Proceedings of the 19th International Symposium on the Packaging and Transportation of Radioactive Materials
PATRAM 2019
August 4-9, 2019, New Orleans, LA, USA

Paper No.
1292

EFFICIENCIES IN PROCUREMENT AND LICENSING OF TYPE B FISSILE PACKAGE

Alison Roberts
TDG Program Officer
Canadian Nuclear Laboratories

Blair Menna
Northern Nuclear Services
Ottawa, Canada

Tiffany Finucane
Process Specialist
Canadian Nuclear Laboratories

ABSTRACT

For any organization, procurement of specialized transport packages requires a significant investment of resources. It may take up to six years to procure and license a transport package for Type B fissile contents. This includes defining the need, selecting a supplier, completion of a design, prototype fabrication and testing, licensing with the Competent Authority, and fabrication. If rework is required at any stage, this timeline can increase significantly.
In order to improve efficiency in procuring and licensing transport packages at Canadian Nuclear Laboratories (CNL), a process improvement exercise was undertaken. The exercise brought together an internal team to map and optimize the CNL procurement process (including design, certification and fabrication) for Radioactive Material (RAM) packages. Type B Fissile packages were chosen as representative of all RAM packages as they typically have the most complex process for procurement. Package procurement requires input from subject matter experts in management systems, procurement, quality assurance, operations, radiation protection, business development and engineering. These experts are required in order to ensure that the final product is compliant to meet CNL's operational and business needs.

Process Improvement opportunities found include leveraging procurement framework contracts with approved suppliers, establishing a standard set of subject matter experts for package review meetings, and improving communication with Competent Authorities during the licensing process. With these process improvements, significant efficiencies were found, most notably a reduction in the time to delivery of the licensed package and in the number of process steps required to complete the procurement and certification.

INTRODUCTION

Transportation is an important aspect of nuclear projects. Specialized transport packages pose a challenge for nuclear organizations seeking interconnected processes with cross-country and cross-border commerce. Unlike conventional packaging and logistics, Radioactive Material (RAM) transportation is a significant investment for nuclear science projects.

The government of Canada is investing a state-of-the-art hot cell and laboratory facility at Canadian Nuclear Laboratories (CNL) that will be used to perform cutting-edge research in advanced nuclear materials. Additionally, CNL has key science and technology initiatives that will require transportation support:

- The siting of a new, small modular reactor on the CNL site
- Development of Targeted Alpha Therapy (TAT) compounds
- Advanced fuel fabrication
- Life extension of existing reactors

In order to support these new business opportunities at CNL, the Transportation Program initiated a process improvement exercise to find efficiencies in the procurement and licensing process for Radioactive Material (RAM) packages. These efficiencies can be found to have parallels within any organization seeking to transport RAM.

Type B Fissile packages have the most complex procurement and licensing process of commonly certified RAM packages. (Arguably, Type C is more complex, but not commonly used). An international revalidation of the certificate from the US DOT was included due to the common need for CNL to ship between Canada and the United States. This type of international certification is typical for commerce, waste management, or repatriation, where shipping through both Canada and the United States is common. This hypothetical scenario was used as the structure to engage in a process improvement exercise.

THE NEED FOR EFFICIENCIES IN DESIGN AND PROCUREMENT

For organizations that subcontract the design and/or manufacture of custom Type B packages, the process for procuring the package can be a substantial project management undertaking. Many nuclear organizations do not have the resources to complete the entire design of a Type B package. Even if the design is adapted from a previous package design—the testing and/or analyses required to adapt a package requires very specific expertise and resources.

What have we learned?

CNL has several strengths it can leverage in customer relationships:

Helpful, resourceful, service-oriented staff

Strong technical expertise, competence, knowledge

There are opportunities for improvement in:

Communications, Integrated Teams,

Timely responsive service, and turnaround times

Most nuclear organizations do not have the resources to complete the entire fabrication of a package internally. If part or all of the design or manufacture of the package is subcontracted, it is a substantial and complicated undertaking—with required emphasis on communication and project management.[1] If a larger project hinges on approval of a new package design, the procurement process for the package is

often the project critical path. Even small improvements to the timeline of package procurement can have large financial benefits if it is the critical path for a very large project. Thus CNL set out to seek improvement actions that could decrease the chance of rework, over-budget, or increased timelines for the procurement process.

