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Radiopharmaceutical Shippers and Carriers Conference



GENERAL COUNSEL & SECRETARY

Lawrence W. Bierlein, Esq.
McCarthy, Sweeney & Harkaway, P.C.
(202) 393-5710

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**RE: Docket Number RSPA-99-6283; - 43
HM-230; RIN 2137-AD39**

Gentlemen:

These comments concerning RSPA's consideration of adopting ST-1 in the Hazardous Materials Regulations are submitted on behalf of the Radiopharmaceutical Shippers and Carriers Conference (RSCC). RSCC members include shippers and carriers of diagnostic and therapeutic radiopharmaceuticals and sealed sources used in therapy, diagnostic imaging, and calibration of instrumentation used in medical applications.

GENERAL COMMENTS

Adoption of new or modified requirements into the domestic regulations for transportation of radioactive materials must be justified in terms of cost and the need for improved safety and performance. The need for changes and additional technical complexity of the regulations such as the nuclide-specific thresholds is not warranted, based on the history of performance in the transportation of radioactive materials. The established safety and performance record of transportation of radiopharmaceuticals to accommodate 12 million medical tests each year has demonstrated that existing controls are effective. The weight of additional burden on shippers and carriers without an additional margin of safety must be avoided, particularly at a time when significant increases in registration fees are proposed.

More of concern than the lack of need for new regulation is the proposed timing of the implementation. The fact that RSPA tentatively plans to make the adoption of ST-1 effective on January 1, 2002, when the IMO and ICAO will likely adopt ST-1 on July 1, 2001, poses significant operational problems and the potential disruption of multi-model and international shipments as detailed in the specific comments. If RSPA were to revise 49 CFR 171.7, and 171.12(d) and (d)(4) to include a reference to ST-1, and modify the hazardous materials table in 172.101 to include the ST-1 proper shipping names, conflict with IMO and ICAO during 2001 could be avoided. RSCC would support rulemaking to initiate these changes. Although this would provide the needed flexibility to enable

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shipper compliance during the transition period, many carriers may be at best confused and at worst unwilling to accept consignments which do not meet the letter of the regulations with which they have been instructed to follow.

While we understand, especially those of us who ship internationally, the intent of RSPA to achieve harmonization with international transportation requirements, the current process used by domestic agencies to retrofit or otherwise adopt IAEA requirements in an inconsistent timeline needs to be changed. This is particularly important now that IAEA has gone to a two-year amendment cycle.

SPECIFIC COMMENTS

1. Scope

Language of the regulations needs to be simplified and clarified, rather than further complicated, to ensure understanding by various segments of the distribution network with a wide range of educational levels. ST-1 uses several terms, the definition and application of which are unclear and vulnerable to subjective interpretation. Examples include "worker", "appropriate training", "unlikely to exceed", "appropriate records", and "regularly occupied working areas." Due to the extensive interface between transport of radioactive materials and sites subject to NRC, Agreement State, and other nuclear regulatory agency jurisdiction, the definition and application of terms need to be clarified and consistent between ST-1 and the regulations of these other agencies, and need to be consistent with international regulations. ST-1 itself (paragraph 302) calls for consideration of the interface between transport and other activities.

2. Activity Limits and Material Restrictions

The scientific basis for the changes to the A_1/A_2 values is understood and justified. The problem with the adoption of these values is that RSPA proposes to adopt them six months after they will be adopted by IMO and ICAO. As a result, multi-modal domestic and international shippers will either be forced to make costly changes to systems to avoid the conflict, or will be subject to refusal by carriers. If RSPA were to allow voluntary compliance with the A_1/A_2 values in ST-1 during the interim period by adding a reference to ST-1 to 171.7 and 171.12(d) and (d)(4), this would enable shippers to continue to transport through the interim period without regulatory conflict.

The domestic Type A_2 limit of 20 Ci for Mo-99 should be retained with the adoption of ST-1. This is needed to allow domestic manufacturers to continue to provide Mo-99 generators to the diagnostic nuclear medicine community.

