IMPACT OF THE RADIATION PROTECTION PROGRAM REQUIREMENT OF ST-1 ON THE UNITED STATES RADIOPHARMACEUTICAL INDUSTRY

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SUMMARY

The 1996 Edition of IAEA ST-1 contains a requirement that the transport of radioactive materials be covered by a Radiation Protection Program (RPP). The U.S. radiopharmaceutical industry makes more than 3 million shipments of radioactive materials each year. These shipments originate from manufacturing facilities and nuclear pharmacies. Although some shipments are made by the manufacturer's personnel, many of these shipments are transported by small carriers that do not operate fixed facilities and do not have radiation protection professionals on staff. Consequently, requiring a small carrier to write and implement a Radiation Protection Program is a costly and difficult requirement.

Until the changes brought on by the RPP requirement in ST-1, the radiation exposures and protection of transport workers were managed by passive controls built into the IAEA and local competent authority regulations. Examples of these passive controls include maximum transport indices (TI) on packages, maximum number of transport indices in vehicles, and separation distances. All of these passive controls were designed to limit radiation exposure to transport workers. In the United States, most of the radiopharmaceutical shipments are handled by independent carriers and not by the manufacturers. In other parts of the world, the manufacturer employs transport workers to deliver the radiopharmaceuticals. Those transport workers employed by the manufacturer are usually included in the fixed facilities' RPP.

It is not obvious that all transport workers who handle radioactive materials need to be covered under a Radiation Protection Program, as long as passive controls are in place. Most would agree that transport workers that handle large numbers of packages or packages with higher potential for exposure could benefit from a RPP. Some method of exempting certain smaller carriers is needed and would result in a more cost effective solution, without any reduction in their level of protection. No such exception currently exists in ST-1. Passive controls that have been in place for many years have proven effective in controlling the radiation doses received by transport workers. Adoption of an RPP requirement that does not recognize smaller transport operations is unduly restrictive and unnecessary.

DISCUSSION

The field of nuclear medicine provides physicians the ability to perform a variety of important diagnostic and therapeutic procedures. These diagnostic procedures include the detection of coronary heart disease, stroke, Alzheimer's, cancer, and complications from AIDS. Early detection usually leads to more effective treatment of these problems. Therapeutically, radiopharmaceuticals are used to treat patients with hyperthyroidism, blood disorders, certain types of cancer, and can offer the relief of pain from certain cancers. There is a tremendous need to get these radiopharmaceuticals into the hands of physicians in a timely manner, due to the very short half-lives. These products must be transported in a safe manner for the protection of the transport workers, and the public. The regulatory controls on the transport of these important radiopharmaceuticals and all radioactive materials can provide that level of safety assurance. However, over-regulation can also be crippling to a small business.

Passive controls have been used effectively in the IAEA recommendations, and by local competent authorities for many years. Passive controls may include radiation level limitations on packages, the use of bar labels to indicate the relative hazards of packages, separation distances, storage requirements based on transport indices, and others. These passive controls limit radiation exposure to transport workers administratively, and without any intervention. These passive controls are also very effective even if those transport workers do not have an extensive knowledge of radiation safety and ALARA (As Low As Reasonably Achievable) principles. That is what makes these controls passive. There is evidence that these passive controls have effectively limited the radiation doses to transport workers in the U.S. to levels below safety standard limits. This, in spite of the fact that there are more than 3 million shipments of radiopharmaceuticals each year in the U.S. Radiation Protection Specialists have other methods of limiting radiation exposure to workers. These other techniques often involve a more sophisticated knowledge of radiation physics and radiation biology. These techniques go beyond the common knowledge usually possessed by transport workers, and non- Health physics managers located in remote transport terminals. These more advanced techniques include things such as structural radiation shielding, time-motion studies, time-distance-shielding calculations and others.

