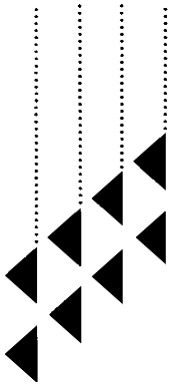
Health Canada Santé Canada

Requirements for the Safe Use of Baggage X-Ray Inspection Systems

Safety Code 29



Canada

Requirements for the Safe Use of Baggage X-Ray Inspection Systems

Safety Code 29*

Environmental Health Directorate
Health Protection Branch

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Foreword

A baggage x-ray inspection system is a machine that is specifically designed to generate x-rays in the low-to-medium keV energy region for use in security screening operations. This Safety Code provides requirements and guidance necessary to ensure that the radiation risks associated with baggage x-ray systems remain negligibly low (i.e., the same as the risks from unavoidable, natural background radiation levels). This approach is in accordance with the 1990 International Commission on Radiological Protection (ICRP) objectives[1] to prevent the occurrence of deterministic effects (those for which the severity of a biological effect increases with dose and for which a threshold may occur) and to reduce the incidence of stochastic (random) biological effects to acceptable levels.

This Safety Code is prepared under authority of Treasury Board Standards[2], is referenced in Canada Labour Code Part II[3], and is directed to personnel in facilities under federal jurisdiction. This publication is aimed at four target groups:

system owners (or administrators);
system operators;
maintenance personnel; and
radiation safety personnel (analysts and inspectors as defined in the RED Act).

This publication is intended to reduce and possibly eliminate any adverse biological health effects of radiation exposure that may arise from baggage x-ray inspection systems. This Safety Code outlines specific responsibilities for the system owner, operator and maintenance personnel, and provides information on safe guidelines and procedures. This publication supersedes Safety Code 21 "Recommended safety procedures for the selection, installation and use of baggage inspection x-ray equipment"[4].

This document may be adopted for use elsewhere. Facilities under provincial jurisdiction should consult the appropriate regulatory authority provided in the Appendix because of differences in provincial statutes and requirements.

This publication was prepared by H.P. Maharaj in accordance with the Bureau of Radiation and Medical Devices internal and external review, and approval criteria. All organizations, agencies and individuals whose comments and suggestions helped in the preparation of this publication, are gratefully acknowledged.

Interpretation or elaboration on any point in this Safety Code may be obtained from the Bureau of Radiation and Medical Devices, X-Ray Section, 775 Brookfield Road, Ottawa, Ontario K1A 1C1.

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1. Introduction

The physical interactions of x-rays with materials yield data which can be analyzed and processed to provide useful information on them. Consequently, machines have been specifically designed to generate x-rays over a wide energy range for use in security screening operations. Machines that generate x-rays in the low-to-medium keV energy range are used for the examination of carry-on baggage, personal items, sealed mail, etc. They are by convention called baggage x-ray systems to which this Safety Code applies. Specialized systems generating x-rays in the MeV range for use on cargo containers are not addressed in this Safety Code.

X-rays are ionizing radiation that can cause cancer in exposed individuals and possibly harmful genetic mutations in their progeny. However, ionizing radiations continue to be utilized in a variety of applications in medicine, industry, research and consumer products because of known or perceived benefits. In recognition of the widespread applications of ionizing radiation worldwide, and the potential adverse human health effects, the International Commission on Radiological Protection (ICRP) has recommended a system of radiological protection[1] which, when followed, would ensure that the risks from ionizing radiations remain low. In this context, baggage x-ray inspection systems must be designed and constructed to conform with regulatory standards, and persons who install, use and maintain them ***must*** know the x-ray hazards inherent with such systems and adhere to recommended procedures.

2. Intent and Scope of This Code

This Safety Code provides requirements and guidance intended to ensure that the radiation risks from baggage x-ray systems remain negligibly low (i.e., the same as the risks from unavoidable, natural background radiation levels). Specific responsibilities for the owner of the system, operator and maintenance personnel are outlined. Information on safety procedures, standards, surveillance and monitoring is provided.

This Safety Code also applies to cabinet x-ray systems used in similiar screening applications. X-ray systems operating at MeV energies and neutron-based systems are not covered by this Code.

