

College of Physicians and Surgeons of Alberta
A Radiation Health Administrative Organization
for the
Delivery of Radiation Health and Safety Services in the
Province of Alberta

Overview

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College of
Physicians
& Surgeons
of Alberta

To serve the public and guide the medical profession

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The College as a Radiation Health Administrative Organization

I. Introduction

In the province of Alberta, all diagnostic and therapeutic x-ray equipment, therapy simulator equipment, cabinet x-ray equipment, Class IIIb and IV lasers, analytical x-ray equipment, and particle accelerators, are governed by the *Radiation Protection Act* and Regulation. Compliance with the *Act* and Regulations is the responsibility of Alberta Jobs, Skills, Training and Labour (formerly Alberta Human Resources and Employment). Effective July 1, 1997, the College of Physicians and Surgeons of Alberta (CPSA) was accredited by Alberta Human Resources and Employment as a Radiation Health Administrative Organization to assume the responsibility of ensuring the safe delivery of radiation health services in the province of Alberta for privately owned medical facilities. Effective December 21, 1999, the CPSA entered into an agreement with the Provincial Health Authorities of Alberta (PHAA), on behalf of the Regional Health Authorities of Alberta (RHA), to provide this service for equipment owned or operated within the Regions and provincial boards. Effective June 2001, at the request of Alberta Human Resources & Employment, the CPSA began acting as the registry for equipment in medical educational institutes (NAIT), podiatry offices and the medical examiners office.

II. Background

In order to focus its primary responsibility to the public, Alberta Jobs, Skills, Training and Labour has moved away from a regulatory role to a facilitator role. The transfer of this responsibility was authorized in the *Radiation Health Administration Regulation* of the *Government Organization Act* allowing professional colleges, associations, and corporations to enter into agreements with the Minister of Jobs, Skills, Training and Labour to administer sections of the *Radiation Protection Act*. These organizations are referred to as **Radiation Health Administrative Organizations** (RHAO).

The College, as an authorized **Radiation Health Administrative Organization**, has been delegated authority for the following:

Radiation Protection Act, Revised Statutes of Alberta 2000, Chapter R-2

- Section 10(2) Issue registration certificates
- Section 10(3) Apply restrictions to certificates
- Section 10(5) Restrict installation, operation, and modification of equipment
- Section 10(7) Registration/re-registration notification requirements
- Section 10(8) Suspension of registration certificates
- Section 10(9) Cancellation of registration certificates
- Section 15(1)(a-d & f) Inspections
- Section 15(3) Remove records
- Section 15(4) Seize samples
- Section 15(5) Apply for restraining order
- Section 16(1) & (3) Remedial action

Radiation Protection Regulation, Alta. Reg. 182/2003`

- Section 10 Require information to assess grounds for issuing registration certificates. Set conditions for obtaining a registration certificate.
- Section 11 Set the term and renewal date of a registration certificate.

Responsibilities of RHAOs include:

- Registering designated radiation equipment
- Administering compliance verification of equipment owners
 - inspections, audits
 - order investigations
- Suspending or canceling registration certificates
- Issuing directives

The *Radiation Health Administration Regulation* also allows companies who provide radiation protection services to enter into agreements with the Minister of Jobs, Skills, Training and Labour to test radiation facilities, radiation equipment, or radiation sources including the review of facility design or shielding for the purpose of verifying compliance. These companies are referred to as **Authorized Radiation Protection Agencies (ARPA)**.

Delegated authority for Agencies includes:

Radiation Protection Act, Revised Statutes of Alberta 2000, Chapter R-2

- Section 15(1) Inspections
- Section 15(1)(e) Conduct tests
- Section 15(4) Seize items and materials

Radiation Protection Regulation, Alta. Reg. 182/2003

- None

Responsibilities of ARPAs include:

- Conducting compliance monitoring activities
 - inspections, audits, etc.
 - investigations
 - tests

III. Process for Registration of Designated Radiation Equipment

All radiation emitting equipment that is designated under the *Radiation Protection Act* and Regulation, must be registered by Alberta Jobs, Skills, Training and Labour or a Radiation Health Administrative Organization authorized by Alberta Jobs, Skills, Training and Labour.

Application for registration must be made for new equipment, relocation of existing equipment, modification to existing equipment, or modification of the protective properties of the facility.

Equipment modifications include, but are not limited to:

- More powerful tube
- New generator

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- Change to safety feature(s) of the unit
- Change in the function of the equipment, e.g. adding a fluoroscopy unit

Facility modifications include, but are not limited to:

- Change in design which alters the walls
- Change in the occupancy factors
- Change in controlled and uncontrolled areas
- Change resulting in a secondary barrier becoming a primary barrier
- Change in location of a unit within the room

The following is the process for registration of equipment through the College of Physicians and Surgeons.

Application for New Equipment – Designated X-ray Equipment

The College will require an application for registration of designated radiation equipment for new equipment.

An application will include:

- a completed application form
- shielding design information for the proposed installation
- owner signature confirming shielding meets requirements

The **College** will:

- receive applications for registration
- review the application for completeness
- acknowledge receipt of the application form and shielding information
- advise the owner to proceed with the installation
- advise the owner that a compliance verification report from an Authorized Radiation Protection Agency (ARPA) is required prior to the issuance of a registration certificate

The **facility** will:

- contact an Authorized Radiation Protection Agency (ARPA) to make arrangements for verification testing to be done on each piece of designated radiation equipment prior to clinical use
- review the Verification Report issued by the ARPA and ensure all deficiencies identified in the report are rectified by the facility and signed-off by the ARPA
- mail a copy of the Verification Report from the ARPA to the College for **each** piece of designated equipment

The **Authorized Radiation Protection Agency** will:

- Complete compliance verification testing and provide a report to the facility as outlined in Section V.

