



Canadian Nuclear  
Safety Commission

Commission canadienne  
de sûreté nucléaire

# Licensing Process Reform

For Nuclear Substances and Radiation  
Devices Licences

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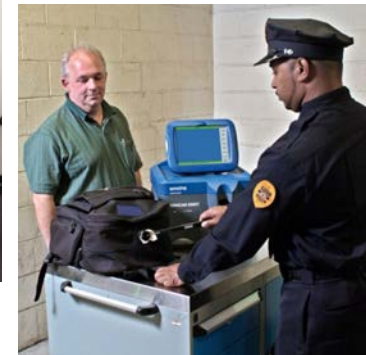
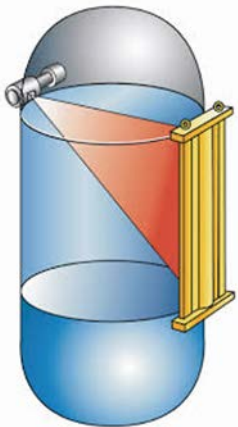
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# Background

## Nuclear Substances & Radiation Devices Licences

- Licensing process through Designated Officer decision
  - Based on application received
- 51 different use types
- Nominal five year licence term



# Pressures & Challenges

- Licences issued by use-type
  - Licensees require one licence for each use-type
- Applicants for low- and medium-risk licences daunted by the application form
  - More work required during licence application assessment
- Licence conditions contain little explanatory information
  - Licensees unsure of regulatory expectations
- Increasing requirements for security of licence
  - Is this licence still valid?



# Proposed Strategy Elements

Revision of licensing process

## Four key elements to this proposed strategy:

- Continue documentation changes
  - Identified in LEAN assessment & others
- Generic licence conditions handbooks
  - Simplified, updated conditions
- Licence consolidation
  - New business rules
- Develop enhanced security measures
  - Allow safe & secure electronic distribution of CNSC licences

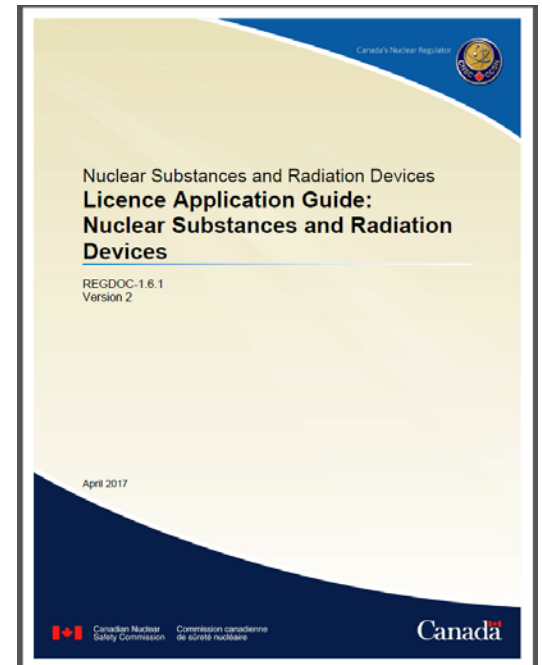


# REGDOC 1.6.1 Changes

## Structure application to the intended use

Use ACR form approach:

- Applicant identifies intended uses
- Application form contains only those elements
- Structured according to information needs
- Appendix documents are related only to selected use-type



# Licence Conditions Handbooks

- Remove bulk of licence condition text from licence
  - Wording on licence would be high level
- Create generic licence conditions handbooks for each use-type
- Simplified licence condition on licence would show licensee which ones in handbook are applicable
- Include information on CNSC expectations
- Easier to update when changes are required
  - keeps the information current, no mass licence amendments necessary



# Licence Conditions Handbooks

- Increased clarity and consistency of regulatory expectations by:
  - Licensees
  - Licensing staff
  - Inspectors
- Simplified licences that are shorter
- Up-to-date compliance criteria and guidance without the need to amend the licence



# Licence Conditions Handbooks

## Licence condition:

***“The licensee shall maintain a thyroid bioassay program”***

In the Licence Conditions Handbook

- Which radioiodines are included
- Monitoring requirements
- Screening requirements
- Actions to take if thyroid burden exceeds limits
- What a licensee will need to have to demonstrate compliance
- References to relevant REGDOCs

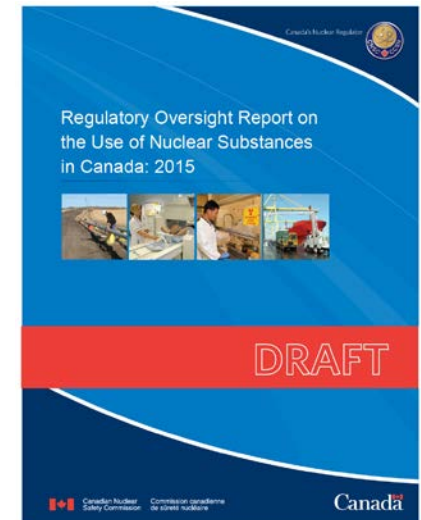




# Licence Consolidation

- Revise use-type approach using Field & Sub-field
  - Commercial (Distribution)
    - Combines three use-types
  - Industrial (Exploration)
    - Combines five use-types
  - Education/Research (Laboratory)
    - Combines five use-types
  - Medical (Human)
    - Combines two use-types

**Field name is based on designation in *Regulatory Oversight Report on Use of Nuclear Substances in Canada***



# Licence Consolidation

- Reduction in number of use-types from 51 to 19
- Since 2011, licensees have been defining operations in the licensing documentation
  - Referenced in licence
- Keeps original work done on risk assessment
  - Combine use-types of similar risk ranking
- Recognizes where specific requirements still apply:
  - Human research – ethics considerations, protocol evaluations
  - Radiography – high risk
  - Portable gauges – often problematic



# Licence Consolidation

- New business rules will be developed
  - Lower risk licence can be included on one of higher risk
    - Industrial (radiography) licence can include use of low-risk x-ray fluorescence device
  - One use-type licence per licensee
    - Licensees will not have a separate licence for each geographical location doing the same licensed activities
  - Related licences combined
    - Manufacturing would include servicing and distribution activities



# Electronic Distribution

- Moving toward full electronic distribution of CNSC licence when issued
  - No paper copies sent
  - Digitally signed
- Protected
- Available directly from the CNSC

**Licensees would receive their licence *faster* and it is secure**



# Enhanced Security Measures

- Licensee would be notified licence can be downloaded
  - Accessible to persons in field situations or different geographical locations
- Licensee could provide access to supplier
  - Supplier downloads licence from CNSC
  - Supplier can be assured that licence was not altered, is genuine and remains valid

**Objective is to enhance security of the licence**



# So where do we go from here?

- Starting with licence consolidation
  - Required for documentation changes
  - Required for licence conditions handbooks
- Prepare discussion paper on proposed consolidation strategy
  - Rationale for consolidation
  - New business rules

**Seek comments and input from licensees**





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