

X-Ray Regulatory Guide
Radiation Safety Program



STATE OF WISCONSIN
DEPARTMENT OF HEALTH SERVICES
Division of Public Health
Bureau of Environmental and Occupational Health
Radiation Protection Section
PO Box 2659
Madison, Wisconsin 53701
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Table of Contents

Introduction	3
Changes in Registration.....	4
SAMPLE OPERATING and SAFETY PROCEDURES.....	4
Posting Notices, Instructions, and Reports to Workers.....	4
OPERATOR SAFETY.....	5
Training Requirements for X-Ray Machine Operators.....	5
Individual Radiation Monitoring Requirements (DOSIMETRY)	5
Proper Use, Location, and Records Review of Personal Monitoring Devices.....	5
Top 10 Dosimeter Do's and Don'ts.....	7
Use of Protective Devices.....	7
Holding of Patients and/or Image Receptor	8
Radiation Incident or Overexposure	8
PATIENT SAFETY.....	8
As Low As Reasonably Achievable (ALARA).....	8
Ordering of X-Ray Exams.....	8
SAFE OPERATION OF IMAGING EQUIPMENT	9
X-Ray Machine Operator Position during an Exposure	9
Use of a Technique Chart.....	9
X-Ray Beam Restriction and Alignment	9
Use of Mobile or Portable Machines.....	9
Use of Fluoroscopic Machines.....	10
Analog Image (Film) Processing.....	11
Digital Image Processing	11
Pregnancy Policy	11
APPENDIX A: Notice to Employee.....	12
APPENDIX B: Operation and Safety Procedure Training Verification SAMPLE	13
APPENDIX C: X-Ray Device Training Documentation SAMPLE.....	14
APPENDIX D: Declaration of Pregnancy SAMPLE	15
APPENDIX E: Protective Device Inspection SAMPLE	16
APPENDIX F: Analog Film Processing Quality Control Instructions	17
APPENDIX G: Darkroom Fog Test Instructions and Log	25
APPENDIX H: Image Processing SAMPLE.....	26

Introduction

Wisconsin Admin. Code § DHS 157.21 (1) requires registrants to develop, document and implement a radiation protection program (RPP), which is to be evaluated annually. Additionally, each registrant is required to instruct staff on the safe operation of their facility's equipment. DHS 157.74 (2) (c) requires these operating and safety procedures be in written form. The information in this regulatory guide is created to summarize the sections of DHS 157 that pertain to your type of facility. This document by itself is NOT the operations and safety procedures or RPP. However, it was designed so that you may use this document and associated appendices to customize an RPP to fit your specific facility; by doing so, create operations and safety procedures that are unique to the registrant's use but address use and safety requirements.

This guide is prepared for facilities that have not developed their own Operating and Safety Procedure Manual (OSPM). These procedures, whether developed independently or with this guide, are to be used to instruct your staff. A written policy or electronic version MUST be available to facility staff and the department. Your staff is required by regulation to be able to demonstrate familiarity with these operating and safety procedures.

A documented RPP would include operating and safety procedures. An RPP will include, but is not limited to, the following:

1. The name of the individual responsible for oversight and annual review of the program.
2. The name of the personnel responsible for ensuring specific requirements and duties, as outlined in the operating and safety procedures. These duties include proper documentation of completion.
3. The methods and procedures for staff to respond and document emergency situations and safety issues.
4. The name of the person who is responsible for reviewing the dosimetry reports and ensuring the staff's occupational dose restrictions are within acceptable limits.
5. The procedures, schedules, and staff responsible for inspection/maintenance of x-ray units, safety devices and other related equipment.
6. Date(s), content of, and staff attending x-ray operations and safety training specific to your facility.
7. Date(s), content of, and staff attending the annual instructions to workers as outlined in Subchapter X.

The pertinent sections of DHS 157 that apply to Medical/Dental practices are: Subchapter I, III, VIII, X, XI and XII. Detailed information is found within Subchapter VIII, DHS 157.74, 75, 76 (Fluoroscopy), 77, and 86. DHS 157.81 covers the requirements for submitting shielding plans for review when new facilities are being constructed and when existing x-ray rooms are being modified. DHS 157.22, 23 and 25 address radiation exposure to the public and radiation machine users/employees.

A copy of the Wisconsin Admin. Code ch DHS 157, Radiation Protection, can be found at the following web address: <http://www.dhs.wisconsin.gov/radiation/license/Xray/index.htm>

Changes in Registration

If there are changes in the registration for this facility, such as change of address or responsible party, written notification must be sent to the Department of Health Services (DHS) within 30 days of the change. Change of ownership requires a new registration with full fees paid by the new owner. Addition of new equipment and/or the replacement/removal of old equipment also needs to be reported to ensure your annual registration fees are accurate. Changes to the registration information may be faxed to 608-267-4799 or mailed to Division of Public Health, Radiation Protection Section, PO Box 2659, Madison, WI 53701-2659. If you would like to send this electronically, please call 608-267-4782.

Current contact information for DHS is available at the following web address

<https://www.dhs.wisconsin.gov/radiation/xray/index.htm>

SAMPLE OPERATING and SAFETY PROCEDURES

Operating and Safety Procedures for your facility

This guide establishes procedures that will minimize radiation exposure to employees. They are provided to comply with regulations enforced by DHS, Radiation Protection Section. The regulations require that each x-ray facility and all x-ray devices at that address be registered with DHS and pay annual renewal fees.

The registrant MUST designate a person responsible for oversight and annual review of these procedures. This person is often referred to as the person-in-control or the radiation safety officer (RSO). This individual has the responsibility and authority for assuring safe radiation practices and serves as the contact person between this facility and DHS. All questions and concerns regarding radiation safety for this facility should be directed to the RSO.

