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Progress in Establishing a Relationship to Build Type B(U) Containers to U.S. Specifications for Isotope Transport

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ABSTRACT

The U.S. Department of Transportation (DOT) has harmonized regulations for transporting nuclear materials with international standards as outlined in International Atomic Energy Agency (IAEA) Safety Standard TS-R-1. The new regulatory requirements mandate that containers built to DOT specifications for transportation of Type B prior to the harmonization be phased out of use by October of 2008. As there are currently no approved Type B(U) containers of suitable size and weight to serve the medical, research and industrial isotope market, the University of Missouri Research Reactor (MURR) has undertaken a process to identify and partner with a vendor to design the first set of Type B(U) containers for production isotope transport under the harmonized DOT and Nuclear Regulatory Commission (NRC) regulations. Issues of cost, timing and the difficulties faced by a U.S. producer to meet the regulations are covered. The challenges faced by a radioisotope production facility that wishes to expand its offerings to customers in the future, yet must detail the exact isotopes to be transported in the safety analysis are discussed. Various 'lessons learned' are covered as are future options.

INTRODUCTION

In April 2002, major changes to 10 CFR 71 were proposed in the Federal Register [1]. These changes bring U.S. regulations for the transportation of radioactive material into harmonization with the international regulations embodied in the International Atomic Energy Agency's (IAEA) Regulations for the Safe Transport of Radioactive Material, Safety Requirements No. TS-R-1 (usually referred to as simply TS-R-1) [2].

The changes proposed for 10 CFR 71 covered the spectrum of radioactive material transportation issues. A notable change included a time limit on how long the certificate approvals on DOT Specification ("spec") packages approved under 49 CFR 178 (prior to the 2002 changes) would

be grandfathered. Under the final regulations [3], the end of the grandfathering period is October 1, 2008 [4].

REGULATORY CHANGES

As of October 1, 2008, major changes will occur for shippers of radioisotopes. For the University of Missouri Research Reactor (MURR), the fleet of packages currently used to ship radioactive materials in Type B quantities will become obsolete and, if new shipping containers are not in place by that date, some Type B(U) shipments of radioisotopes used in cancer treatments, medical diagnostic techniques and various industrial applications will cease.

MURR's Unique Challenges

MURR is a major center for the production of radioisotopes and radiochemicals for research, medical applications and industrial needs. In 2006, MURR sent out in excess of 1000 shipments of radioactive materials comprising over 40 different radioisotopes to U.S. and international clients. Many of those shipments contained Type B quantities of radioactive materials. Shipments in 2007, to date, indicate that the 2006 numbers will be surpassed.

MURR currently operates and maintains, through an NRC-approved quality assurance (QA) program, a fleet of 6M spec packages (built to the old 49 CFR 178.354 standard) and 20WC1 spec packages (built to the old 49 CFR 178.362 standard) to meet its Type B shipping needs and a variety of approved packaging for Type A shipments. The more heavily shielded 20WC1 packages are used to ship bulk high-activity materials.

The 6M packages weigh less than 68 kg (150 pounds) fully-loaded and are used to transport moderate levels of medical and industrial radioisotopes. The weight limit for these packages is critical for MURR's business model as packages under 68 kg (150 pounds) may ship next-day at regular shipping rates. Packages with weights over 68 kg (150 pounds) would cause the cost structure to escalate significantly (approximately triple). The higher costs for shipping heavier packages would have a considerable impact on the current market for these radioisotopes. In addition, the heavier packages would need to travel as ground freight, increasing shipping time to at least three days and resulting in reduced product activity due to radioactive decay.

Ending shipments of Type B quantities of materials is not a viable option. MURR is the major, and in some cases sole, provider of active material for cancer-fighting radiopharmaceuticals. Owing to ongoing transportation challenges, forcing our clients to turn to foreign reactors for their radioisotopes would jeopardize U.S. patients. In addition, MURR receives roughly 1/3 of its annual income from shipments of Type B quantities of radioisotopes.

Breaking shipments into Type A quantities is also not feasible as the A_2 values for many of the radioisotopes are not high enough to distribute the material in Type A quantities in the forms we currently ship them[5]. In addition, breaking the material into Type A quantities would create significant challenges for MURR's adherence to the "As Low As Reasonably Achievable" (ALARA) radiation exposure guideline.

There are no radioactive materials packages approved for use past the October deadline that can legally carry the wide variety of isotopes shipped from MURR. This flexibility in approved package contents is key to MURR's ability to meet researcher and client demand for an expanding array of radioisotopes and radiochemicals.

SHIPPING CONTAINER STRATEGIES

As the authors reported earlier[6], MURR began work on replacing the Type B shipping package fleet over four years ago, when it became clear that industry was not going to spend the large sums of money required to design, test and certify a new Type B(U) package design suited to general use. This assessment is illustrated by the fact that only one package for medical isotopes has successfully navigated the NRC package approval process as of this writing. This is the MIDUS Type B(U) package designed by Energy*Solutions*, Spent Fuel Division. This package is approved solely for the shipment of molybdenum-99 (and its daughter products) in a liquid form of natrium molybdate. The approval of this package was not completed until May 15, 2007 [7].