3. Responsibility and Personnel

If radiation risks are to remain low, in conformity with the ICRP objectives, personnel in every facility where baggage x-ray systems are installed must maintain strict adherence to the responsibilities charged to them. The responsibilities affecting the system ownership, operation and maintenance are indicated below.

3.1 System owner

The ultimate responsibility for the radiation safety of a baggage x-ray inspection system rests with the owner. The system owner must ensure that the baggage x-ray system(s) meets all applicable radiation safety standards. For some applications, this responsibility may be delegated to staff (e.g., a senior operator or a senior maintenance worker or the facility health and safety officer, henceforth, called the system owner or designee).

In every facility where a baggage x-ray inspection system is in use, the system owner or designee is responsible for:

1. ensuring that the baggage x-ray inspection system(s) is positioned for its intended use in accordance with the requirements set out in section 4.1.2 of this Safety Code;
2. ensuring that all operators and maintenance personnel have received training on the proper operation and x-ray hazards relevant to the baggage x-ray system(s) installed (prior to using the x-ray inspection system);
3. ensuring that the training program, referred to in paragraph 3.1.2, is reviewed (and revised as may be necessary) by the appropriate radiation protection regulatory authority;
4. prescribing radiation safety guidelines, safe operating and emergency procedures, and making readily available a copy of this Safety Code for reference by operators and maintenance personnel;
5. implementing a method of verification, supervision and periodic review to ensure that all operators and maintenance personnel have read and understood the relevant parts of this Safety Code, including the applicable radiation safety guidelines and proper operating procedures (before using a baggage x-ray inspection system);

6. establishing a maintenance program, taking into account the age and frequency of use of the baggage x-ray inspection system, that ensures all safety devices and components critical to x-ray production and x-ray shielding are routinely checked, and the defective parts replaced or repaired;
7. ensuring that maintenance personnel utilize a properly functioning and appropriately calibrated ionization-chamber survey meter to perform radiation measurements when certain maintenance functions (see section 4.1.3.2 of this Code) and other safety checks are required;
8. conducting prompt investigations of all radiation accidents* and unsafe events,** and submitting reports to the system owner, if applicable, and to the appropriate radiation protection regulatory authority within 5 calendar days;
9. ensuring that victims of radiation accidents receive specialized medical attention (e.g., consultation with a radiation oncologist, or a physician knowledgeable in the biological effects of ionizing radiation exposure to humans);
10. determining the appropriate corrective measures following radiation accidents and unsafe events, and ensuring that such measures are implemented effectively; and
11. ensuring that a trained maintenance worker or senior operator is available at the x-ray inspection system to assist or carry out operational and maintenance system functions unfamiliar to the radiation inspector during a radiation protection survey, and that a copy of the most recent survey report specific to that system, including summaries of corrected measures recommended and instituted, is available to the radiation inspector.

3.2 X-ray inspection system operators

All operators of baggage x-ray inspection systems must:

1. receive training, authorized by the system owner or designee, on the operation and x-ray safety relevant to the x-ray inspection system(s) intended for use;

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* A radiation accident is an unintentional exposure of humans to ionizing radiation that could result in adverse health effects.

** An unsafe event is any action that could result in the unnecessary exposure of humans to x-rays due to improper procedure or improper installation or of the x-ray inspection system.

2. demonstrate their competence in the operation of the x-ray system and a working knowledge of safe operational procedures to the system owner or designee;
3. read and understand sections 3.2 and 4.2 of this Safety Code, including all applicable radiation safety guidelines and proper operating procedures prescribed by the system owner or designee, and by the appropriate radiation protection regulatory authority, before operating any baggage x-ray inspection system;
4. stop the operation of the baggage x-ray inspection system, if any radiation accidents and/or unsafe events occur, and immediately notify the system owner or designee of such conditions; and
5. acknowledge that persons who operate a baggage x-ray inspection system are responsible for carrying out the work in a safe manner consistent with the guidance given in paragraph 3.2.3 in order to ensure their own protection and that of others.