Posting Notices, Instructions, and Reports to Workers

Employees must be familiar with the "Notice to Employees" document, which needs to be posted in an employee accessible area.

The location of written operations and safety procedures and location of where the regulations can be accessed is to be written in the lined box at the top of the "Notice to Employees" sign.

The certificate of registration, issued annually at the time of registration renewal, the operating and safety procedures and any notices of violations involving radiological working conditions are located at or nearby the x-ray department.

The practice is required to provide staff access to the regulations. Your rights and obligations as a radiation worker are found in DHS 157.88.

A copy of the Notice to Employees is available at our website

<https://www.dhs.wisconsin.gov/radiation/index.htm> or by calling the Radiation Protection Section at 608 267-4782.

OPERATOR SAFETY

Training Requirements for X-Ray Machine Operators

Training requirements will vary depending on the application or intended use. See the appendices for your x-ray device's specific training requirements for operators.

In general, all operators of x-ray machines must be trained to operate the equipment safely, i.e., adequate collimation, procedures for mobile/portable x-ray units:

1. In selection of proper technique factors (time, mA, mAs or kVp)
2. To position the animal equipment properly
3. To process the image properly
4. In the use of personal protective equipment (apron, gloves, thyroid collar, etc.)
5. In the use of fluoroscopic equipment (for detailed training in fluoroscopy, see the separate section titled Use of Fluoroscopic Machines within this document)

All operators shall acknowledge receipt of this training by signing an Operation and Safety Procedure Verification form located in or nearby the location of the x-ray device. (Operation and Safety Procedure Verification wording can be found in **Appendix B**).

Training documentation will include a copy of the operating and safety procedures, as well as specific equipment-use training, date(s) of the training, a list and signatures of staff in attendance, and the qualifications of the person providing the instruction. (Training documentation wording can be found in **Appendix C**).

X-ray machine operators need to be trained on each piece of x-ray equipment they will be using. Although they may have used similar equipment in the past, each unit could have unique operating characteristics.

Individual Radiation Monitoring Requirements (DOSIMETRY)

Any adult who is likely to receive a dose from occupational exposure to radiation in excess of 5 mSv (500 millirem) in a year must use an individual monitoring device. In a medical/clinic setting where the doctor/owner is the only x-ray machine operator, monitoring devices are not required. Any associate doctors and/or employees who are likely to receive a dose from occupational exposure to radiation in excess of 5 mSv (500 millirem) in a year must use an individual monitoring device. Guidelines for dosimetry requirements for your specific use or type of x-ray units can be located in the appendices.

Proper Use, Location, and Records Review of Personal Monitoring Devices

1. Individual monitoring devices must be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar) in accordance with DHS 157.25(3). If a "control" monitor device is supplied, it is to be kept in a location outside of the x-ray room.
2. Additional individual monitoring devices used for monitoring the dose to the embryo/fetus of a declared pregnant woman must be located at the waist and under any protective apron.
3. The assigned monitoring device must be worn only by that individual.

4. When wearing a protective apron, multiple individual monitoring devices may be worn. When multiple devices are worn, occupational doses shall be determined in accordance with DHS 157.25(3) (b)
5. If multiple individual monitoring devices are worn by a declared pregnant woman, dose to the embryo/fetus and the occupational dose to the woman shall be determined in accordance with DHS 157.25(3) (b).
6. An individual's personal monitoring device, when not being worn will be stored in an area that is away from rooms where radiation machines are in use. <Specify name> is responsible for the occupational dose records and exchanging the individual monitoring devices on <Specify exchange dates>. The individual monitoring device readings (dosimetry/film badge reports) are located in/at <Specify posting or records location>.

NOTE: Modality interns or students should be provided dosimetry through their school.
7. If any employee is working for multiple employers and receives an occupational dose, they shall report that dose to the RSO at each employer so that it can be included in their annual record of occupational dose. Employees are responsible for reporting their exposure from each job to each employer. The cumulative exposure from each job is the annual occupational exposure. No employee is allowed to exceed 50 mSv (5 rem) in a calendar year from ALL EMPLOYERS COMBINED during that year. An employee working for a single employer but working at multiple affiliated sites must be assigned only one dosimeter, not one for each location.
8. If any employee is pregnant or becomes pregnant, she may voluntarily inform the RSO or employer in writing of the pregnancy. A sample form letter can be found in Appendix D. If the RSO or employer is informed of the pregnancy, the employer must ensure that the dose to the embryo or fetus does not exceed 5 mSv (500 mrem) during the entire pregnancy and no more than 0.5 mSv (50 mrem) in any month. The dose to the monitoring device worn at the waist level is considered to be the fetal dose. Pregnant workers shall be monitored for radiation exposure if they routinely participate in radiographic procedures. If the employee chooses to wear a leaded apron and have dosimetry, two monitors are recommended; one device will be worn at the neck and the second under the apron at the waist level. If an apron is not worn, only one monitor may be assigned and that shall be worn at the waist level. If an employee does not declare their pregnancy in writing, for radiation safety purposes they are not considered to be pregnant and the annual individual occupational exposure limit of 50 mSv (5 Rem) applies.

Wisconsin Admin. Code § DHS 157.88 Subchapter X discusses the requirements for notifying the employee of their monitoring results. Each employee who wears a monitor should be shown the monitor report and acknowledge seeing the results by initialing the report by their name. Social security numbers do not need to be used for identifying each employee. An employee number may be used for identification.