While the MIDUS package might serve as a heavier (at 727 pounds (330 kg), maximum weight) 20WC1 analogue, there are no packages in the pipeline that could serve to replace the light weight, 6M portion of MURR's fleet and none which are approved to carry the wide range of isotopes produced and shipped by MURR.

Some considerations were given to retrofitting the existing 6M and 20WC1 designs and attempting to take these upgraded package designs through the NRC approval process. It quickly became clear that such an approach was not likely to achieve success. The designs are not amenable to meeting the leak test requirements of 10 CFR 71. MURR did not think it likely that proper materials certificates could be assembled for the existing components such as the depleted uranium (DU) inserts in the 20WC1 packages. In addition, for MURR to manufacture these packages, a separate QA process would have to be developed and maintained and new skilled staff would need to be hired which, under current budget pressures, is not feasible.

MURR looked to international suppliers as well. As 10 CFR 71 harmonizes U.S. regulations with TS-R-1, it was assumed that foreign manufacturers would be able to offer a variety of off-the-shelf designs. One vendor, Croft Associates, Ltd., out of the United Kingdom, was found to manufacture two shipping packages that could provide replacements for the DOT spec packages currently used by MURR. Croft's 2799H SAFKEG and 2835A SAFKEG designs provide analogues for the soon-to-be obsolete 6M and 20WC1 spec packages. However, these designs are not approved by NRC for use in the United States.

Conventional Request for Bid Approach

In 2005, with no NRC-approved designs available from either domestic or international suppliers, MURR made the decision to issue a Request for Bids (RFB), soliciting vendors to provide MURR with price and design information for a new generation of packages. The first request in 2005 received no responses. A second RFB was issued in early 2006 and resulted in one response that was not deemed feasible due to budget factors.

Request for Proposal Approach

After two RFBs failed to generate an adequate response, an engineering team was assembled in the summer of 2006 to determine if MURR could build upon existing QA and current Good Manufacturing Programs (cGMP) and act as the designer of a new fleet of shipping packages, with the expectation that manufacturing could then be contracted out. The internal study concluded that it would be possible to develop such a capability, but that uncertainty existed as to whether MURR could accomplish design, regulatory approvals, and manufacturing in time to meet the October 1, 2008 deadline. The lack of experience in both shipping package design and the mechanics of the NRC approval process were large components of that uncertainty.

In spite of the uncertainty associated with MURR taking on design, regulatory approval and manufacturing oversight tasks, MURR did decide to issue a Request for Proposal (RFP) in March of 2007 [8]. This request differed from the earlier RFB in that the structure allowed potential vendors more flexibility in the designs and cost structures that they were asked to provide. In addition, the RFP allowed for a cooperative approach with respect to the licensing process.

The RFP Requirements

The RFP asked potential vendors to deliver cost and design information for:

A. Providing Type B(U) packages that weigh under 150 pounds, fully loaded, to act as a replacement for the 6M packages.
B. Providing Type B(U) packages with no weight restriction, to serve as replacements for the 20WC1 packages.
C. Providing both A and B, above.

The proposals were graded according to price (50%), previous experience of the vendor (20%), any risk-sharing proposals (15%), impact of the design on current operating procedures (15%) and 5% if the vendor met the criteria of a minority-owned or woman-owned business.

MURR received four proposals in mid-April of 2007. The proposals all met the technical criteria of the RFP. Unfortunately, one proposal was not evaluated as the cost structure was too high.

The RFP Responses

The three remaining proposals were all excellent designs from proven manufacturers. These designs were evaluated by the shipping and engineering groups to determine the impact upon facility operations. The costs were reviewed and compared, the other parameters evaluated and a score was calculated for each vendor.

The contract was awarded to Croft Associates, Limited, as determined by the grading formula. Croft offered a competitive price, significant previous experience and a unique risk-sharing model to develop, license and supply two packages designated SAFKEG-LS and SAFKEG-HS.

Croft Associates has over 25 years of experience in designing and building radioactive materials packages. In the U.S., Croft Associates has designed and built two packages, the 2799E SAFKEG and 3940A SAFKEG for the U.S. Department of Energy (DOE)[9][10].

In addition to having the lowest cost structure and extensive previous experience, Croft Associates proposed a unique risk-sharing mechanism that would allow MURR to potentially benefit financially in the future for the risk of underwriting the design and approval of new shipping packages. MURR will pay all expenses related to: prototype manufacture, testing, compilation of the Safety Analysis Report for Packaging (SARP), NRC review fees (as provided for in 10 CFR 170) and manufacture of approved designs. In return, Croft will forward a royalty payment on any future U.S. sales of the SAFKEG-LS and SAFKEG-HS designs. MURR will not hold any interest in the Certificate of Compliance (CoC).

This structure allows for the potential for some return on the substantial investment MURR is making in the design and approval process for a new multi-isotope Type B(U) package.

