurately assess the
 radiation danger, it is essential that the person performing the survey be competent in the use of
 the survey meter.
- Make necessary notifications to local authorities as well as the agency as required. Appendix P contains typical agency incident notifications required for fixed gauge licensees. (Even if not required to do so, you may report ANY incident to the agency by calling (804) 864-8150 during normal business hours. For immediate notifications after normal business hours, the 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological. VDH notification is required when gauges containing licensed material are lost or stolen and when gauges are damaged or involved in incidents that result in doses in excess of 12VAC5-481-1100 limits. Reporting requirements are found in 12VAC5-481-1110.

Copies of operating and emergency procedures must be posted at each location of use or if posting procedures is not practicable, a notice that briefly describes the procedures and states where they may be examined may be posted instead.

Copies of operating and emergency procedures should be provided to all gauge users.

Appendix M

Model Leak Test Program

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently. Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and the use of instruments
- Mathematics and calculations basic to the use and measurement of radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- A NaI(Tl) well counter system with a single or multichannel analyzer or an equivalent detector will be used to count samples from gauges containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system or equivalent detector will be used to count samples from gauges containing beta-emitters (e.g., Sr-90) or alpha emitters (e.g., Am-241).

Frequency for Conducting Leak Tests of Sealed Sources

• Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as gauge serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide contained in the gauge.
- Using the selected instrument count and record background count rate.
- Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be

within \pm 5% of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).

• Calculate efficiency.

For example:

cpm from std) - (cpm from bkg)] = efficiency in cpm/Bq
activity of std in Bq

cpm = counts per minute

Where: std = standard

bkg = background

Bq = Becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or microcuries).

For example:

<u>cpm from wipe sample</u>) - (<u>cpm from bkg</u>)] = Bq on wipe sample efficiency in cpm/Bq

- Sign and date the list of sources, data and calculations. Retain records for 3 years.
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify the agency.

Reference: See the NRC webpage at http://www.nrc.gov to obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services", dated June 1985.

Appendix N

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Applicants should review the section in this document on 'maintenance', which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine operations include installation of the gauge, initial radiation survey, repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding), gauge relocation, replacement, and disposal of sealed sources, alignment, removal of a gauge from service, and any other activities during which personnel could receive radiation doses exceeding VDH limits.

Any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the gauge is tested and functions as designed, before the unit is returned to routine use.

If non-routine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed and personnel performing these tasks could receive radiation doses exceeding VDH limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes in less than one minute, an unshielded cesium-137 source with an activity of 100 millicuries can deliver 0.05 Sv (5 rems) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. However, gauges can contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 0.05 Sv (5 rems) per year.

Thus, applicants wishing to perform non-routine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributors instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry (if required)). Accordingly, provide the following information:

Describe the types of work, maintenance, cleaning, repair that involve:

- Installation, relocation, or alignment of the gauge
- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- Replacement and disposal of sealed sources
- Removal of a gauge from service
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding VDH limits.

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

A licensee may initially mount a gauge, without specific VDH, the NRC or another Agreement State authorization, if the gauge's SSDR Certificate explicitly permits mounting of gauges by users and under the following conditions:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor;
- The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by NRC or another Agreement State;
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;
- The gauge must be received in good condition (package was not damaged); and
- The gauge must not require any modification to fit in the proposed location.

Mounting does not include electrical connection, activation, or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by VDH, the NRC or another Agreement State to perform such operations.

- Identify who will perform non-routine operations and their training and experience. Acceptable training would include manufacturer's or distributor's courses for non-routine operations or equivalent.
- Submit procedures for non-routine operations. These procedures should ensure the following:
 - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
 - the source is secured against unauthorized removal or access or under constant surveillance;
 - appropriate labels and signs are used;
 - manufacturer's or distributor's instructions and recommendations are followed;
 - any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration; and
 - before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.
 - Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits.
- Verify possession of at least one survey instrument that meets the criteria in 'Survey Instruments' in VAREG 'Guidance for Fixed Gauge Devices'.
- Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
 - commit to performing surveys with a survey instrument (as described above);
 - specify where and when surveys will be conducted during non-routine operations; and
 - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 12VAC5-481-1050.

Appendix O

Major DOT Regulations; Sample Shipping Documents, Placards and Labels

Major DOT Regulations; Sample Shipping Documents, Placards and Labels

The major areas in the DOT regulations that are most relevant for transportation of typical fixed gauges that are shipped as Type A quantities are as follows:

- Hazardous Materials Table, **49 CFR 172.101**, Appendix A, list of hazardous substances and reportable quantities (RQ), Table 2: radionuclides
- Shipping Papers **49** CFR **172.200**, **172.201**, **172.202**, **172.203**, **172.204**: general entries, description, additional description requirements, shipper's certification
- Package Markings 49 CFR 172.300, 172.301, 172.303, 172.304, 172.310, 172.324: General
 marking requirements for non-bulk packagings, prohibited marking, marking requirements,
 radioactive material, hazardous substances in non-bulk packaging
- Package Labeling 49 CFR 172.400, 172.401, 172.403, 172.406, 172.407, 172.436, 172.438,
 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles 49 CFR 172.500, 172.502, 172.504, 172.506, 172.516, 172.519, 172.556:
 Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information, Subpart G, **49 CFR 172.600, 172.602, 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49** CFR **172.702**, **172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.801, 172.803, 172.805: Applicability of the radiation protection program, radiation protection program, recordkeeping, and notifications
- Shippers General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 173.410, 173.412, 173.415, 173.431, 173.433, 173.435, 173.441, 173.443, 173.448, 173.475, 173.476: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A1 and A2, table of A1 and A2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials
- Carriage by Public Highway General Information and Regulations, Subpart A, 49 CFR 177.816, 177.817, 177.834(a), 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Note: Type B shipping packages transport quantities of radionuclides greater than Type A allowable quantities. Requirements for Type B packages are in **12VAC5-481-3000**.

Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface, (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package.
- Two labels are required on opposite sides of the package, excluding the bottom.

Determination of Required Label

| Size: Sides: ≥ 100 mm Border: 5-6.3 mm | RADIOACTIVE 1 | RADIOACTIVE II | RADIOACTIVE III |
|---|--|--|--|
| | 49 CFR 172.436 | 49 CFR 172.438 | 49 CFR 172.440 |
| | WHITE-I | YELLOW-II | YELLOW-III |
| Required when: | Surface radiation level ≤ 0.005 mSv/hour (0.5 mrem/hour) | 0.005 mSv/hour (0.5 mrem/hour) < surface radiation level ≤ 0.5 mSv/hour (50 mrem/hour) | 0.5 mSv/hour (50 mrem/hour) < surface radiation level ≤ 2 mSv/hour (200 mrem/hour) |
| Or: | TI = 0 [1 meter dose rate < 0.5 mrem/hour] | $TI \le 1$ [1 meter dose rate \le 1 mrem/hour] | $ 1 < TI \le 10 $ [1 meter dose rate ≤ 10 mrem/hour] |

Content on Radioactive Labels

RADIOACTIVE label must contain (entered using a durable, weather-resistant means):

- (1) The radionuclides in the package. Symbols (e.g., Ir-192) are acceptable.
- (2) The activity in SI units (e.g., Bq, TBq) or both SI units with customary units (e.g., Ci, mCi) in parenthesis.
- (3) The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels.

Some Special Considerations for Labeling Requirements

- Radioactive material, excepted packages (e.g., Limited Quantity, Radioactive Instrument and Article) are excepted from labeling.
- The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§172.402(c)]

Appendix P

VDH Incident Notifications

VDH Incident Notifications

Table 17. Typical VDH Incident Notifications Required for Fixed Gauge Licensees

| Event Telephone Written Report Regulatory | | | | |
|---|--------------|--------------------------|---------------------|--|
| Event | Notification | Witten Report | Requirement | |
| Theft or loss of material | Immediate | 30 days | 12VAC5-481-1090 | |
| Whole body dose greater | miniculate | 30 days | 12 (11 (25-401-10)) | |
| than 0.25 Sv (25 rems) | Immediate | 30 days | 12VAC5-481-1110 | |
| Extremity dose greater than | miniculate | 30 days | 12 11 12 11 10 | |
| 2.5 Sv (250 rems) | Immediate | 30 days | 12VAC5-481-1110 | |
| Whole body dose greater | miniculate | 30 days | 12 (1105 401 1110 | |
| than 0.05 Sv (5 rems) in 24 | 24 hours | 30 days | 12VAC5-481-1100 | |
| hours | 21110415 | 20 days | | |
| Extremity dose greater that | | | | |
| 0.5 Sv (50 rems) in 24 hours | 24 hours | 30 days | 12VAC5-481-1100 | |
| Whole body dose greater | 21110413 | 30 days | 12 11 12 11 10 1 | |
| than 0.05 Sv (5 rems) | None | 30 days | 12VAC5-481-1110 | |
| Dose to individual member | Tione | 30 days | 1#111UJ-TU1-111U | |
| of the public greater than | None | 30 days | 12VAC5-481-1110 | |
| 1mSv (100 mrems) | Tronc | 30 days | 12 (AC3-401-1110 | |
| Filing petition for | | Immediately after filing | 12VAC5-481-500 E & | |
| bankruptcy | None | petition | F | |
| Expiration of License | None | 60 days | 12VAC5-481-510 D | |
| Decision to permanently | Trone | oo days | 12 11 (3-401-310 B | |
| cease licensed activities at | None | 60 days | 12VAC5-481-510 D | |
| entire site | Trone | oo days | 12 VACS-401-310 B | |
| Decision to permanently | | | | |
| cease licensed activities in | None | 60 days | 12VAC5-481-510 D | |
| any separate building or | Trone | oo days | 12 11 63-401-310 B | |
| outdoor area that is | | | | |
| unsuitable for release for | | | | |
| unrestricted use | | | | |
| No principal activities | | | | |
| conducted for 24 months at | None | 60 days | 12VAC5-481-510 D | |
| the entire site | 1.0110 | oo aayo | | |
| No principle activities | | | | |
| conducted for 24 months in | None | 60 days | 12VAC5-481-510 D | |
| any separate building or | T (OHC | oe aujs | 12 (1100 101 010 2 | |
| outdoor area that is | | | | |
| unsuitable for release for | | | | |
| unrestricted used | | | | |
| Event that prevents | | | | |
| immediate protective | Immediate | 30 days | 12VAC5-481-1100 | |
| actions necessary to avoid | | | 12VAC5-481-1110 | |
| exposure to radioactive | | | | |
| materials that could exceed | | | | |
| regulatory limits | | | | |

| Event | Telephone Notification | Written Report | Regulatory Requirement |
|-------------------------------|---------------------------|----------------|---------------------------|
| Equipment is disabled or | | | • |
| fails to function as designed | 24 hours | 30 days | 12VAC5-481-1110 |
| when required to prevent | | | |
| radiation exposure in excess | | | |
| of regulatory limits | | | |
| Unplanned fire or explosion | | | |
| that affects the integrity of | 24 hours | 30 days | 12VAC5-481-1110 |
| any licensed material or | | | |
| device, container, or | | | |
| equipment with licensed | | | |
| material | | | |

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during business hours and (804) 674-2400 or (800) 468-8892 after business hours. Identify the emergency as radiological.