Records of employee exposure must be retained, even after the employee has left. Upon departure, each employee must receive a copy of their final monitoring report that shows their exposure for the entire employment period. The information on the periodic monitor report may be recorded on facility letterhead and include the phrase "This report is furnished to you under the provisions of Wis. Admin. Code ch. DHS 157, Radiation Protection. You should retain this report for future reference."

Top 10 Dosimeter Do's and Don'ts

DO WEAR IT when working. It has no value in your locker or purse.

DON'T WEAR IT when you are receiving x-rays for your own health care.

DON'T WEAR IT away from the workplace.

DON'T WEAR IT under your apron unless you are wearing two dosimeters. Leave your dosimeter in the same place every day when you leave work so you know where it is.

DO TURN IT IN on time. A gap in time will make analysis more difficult, less accurate, and reduces legal and historical value of the reports.

DO PLACE the control dosimeter in an area outside of the x-ray room; the dose to the control is subtracted from each dosimeter and needs to be accurate.

DO REPORT LOST OR DAMAGED dosimeters immediately. Prevent damage by not leaving your dosimeter in areas of high temperature such as your dashboard or in the clothes dryer.

DON'T PLACE a personal dosimeter in an area where it can be exposed to stray or scatter radiation. Additional control dosimeters can be assigned to test this.

DON'T SHARE dosimeters; this is not permitted. An average for a shared dosimeter is meaningless to each individual.

DON'T TAMPER with your dosimeter or anyone else's. The reports are legal documents and are regarded as real exposures received.

Use of Protective Devices

Below are general guidelines for when to use aprons, gonadal shielding, etc. Some examples specific to x-ray devices intended use are provided in the appendices.

1. Use protective devices, such as lead aprons, gloves, and shields, to reduce exposure to radiation and keep radiation exposure as low as reasonably achievable (ALARA). Protective devices must be used or provided in the following situations:
 - a. When it is necessary for an individual other than the patient to remain in the room or hold a patient.
 - b. When it is necessary to protect other patients or staff who cannot be moved out of the room and are closer than 2 meters (6.5 feet), ex., critical care areas, emergency rooms, or trauma units.
2. If fluoroscopic procedures are being performed, protective devices shall be utilized; lead drapes and hinged sliding panels shall be in place to reduce the scatter (secondary) radiation to the operator.
3. Protective devices, gloves, aprons, and thyroid collars are stored <Specify location>.
4. Protective devices must be radiographically or fluoroscopically evaluated every two years for defects. The medical director or RSO must review these images. These devices should be checked annually for defects such as holes, cracks, or tears. This check can be done by visually inspecting or feeling the protective devices or by x-raying these items. If a defect is found at the time of either the radiographic or visual check or on any other occasion, notify the RSO and

remove the device from service until it can be repaired or replaced. A record will be kept of these checks and be made available to an inspector. See Appendix E.

5. The x-ray exposure control (switch) shall be located within the shielded area and at least 1 meter (3.3 feet) from the open end of the protective barrier. This switch must be permanently mounted/secured preventing the operator from stepping beyond the barrier edge during the exposure.

Holding of Patients and/or Image Receptor

1. If a patient or image receptor must be supported during an imaging procedure, use a mechanical holding device when circumstances permit. Situations where mechanical devices cannot be routinely used are as follows:
<Insert facility specifics>
2. If it becomes necessary for an individual to hold a patient or image receptor, the holder shall not be pregnant. They must utilize protective devices, must be visually monitored, and have no unprotected body part within the direct beam.

Radiation Incident or Overexposure

If any person suspects that there has been an excessive exposure or a radiation incident (i.e., exposing yourself or a co-worker to the direct beam), immediately notify the RSO who will then notify DHS by phone 608-267-4787 and by fax 608-267-4799. DHS will investigate the alleged incident.

PATIENT SAFETY

As Low As Reasonably Achievable (ALARA)

To meet the intent of ALARA, the operator shall:

1. Use the lowest possible radiation exposure for each exam to obtain a diagnostic image, i.e., using the fastest speed image receptor available with the shortest exposure time.
2. Avoid repeat x-rays by setting the correct technique obtained from technique charts available or using proper, preprogrammed settings within the x-ray control.
3. Accurately position the tube head and image receptor.
4. Provide protection to gonads for patients of childbearing age unless the shield interferes with the exam. Where applicable, protection of the thyroid is recommended.
5. If the gonads are in or within 5 centimeters of the x-ray beam, shields must be used unless the use of the shield interferes with the diagnostic procedure. Properly sized gonadal cups generally do not interfere with measurement points in the pelvis.
6. Ensure the primary beam collimation is NOT opened larger than the image receptor.

Ordering of X-Ray Exams

No x-ray exams shall be taken unless ordered by a licensed healing arts practitioner. DHS 157 defines a licensed practitioner as a chiropractor, dentist, physician, podiatrist, physician assistant, nurse practitioner, radiologist's assistant, or physical therapist licensed in Wisconsin. This may be a verbal order so long as there is a corresponding signed order entry in the patient chart or computer file. Orders require the signature of the licensed practitioner.

SAFE OPERATION OF IMAGING EQUIPMENT

X-Ray Machine Operator Position during an Exposure

1. The operator must be able to continuously view and communicate with the patient while remaining behind the barrier. The operator must be able to see every entrance to the room from the operator position. Entrances can be monitored directly, with mirrors or interlocks.
2. During the exposure, the operator must be positioned within the barrier walls or during fluoroscopy so that their exposure is As Low As Reasonably Achievable (ALARA). Remember TIME, DISTANCE, and SHIELDING. When a patient needs to be supported, lead aprons, gloves, or other shielding shall be used for protection.