3.3 Maintenance personnel

All personnel responsible for the maintenance of baggage x-ray inspection systems must:

1. attend and successfully complete a course, which:
   (i) is authorized by and acceptable to the system owner or designee or the system manufacturer;
   (ii) covers the operation, maintenance, repair and x-ray safety hazards relevant to the x-ray inspection system(s); and
   (iii) has the x-ray safety part reviewed or administered by the appropriate radiation protection regulatory authority;
2. read and understand sections 3.1, 3.3, 4.1 and 4.2 of this Safety Code including all applicable radiation safety procedures and operating guidelines that are prescribed by the system owner or designee, and by the appropriate radiation protection regulatory authority;
3. provide the system owner or designee with an explicitly written report of any imminent or foreseen user and/or operator procedure or action that can cause a radiation accident and/or unsafe event, as soon as such a procedure or action is identified;
4. use a properly functioning and appropriately calibrated ionization-chamber survey meter to monitor radiation levels during maintenance operations, especially for the replacement of an x-ray tube (or its shielded housing) or the relocation of an x-ray inspection system as described in paragraph 4.1.3.2 of this Safety Code, and for other radiation safety checks when warranted;

5. respond and investigate promptly all user and/or operator reports of the x-ray inspection system malfunctions, device and component failures, emergencies, etc., and resolve the problem(s) satisfactorily before the x-ray inspection system is used; and
6. acknowledge that maintenance personnel are responsible for carrying out the work in a safe manner consistent with the guidance presented in this section in order to ensure their own protection and that of others.

4. Standards, Surveillance and Monitoring

Within the scope of the ICRP system of radiological protection including the As Low As Reasonably Achievable (ALARA) principle, the collective equivalent dose(1) associated with the use of baggage x-ray inspection systems must be minimized. This use involves a large number of individuals and, therefore, the x-ray inspection systems and human factors must be considered.

4.1 X-ray systems

4.1.1 Regulatory standards

All baggage x-ray inspection systems sold in Canada ***must*** conform to the Radiation Emitting Devices (RED) Regulations (Schedule II, Part IV), at the time of sale. These regulations are promulgated under the RED Act, and it is the responsibility of the manufacturer or distributor to ensure that the x-ray system conforms to the regulatory requirements. Since the regulations are subject to amendments in order to reflect changes in technology, information on their current applicability may be obtained by contacting the X-Ray Section, Bureau of Radiation and Medical Devices, Health Protection Branch, National Health and Welfare, Ottawa, K1A 1C1. Any violation of the RED Act is a criminal offence.

When selecting or procuring a baggage x-ray inspection system, the owner (or designated representative) is advised to obtain a copy of the most recent regulations to become familiar with those requirements, and to enquire of the intended manufacturer or importer if the product complies with those current regulations. (These actions may eliminate or minimize the need for modifications to the system. Such modifications may be costly and cause considerable inconvenience because of disruption in service.)

4.1.2 Installation requirements and commissioning tests

Baggage x-ray inspection systems must be used in a manner that will minimize the number of people in close proximity, so as to lower the possibility of external x-ray exposure. The following requirements apply to all facilities:

(1) Every baggage x-ray inspection system must be located in such a way that under conditions of use:
    (i) individuals whose baggage (or other belongings) is to be screened with the x-ray inspection system must be more than 0.50 meters away from the access openings of the irradiation chamber while the x-ray beam is on; and
    (ii) members of the general public, excluding staff authorized to work with or near the systems and those individuals whose baggage (or belongings) is to be screened, must be more than 2 meters away from the x-ray inspection system.

(2) Every baggage x-ray inspection system must be thoroughly tested and verified by trained maintenance personnel, as per section 3.3, to ensure that all radiation shielding components and safety devices, including warning lights are installed and functioning, *before* the x-ray system is commissioned for use.

4.1.3 In-house surveillance and maintenance

The reliability and safety of any physical system decreases with age and use because of component wear. Consequently, to ensure safe and reliable operation after baggage x-ray inspection systems are installed, the system owner or designee must establish and enforce a suitable maintenance program that accounts for the age and frequency of use of that system.

4.1.3.1 In-house surveillance

Subsequent to the commissioning tests indicated in section 4.1.2(2) and before any baggage x-ray inspection system is used, trained personnel (maintenance worker or senior operator) must undertake the following procedures:

    (i) test and ensure that all safety devices (interlocks, switches, warning lights, indicators, etc.) are functioning, as intended;
    (ii) examine and ensure that all radiation shields (panels, lead drapes, etc.) are free from structural damage that could compromise barrier protection;

(iii) verify that the x-ray inspection system is not exposed to snow or rain, that liquid-filled containers are not placed on top of the x-ray system, and that warning signs at the access openings of the irradiation chamber, including the x-ray "ON" lights, are in clear view; and

(iv) ensure that the requirements to limit public access, as specified in section 4.1.2(1), are satisfied.

