

**REGULATORY GUIDE B3**  
**COMPLYING WITH TITLE B - DENTAL FACILITIES**



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## **REGULATORY GUIDE B3 COMPLYING WITH TITLE B – DENTAL FACILITIES**

Each dental facility that is registered with the Department is required to comply with Title B, which are the regulations concerning x-ray equipment. This guide is intended to assist the dental facility in complying with Regulation 61-64, X-Rays (Title B).

### **FACILITY REGISTRATION APPROVAL** (See RHB 2.4)

Prior to installing an x-ray machine, a facility must apply to the Department for a Facility Registration Approval (FRA). The facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3. To receive a Facility Registration Approval, complete and return the FRA request form DHEC 0845 along with the application fee, including the following information:

- 1) Facility Name, Location Address, and Mailing Address
- 2) The name of the Radiation Safety Officer (RSO) who is responsible for radiation protection and the individual's qualifications to serve in this capacity
- 3) Manufacturer, model #, and type and make of x-ray equipment to be installed. For example:
  - i. Siemens Polydoros 80 Rad/Fluoro unit
  - ii. Belmont Model 071 Dental unit
- 4) The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved, then provide the information for all companies.
- 5) Operating policies and procedures. See below under "Operating Procedures"
- 6) A shielding plan, if required. Shielding review fees must accompany the shielding plan. (Cephalometric units, and Pan/Ceph combos, TMJ units, and Dental CT units) (See RHB 2.3.2)
- 7) There is a \$62.50 non-refundable fee required for registration of new facilities.
- 8) The application fee must be submitted with the facility registration approval request. The \$62.50 should be sent in the form of a check or money order made out to SCDHEC.
- 9) After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

### **SHIELDING PLANS** (See RHB 4.4)

Before construction, a facility is required to submit a radiation shielding plan to the Department for review and acceptance for cephalometric, combination panoramic/cephalometric, TMJ, and Dental CT units. The shielding plan must be reviewed by a Class III or a Class IV vendor. See Regulatory Guide B6 for assistance. The shielding plan review fee must be submitted along with the shielding plan. Intraoral dental units usually do not require shielding plans unless installed in a modular layout. Modular dental units commonly do not have complete barriers or walls between adjacent x-ray areas, and therefore, require a shielding plan and may require an area survey. In addition each control shall provide an audible or visible signal of exposure.

### **REGISTERING EQUIPMENT** (See RHB 2.5)

All x-ray equipment is required to be registered with the Department within thirty (30) days of acquisition. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect the x-ray facility or x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved operating procedures. In addition, upon registration of equipment (a control), the Department shall issue the facility a registration sticker to be placed on each control. The registration stickers shall be placed on the control panel in a clearly visible location.

### **REQUIREMENTS FOR OPERATING PROCEDURES** (See RHB 4.2.3)

All facilities are required to have written operating procedures available to all x-ray operators. Each registrant shall maintain documentation indicating that each operator has read and agrees to adhere to the operating procedures and shows competency in operating the x-ray equipment. Generic procedures obtained from vendors shall be modified to reflect the actual practices of the facility. The procedures must include the following items, as a minimum:

- 1) **Policies and Procedures for Patient Holding.** The procedures must state whether or not, as a matter of policy, patients and/or films will be held at that facility. Whenever possible, an adult accompanying the patient should be used for holding. Pregnant females should not be used to hold a patient. Methods for protecting the human holder, such as wearing lead aprons and gloves, may be included. If a facility is required to routinely hold patients and/or films, then procedures to ensure that no one person is used routinely to hold patients must be included. If an employee may be required to hold patients or films more than three times a quarter, then the procedures must also address personnel monitoring of human holders.

Neither the dentist nor his assistant shall hold patients or films during the exposure, nor shall any individual be regularly used for this service.

- 2) **Policies and Procedures for Pregnant Workers.** Procedures to be followed when a worker declares her pregnancy should be included, as well as methods of informing workers of the total exposure received during gestation. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.
- 3) **Policies and Procedures Regarding the Use of Gonadal Shielding.** The proper use and placement of gonadal shielding must be addressed. If such shielding interferes with individual projections, then those projections should be specified.

The lead aprons and gloves must be checked annually for cracks and holes that could compromise the radiation protection they provide. Documentation of this testing shall be kept for two years or until the next Department inspection.