Use of a Technique Chart

1. Technique charts are required for systems with adjustable techniques, such as kV, time and mA (x-ray tube current). A technique chart aids in reducing the exposure to the operator and patient by providing a standard technique based on patient size and type of study.
2. Technique charts are to be displayed in the vicinity of the control panel of each x-ray machine.
3. Some units have programmed techniques built into the control. If programmed techniques are no longer correct, written charts must be created and used or the programmed techniques must be updated by your service vendor or unit manufacturer.
4. Any technique found on a chart or within the internal pre-sets that are not accurate need to be discussed with the RSO and corrected.
5. When switching from analog film to digital imaging, be sure to post new technique charts. Exposure factors needed to produce a diagnostic image are often reduced for digital imaging.

X-Ray Beam Restriction and Alignment

1. To meet the intent of ALARA, the useful x-ray beam shall be restricted to the area of clinical interest. Use the centering and beam-limiting devices (collimators, et al.) provided on the x-ray machine.
2. If the unit has automatic collimation and the system fails, the RSO must be notified immediately and have the unit repaired. Automatic collimators must continue to function per manufacturer's recommendations unless repair parts are no longer available. If the automatic collimator cannot be repaired, you must notify the DHS Radiation Protection Section.
3. Collimators are **NEVER** allowed to be open wider than the image receptor.
4. Units that use apertures for collimation must have a means to center the x-ray beam to the image receptor or the area of clinical interest.

Use of Mobile or Portable Machines

1. DHS 157 defines mobile x-ray equipment as mounted on a permanent base with wheels and/or casters for moving while completely assembled; portable x-ray equipment is defined as hand-carried. Battery-operated, hand-held dental x-ray devices must be approved by DHS prior to use.
2. The x-ray machine operator must be positioned so that his/her exposure to scatter radiation is as low as reasonably achievable (ALARA). *The operator shall remain 2 meters (6.5 feet) or more away from the tube and patient unless behind a barrier. The operator should never be in line with the direct beam.

3. If the x-ray machine operator must be closer than 2 meters (6.5 feet) from the patient or tube, the operator must wear a lead apron. Lead aprons must be available at any location where a mobile or portable device is used, i.e., typically aprons are stored with or on a mobile or portable device.
4. If using a portable or mobile device in the same location for more than one week, the equipment is considered stationary and must meet all the requirements of a stationary unit.
5. No person may hold the x-ray tube housing during the exposure. A stand or other means of support shall be used during the exposure. There is the possibility of electric shock from improper grounding if the machine is held.

**Approved battery-powered dental x-ray devices are exempt from the 2 meter rule and wearing of lead apron requirement when manufacturer specifications are followed, i.e., use of the back scatter shield.*

Use of Fluoroscopic Machines

Only a licensed practitioner or a licensed radiographer may operate fluoroscopic machines.

Prior to beginning any fluoroscopic procedure the five-minute timer needs to be reset.

All operators of fluoroscopic machines must have documented training of all aspects from DHS 157.76 (11) as follows:

- (a) *The facility shall ensure that only a licensed practitioner or a radiologic technologist who is trained in the safe use of fluoroscopic x-ray systems is allowed to operate these systems. All fluoroscopic x-ray images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner.*
- (b) *The use of fluoroscopic x-ray systems by radiologic technologists shall be performed under the supervision of a licensed practitioner for the purpose of localization to obtain images for diagnostic purposes.*
- (c) *Radiologic technology students may not operate fluoroscopic x-ray systems except under the direct supervision of a licensed practitioner or radiologic technologist.*
- (d) *Fluoroscopic x-ray systems may not be used as a positioning tool for general purpose radiographic examinations.*
- (e) *The registrant shall require the operator of a fluoroscopic x-ray system to meet either of the following requirements:*
 1. *Is certified by the American Board of Radiology or board eligible.*
 2. *Has completed training to include the following:*
 - a. *Principles and operation of the fluoroscopic x-ray system.*
 - b. *Biological effects of x-ray.*
 - c. *Principles of radiation protection.*
 - d. *Fluoroscopic outputs.*
 - e. *High level control options.*
 - f. *Dose reduction techniques for fluoroscopic x-ray systems.*
 - g. *Applicable state and federal regulations.*

As stated in DHS 157.74 (2) (d) 2, All persons, including any patients who cannot be removed from the room, shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that all parts of the person's body are at least 2 meters from all of the following:

- a) The tube head.
- b) The direct beam.
- c) The nearest part of the examined patient's body being struck by the useful beam.

Lead gloves are required to protect the operator's hands during fluoroscopy if they are adjacent to the collimated field. If this facility has a mini C-arm, a protective apron is not required by regulation as long as the operator or anyone within 6 feet of the c-arm **is wearing dosimetry**.

An annual measurement of both typical and maximum air kerma shall be made by a medical physicist or a person approved by a medical physicist.

All fluoroscopic devices must meet the requirements of Wis. Admin. Code ch. DHS 157.76, Wisconsin Radiation Protection Code.

Analog Image (Film) Processing

Analog imaging processing regulations and guidelines are located in Appendix X

Digital Image Processing

Following the manufacturer recommendations for digital image quality control is required. In the absence of any manufacturer recommendations, the radiation protection section will work with a facility to create a customized digital QC program specific to the system and x-ray unit in use.

Pregnancy Policy

Each registrant shall include in their written radiation safety and procedure manual their policy regarding the safety measures taken when an employee declares, in writing, that she is pregnant. The registrant is required to ensure that the embryo will not receive a radiation dose from occupational exposure that exceeds 500 mRem during the entire pregnancy. The registration will need to provide a personal dosimetry to document the exposure is below this limit. Pregnancy Policy wording is found in Appendix D.