4.1.3.2 Maintenance guidelines

It is not possible to provide guidance in this Safety Code for all scenarios that could cause unsafe events. When such events occur, the procedures indicated in paragraphs 3.1.8 and 3.3.6 apply.

(1) Moving and/or relocating an x-ray inspection system

Moving and/or relocating x-ray systems can affect components critical to safety. If a baggage x-ray inspection system is moved and/or relocated, maintenance personnel and/or other suitably qualified person(s) (e.g., senior operator(s)) on site, appointed by the system owner or designee, must observe the following procedures:

(i) test and ensure that all safety interlocks are functioning properly as intended by design;

(ii) examine and ensure that all radiation shields are free from structural damage (i.e., puncture, hole, dent, missing part);

(iii) examine and ensure that the lead clamps that hold the anode and cathode terminals onto the chassis of the x-ray tube housing assembly are positioned correctly;

(iv) conduct the normal in-beam quality imaging-tests and, if discrepancies exist, investigate the x-ray tube assembly, the collimator setting, and the radiation exposure parameters (tube current, high voltage, filters, etc.) for possible causes; and

(v) ensure that all problems are resolved satisfactorily before the x-ray inspection system is used.

Note: Moves of a few centimeters may not warrant all these procedures. If an ionization-chamber survey meter is used for performing in-beam quality imaging-tests, the average meter readings must be compared with those taken before the x-ray inspection system was moved, and differences of more than 10% must be investigated as to root cause. The proper functioning of the survey meter should be checked first, followed by the items indicated in paragraph 4.1.3.2(1)(iv).

(2) X-ray tube or its shielded housing

Whenever an x-ray tube or its shielded housing is to be replaced, strict adherence to the manufacturer's instructions in the maintenance manual must be followed. In addition, the following procedures must be undertaken:

(i) identify and clearly mark 5 or 6 positions (where radiation measurements will be made) at the top and at the sides of the x-ray tube-head assembly cover, before proceeding with the intended replacement task;

(ii) make and record radiation measurements (using the "rate mode" option on the ionization-chamber survey meter provided) at each position while the x-ray system is emitting x-rays in the continuous mode under normal operating conditions;

(iii) remove the x-ray tube-head assembly cover and follow the appropriate manufacturer's procedures to complete the intended replacement task;

(iv) replace the x-ray tube-head assembly cover, and repeat procedure 4.1.3.2(2)(ii);

(v) compare the average meter (rate) readings obtained in procedures 4.1.3.2(2)(ii) and 4.1.3.2(2)(iv) and, if differences greater than 10% occur, identify and correct the problem;

(vi) examine and ensure that the lead clamps that hold the anode and cathode terminals onto the chassis of the x-ray tube housing assembly are positioned correctly; and

(vii) ensure all problems are resolved satisfactorily before the x-ray system is released for use.

Note: If problems arise during the field situations indicated in (1) and (2) above or in other circumstances, maintenance personnel must maintain detailed and complete records, inform the system owner or designee of such problems, and take appropriate corrective actions. If problems persist, contact the appropriate radiation protection regulatory authority. (Facilities under federal jurisdiction may contact the X-Ray Section of the Bureau of Radiation and Medical Devices. Other facilities should contact their provincial regulatory authority as per Appendix.) If there are no problems, the x-ray inspection systems may be returned into operation.