- 4) **Policies and Procedures for Pregnant Patients.** The procedures should include methods for determining possible patient pregnancy. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate measures are taken. X-ray techniques for minimizing fetal exposure should be included. Methods of determining fetal exposure and procedures to follow for advising the woman and her practitioner of the exposure received by the fetus may also be included.

- 5) **Policies and Procedures for Personnel Monitoring.** See "Personnel Monitoring." The operating procedures must state whether or not personnel monitoring devices will be used at the facility. The procedures may tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges may be stated. The location of control badges may be given. The policies for reporting and investigating over-exposures should be stated. A prohibition against intentionally exposing any control or personnel badge should be included. Procedures may also be included instructing workers on how they may obtain the results from the monitoring.
- 6) **Procedures for Training New Employees.** See "Training."
- 7) **Methods for Quality Assurance.** The procedures must state the methods that the facility will use to assure that they are producing quality radiographs. This may vary widely from facility to facility. At a minimum, two items must be addressed in the quality assurance plan. These are (a) standards for the proper performance of the x-ray system and (b) standards for processing. See "Quality Assurance."

### **PERSONNEL MONITORING** (See RHB 3.12)

Personnel monitoring is required in the following situations:

- 1) When an employee is likely to receive greater than 10% of their occupational dose limit for one year (Reference RHB 3.4, RHB 3.7, and RHB 3.8)
- 2) When an employee may be required to hold patients or films more than three times in a quarter
- 3) When an individual enters a high radiation area
- 4) All operators of mobile or portable x-ray equipment
- 5) Declared pregnant workers who request an additional badge for monitoring doses underneath lead aprons
- 6) When the Department deems it necessary.

The Department recommends instituting a personnel monitoring system for a period of at least one year to ensure that all individuals entering a restricted area do not receive a dose which would require personnel monitoring. If procedures require an individual's extremities to be in or near the primary beam, then ring badges should also be used. After monitoring for a year, if the doses received are well below 10 percent of the allowable exposure limits, the monitoring may be discontinued. The monitoring should be reinstated if new procedures are added, if the x-ray workload increases, if new employees are given x-ray duties, or after any changes that may affect the doses received. The records from monitoring must be retained indefinitely or until this Department authorizes their disposal, even if the service is discontinued.

When a protective lead apron is worn by the operator, and a personnel monitoring device is used, the monitoring device must be worn at the collar outside of the apron. The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the

National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is required to be monitored. Prior Departmental approval is required for any changes to the dose of permanent record. Calculated doses from lost or damaged badges are excluded from this requirement. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm.

### **PRIOR OCCUPATIONAL EXPOSURE** (See RHB 3.20)

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current calendar quarter or states the nature and amount of any prior occupational dose during the current calendar quarter. For the purpose of this statement, the current calendar quarter is interpreted to mean the most recently available calendar quarter. The registrant must maintain these written statements until the Department authorizes their disposal.

### **OCCUPATIONAL EXPOSURE AT MULTIPLE FACILITIES** (See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

### **TRAINING PLANS** (See RHB 4.2.2)

Each dental facility is required by RHB 4.2.2.8 to ensure that all x-ray operators meet the requirements of the South Carolina Dental Practice Act. Regulation 39-16 Dental Radiography states, "On or after July 1, 1985, all personnel in a dental office who place and expose radiographic films shall have successfully completed a structured course of training in radiation safety." Employees who are certified Dental Assistants, registered Dental Hygienist or are certified by the South Carolina Board of Dentistry or the Dental Assisting National Board are considered to meet the basic training requirements. Other structured courses of training include, but are not limited to, x-ray certification through the South Carolina Dental Association, radiation safety training through Landauer and radiation safety training through a technical school. Valid certificates must be available documenting this structured training.

Each operator, including physicians, is also required to receive training specific to the equipment and procedures in use at the facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 4.2.3. This training must be documented for each operator and maintained at the facility. For new employees, this training must begin within 30 days after employment.