APPENDIX A: Notice to Employee

DEPARTMENT OF HEALTH SERVICES
Division of Public Health
P-45027 (03/2017)

STATE OF WISCONSIN
Wis. Admin. Code § DHS 157.88 (1)

NOTICE TO EMPLOYEES

The Wisconsin Department of Health Services (DHS) has established standards to protect you from hazards associated with radioactive materials and radiation emitting machines and has established certain provisions for the options of workers engaged in work under a DHS license or registration. In particular, the following information is available for your review:

Wisconsin Admin. Code ch. DHS 157; Subchapter III - Standards for Protection from Radiation

Wisconsin Admin. Code ch. DHS 157; Subchapter X - Notices, Instructions and Reports to Workers

Any other documents your employer must provide, as noted below in "Your Employer's Responsibility." These may be found at the following locations:

YOUR EMPLOYER'S RESPONSIBILITY	REPORTS ON YOUR OCCUPATIONAL RADIATION DOSE HISTORY
<p>Your employer is required to:</p> <ol style="list-style-type: none">1. Apply these regulations to work involving radiation sources.2. Post or otherwise make available to you a copy of the license, conditions, or documents incorporated in the license by reference and amendments, and/or registration certificate(s) and operating procedures that apply to work you are engaged in and how their provisions apply to you.3. Post any Notice of Violation involving radiological working conditions, proposed imposition of civil penalties, or orders.	<ol style="list-style-type: none">1. DHS regulations establish occupational limits for exposure to radiation and for concentrations of radioactive material in air and water. The regulations require your employer to give you a written report if you receive a dose in excess of any applicable limit. The limits on your occupational dose are in § DHS 157.22(1); (7) and (8). While these are your maximum allowable limits, your employer is required to take steps to keep your radiation dose as far below limits as is reasonably achievable.2. If the regulations require your employer to monitor your radiation exposure:<ol style="list-style-type: none">a. Your employer must advise you annually of your exposure to radiation if the reported dose exceeds 100mRem or if you request it.b. Upon termination of employment, your employer must give you a written report of your radiation exposure if you request it.
<p>YOUR RESPONSIBILITY AS A WORKER</p> <p>You should:</p> <ol style="list-style-type: none">1. Know the provisions of Wis. Admin. Code ch. DHS 157 "Radiation Protection," the precautions, the operating procedures, and the emergency procedures that apply to the work in which you are engaged.2. Observe the provisions for your own protection and protection of your coworkers.3. Report unsafe working conditions and violations of the license, registration conditions, and/or regulations to your employer or DHS.	<p>INSPECTIONS</p> <p>All licensed or registered activities are subject to inspection by the State of Wisconsin, Department of Health Services. Any worker or worker's representative who believes that violations of Wis. Admin. Code ch. DHS 157 "Radiation Protection," or the terms of the employer's license or registration has occurred may request an inspection. The request must be in writing and sent to the address listed below. The request must describe the alleged violation in detail and be signed by you or your representative. During inspections, DHS inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition that he or she believes contributed to or caused a violation as described above, § DHS 157.89(4)</p>
<p>WHAT IS COVERED BY THESE REGULATIONS</p> <ol style="list-style-type: none">1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas.2. Measures to be taken after accidental exposure.3. Personnel monitoring, surveys, and equipment.4. Caution signs, labels, and safety interlock equipment.5. Exposure records and reports.6. Options for workers regarding Department inspections.7. Related matters.	

Direct all inquiries to:
Department of Health Services, Radiation Protection Section,
1 West Wilson St., Room 150, P.O Box 2659, Madison, WI 53701-2659
Phone: 608-267-4797 Fax: 608-267-4799

POSTING REQUIREMENTS

Copies of this notice must be posted in every establishment where employees are engaged in activities licensed or registered by the State of Wisconsin, Department of Health Services. Posting must permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment (§ DHS 157.88).

APPENDIX D: Declaration of Pregnancy SAMPLE

Declaration of Pregnancy

DHS 157 defines a “Declared Pregnant Worker” as a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and her estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

DHS 157.22 (8) Dose to an embryo or fetus states:

1. A licensee or registrant shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (500 mrem).
2. A licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in par. (a).
3. The dose equivalent to an embryo or fetus is the sum of all of the following:
 - a. The deep-dose equivalent to the declared pregnant woman.
 - b. The dose equivalent to the embryo or fetus resulting from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.
4. If the dose equivalent to the embryo or fetus is found to have exceeded 5 mSv (500 mrem), or is within 0.5 mSv (50 mrem) of this dose, by the time the woman declares the pregnancy to a licensee or registrant, a licensee or registrant shall be deemed to be in compliance with par. (a), if the additional dose equivalent to the embryo or fetus does not exceed 0.5 mSv (50 mrem) during the remainder of the pregnancy.

SAMPLE Pregnancy Policy Declaration

I, _____ (print name) have read the above definition of a “Declared Pregnant Worker” and associated DHS 157 code regulations concerning the dose to an embryo or fetus and understand them. By declaring my pregnancy in writing, I understand I have reduced my maximum permissible deep-dose equivalent exposure to 5 mSv (500 mrem) during the entire pregnancy. With this understanding I am voluntarily informing _____ (name of employer, supervisor or RSO) that I meet the above definition of a “Declared Pregnant Worker” and request that a fetal dosimeter be issued to me. I estimate the date of conception to be _____ (month) _____ (year).