Discussions in Vienna during the development of the 1996 edition of ST-1 included the provision for a required Radiation Protection Program for transport workers handling radioactive materials. The benefits to having transport workers covered under a RPP are obvious. A facility having a RPP would be much more likely to have some of the more sophisticated methods of limiting radiation exposure to workers. RPPs typically would require the consultation of a professional Radiation Protection Specialist. The benefits gained from having an effective RPP would be additive, to the exposure reductions already being achieved by the passive controls. IAEA Safety Series No. 120 contains a thorough review of the elements of effective Radiation Protection Programs. The RPP requirement clearly has a benefit to larger transport operations. However, a smaller transport operation does not have the same needs or ability to implement a large RPP. This intent was clearly specified in paragraph 301 of ST-1 where it states: "A Radiation Protection programme shall be established for the transport of

Materials - NUREG-0154. The DOT also has data from major radiopharmaceutical transport companies in the U.S. From this data the DOT has approximated an exposure index value of 4.5 uSv (0.45 mrem) per TI. The U.S. radiopharmaceutical industry has seen this value ranging from between 2.4 uSv (0.24 mrem) and 10 uSv (1.0 mrem) depending on what activities the transport workers were actually performing. The industry in the U.S. does not dispute the use of 4.5 uSv (0.45 mrem) per TI. DOT's desire was to use 1 mSv (100 mrem) as a threshold dose, below which a Radiation Protection Programs would not be required. Based on the 4.5 uSv (0.45 mrem) per TI exposure index, these transport workers could handle 200 TI and remain below the 1 mSv (100 mrem) value. This 200 TI became the proposed limit, below which transporters were exempt from the requirements of a RPP. This exemption value was proposed in their rulemaking to adopt several of the provisions of ST-1 in the U.S. It is very important to the U.S. radiopharmaceutical industry that some method of exempting small carriers is put into effect.

The radiopharmaceutical manufacturers and transporters in the U.S. were not pleased with the DOT's use of 200 TI as the exemption level. The industry felt that value was too low and would only exempt a very small number of transporters. A transporter handling one or two packages a week could easily exceed the 200 TI per year value, and would be required to operate under a RPP. The risk associated with handling only one or two packages per week does not pose a significant enough risk to justify a requirement for a RPP. Passive controls already in place can be relied on to provide this type of small operation with adequate protection. The industry has been proposing a higher value of 1000 TI per year, as the exemption level. This value was chosen because using an exposure index of 4.5 uSv (0.45 mrem) per TI, it would yield an annual dose less then 5 mSv (500 mrem). This proposal was filed as a Petition for Rulemaking with the DOT by the Radiopharmaceutical Shippers and Carriers Conference (RSCC). The RSCC is a U.S. based trade association of the manufacturers and transporters of radiopharmaceuticals. The petition proposed that the transporter be required to demonstrate that each worker was handling less than 1000 TI per year, or that the dose they received was less than 5 mSv (500 mrem).

The DOT has now withdrawn the rulemaking to require RPPs for all transport operations. DOT will continue to work with the industry in the U.S. to develop a U.S. requirement that employs the principles of a RPP as contained in ST-1, without it being a unnecessary burden to smaller carriers. The industry is pleased with the approach DOT has taken, and has vowed to work with them to develop a new regulation with an appropriate exemption for small transporters. The industry will continue to maintain that a level of 1000 TI handled per year is the appropriate exemption level. Any exemption lower than that will burden smaller transporters with costs that do not have a corresponding benefit.

CONCLUSION

The U.S. radiopharmaceutical industry ships more than 3 million packages each year to physicians and hospitals around the country. These important diagnostic and therapeutic drugs account for more than 10 million nuclear medicine procedures each year in the U.S., that provide lifesaving diagnostic information to physicians. It is important that these shipments be made safely, and in an efficient manner. To require

all transporters to develop and operate under a Radiation Protection Program is unnecessary because of passive controls already in place in the industry. Passive controls have worked well for many years controlling the doses to transport workers, and providing a safe working environment. A level of exemption is needed, below which these passive controls are the principle means of protecting the transport workers. The U.S. radiopharmaceutical industry is proposing an exemption level of 1000 TI handled per year as the appropriate level. Under the industry's recommendation, any transporter handling more than 1000 TI per year would be required to develop an RPP in addition to following the conventional passive controls. Anyone handling less than 1000 TI in a year, or providing evidence that workers receive less than 5 mSv (500 mrem) would be exempt from the RPP requirement. The issue of an exemption should be worked out before further development of implementing regulations in the U.S. proceeds. If such an exemption is not adopted, significant expenditures will be required by the industry, with no additional benefit to worker safety, or public welfare.

REFERENCES

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