



DEPT. OF TRANSPORTATION
DOCKETS
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June 28, 2000

Dockets Management System
U.S. Department of Transportation, PL401
400 Seventh Street, SW
Washington, D.C. 20590-0001

Reference: Docket No. RSPA-99-6283 (HM-230) - 34

Gentlemen:

On behalf of E.I. du Pont de Nemours and Company ("DuPont") I am submitting comments in response to DOT's Advance Notice of Proposed Rulemaking concerning the adoption of IAEA Safety Series 6, 1996 ("ST-1") published in the Federal Register (i.e. 64 FR72633, dated December 28, 1999). DuPont welcomes the opportunity to comment.

DuPont is one of the largest shippers in the world with a transportation budget exceeding \$1,500,000,000. During 1999 DuPont shipped over 3,000,000 shipments worldwide via air, rail, motor carrier, and ocean carrier. Recent estimates indicate that approximately 40% of DuPont's shipments are considered hazardous and are regulated under existing Department of Transportation regulations. Included in the annual statistics for hazardous shipments are 200,000 shipments (500,000 packages) of medical supplies containing low level amounts of radioactive materials.

Radiopharmaceuticals are important tools in the diagnosis and treatment of many life-threatening diseases including cancers. The life span of radioactive medical supplies is short; timely delivery is critical, and could literally mean the difference between life and death to seriously ill patients. DuPont has shipped radiopharmaceuticals for 38 years without a safety incident or a release.

DuPont appreciates DOT's efforts to harmonize federal requirements with the proposed international standards for hazardous materials known as ST-1; however, any costs incurred by shippers, carriers, and ultimately the consumer in the implementation of ST-1 should be commensurate with anticipated improvements in safety performance. The adoption of ST-1 or some form thereof is inevitable. DuPont has reviewed the comments contained on the DOT website and wishes to add the following comments:

DuPont foresees a reduction in the network of carriers of radioactive materials as a real possibility if ST-1 were implemented. Although the majority of radiopharmaceuticals are transported by common carriers holding exemptions, non-exempt carriers who qualify as "small entities" under the Regulatory Flexibility Act of 1980 also play a vital link in the distribution network. The costs incurred in implementing and maintaining the ST-1 standards (including the radiation protection program) will be difficult for small carriers to absorb and could result in many of them opting not to transport radiopharmaceuticals. Fewer shipping options will translate into more shipping delays and higher freight costs.

The proposed changes in the proper shipping names and UN identification numbers including the marking of UN numbers on all packages will be costly and burdensome for shippers. Changes necessary for compliance with ST-1 will include the reprinting of procedural manuals, reprinting of shipping cartons, and the updating of computer systems. Limited Quantity packages which did not previously require UN numbers will now require numbers. Drivers and shipping personnel who handled shipments of radioactive materials without any serious reservations in the past may be reluctant to handle the same shipments with the added marks and numbers resulting in confusion and further delays in shipping and delivery. Historically there have been no safety issues with Limited Quantity packages, and DuPont questions whether these proposed changes are justifiable.

The adoption of ST-1 will require significant changes in placarding requirements. Currently carriers transporting Yellow III packages must placard. If ST-1 is adopted, all White I and Yellow II will also require placarding. DuPont supports the position of NIST (see RSPA-99-6283-10) that the proposed placarding change is out of proportion and inconsistent with placarding requirements for other hazardous materials. The placarding of shipments that did not previously require placarding will restrict the routes over which carriers transporting these shipments can travel, and in emergency situations will result in personnel taking unnecessary precautions in handling. Placarded shipments must be hauled by licensed commercial drivers, and labor shortages of commercial drivers could cause further delays. In addition, the skills of commercial drivers dictate higher wages which will be incorporated into the higher prices for radiopharmaceuticals.

Executive Order 12866 requires agencies to regulate in the "most cost-effective manner," to make a "reasoned determination that the benefits of the intended regulation justify its costs," and to "develop regulations that "impose the least burden on society."

Undoubtedly the implementation of ST-1 will have a sizable economic impact on shippers, carriers and customers. ST-1 has not been implemented yet in the international community, so there is no record of improved safety to which DOT can point to justify the proposed changes. If DOT plans to go forward with adopting ST-1, all proposed exceptions should be given careful consideration. To reduce the burden and lessen the disruption to the distribution network, DuPont proposes a grace period for domestic shipments of radioactive materials during which any portions of ST-1 that are adopted are phased in.