PROCESS IMPROVEMENT EXERCISE

What have we achieved?
Once implemented, CNL anticipates that the **process improvements will result in**
86% Process time decrease
240 Fewer process steps

The process improvement exercise is one that can be completed by any organization that is looking to become lean and gain efficiencies in the procurement and licensing of RAM packaging. A process specialist was brought in to write a project charter, to outline the problem, and to request resources from the team member departments. Team members were recruited from Quality Assurance, Quality Control, Health Physics, Engineering, Business and Development, Operations, Procurement, Decommissioning Waste Management, and Transportation.

It was determined that the strengths that CNL can leverage from the current process state are the team member's strong technical expertise, helpfulness, resourcefulness, service-oriented attitude, competence, and current knowledge. Opportunities for improvement were identified as communication, team integration, turnaround times, and overall costs.

The volunteers from each department came together in a five day process improvement exercise to map the commonly-understood process for the procurement and licensing of a transport package for Type B fissile contents. The team then brainstormed a map of the desired future state of the process.

A collaborative approach was used to create the value stream map of the current state. Sticky notes were aligned for each process step, where a new sticky note denotes either a completed process output or a change-of-hands. The 337 process steps that were determined for the current process map can be seen in **Photo 1**.

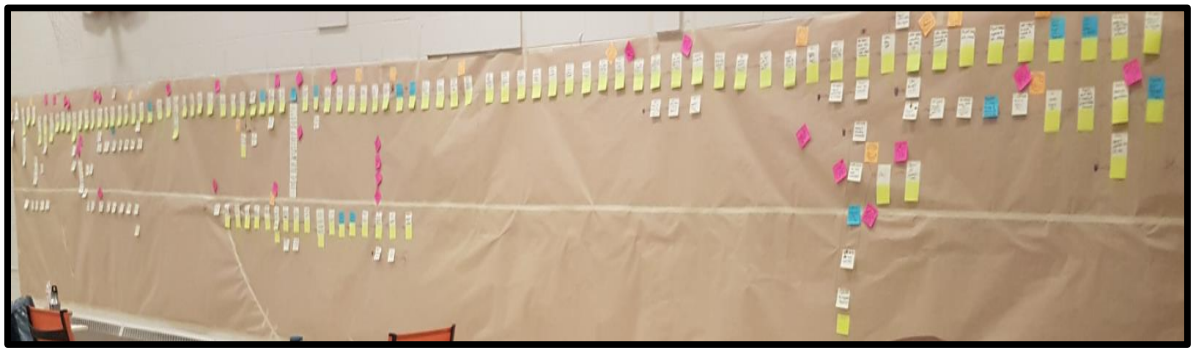

Photo 1. Commonly understood, "current state" process flow mapping.

The future state map, as seen in **Photo 2**, was determined by consensus brainstorming, without being held to previous processes. The team drafted a future state value stream map with 97

process steps and 16% of the steps were identified as purely value-added to the customer as opposed to 4.7% in the current state.

Table 1. Process steps from current to future state after improvement.

	Current State	Future State
Number of process steps	337	97
% of purely value-added steps	4.7%	16%

With 240 process steps removed, there was a risk that a process step with significance may have been missed. A verification was made that no value-added steps were removed from the future state drafted by the team. The quality verification of the future state determined that the team had maintained all of the same outputs as the current state.

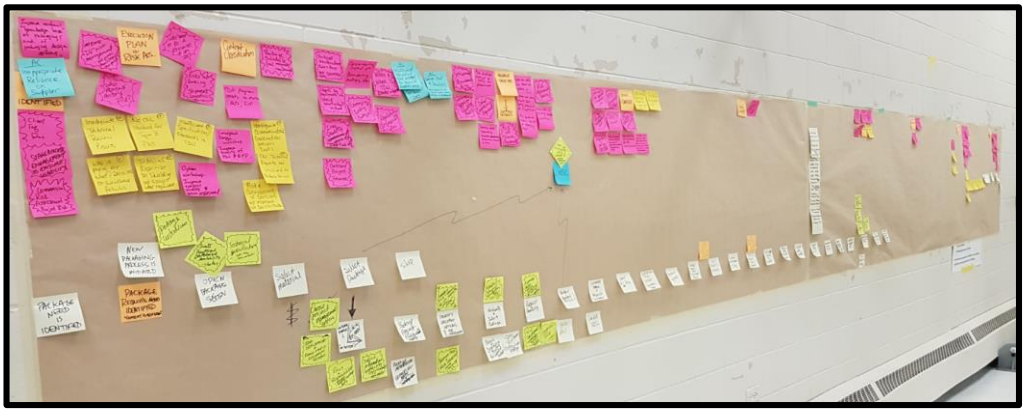

Photo 2. Desired "future state" process flow mapping.