_____ (SIGNATURE) _____ (Date Signed)

APPENDIX F: Analog Film Processing Quality Control Instructions

USING A MEDICAL STEP WEDGE

1. When chemistry in the processor is new, produce a radiograph of the step-wedge. Use the directions from the manufacturer. You want an image that will demonstrate all steps if possible.
2. Use identical control settings on your x-ray unit, along with the same type of film, distance, etc., to make the radiograph of the step wedge. A typical technique would be 5 mAs, 70 kVp at 40" SID. Once the correct exposure settings are determined, be certain to use the same mA, time, (mAs), kVp and distance for all future tests. Also, follow the manufacturer guidelines for a warmup period for the processor to be sure the developer temperature is consistent. In the absence of these guidelines allow for a 20-minute warmup.
3. Date and keep this as your "Master" film for the current batch of chemistry. Select a middle step on the film as your control step.
4. On the next day that you're going to develop patient films, you are to perform the step wedge QC test again—BEFORE YOU DEVELOP PATIENTS' FILMS.
5. Compare the control step of the new test film to the control step of the master.
6. You are to repeat this test each DAY that you are going to develop patients' films.
7. Over time you may begin to see your test films vary in density. The control step may have the same density as a step above or below (lighter or darker) than that of the master. One step either way is allowable. If the test step is off by more than one step, above or below when compared to the master image, then a source of the problem needs to be identified. The first possible solution is to replace the chemistry. DO NOT GO BACK AND ADJUST THE TECHNIQUE FACTORS TO CREATE A PASSING TEST FILM.
8. After you've adjusted or replaced the chemicals, expose a step wedge and develop the film to see if the processor is back within standards. If the test film matches the steps of the master film, you can process the patient's films. If, after adding/adjusting chemicals, the processor is still not developing films properly, change the chemical or call your service vender for guidance. DO NOT PROCESS PATIENTS' FILMS IF THE TEST FILM DOES NOT SHOW THE PROCESSOR IS WITHIN TEST STANDARDS.
9. Keep in mind that when you replace your chemistry you will need to make a new master film.

For recordkeeping purposes:

1. Graph the results of your QC tests. This will allow you to see how your processor is doing over time.
2. Sample graphs and crossover and re-averaging charts and instructions are attached.
3. Keep the most recent month's films and all graphs on file to demonstrate that the test is being done. These will be reviewed when your site is inspected.

APPENDIX F Continued

ANALOG FILM PROCESSING QUALITY CONTROL INSTRUCTIONS

SENSITOMETER/DENSITOMETER METHOD

A sensitometer is a device designed to expose one or both surfaces of the film to pre-set light source, imprinting an image of graduated density steps on the film.

A densitometer is a device designed to measure the density of the steps created by the sensitometer on the processed film.

By charting the density of specific steps, the operator can determine whether the processor has changed since the last test. If the processor has changed by more than an acceptable amount, usually by one step on a 21-step sensitometer or 0.15 density, then a determination of the cause of the change needs to be made before patient films can be processed. A processor must be within control specifications established before patient films are processed.

Establishing a control baseline is critical to proper testing. The following steps can be used to establish your baseline charts:

Tools Needed

1. Thermometer—Should be a **non**-mercury thermometer, either electronic or dial type capable of determining temperature of the developer within 0.5 degree F. A common fever thermometer can be obtained at any variety store and will be accurate as long as the recommended temperature of the developer is over 90 degrees. These have sufficient range and accuracy to be used for testing the processor developer temperature. Thermometers built into the processor are not always accurate or consistent. It is important to verify the actual temperature and make adjustments accordingly.
2. Sensitometer—A simulated light source that is capable of exposing the film using either blue or green light. Be sure you utilize the proper light setting for testing that is compatible with your film type.
3. Densitometer—Used to measure the density steps on the processed film.
4. Quality Control Film—A box of film used exclusively for quality control. It must be the same type of film used for your patient exams. If you primarily use 14 x 17 film, the QC film may be 8 x 10 so long as it is the same type of film. Also, film is blue sensitive or green sensitive depending on the type of screens you use in your cassettes. You must use film that is compatible with your screens for proper exposure. Your x-ray supplier can advise you on the film screen combination you are currently using.
5. Processor Quality Control Charts—Useful tools for graphically plotting QC values and determining trends or values that are out of the control aims. Charts generally come with QC kits and a sample chart is attached to this packet.

Sensitometer Steps

1. Set the blue/green switch to the type of film you are using. If you do not know whether your film is blue or green sensitive, check with your film vendor. In the darkroom with the lights off, insert the long edge of the film into the slot of the sensitometer. The "Clam Shell" style sensitometer is

activated when it is closed and the lid is pushed down, others have a button to push. Hold either until the tone stops.

2. **Follow the manufacturer guidelines for a warmup period for the processor to be sure the developer temperature is consistent. In the absence of these guidelines, allow for a 20-minute warmup.** To establish your initial chart numbers, run five films and average the numbers to obtain your initial values according to the instructions below. Once the initial values are established, expose and process one film per day. It is important to expose the film on the same side each time, run it on the same side of the processor and when possible run it at the same time of the day. Also listen to the tone of the sensitometer when the film is exposed. The blue and green settings have a different tone. Exposing the film using the wrong blue or green setting will result in measured values that are too high or too low. This is the first thing to check if your numbers are off.