In addition to radiopharmaceuticals, naturally occurring radioactive materials are shipped by the DuPont Minerals Business. DuPont Minerals also wishes to comment at this time:

The DuPont Minerals Business appreciates the opportunity to comment on the DOT advance notice of proposed rulemaking (64 FR 72633) concerning harmonization with the IAEA ST-1 document. Our business manages low levels of naturally occurring radioactive material contained in our raw material ores and selected mineral products. Transportation related costs from over-regulation of materials with low radionuclide content could have a material impact on our business, as well as on our minerals customers, many of whom are small business entities, without a commensurate increase in public safety. Our comments are listed below:

Naturally Occurring Radioactive Material Exclusion

Paragraph 107(e) of ST-1 excludes naturally occurring radioactive material as follows: “natural material and ores containing naturally occurring radionuclides which are not intended to be processed for use of these radionuclides provided the activity concentration of the material does not exceed 10 times the values specified in paras 401-406.

DuPont believes that the Department of Transportation (DOT) should maintain this exclusion as written. We fully support the existence of an exclusion for natural based material and ores which are not intended to be processed for their naturally occurring radionuclide content, at the 10 times level specified in ST-1.

In support, the IAEA Special Working Group on Exemption (in 1996) reported their “broad consensus” on the proposed exclusion, which subsequently became paragraph 107(e), and further stated that “The factor 10 was selected taking the following considerations into account: - the exemption values refer to the activity of the parent nuclide, if daughter products are involved; - the exemption values that were derived for the transport specific scenarios were almost always lower than the ones that were derived for the Basic Safety Series.” In fact, the report goes on to note that “There were one or two reservations on the factor that was felt to be too low” (emphasis added).

Indeed, paragraph 107.5 of the draft IAEA guidance for ST-1 [Advisory Material for the Regulations for the Safe Transport of Radioactive Material (1996 Edition), IAEA Safety Standards Series ST-2, 2/19/99 draft] further explains the scope of the exclusion, and an excerpt is shown below:

107.5: “The scope of the Regulations includes those natural materials or ores which form part of the nuclear fuel cycle or which will be processed in order to use their radioactive properties. The Regulations do not apply to other ores which may contain naturally occurring radionuclides, but whose usefulness does not lie in the fissile, fertile or radioactive properties of those nuclides, provided that the activity concentration does not exceed 10 times the exempt activity concentration values. Natural material and ores containing natural occurring radionuclides which are processed are also exempt from the Regulations (up to 10 times the exempt activity concentration values) where the physical and/or chemical processing is not for the purpose of extracting radionuclides, e.g., washed sands, tailings from alumina refining, etc. Were this not the case, the Regulations would have to be applied to enormous quantities of material that present a very low hazard...” (emphasis added).

We agree with the advisory statement. Application of ST-1 without the section 107(e) exclusion would substantially increase the number of “radioactive” materials subject to regulatory control, including such commercially important materials such as phosphate rock, copper ores, granite and brick construction materials, refractories, fertilizers and agricultural products, zircon, and bauxite, to name only a few. Absent the regulatory exclusion, the transportation related financial impact on small businesses (e.g., building construction/renovation, abrasive blasting, foundries, refractories/ceramics) could become disproportionately large for materials which are not markedly different from the natural landscape as compared with radioactive materials that have been regulated by DOT in the past. It is not the intent of ST-1 to inappropriately expand the universe of regulated material, not should it be the intent of the DOT.

It appropriate to distinguish materials “intended to be processed” for their radionuclide content from materials that incidentally contain radionuclides but are used for other purposes. Such an intent-based test is feasible, and is analogous to the regulatory approach used to distinguish NRC-regulated “byproduct” material from other categories of materials. For example, one definition of “byproduct materials” under the Atomic Energy Act of 1944 (42 USC §2011, et seq.) is “tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content (42 USC §2014).

In addition, ST-1 has provided further strengthening of the process intent distinction in the definition of LSA material (section II, 226(a)(i)), by stating that LSA-1 material includes “other ores containing naturally occurring radionuclides which are intended to be processed for the use of these radionuclides”.

Activity Limits and Material Restrictions

We believe it is important to note that naturally occurring radionuclide limits contained in Table I (ST-1, section IV) refer to parent nuclides and their progeny in equilibrium, for those radionuclides that contain a decay series. For example, the 1 Bq/g activity concentration for both exempt natural uranium and natural thorium includes both the parent nuclides as well as all their significant progeny (reference footnote (b)).

Use of this ST-1 methodology for determining exemption limits, or naturally occurring 10X exclusion limits, is critically important in applying ST-1 as it was intended to be used. For example, a material containing natural uranium at 3 Bq/g, and/or a material containing natural thorium at 3 Bq/g would be excluded from the standard (natural uranium or thorium at 10 times the Table I value of 1 Bq/g, or 10 Bq/g).

Indeed, the draft IAEA guidance for ST-1 [Advisory Material for the Regulations for the Safe Transport of Radioactive Material (1996 Edition), IAEA Safety Standards Series ST-2, 2/19/99 draft] states in paragraph 401.6: “It must be emphasized that, in the case of decay chains, the values in Table I columns 4 and 5 of the regulations relate to the activity or activity concentration of the parent nuclide.”