The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

## QUALITY ASSURANCE (See RHB 4.2.16)

As stated above, the two items that should be addressed in a quality assurance plan are (1) standards for equipment performance tests (initial and periodic calibrations), (2) standards for processing, and (3) Cassette care if applicable. The following items should be contained in the quality assurance plan, as appropriate:

- 1) A list of the parameters to be monitored, the frequency of monitoring and the limits that require corrective action to be taken
- 2) A description of the procedures to be used for monitoring each parameter
- 3) Procedures to be followed to call problems to the attention of those responsible for correcting them
- 4) A list of the records, along with sample forms, that the facility is using; Notations should be made concerning the length of time that each type of record is kept before discarding.
- 5) Results of acceptance testing of new equipment.

The following items should be checked, at a minimum, for the Department to consider the quality assurance program acceptable. These items are not inclusive of all items that could be addressed in a quality assurance program. Quality assurance programs vary widely from facility to facility, and it is each registrant's responsibility to evaluate the performance of their x-ray imaging systems and tailor their quality assurance plan accordingly. Employees of the facility may or may not be the individuals carrying out the quality assurance monitoring listed below. In most facilities, the quality assurance testing will probably be performed by a combination of the facility and an x-ray vendor. A facility that chooses to have a x-ray vendor perform some or all of the quality assurance monitoring must use a vendor that is registered with DHEC to provide those services. A list of registered vendors is available at our website.

- 1) **Standards for Equipment performance tests in accordance with RHB 4.2.16.1.3.1.** Written standards must be established for the proper performance of each x-ray imaging system under the registrant's control. Routine testing must be carried out every two (2) years, at a minimum, to ensure accordance with the standards. Some x-ray units, because of their high workload, may require testing more frequently.

The following items, as appropriate, should be included in the x-ray system standards for intraoral dental equipment. Items marked with an asterisk (\*) indicate that this item may be tested by the vendor or the facility.

- Half-value layer (HVL)
- Exposure reproducibility
- mA/mAs linearity
- kVp accuracy
- Timer reproducibility and accuracy
- Visual and audible indication of exposure
- Patient exposure at skin entrance (bitewing and/or periapicals)
- Mechanical support of tubehead
- Integrity of passthrough interlocks
- Integrity of lead aprons, gloves, and other protective clothing \*

These items should be checked upon initial installation and after any maintenance or repair that could affect their status: Adherence to the approved shielding plan, if applicable; minimum source to skin

distance; x-ray beam size; and proper indication of multiple tubes on units so equipped.

The following items, as appropriate, should be included in the x-ray system standards for panoramic dental equipment. Items marked with an asterisk (\*) indicate that this item may be tested by the vendor or the facility.

- Half-value layer (HVL)
- Visual and audible indication of exposure
- Mechanical support of tubehead
- Numerical data
- Integrity of lead aprons, gloves, and other protective clothing \*

**NOTE:** Facilities using cephalometric and/or dental CT units should refer to Regulatory Guide B2 for assistance in setting standards for performance of the x-ray equipment. Ceph units are considered medical units by the Department and are subject to the requirements for medical units. “Cone” or Dental CT units are considered computed tomography units by the Department and are subject to the requirements for CT units. Therefore cephalometric, dental CT and panoramic/cephalometric combo units must be tested in accordance with the guidelines set forth for medical or computed tomography units.

- 2) **Standards for Processing.** The following items should be checked as components of the final diagnostic image obtained. Again, these items are not all inclusive, and should be tailored to meet the individual facility conditions.
- a) Processor quality assurance. The quality assurance plan should address the care, maintenance, and cleaning of the processor.
  - b) Evaluation of darkroom and film. Darkrooms must be light tight to the dark adapted eye. Daylight film boxes must also be light tight. Record of cassette and screen cleaning for Pan and cephalometric units.
  - c) The evaluation of cassettes should be done by assigning each cassette its own number and defining the frequency upon which it is inspected and cleaned, as well as what criteria indicates that the cassette should be replaced.

For new facilities, the quality assurance plan will be reviewed by the Department before registration of the x-ray equipment. For existing facilities, the quality assurance plan will be reviewed at the first inspection after the effective date of the regulations. For all facilities, records of quality assurance testing and monitoring will be reviewed on each inspection conducted. Facilities must maintain records for all testing and checks performed.

### **PASS THROUGHHS** (See RHB 4.5.11.3)

Each unit that is installed so that it may be shared between rooms shall be installed so that its pass throughs are securely interlocked in a functional, permanent manner. In other words, if the tube is being used in one room, a means must be available to keep the unit from operating if the door in the cabinet to the other room is open.