3. Communications Changes

Adoption of communications requirements of Section V of ST-1 again would impose unnecessary burdens on shippers without commensurate benefit to the safety of workers or the public.

The first area of concern is the change in the UN identification numbers and proper shipping names. It is understood that these changes were designed to provide more meaningful information on package contents to emergency response handlers of these packages in the distribution network. Based on the experience of our industry, however, we have found that expansion or complication of requirements concerning package marking and labeling tend to be counterproductive, in that the target audience for the intended improvement of communication often is confused by the additional information, as would be some carriers and end users of these packages. This concern is exacerbated by the timing of the proposed adoption of this requirement, particularly for international shipments. If adopted with ST-1, compliance with the requirements should be optional for the six-month interim period.

With the changes to the schedule of UN numbers and proper shipping names, ST-1 calls for marking the outside of excepted packages with UN number preceded by the letters "UN." The benefit of this requirement is not understood and its need is unidentified. Manufacturers and shippers of excepted quantities of radioactive material, especially life science research radiochemicals, have established with carriers and end users an understanding of the contents of excepted packages in accordance with current regulatory requirements. Of the several thousand packages shipped each week, a very small percentage become involved in incidents where a response is required external to the distribution system. In these incidents, even rarer is a situation where containment is breached. Ultimately the safety of those in contact with excepted packages is established by the limitation of activity in the package as required for excepted packages.

The addition of the UN identification number with the letters "UN" would do little to enhance the understanding of the contents of excepted packages or the safety of individuals responding to excepted package incidents. The addition would more likely confuse carriers and end users. The addition of the UN identification number and the letters "UN" should for excepted packages should not be adopted with ST-1.

The second concern involves the placarding of "freight containers carrying packages other than excepted packages." This should not be required as called for in paragraph 546. This provision is established in the domestic transport regulations and adoption of this requirement under ST-1 would not be based on any demonstrated need to improve on safety. What adoption would do is subject a large number of small carriers to the proposed registration and increased fee requirements. The ability of manufacturers to deliver short-lived diagnostic products to critical users would be jeopardized by the loss of carriers who may decide that the added costs associated with these additional fees precludes them from continuing in business of carrying radioactive materials. The domestic exception from the vehicle placarding requirements for unlabeled radioactive packages should be retained.

Finally, the use of SI units should be required with the adoption of ST-1 as included in paragraphs 543 for labeling and 549 for shipping papers. However, to maintain

continuity with current practices, traditional units should be allowed to be used with SI units for domestic shipments.

4. Requirements for Radioactive Materials and for Packagings and Packages

The allowance for the use of strong, tight packages for domestic exclusive use transport of LSA/SCO materials needs to be retained in 173.427.

5. Transitional Arrangements

Industry is highly dependent upon the use of Type B containers to transport bulk radiochemicals used in the formulation of radiopharmaceuticals. The containers used over the years have a flawless performance record and this is due to the capital investment made in their design and construction, and the numerous regulatory limitations imposed on their use. The regulations need to be clarified as to how packages manufactured under earlier versions of SS6 will be phased out, and how and if these packages could be revalidated.

With recognition that multilateral approval is required for continued use of packages manufactured to a design approved under the provisions of the 1973 Editions of the IAEA Regulations, and for packages designed under the provisions of the 1985 Edition of the Regulations for use after December 31, 2003, there is a concern that competent authority resources will be consumed by approval requests. With this in mind, we recommend that relief be provided under the requirements of 173.471 for domestic Type B shipments for expeditious review or extended expiration dates of U.S. competent authority certificates.

6. Other Changes

Radiation Protection

The general provisions for a radiation protection program are included in paragraphs 301 - 309 of ST-1. The intent is to provide a system for minimizing radiation dose to workers and the public.