In order to evaluate the benefits of the new process, the team agreed on the expected process time and the wait time between steps. With these metrics, is was determined how much total time was saved by following the future state process. As outlined in **Table 2**, the median time to complete the process was reduced from 3.7 years to 1.5 years. This is not only time savings for completion of the project, but also substantial reduction in person-hours required to work on the process.

Table 2. Timeline summary from current to future state after improvement.

	Current State			Future State		
	Minimum	**Maximum**	**Median**	**Minimum**	**Maximum**	**Median**
Process Time	1440 hrs	2472 hrs	1956 hrs	232 hrs	304 hrs	268 hrs
Wait Time	293 Days	2215 Days	1254 Days	157 Days	1035 Days	596 Days
Total Time	1 Year	6.3 Years	3.7 Years	0.25 Years	2.8 Years	1.5 Years

Once the team was unanimously satisfied with the future state process, the team reported back to line management to get their buy-in for the process change. The team identified kaizens (improvement actions)[2] necessary to move the process from current to future state. 37 kaizens were identified by the team and prioritized.

Kaizen

A kaizen is from the Japanese word "Improvement". The kaizen process can be broken up into 6 steps:[2]

1. Determine Improvement Potential

2. Determine current methods

3. Investigate New Methods

4. Plan for Implementation

5. Follow Through with Improvement

6. Analyze Impact on Process

Future and ongoing work by the team includes continued execution of the kaizens and monitoring of the results. Metrics will be monitored in the coming years to determine if the process improvement results are achieved as expected.[3]

IMPROVEMENT ACTIONS

The improvements resulting from the exercise can be loosely placed into three phases of the packaging process: the initial examination of packaging options, contractor management of design, and certification with Competent Authorities. A few of the 37 kaizens from each of these phases will be discussed below—selected based on the applicability to other organizations and the scope of the action.

EXAMINATION OF PACKAGING OPTIONS- IMPROVEMENTS

The decision of what RAM packaging is needed for a product (or waste) is often an iterative process. As a new product develops, the packaging needs for the project may change. The amount of material that needs to be transported can increase as a project matures or the radioisotopes may change—leading to a changing target for packaging options.

The process improvement kaizens that were identified for the examination of packaging options are to include all subject matter experts in the full iterative process for determining an appropriate packaging solution, gathering an accurate characterization fingerprint early in project development, and making sure that realistic expectations are set regarding timelines for packaging changes due to evolving needs.

Packaging Options-

Radioisotopes and their quantity may evolve during **product development**.

Environmental remediation may produce waste with a changing isotopic fingerprint.

Having all subject matter experts involved with every stage of the selection of packaging options process—while an initial expense—pays off when the packaging option works with all aspects of packaging compliance.

It was found that gathering an accurate characterization fingerprint early in project development is an often overlooked aspect of nuclear projects. The nuclear industry is comfortable with radiation safety considerations when planning a new project. It is often overlooked that the detailed characterization needed for package selection goes beyond what is

needed for radiation protection for Nuclear Energy Workers. This can lead to project delays if the isotopic characterization changes after package selection.

The timeline for adapting to unanticipated changes in package needs is an important project consideration. A change in contents to a certified package, for example, requires an amendment request to the Competent Authority. Similarly, if a larger package size or new package feature is needed, a reasonable timeline needs to be understood for the design change.

Modular packaging systems and packages that are certified to contain a broad set of allowed contents allow flexibility for evolving needs. A modular packaging system may have several packages with the same design, but scaled sizes, or with nested shielding. Scaling a package design requires Competent Authority approval, but the design and analysis are greatly simplified.

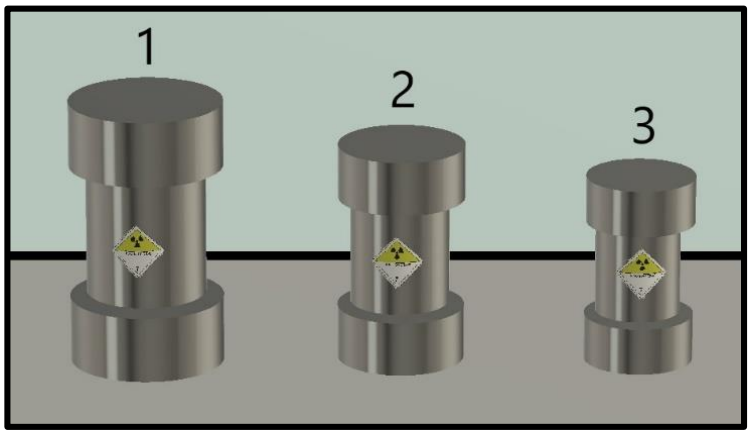

Figure 1. An example of a modular packaging system of scaled design.