The contract was signed in August of 2007. Design work is being finalized to be followed soon by prototype manufacture for both a SAFKEG-LS (6M analogue) and SAFKEG-HS (20WC1 analogue).

QA Program Challenges

Croft Associates maintained an NRC-compliant Quality Assurance (QA) program until June of 2006, when, after applying for recertification, they were informed that NRC was restricting QA program approval to NRC Licensees, Certificate of Compliance holders or applicants[11]. As Croft Associates did not meet any of those criteria at the time, their QA program was not recertified.

Now that the shipping package contract has been signed, Croft Associates has forwarded a Quality Assurance Program Description Manual (QAPDM) to NRC as part of their effort to have their QA program reapproved to meet the provisions of 10 CFR 71, Subpart H and NRC review has commenced.

Croft Associates maintains a QA program in accordance with ISO9001 standards and undergoes audits from the British Standards Institute indicating a high level of QA proficiency[12]. While it is currently assumed by MURR that Croft Associates will experience little trouble having their QA program approved, this issue is of critical importance and is being followed closely.

Other Challenges

Other challenges include the compilation of a SARP for each package. There is a SARP for the designs that the SAFKEG-LS and HS packages are based upon, but the information is tailored to the needs and requirements of U.K. regulators. The NRC has areas of focus that differ from those of the U.K. regulator. This challenge will be mitigated somewhat by the extensive documentation available from the NRC via its ADAMS database.

Materials issues could provide a challenge as well. Croft Associates proposes to use cork as an insulating material instead of the foams and celotex commonly used in the U.S. Materials properties are available from industrial cork manufacturers and from testing in support of Croft's applications for DOE approval of other packages. In addition, cork has been used in the U.K. for over 50 years by Croft Associates and other package designers. It remains to be seen if the NRC will have the same view of this material as other regulators and competent authorities.

The contents specification also presents a challenge as MURR's large variety of products require a range of product packages and shielding inserts to be carried within the cavity of the SAFKEG-LS and SAFKEG-HS packages.

MURR also faces a number of internal issues. These include, but are not limited to:

1. The cost of the project.
2. Planning for changes in shipping procedures. The new leak test procedures will add a time-consuming layer to the shipping process. MURR must begin to review procedures and study how the leak tests will affect shipping schedules and ALARA concerns.
3. MURR may need to request that Croft Associates update the CoC if the list of approved isotopes proves to be insufficient to meet the needs of researchers, radiopharmaceutical manufacturers and industry. By guessing wrong now on the isotope list, MURR may face delays in the future in providing radioisotopes or radiochemicals in Type B quantities if updating the CoC for the packages takes longer than forecast.

LESSONS LEARNED

Regulatory changes have a significant impact on operations, particularly in the financial area. MURR estimates that it will cost at least $2 million to become compliant with the new shipping regulations, excluding potential increased shipping costs for end-users and customers of medical and industrial radioisotopes. The nuclear medicine industry should have been more actively involved in the comment period to inform the authorities of the operational and financial implications of these regulatory changes.

MURR should have acted during the comment period of the new regulations to inform the DOT and NRC of research and industry trends that MURR must respond to as a radioisotope and radiochemical producer.

In addition, MURR has been forced to change paths multiple times: as assumptions of the state of the market for packages proved unrealistic when it became apparent that suppliers were not going to automatically develop new shipping packages, when the Requests for Bids were not successful, and when the option of manufacturing the shipping packages privately did not appear to be feasible. A better understanding of the market could have prevented some, but not all, of the delays.

NRC and DOT both provide a wealth of information via their websites. Sifting through the huge number of reports, regulations and data provides a challenge at times. Learning where and how to search is a learning process, but one with a very valuable end result.

Organizations need to consider strategies that are outside of their normal activities in order to be successful in this changing environment. MURR has undertaken a strategy that will require it to be heavily involved in the design and licensing of new shipping packages. By being willing to undertake these new activities, this should allow MURR to have extensive oversight of the process and allows MURR to forecast its ability to continue with radioisotope production and sale. The ability to reap some financial benefits from subsequent production of these packages is also very unusual for a university and required significant coordination with the procurement and legal staffs. This coordination took far more time to accomplish than anticipated, driving back the contract signing deep into 2007, proving once again that early planning and execution is critical in such large design projects.

CONCLUSION

In summary, MURR currently runs a fleet of Type B shipping packages that is flexible in terms of weight, shielding and approved contents. After October 1, 2008 this fleet can no longer be used. There are no replacements available on the open market that can meet MURR's needs for flexibility and multi-isotope use.

MURR has contracted with a firm experienced in the design, testing, licensing, and manufacturing of shipping packages to provide new packages that meet the requirements put forth in 10 CFR 71. The ability to ship Type B quantities of radioisotopes is critical to MURR's mission. This initiation of this contract represents a new approach for MURR whereby the customer and supplier agree to collaboratively approach the effort and to share in the financial risks and potential rewards. This approach may serve as a model for other institutions that are required to develop equipment needed to meet evolving technical and regulatory requirements.

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