The **College** will:

- review the contents of the compliance verification report for completeness
- contact the facility/Authorized Radiation Protection Agency for clarification if required
- maintain a database for each piece of equipment to be registered

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- issue a Certificate of Registration for each piece of equipment

Applications for New Equipment – Class 3b and Class 4 Lasers

The College will require an application for registration of for new laser equipment.

An application will include:

- a completed application form;
- a compliance verification report.

The **College** will:

- receive applications for registration;
- review the application for completeness;
- review the contents of the compliance verification report for completeness;
- contact the facility/Authorized Radiation Protection Agency for clarification if required;
- maintain a database for each piece of equipment to be registered;
- issue a Certificate of Registration for each piece of equipment

Notification of Change

The College will require a notification of change form whenever a modification to the protective properties of a facility has occurred, or when an existing piece of equipment is modified or relocated.

A Notification of Change will include:

- a completed notification of change form
- a compliance verification report

The **College** will:

- review the notification of change form
- review the compliance verification report contents for completeness
- contact the facility/Authorized Radiation Protection Agency for clarification if required
- update the equipment database and files
- issue a new certificate if appropriate

Certificates of Registration

Certificates of Registration are issued by the College to the owner of the equipment pending:

- Completion of an application form.
- Confirmation via the Compliance Verification Report that the facility and the equipment meet the required standards.

Certificates are issued for each application for equipment and are re-issued every four years.

IV. Process for Confirmation of Equipment Status

Confirmation of the status of equipment is required annually. The registration year is December 1 to November 30.

The **College** will:

- Generate a computer "profile" for each piece of equipment and send to the owner of the equipment. This includes:
 - Owner name and address
 - Facility name and address
 - Equipment type, number, location, manufacturer, model, serial number, and date of manufacture

The **facility** will:

- Verify that the status of equipment is the same. If there have been changes, a "*Notification of Change Form for Designated Radiation Equipment*" must be forwarded to the College.

V. Compliance Verification

In order to ensure designated radiation emitting equipment, personal protective equipment, and the radiation facility comply with the *Radiation Protection Act* and regulations under the Act, compliance verification must be done prior to the equipment being registered.

Compliance verifications are performed by an Authorized Radiation Protection Agency for new equipment, relocation of existing equipment, modification to existing equipment, modification of the protective properties of the facility, as described in Section 10 (5) of the Act, or upon recommendation by the Radiation Health Administrative Organization.

The designated person from the Authorized Radiation Protection Agency completes a Compliance Verification Report for each piece of equipment. If the equipment or facility does not comply, the Authorized Radiation Protection Agency may do a follow-up visit and, pending written confirmation from the facility, must prepare an addendum to the report advising of compliance. Original reports are provided to the owner. Owners subsequently forward a copy of the report to the College with the application for registration of equipment.

Reports must contain the following information:

- Date of compliance verification
- Verification that shielding calculations are adequate
- Installer name, address and phone number
- Facility designer name, address and phone number
- Drawing of facility shielding parameters/content
- Description of parameters verified
- Numeric results of tests completed
- Statement indicating that the equipment and facility comply. Alternatively, recommendations stating what has to be done in order to achieve compliance.
- Signature of the person who completed the verification.

Compliance verification will:

- Ensure that the design, construction, and function of the facility and equipment comply with the *Radiation Protection Act* and Regulation.
- Ensure that worker and public exposures are within the limits specified in the Radiation Protection Regulation.
- Ensure that patients who undergo a particular radiographic procedure receive similar doses regardless of the equipment/operator used.
- Confirm that the principle of ALARA (as low as reasonably achievable) has been utilized within the facility design.
- Verify that the shielding has been calculated and installed correctly.

The owner of the equipment is responsible for making arrangements with an Agency for the verification testing to be done. Compliance Verification checklists are available upon request.. The owner is also responsible for ensuring that shielding is adequate.

VI. Compliance Monitoring

Subsequent to compliance verification testing, the facility will have an internal quality control process in place to monitor compliance and ensure systematic compliance with applicable legislation regarding Radiation Health and Safety Services on an ongoing basis.

The quality control program includes a defined list of tests/measurements that are performed at defined frequencies, as outlined in *the Quality Assurance Section* and *the Radiation Safety section* of the *Imaging Standards & Guidelines*. For facilities accredited by a College program, an in-depth review of documentation to monitor compliance may be done in conjunction with the four year accreditation review.

VII. Investigation of Complaints/Incidents

If it is determined through any source that a condition in a radiation facility, radiation equipment or a radiation source contravenes the *Radiation Protection Act* or poses an unnecessary exposure risk to patients or staff, the College may issue a written directive that:

- Prohibits the use of the radiation facility, radiation equipment or radiation source until it is repaired or altered.
- Requires the owner to take any action that may be prescribed in the directive for remedying the danger/risk.

Upon receipt of a written complaint, the complainant will be acknowledged, the physician involved will receive a copy of the complaint, and an inquiry will begin.

The inquiry may include a review of relevant information and interviews. Independent experts may be asked to provide opinions and advice.

The final findings of the inquiry may advise that there be:

- No further action, although corrective advice or some other remedy may be offered to the physician.
- Referral for possible disciplinary action to the physician.

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At the conclusion of the inquiry, a written opinion will be forwarded to the complainant.

The inquiry may take up to four months to complete, depending on the complexity of the complaint and the evidence.