Radiation protection programs (RPP's) have been used for many years by larger carriers in support of DOT exemptions for handling larger consignments (e.g., total TI greater than 50), and by shippers and carriers holding radioactive materials licenses. These programs have been productive in the minimization of dose and have provided useful data concerning the dose received as a function of the amount of radioactive material and packages handled.

A significant concern arises when RPP's are required for smaller carriers with the adoption of ST-1. Regardless of the fact that current regulations provide suitable protection to workers with smaller carriers and the public, smaller carriers would likely not have the resources to develop and implement such a program and would not be in a

position to continue in the business. Loss of these down-stream carriers would eliminate critical links in the distribution of radiopharmaceuticals and other key products to remote destinations.

In addition to the hardship placed on smaller carriers, there are concerns for all carriers. The requirements for RPP's include actions for which compliance will not be possible to demonstrate. For example, how would it be possible to document that, as required under 306 (b), radioactive material in transit is segregated "sufficiently" from members of the public to the extent that the critical group does not receive 1 mSv in a year? The passive controls already in place for maximum package, consignment, and vehicle dose rates provide adequate for protection of the public. Categorical exclusions for distribution segments where documented doses are less than 1 mSv should be considered.

The issue of terminology was introduced in the general comments. This applies specifically to radiation protection. Paragraph 305 (b) calls for "work place" monitoring or individual monitoring of "workers" where it is "assessed" that the effective dose is "likely" to be between 1 and 6 mSv in a year. What do "work place" and "workers" mean? Regardless, this approach to monitoring is inconsistent with NRC, Agreement State and other state regulations, which require monitoring of individuals who are likely to receive an annual occupational dose greater than or equal to 5 mSv.

Unless it is based on realistic and clearly defined performance expectations, the systematic approach for RPP's provided in ST-1 could result in serious disruption in the timely distribution of time-sensitive radiopharmaceuticals, and the capability of these and other radioactive materials to be transported without unnecessary additional regulatory burden. If the proposed increase in registration fees is not enough to reduce the already limited number of carriers willing to continue to carry radioactive freight, then perhaps the additional burdens associated with ST-1 radiation protection programs will be.

Adoption of ST-1 should not include the requirement for RPP's. These should be addressed by RSPA in separate rulemaking. In addition, the RSCC has submitted to RSPA a proposed change to ST-1 that has been accepted and reformatted as an identified problem for consideration by the September 2000 IAEA Revision Panel. The support that RSPA has provided in the industry's effort to resolve the problems with RPP's in ST-1 is appreciated and we would be willing to participate in discussions in September in the effort to complete resolution.

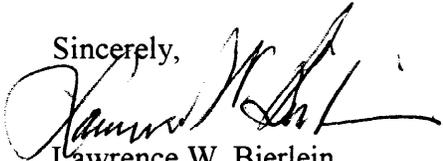
Quality Assurance

The provision for quality assurance programs in ST-1 should not be adopted without justification. Based on the history of transportation of radioactive materials, the passive controls already in place appear adequate. This is especially true for less than Type B quantity packages which, by limitation already established on quantity of content, should be categorically excluded.

Paragraph 310 includes wording that, as previously discussed, is subject to unilateral interpretation and applicability. It states that "programmes based on ... standards acceptable to the competent authority" and competent authority approval "shall ... be contingent upon the adequacy of the quality assurance programme." It has been this industry's experience that a single individual within the authority's organization can subjectively determine compliance based on his/her interpretation or opinion without regard for established agency or industry standard. There have also been many examples where one competent authority does not agree that a program approved by another competent authority is acceptable. The expectations in 310 are not clear and should not be adopted.

RSCC appreciates the solicitation that RSPA has extended to our industry for comments on the ANPRM and the willingness and availability demonstrated to discuss the issues. If you have any questions or need additional information concerning these comments, please feel free to contact us.

Sincerely,



Lawrence W. Bierlein
General Counsel and Secretary

RSCC
McCarthy, Sweeney & Harkaway, P.C.
Suite 600
2175 K Street, N.W.
Washington, DC 20037