An ideal approach to packaging options allows for adaptability and scalability in a new project development. Planning and allowing for an appropriate timeline for packaging changes prevents potential project delays and project adaptability.

CONTRACTOR MANAGEMENT OF DESIGN- IMPROVEMENTS

Contracting out the design of a RAM package is common practice due to the specialized resources needed for package testing and simulations. Design practices are constantly changing and following the most current testing and analysis practices ensures the smoothest path to licensing. Companies who specialize in the design of packages have base-line sensitivity analysis for their simulation software that can be used to initiate new design simulations. Given the complexity of completing in-house RAM package design, subcontracting the work is sometimes the only option, but poses a challenge for project management. CNL sought to find process improvements within the design steps.

The CNL process for completing the design of a Type B Fissile package follows the steps in **Table 3**. It is assumed that the design process starts with a clear transportation need outlined by the project and ends when a full design package is returned by the contractor.

Table 3. Design Development Steps

#	Design Development Steps
1	Search for commercially available package that could fulfil the project needs or readily adapted for the new contents.
2	Prepare Scope of Work.
3	Budget approved.
4	Request For Proposal (RFP).
5	Contract execution team assembled.
6	Proposals screened by Contract Execution Team.
7	Contract issued to supplier.
8	Kick-off with supplier.
9	Deliverables agreed upon. PEP PQP Design Plan Verification Plan BOD Preliminary Analysis Plans SAR 30% SAR 90% Fabrication Drawings ITP & PRO's FAT Plans Shielding Integrity Plan Training Manuals Maintenance Manuals Operating Manual & PRO's Design Completion Assurance History File
10	Deliverables round-table with subject matter experts.
11	Final design acceptance.

There are many steps between identifying a package need and the completion of a package design. Not included in the list is certifying the design with the Competent Authority, addressed below. In order to decrease the complexity of the process and increase the quality of the final design, CNL is pursuing the following process improvements.

Procurement Framework Contracts

The first process improvement for the design phase is to leverage procurement framework contracts to reduce the cost and time required to achieve the required level of confidence in a package supplier.

> Adding a potential credible supplier to the **Approved Supplier List (ASL)** prior to the start of a project saves valuable time.

A procurement framework contract can be initiated with recurrent contractors to prepare for future contracts. This allows for the quality assurance audits to take place before the work becomes critical path during a project.

Additionally, the terms and conditions can be negotiated with a contractor in order to not delay the project. Procurement framework contracts then provide the appropriate due diligence to start a contract with a package supplier earlier and accelerate project timelines.

Subject Matter Expertise in Supplier Evaluations

Technical expertise is necessary to perform a supplier evaluation. Contract management needs subject matter experts included in the supplier evaluation for subcontracting package design.

The first formal meeting with the package designer is an important part of managing a package design contract. This meeting can often involve two groups: the project management team to discuss the schedule and the technical team to allow for direct communication between technical experts from both companies. Relevant technical expertise for package may include criticality, thermal, structural, materials, shielding, quality assurance, radiation protection, and operations. It was found that technical experts were not always included in the "kick-off" meeting and the initial connection between technical experts was lost. The process improvement was to establish quorum for the initial kick-off meeting as well as to create a list of subject matter expertise that CNL would need in order to fully engage the technical experts from the supplier's organization.

Identifying Supplier Strengths and Weaknesses

The identification of supplier strengths and weaknesses before the supplier kick-off meeting was also identified as an area for process improvement. Because package contracts require regulatory compliance, it is important to keep track of potential supplier weaknesses during the design or manufacturing process. Suppliers may have a weakness in one of the aspects of package design or manufacturing that needs to be more closely monitored.

For example, if a supplier is not as experienced with the physics of criticality due to having more experience with non-fissile packages, this is an aspect that needs to be monitored more closely throughout the contract. If the supplier's strengths and weaknesses are identified before the initial supplier kick-off meeting, the project risks can be mitigated to avoid potential regulatory compliance issues further along the project.