Densitometer Steps

1. When the initial five films come out of the processor, measure the density steps as follows:
 - a. Measure the density steps numbered eight to 14 on each of the exposed strips. Record the values and average the numbers for each density step.
 - b. Determine which step will be used for the speed or Mid Density (MD) value by selecting the step that is closest to a density value of 1.20 but NOT less than 1.10. This can be over 1.20. Write this value on the chart at the center line and plot the point under the first day. This is your operating baseline or aim point. Also write down the step number used for reference.
 - c. Next, select the density steps that will be used to determine the contrast or density difference (DD) value. First select the density step with a value closest to, but not less than 0.45. Then select the density step closest to 2.20. This value can be slightly higher than 2.20. Subtract the lower number from the higher value to determine the DD. Write this value on the chart at the center line and plot the point under the first day. This is your operating baseline or aim point. Also write down the step number used for reference.
 - d. Establish the base plus fog value by measuring step one and average this value. Write this value on the chart at the center line and plot the point under the first day. This is your operating baseline or aim point. Also write down the step number used for reference. **IF this value exceeds 0.23, you may have a darkroom fog problem or improper safe lights.**
 - e. Establish control limits for speed (MD), contrast (DD), and base plus fog. For MD and DD values, the range should be +/- 0.20 and base plus fog should not increase by more than 0.03.
 - f. Measured developer temperature can also be plotted on the attached chart.
2. Continued charting requirements are as follows:
 - a. **Each daily test film must be measured, plotted, and within an acceptable range before any patient films are processed. State inspectors will request to review these records at an inspection.**
 - b. There are two factors to watch when plotting the MD and DD values. It is important to watch for high or low trends that seem to be leading to the 0.20 limit. **YOUR PROCESSOR IS OUT OF CONTROL LIMITS IF ANY VALUE IS +/- 0.20 OR GREATER. DO NOT PROCESS PATIENT FILMS UNTIL THE REASON IS DETERMINED AND QC TESTING IS BROUGHT BACK INTO AN ACCEPTABLE RANGE.** The most common solution is adding fresh chemistry; however, service may be required to adjust developer temperature or replenishment rates if your patient volumes have changed significantly.

- c. The base plus fog cannot go higher than 0.03 above the aim point. Again, this usually means there is a darkroom fog problem or safelight.
- d. QC films need to be done every day before patient films are processed or at least once a week even if no patient films are taken. The only exceptions are podiatry practices, which are required to test only once a week and if an office is actually closed for a week or more, a note should be written on the chart explaining the gap.

Processor Maintenance Tips

Always follow manufacturer and/or service supplier recommendations for upkeep and maintenance of your processor. In the absence of the recommendations, here are a few tips to follow:

1. The chemistry should be drained about every four weeks. At that time the racks and tanks should be cleaned.
2. Fresh chemistry should be added. Some processors require developer starter. BE VERY CAREFUL refilling the chemicals as fixer spilled into the developer will ruin (contaminate) the developer.
3. Fresh replenisher should be mixed as needed. The replenishment tanks should NEVER be allowed to run dry.
4. Chemistry filters in the processor must be changed according to the manufacturers' schedule.
5. It is often recommended that the lid of the processor be opened or removed at night. Check with your service vendor or operators manual to see if this is recommended.

APPENDIX F Continued

ANALOG FILM PROCESSING QUALITY CONTROL INSTRUCTIONS

PROCESSING WITH HAND/DIP TANKS

Offices using hand-processing techniques are not required to test the developer activity but it is strongly suggested. Monitoring of the developer temperature with a **non**-mercury thermometer is required.

Steps for QC of hand/dip tanks are as follows:

1. Tools needed, if performed, are a step wedge, thermometer, and a timer.
2. Hand-processing chemistry should be changed at least every three months. The developer should never turn green or smell like ammonia. If this occurs, it should be changed immediately.
3. You must have a thermometer to measure the developer temperature and process the film according to a time/temperature chart. Increasing the x-ray exposure factors in order to shorten the development time SHALL NOT be done. This is a violation of the ALARA principle described earlier in this document.
4. A timer must be used to accurately process the film according to the time/temperature chart. "Sight" development is not permitted. This leads to inconsistency and higher repeat patient exposures.
5. While it is difficult to obtain consistent step wedge QC films using hand processing, it is possible. The QC film needs to be exposed and processed precisely each time, with care and attention to the developer temperature. The test results will differ greatly from automatic processor results and may not reflect the actual condition of the developer.

APPENDIX F Continued

ANALOG FILM PROCESSING QUALITY CONTROL INSTRUCTIONS

Hand Film Processing Time and Temperature Chart

The temperature of each solution shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature specified by the film manufacturer or, in the absence of such recommendations utilize the following time-temperature chart:

Developer Temp Degree C	Time/Minutes	Developer Temp Degree F
26.7	2	80
26.1	2	79
25.6	2 ½	78
25.0	2 ½	77
24.4	3	76
23.9	3	75
23.3	3 ½	74
22.8	3 ½	73
22.2	4	72
21.7	4	71
21.1	4 ½	70
20.6	4 ½	69
20.0	5	68
19.4	5 ½	67
18.9	5 ½	66
18.3	6	65
17.8	6 ½	64
17.2	7	63
16.7	8	62
16.1	8 ½	61
15.6	9 ½	60

The non-mercury thermometer shall indicate the actual temperature of the developer to within +/- 0.5°F.

The timer shall signal the passage of a pre-set time as short as two minutes.

Film should be rinsed between developer and fixer.

Immersion time in the fixer is usually twice the developer time.

A minimum of 15 minutes in flowing water is required for proper washing.

