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
Electonic 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