### **MANUAL FILM PROCESSING** (See RHB 4.2.17.1)

When a facility performs manual film processing, the following items are required to be used by the facility:

- 1) Processing tanks that are mechanically rigid and corrosion resistant.
- 2) A dedicated darkroom thermometer to measure developer temperature. Developer temperature must be within 60°F and 80° F (16° C to 27° C).
- 3) A dedicated darkroom timer to set film processing time.
- 4) Documentation to show when the film processing chemicals are changed.
- 5) If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.
- 6) A time-temperature developing chart.

### **SIGHT DEVELOPING OF RADIOGRAPHS IS NOT ACCEPTABLE FOR PROCESSING FILMS.**

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

### **AUTOMATIC FILM PROCESSING** (See RHB 4.2.17.2)

When a facility uses an automatic processor or other closed processing system, the following items are required:

- 1) Processing chemical temperatures consistent with the type of film(s) being processed
- 2) Appropriate film processing chemicals and replenishment rates
- 3) If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.
- 4) Film immersion times consistent with the developer temperature

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

### **X-RAY FILM PROCESSING** (See RHB 4.2.17)

Film storage boxes in x-ray rooms must be "light-tight" and incorporate adequate shielding to prevent fogging of undeveloped film from stray radiation. Film must be stored in a cool, dry place protected from stray radiation. Film in open packages must be stored in a light tight container. Film should not be stored where it can be exposed to chemical fumes or radiation. Film that is expired or outdated shall not be used, unless it has been properly stored, and passes a sensitometric test for base + fog, and speed.

Film developing solutions should be properly stored; they should never be allowed to freeze. They must be prepared according to the directions given by the manufacturer, and maintained in strength by replenishment or renewal.

### **NON FILM BASED IMAGING SYSTEMS**

Users of digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital system.

The manufacturer's current operating manual shall be available for Department review.

### **ADMINISTRATIVE REQUIREMENTS** (See RHB 4.6.1.1 and RHB 3.15 and RHB 3.16 and RHB 4.2.6.4)

The following items are required to be posted or present at x-ray facilities:

- 1) Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign. Only rooms containing cephalometric or dental ct units are considered to be radiation areas.
- 2) Technique charts. A technique chart must be posted at each control panel, which states the patient's body part and anatomical size versus technique factors (kVp, mA, and time) to be used. For dental units that have a set kV and mA, the technique chart needs to state the time of exposure that will be used. Some dental units are considered to have a built-in technique chart that selects the mAs when a tooth is selected.
- 3) A sign must be posted in a conspicuous area that notifies patients to inform the technologist if they are pregnant or might be pregnant.
- 4) The x-ray control must have a label on it which states "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed." This label shall be legible and in clear view.
- 5) A "Notice to Employees" must be posted in an area where it can be reviewed by all employees. A copy of this form is available on the DHEC website.

### **MISADMINISTRATIONS** (See RHB 1.11)

Misadministration, in a dental office, means the administration of (1) radiation to the wrong patient or (2) performance of a diagnostic or therapeutic procedure other than that ordered by a prescribing physician. Situations that would not constitute misadministration would include, for example, incorrect ordering of an exam, such as ordering a periapical x-ray when a bitewing x-ray was desired. Another example that is not misadministration would be if, after review of films from an exam, a dentist decides that additional views are necessary to adequately image the area of interest. Repeat films performed due to patient motion, processing errors or problems, incorrect patient positioning, or improper radiographic technique selection are not considered misadministrations.

Each registrant must retain records of misadministrations. The record must contain the name of all individuals involved in the misadministration, the patient's social security number or identification number, a brief description of the event, and the action taken, if any, to prevent recurrence. The records of misadministration must be maintained for three years for diagnostic misadministrations.

The action that a registrant must take in response to a misadministration depends on the type of misadministration that occurs. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for Department review, and maintain the records for three years.

### **OVEREXPOSURES** (See RHB 3.24 and RHB 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposures depends on the exposure that an individual receives. Immediate, 24 hour, and/or thirty day written notification may be required. See RHB 3.24 concerning radiation levels and the requirements for reporting.