4.1.4 Radiation protection surveys

A radiation protection survey is intended to establish that the x-ray inspection system functions according to applicable performance standards, and that it is used and maintained to provide maximum x-ray safety to all individuals. To achieve this objective, the following requirements apply:

1. Baggage x-ray inspection systems must be surveyed regularly. While the frequency of surveys depends on the conditions of use, performance history and type of x-ray system, the appropriate radiation protection regulatory authority should determine the required survey frequency. (For facilities under federal jurisdiction, inspections may occur once every two to three years.)
2. A radiation protection survey must be requested from the appropriate radiation protection regulatory authority when:
   (i) x-ray systems of uncommon or new designs are installed (permission may be granted in special cases for restricted use after consultation with the regulatory authority);
   (ii) in-house surveillance tests have failed to identify and correct any radiation emissions that exceed the regulatory limit and/or the operational values needed to establish image quality assurance criteria during normal use or following modifications or maintenance operations; or
   (iii) a radiation accident has occurred.
3. Surveys must be performed by the appropriate radiation protection regulatory authority. Authorized equivalents may be permitted provided that prior approval has been obtained from the appropriate regulatory authority.
4. Surveys must include:
   (i) an inspection of all safety devices and radiation shields;
   (ii) radiation measurements over the entire x-ray inspection system that are carried out under simulated worst-case conditions, to ensure compliance with the regulatory limit ($0.5\ mR\ h^{-1}$ ($0.13\ \mu C\ kg^{-1}\ h^{-1}$) at 5.0 cm from any external surface of the x-ray inspection system);
   (iii) an assessment of occupational and public exposures when stray radiation has exceeded the regulatory limit; and
   (iv) a safety and performance assessment of the x-ray inspection system between survey periods by reviewing:
      (a) the most recent survey report specific to the system being surveyed, together with any corrective measures recommended and/or instituted on that system or at the facility since the last survey,

(b) maintenance records that identify which components critical to safety were replaced or repaired, and the tests carried out and their results, and

(c) reports of radiation exposure incidents or unsafe events or accidents, including the corrective actions implemented; and

(v) appropriate audits to ensure compliance with section 3.1 of this Safety Code.

5. Survey reports must include the following:
   (i) an identification of the baggage x-ray inspection system revealing the system manufacturer, brand name, model number, and year of manufacture;
   (ii) an assessment of the safety devices, radiation shields and the occupational exposure levels to personnel and the general public; and
   (iii) specific corrective actions, if any, that are required for compliance with this Safety Code, including the completion date.
6. After a baggage x-ray inspection system has been decommissioned, all reports of surveys, accidents, radiation exposure incidents and x-ray system misuse, must be retained for a period of at least three years by the system owner or designee at the facility at which the x-ray inspection system was last operated.

4.2 Human considerations

4.2.1 Safe operating guidelines

Even though operational baggage x-ray inspection systems may conform to the requirements set out in the RED Regulations (Schedule II, Part IV) and preventive maintenance programs ensure safety and reliability, improper use may lead to unnecessary external x-ray exposures and accidents. To reduce this possibility, the following minimum guidelines apply to all facilities utilizing baggage x-ray inspection systems:

1. No person must commit any acts that cause unsafe events on an x-ray system when it is in operation. Lifting the lead drapes for any reason when the x-ray beam is on, or exposing any part of the body to the x-ray beam, or covering the x-ray ON lights or x-ray warning signs are examples of unsafe events.

Note: Although an x-ray inspection system may be specifically installed or arranged to prevent lifting the lead drapes as indicated above, or to prevent access to the entrance and exit openings of the irradiation chamber, appropriate safety warnings (written statements

coupled with suitable light indicators) must be **legible** and **in clear view** at the point where items are initially presented for x-ray screening.

2. No person must create physical or mechanical conditions that ultimately make the x-ray inspection system unsafe to operate. Defeating safety devices, placing liquid-filled containers on an x-ray inspection system, positioning x-ray inspection systems in confined spaces for carrying out routine maintenance and operational test functions, and positioning x-ray inspection systems for use in areas exposed to rain or snow are examples of hazardous conditions.
3. Operators and maintenance personnel must forbid unauthorized individuals from remaining near an x-ray inspection system longer than is warranted.

4.2.2 Personal exposure monitoring

Personal dosimeters are intended to monitor occupational doses, thereby, providing a mechanism for restricting future radiation exposures to an individual so that the recommended maximum permissible limits are not exceeded. The results of extensive radiation surveys performed by the Bureau of Radiation and Medical Devices have shown that when baggage x-ray systems comply with the RED Regulations (Schedule II, Part IV) and are maintained and operated by competent personnel, there is no detectable radiation exposure above natural background to the operator. In addition, an analysis of stray radiation survey data that spanned an 8-year period (1978-1985) revealed that the estimated exposure at the positions occupied by baggage x-ray system operators were indistinguishable from background radiation levels[5]. There is no evidence of increased cancer risk at natural background levels[6]. Hence, personal monitors are neither required nor recommended.