However, in application of the current transportation standard, DOT requires each of the nuclides in a decay series to be counted against the 70 Bq/g exemption criteria, which is a different approach as compared with the ST-1 method noted above. Misuse of the ST-1 Table I values for each radionuclide in a series would effectively negate the natural material and ores exclusion. For example, a natural uranium and/or thorium containing material would require division of the exclusion by either 14 and/or 10 daughter isotopes if the limit were misapplied, and materials with extremely low radionuclide content would mistakenly be regulated.

It is imperative that DOT recognizes that the approach used in ST-1 departs from the currently applied method of radionuclide calculation, and that conformance with ST-1 requires a new method of calculation to determine limits for decay series radionuclides.

Definition: Natural Uranium, Natural Thorium

Paragraph 246 of ST-1 defines natural uranium as follows: “Natural uranium shall mean chemically separated uranium containing the naturally occurring distribution of uranium isotopes (approximately 99.28% uranium-238, and 0.72% uranium-235 by mass).”

We believe that this definition is overly restrictive, in that chemically separated uranium is the only form referred to. Indeed, the restrictive use of this definition would exclude most materials containing naturally occurring uranium, where chemical separation has not occurred, and it is not intended for chemical separation to occur. Note that the natural material exclusion in 107(e) can only be utilized for materials not

intended to be process for their radionuclide content. As such, the definition for natural uranium is at odds with the intent of ST-1.

The current definition for natural uranium contained in 29 CFR 173.403 is more meaningful and appropriate: “Natural uranium” means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder essentially uranium-238).” Chemical separation is not applied. In adoption of the ST-1 standards, we encourage the replacement of the definition in ST-1 with that contained in the current DOT regulation.

ST-1 does not provide a definition for natural thorium. Accordingly, we encourage the adoption of the definition currently contained in 29 CFR 173.403: “Natural thorium means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 percent by weight of thorium-232).”

The inclusion of the definitions for natural uranium and thorium as specified above would ensure that non-excluded (107(e)) uranium and thorium containing materials would be considered low toxicity alpha emitters as defined in paragraph 227 of ST-1.

LSA & SCO Packaging

We support the provision in ST-1, paragraph 523, which enables the transport of unpackaged LSA-1 and SCO-1 under exclusive use, while ensuring non-release of radioactive material into the conveyance, and encourage DOT to adopt this provision.

We also agree that pipes containing SCO-1 can in essence, serve as their own package, as is noted in draft ST-2, paragraph 523.1: “According to para 241(a)(iii) and 523(c), SCO-1 is allowed to have non-fixed contamination on inaccessible surfaces in excess of the values specified in para. 241(a)(i). Items such as pipes resulting from the decommissioning of a facility shall be prepared for unpackaged transport in a way to ensure that there is no release of radioactive material into the conveyance. This can be done, for example, but using end caps or plugs at both ends of the pipes...”

It is also important to note that the labeling covered in paragraph 540 of ST-1, regarding LSA-1 or SCO-1 when shipped under provisions of paragraph 523, is only a recommendation, and is not required by regulation. Indeed, ST-2, paragraph 540.1, states: “...In situations where it is desirable to clearly identify the consignment as carrying radioactive material, the Regulations explicitly allow such an identifier to be marked on the wrapping or receptacle. It is important to note that the Regulations do not require such marking; the option is, however, made available for application where it is considered useful” (emphasis added). We believe that DOT should similarly enable flexibility in labeling as ST-1 does in paragraph 523 and 540.

In addition, DOT currently enables an exception from marking and labeling requirements for LSA and SCO, for domestic transportation, as covered in 29 CFR

173.427(a)(6)(vi). We believe that DOT should include this exception in its proposed rulemaking.

Definition: LSA Material

Paragraph 226(a)(iv) of ST-1 for LSA-1 material includes the following: “Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the values for activity concentration specified in paras 401-406, excluding fissile material in quantities not excepted under para. 672.”

However, the IAEA Special Working Group on Exemption (in 1996) recommended a modified paragraph, as follows: “radioactive material (for which the A_2 value is not unlimited) in which the activity is distributed throughout and the estimated specific activity does not exceed 30 times the exemption level in terms of activity concentration” (emphasis added).

We believe the intent of the working group, in referencing the A_2 value, was to clearly distinguish paragraph 226(a)(iv) from 226(a)(iii), which specifically covers radioactive material for which the A_2 value is unlimited. As such, we encourage DOT to include the reference “for which the A_2 value is not unlimited” in its definition of LSA-1 in its proposed rulemaking.

DuPont appreciates this opportunity to comment.

Very truly yours,



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