### **RECORDS**

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation, and major components (RHB 1.10.1)
- Records showing model and serial numbers of all tubes, controls, and beam limiting devices (RHB 1.10.2.1)
- Records of surveys, equipment performance test (to include corrective action), maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services (RHB 1.10.2.4)
- Copies of all correspondence with the Department (RHB 1.10.2.5)
- Records of misadministrations (RHB 1.11.3)
- Records of prior occupational dose for employees (RHB 3.20)
- Records of personnel monitoring results (RHB 3.22)
- Records of employee training to include operator certification (RHB 4.2.2.7)
- A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room. (RHB 4.4.6) (For cephalometric and dental ct units only.)
- Any other records of routine checks or testing that are required to be carried out.

## **INSPECTIONS**

The Department conducts routine periodic inspections of x-ray facilities. Most dental facilities are on a four year inspection frequency schedule. The Department will also conduct inspections if a complaint is received or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. Generally, an inspection requires use of a dental x-ray unit for about thirty minutes per tube. **The Department does have the right to make unannounced inspections.**

The inspection consists of checking/verifying the operation of the x-ray equipment and reviewing records as outlined in the attached checklist. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. At the conclusion of the inspection, the inspector will conduct an exit interview to discuss items of non-compliance.

The inspector may leave an inspection report at the conclusion of the inspection or send a written report to the facility within approximately two weeks of the inspection. Any violations and/or recommendations will be included in this report. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate the corrective action that will be taken to correct any violations. The Department will respond, in writing, to the twenty day notification as needed.

All corrections must be made within sixty (60) days of receipt of the inspection report. The facility must notify the Department, in writing, by this date that corrections have been made. Corrective action must be described for

each violation. The facility has the option of accepting Departmental recommendations. Each violation and recommendation must be addressed individually. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state so in their response. After the Department has received the sixty day notification and accepted the corrective action, a Completed Corrective Action letter will be sent to the facility.

## **QUESTIONS**

If you have questions, please feel free to call or write:

SC Department of Health and Environmental Control  
Bureau of Radiological Health  
2600 Bull Street  
Columbia, SC 29201  
(803) 545-4400  
FAX (803) 545-4412

## **REGULATORY GUIDES**

- B1 - Registration of X-ray Facilities and Equipment
- B2 - Complying with Title B - Medical Facilities
- B3 - Complying with Title B - Dental Facilities
- B4 - Complying with Title B - Facilities Utilizing Analytical or Industrial X-ray Equipment
- B5 - Vendor Registration and Responsibilities
- B6 - Shielding Plans
- B7 - Complying with Title B - Mammography
- B8 - Complying with Title B - Bone Densitometers
- B9 - Complying with Title B - Veterinary Facilities
- B10 - Complying with Title B - Hospitals

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## **CHECKLIST FOR DHEC INSPECTION**

**Please have available the following records for the DHEC Inspector:**

- \_\_\_ Records from x-ray performance testing, including equipment performance test and service records
- \_\_\_ Written operating procedures that address (Patient Holding, Pregnant Workers, Pregnant Patients, Gonadal Shielding, Personnel Monitoring, Training Plan, Quality Assurance)
- \_\_\_ Documentation of all x-ray equipment operators to adhere to the Operating Procedures and have Machine Specific training on equipment in the office
- \_\_\_ X-Ray operators must have:
  - A South Carolina Dental Hygiene license or,
  - A diploma from an American Dental Association (ADA) accredited school in Dental Hygiene or Dental Assisting or,
  - A South Carolina State Board of Dentistry Certification or,
  - Certificate from Dental Assisting National Board (DANB) or,
  - Certificate from South Carolina Dental Association (SCDA) or,
  - Certificate documenting completion of a structured course of training in radiation safety
- \_\_\_ Personnel monitoring reports, if applicable
- \_\_\_ Records of previous occupational dose for employees, if applicable
- \_\_\_ Records of occupational dose for employees working at multiple locations, if applicable
- \_\_\_ Records/documentation from processor maintenance and cassette cleaning if applicable

**Please be familiar with, and be prepared to show the DHEC Inspector the following items:**

- \_\_\_ Posted technique charts at each control
- \_\_\_ Posted pregnancy posters
- \_\_\_ Posted radiation area signs, if required
- \_\_\_ Posted "Notice to Employees"
- \_\_\_ A copy of your shielding plan and/or area survey, if applicable