In 1990, the ICRP recommended average annual whole-body dose equivalent limits of 20 mSv y^{-1} (2 rem y^{-1}) and 1 mSv y^{-1} (100 mrem y^{-1}) for a radiation worker and a member of the public, respectively (ICRP 1990[1]). These limits do not include medical and natural background radiation exposure contributions since they are judged to be beneficial and unavoidable, respectively. The surveys and analysis results mentioned above are not inconsistent with the recently ICRP revised maximum permissible dose equivalent limits for members of the public.

References

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3. Department of Labour. Canada Occupational Health and Safety Regulations. Ottawa: Canada Gazette; Revised Statutes of Canada, Chapter L-1; (SOR/86-304); 1984.

4. Department of National Health and Welfare. Recommended Safety Procedures for the Selection, Installation and Use of Baggage Inspection X-ray Equipment. Ottawa, Ontario: Environmental Health Directorate; Safety Code-21; 78-EHD-20; 1978.

5. Maharaj, H.P. Stray radiation from baggage x-ray equipment: Results and Implications. Health Physics. 54:141-148; 1989.

6. National Research Council. Health effects of exposure to low levels of ionizing radiation. Washington: National Academy Press; BEIR V; 1990.

Appendix

Provincial agencies responsible for radiation safety

Alberta
Alberta Radiation Health Service
Occupational Health and Safety
4th Floor, Donsdale Place
10709 Jasper Avenue
Edmonton, Alberta
T5J 3N3
Tel: (403) 427-2691
FAX: (403) 427-5698

British Columbia
Worker's Compensation Board of British Columbia
P.O. Box 5350 Stn Terminal
Vancouver, British Columbia
V6B 5L5
Tel: (604) 231-8374 (toll free within BC 1-888-621-7233)
FAX: (604) 279-7410

Manitoba
Radiation Protection Service
Department of Medical Physics
Manitoba Cancer Foundation
100 Olivia Street
Winnipeg, Manitoba
R3E 0V9
Tel: (204) 787-2211
FAX: (204) 775-1684

New Brunswick
Radiation Protection Services
Department of Health and Community Services
2nd Floor, Carleton Place
King Street
P.O. Box 5100
Fredericton, New Brunswick
E3B 5G8
Tel: (506) 453-2360
FAX: (506) 453-2726

Newfoundland
Medical and Hygiene Services
Employment and Labour Relations
Fall River Plaza
P.O. Box 8700
St. John's, Newfoundland
A1B 4J6
Tel: (709) 729-2644
FAX: (709) 729-2142

Northwest Territories
Occupational Health and Safety Division
Safety and Public Services
Government of the Northwest Territories
P.O. Box 1320
Yellowknife, N.W.T.
X1A 2L9
Tel: (403) 920-8616
FAX: (403) 873-7706

Nova Scotia
Department of Health and Fitness
P.O. Box 488, Station "M"
Halifax, Nova Scotia
B3J 2R8
Tel: (902) 424-4077
FAX: (902) 424-0558

Ontario
Radiation Protection Service
Ontario Ministry of Labour
81 Resources Road
Weston, Ontario
M9P 3T1
Tel: (416) 235-5922
FAX: (416) 235-5926

Prince Edward Island
Division of Environmental Health
Department of Health and Social Services
P.O. Box 2000
Charlottetown, P.E.I.
C1A 7N8
Tel: (902) 368-4970
FAX: (902) 368-4969

Quebec
Service de Radioprotection
Ministère de l'Environnement
Gouvernement du Québec
6072 est, rue Sherbrooke
Montréal, Québec
H1T 3X9
Tel: (514) 873-1978
FAX: (514) 873-8953

Saskatchewan
Radiation Safety Unit
Department of Human Resources,
Labour and Employment
Saskatchewan Place
1870 Albert Street
Regina, Saskatchewan
S4P 3V7
Tel: (306) 787-4486
FAX: (306) 787-2208

Yukon
Consumer, Corporate and Labour Affairs Branch
Department of Justice
P.O. Box 2703
Whitehorse, Yukon
Y1A 2C6
Tel: (403) 667-5450
FAX: (403) 667-3609