APPENDIX G: Darkroom Fog Test Instructions and Log

DARKROOM FOG TEST INSTRUCTIONS AND LOG

It is recommended that a darkroom fog test be performed every six months AND anytime base plus fog on your QC test increases over 0.03. It should also be done if the safelight filter or bulb is changed. Please use the following steps:

1. Cut a piece of cardboard from inside your film box in half. This is your test tool and should be kept for future use.
2. Sensitize a piece of x-ray film using the following steps:
 - a. Place a cassette (the smallest size you use works best) in the bucky.
 - b. Find and keep for future use a test object with a uniform density (a piece of 1" Plexiglas, a jar lid, a paperback book, etc.).
 - c. Place this object in the center of your image and expose using a technique of 2 to 5 mAs and 60 kVp.
3. In the darkroom, with the safelight on, take the sensitized film out of the cassette and place it within the cardboard test tool. Half the film should be covered, the other half exposed to the safelight.
4. Place something, even your hand, on the cardboard side so light cannot leak under the cardboard edge.
5. After two minutes process the film as usual.
6. If your facility has a densitometer and there is a significant line between the two sides, measure both sides. If the difference is greater than 0.05, the darkroom fog is out of limits and the source needs to be identified and fixed.
7. If you do not have a densitometer and see a significant visible line, there is concern for darkroom fog and a source should be identified and fixed.
8. Possible sources of darkroom fog include, but are not limited to, cracked safelight filter, bulb wattage in the safelight is too great (usually 15 watt or less is recommended), loose or shifted ceiling panels, light leak around the door jamb (especially the floor space), and fogging of your unexposed film by accidental exposure to room light.

APPENDIX H: Image Processing SAMPLE

IMAGE PROCESSING

Analog Film Processor Quality Control Testing and Records

Automatic processing control tests shall be performed and analyzed on days when patient films are being processed and prior to the processing of the first films of the day. It is recommended that the automatic processor be tested at least once a week even if films are not processed that week.

1. Quality Control (QC) of the processing system is an often overlooked area of radiography, yet it is the most critical to consistent, quality images. Processor testing procedures are found in Appendix F, Film Processor Testing Procedures.
2. Regardless of the test tool utilized (Step wedge or Sensitometer/Densitometer), for processor QC testing, the written documentation must be retained until the next state inspection is completed. If patient films are processed four days a week or greater the proper QC test method is with a Sensitometer/Densitometer. For a facility that processes patient films three days a week or less than QC with a step wedge is sufficient.
3. State inspectors will check to see if the processor QC is being performed by verifying current and historical records. They will check for current master or control films. All others can be discarded once documented.

Proper Care and Storage of Film and Intensifying Screens

1. Intensifying screens in the cassettes and the type of film must be compatible. Never use green sensitive film with blue light emitting screens or vice versa. Check with your film supplier if you are uncertain.
2. Intensifying screens should be changed in the cassettes at least every five years and cassettes should be replaced if they become damaged, exhibit artifacts, have light leaks, or become warped. Screens age and lose their light-emitting ability, which may require higher radiation exposures.
3. Intensifying screens in the cassettes must be cleaned with a special screen cleaner at least once a month or when dust artifacts are noted on the films, whichever is shorter. Follow the cleaner manufacturer's instructions for cleaning. Never use alcohol-based cleaners. Never put film into wet cassettes. This will ruin the screens.
4. Unexposed film should be stored according to the manufacturer recommendations.

Cassette, Film and Chemistry Storage and Conditions

1. Unexposed cassettes/films are stored <Describe location and procedures for storage>.
2. Unexposed film should be stored according to the manufacturer recommendations. This is usually in a temperature and humidity-controlled location. Unexposed cassettes/films stored adjacent to the x-ray room must be protected with at least 1/16" lead or equivalent. This may be a lead-lined image receptor bin, box, or cupboard.
3. Film shall be developed by the time and temperature recommended by the manufacturer. These specifications are posted in/at <Specify location>. This is usually near the processor in the darkroom. Ideally films should be developed within 24 hours of exposure. It is also important to do the following:
 - a. Check the developer temperature at the beginning of the workday using a thermometer that does **NOT** contain mercury.

- b. Manual processing system temperature should be checked throughout the workday.
 - c. In the absence of manufacturer's recommendations for automatic processors, run two clean unexposed films through the processor at the beginning of the workday or if the processor has been sitting idle for four or more hours.
4. Expiration dates on film and chemicals should be checked periodically. New film or chemicals should be rotated so the oldest are used first. Do not use film or chemicals after the expiration date. Pre-mixed developer has a limited shelf life (usually 30 days) and supplies must be used or discarded appropriately. Follow the processor manufacturer instructions for daily, weekly, and monthly cleaning procedures.
 5. Chemicals will be replaced by <Specify responsible person> according to the manufacturer's or chemical supplier's recommended interval, which is <Specify frequency>. This should be done monthly at a minimum

Darkroom and Safelight Conditions

1. The darkroom needs to be light tight and properly ventilated. Ventilation is especially important if the control panel is located in the darkroom. Corrosive fumes can destroy the electronics in the control panel unless the fumes are vented out of the building.
2. Dust should be controlled in the darkroom. Ceiling panels in suspended ceilings can move up and down when the door is opened and closed, releasing dust into the darkroom. Daily cleaning of all surfaces in the darkroom is recommended.
3. It is recommended that fog tests of the dark room be conducted every six months and/or when the filter, bulb, or other configuration changes in the dark room to be certain the room is light tight and not causing fog on the images. Refer to **Appendix G**.
4. The safe light(s) in the film processing/loading area is/are provided under these conditions and should not be changed without authorization from the RSO.
 - a. Safe light filter type: _____ (GBX recommended for blue or green sensitive image receptor)
 - b. Bulb wattage: _____ (15 watts or less is recommended to prevent damage to the filter)
 - c. Distance from work surfaces: _____ (inches)
 - d. For any changes with the safelight, a dark room fog test is recommended.
5. If you see light leaks around doors, ceilings, or other openings in the darkroom, notify the RSO to have these light-leaks blocked.

Alternative Processing Systems

Users of daylight processing systems, laser processors, self-processing (Polaroid) film units, or other alternative processing systems shall develop procedures following manufacturer's recommendations for image/film processing and machine maintenance.