Round Table Reviews

One way to integrate subject matter experts into the process is to leverage round-table reviews of design deliverables. Often when subject matter experts are providing their reviews in an integrated setting, the result is a more thorough review that meets the needs of all of the subject matter experts. Package design has multiple highly-technical facets. In order to get design deliverables to meet the needs of each technical facet, a round-table discussion allows for questions and response from each technical expert in real-time instead of an iterative written set of questions and answers that could span weeks.

Round Table Reviews-

Integrating technical expertise results in a more thorough review.

CERTIFICATION WITH COMPETENT AUTHORITIES- IMPROVEMENTS

RAM transportation across borders requires knowledge of the subtle differences between regulations in the respective countries. A visual example of this is the difference between the Class 7 Radioactive Materials Placard in Canada and United States.

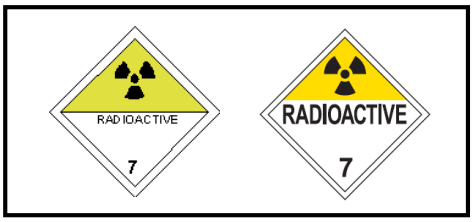

Figure 2. Comparison of text size, white border width, and yellow triangle position between radioactive material placards in Canada (Left) and United States (Right).

There are subtle differences between RAM transportation in Canada and the United States. As a matter of practice, CNL now requires that its Safety Analysis Reports meet the stricter regulatory requirement from the two countries. Fortunately, there is now published guidance that CNL can refer its suppliers to[4] for this guidance.

One of the process improvements found to improve communications with the Competent Authority is to present ongoing priorities to the CNSC Transportation Project Officer and to provide scheduling updates for submissions upcoming. This allows for the Project Officer to plan for upcoming work and to prioritize when multiple design certifications are requested in parallel.

Additionally, when addressing a Request For Additional Information during SAR submission, CNL found that holding meetings or conference calls with the Project Officer allows for better communication and disposition of comments than an iterative written approach. Face-to-face communication prevents miscommunications, given the large size of design certification documents and the detailed technical nature of the material.

CNL is working on better coordinating Cost Recovery funding for Competent Authorities who seek funds to recover the cost of SAR evaluations. It can be difficult to coordinate payments with the technical submission of requests, but the Canadian Nuclear Safety Commission (CNSC) is not able to accept submissions without the payment. This has led CNL to seek better methods than cheque requisition to send funds, as the payments are mixed together for any parallel projects and causes project delays while the payments are aligned with the applications.

Improving communication methodologies allows for improved planning both by the Competent Authority and CNL to plan staffing requirements and project timelines.

CONCLUSIONS

A common thread with all of the process improvements is improving the quality of communication and having reasonable expectations regarding timelines and costs for RAM packaging. RAM packaging has many technical facets—communication pathways are highly complex and vital to successful RAM packaging procurement and licensing.

Unlike conventional packaging and transport, RAM packaging and transport can take up a substantial amount of the budget and timeline for new nuclear projects. Planning ahead and optimizing the process can bring large process improvements.

CNL's process improvement found a 2.2 year timeline decrease for the procurement and licensing of a Type B fissile package from 37 kaizen improvement actions. Kaizens that can be applied to any company looking to procure and license RAM packaging include:

- Leveraging procurement framework contracts for package suppliers.
- Ensuring that the essential subject matter experts are included in the supplier evaluation.
- Identification and management of supplier strengths and weaknesses.
- Using round-table discussions for review of project deliverables.
- Including subject matter experts in the full iterative process of package selection.
- Gathering an accurate characterization fingerprint early in project development.
- Selecting modular or scalable packages during the package selection process.
- Communicating with Competent Authority when a SAR submission is upcoming.
- Meeting with the technical officers from the Competent Authority face-to-face.
- Coordinating Cost Recovery funding for Competent Authority submissions.

Implementation of one or more of the listed process improvement actions can bring reductions in cost and timelines for any nuclear corporation seeking to procure or licence RAM packaging. CNL is working to implement the process improvements to align themselves for upcoming cutting-edge research.

REFERENCES

[1] Heerkens, G. (2002). *Manager's Guide to Project Management.* McGraw-Hill.

[2] Kato, I. (2011). *Toyota Kaizen Methods: Six Steps to Improvement*. CRC Press.

[3] George, Michael L. (2002). *Lean Six Sigma: Combining Six Sigma Quality with Lean Production Speed (1st ed.).* McGraw-Hill Education.

[4] RD-364 / NUREG-1886: *Joint Canada – United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages*.