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Secretary
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**WRITTEN COMMENTS IN ADDITION TO ORAL COMMENTS
PRESENTED AT THE 9/26/00 PUBLIC MEETING
ON 10CFR PART 71, PROPOSED REVISION
COMPATIBILITY WITH ST-1**

Issue 1. Changing Part 71 to SI Units Only

General comments.

ST-1 requires use of SI units only on transportation packages and shipper's paperwork, but does not address or prohibit the use of the use of the dual-unit system, as called out in the NRC metrification policy, by member countries for internal use.

Application of SI methodology to other disciplines has not been commonplace. Astronomers do not express the speed of light as 0.3 tetrameters/second or a light-year as 9.5 examillimeters. Federal/state/local authorities do not publish speed limits in terms of __ megamillimeters/ hour

Factors for consideration

The changes of relevant documents to SI units for Certificates of Compliance (COC's) and licensing packages to SI units only has major potential cost impact. The possible financial implications for COC certificate holders, part 71 QA program holders and license holders must be addressed separately.

Possible financial implications for COC certificate holders and part 71 QA program holders.

Current COC's in our possession are not issued using SI or dual units. If the NRC Transportation Branch requires that changes in the COC's, the Part 71 Program Plans and implementing documents such as loading/labeling instructions included in the COC approval package and as part of Part 71 QA Program Plan require specific formal review and approval by this entity, not as part of normal reviews, these reviews could easily exceed \$15,000.00 per package or Part 71 QA Program Plan review, based on our knowledge of reviews performed for J.L. Shepherd and Associates (JLS&A) and talks with other COC holders. This does not include the time required by the certificate/QA program holder for internal review, audits, making the necessary changes in these programs and interfacing with this branch, which is of equal magnitude to the NRC direct costs.

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SECY-02

Consequently the potential cost per COC package or QA review would be \$30,000.00 or greater. Because the change from dual-unit to SI units only has no positive impact in reducing radiation exposures to operating or transport company personnel, increasing safety of transport or the safety of the general public, the cost of implementing it could be excessive for achieving no tangible results.

If these formal reviews and approvals are required for a compliance deadline date, there is the potential problem of timely response by the Transportation Branch if each COC package with supporting drawings and instructions and each Part 71 QA Program Plan requires this action, due to the immediate back log volume.

Because ST-1 does not address or prohibit dual-unit systems on the COC's themselves or the implementing documents, we would like to suggest that dual-use units be phased in as the COC's, with their implementing documents and drawings used as part of the COC itself, come up for renewal or package retesting. We would also like to suggest that conversion to dual-use units be voluntary for QA Program Plans and their implementing documents.

Possible costs for NRC/Agreement State license holders.

Part 71 references Part 20, 21, 30, 39, 40, 70, and 73

Implementing this program for transportation could impact all other Parts referenced in Part 71, per the above list. This could require that each holder of a NRC or Agreement State radioactive materials license which incorporates English (better termed traditional or dual-unit systems would be forced to rewrite the license, including all Radiological Safety Programs, and that each licensing agency, NRC or Agreement State, would be forced to re-write their licensing programs and licenses. The Code of Federal Regulations for 10 and 49 would also need to be rewritten in their entirety.

We have discussed this with Radiation Safety Officers at major universities, for example, and they predict that the cost for this conversion would be in the range of \$250,000.00-\$500,000.00 per year for no tangible reduction of radiation exposure or increase in public health and safety. The overall cost could be in the range of hundreds of millions of dollars. The time to achieve it would be measured in years, not months. The congestion at licensing agencies would be enormous with obvious results.

Risks and safety impacts which might occur in shipments because of possible confusion or erroneous conversion between the currently used English units and SI units

Workers in the transport industry who handle RAM shipments typically do not have four year college degrees, doctorates or other advanced degrees. Most drivers, but certainly not all, have high school diplomas. Typically material handlers do not have high school diplomas and many have only limited literacy in written and spoken English.

The increased complexity of dealing with SI units, especially in dealing with orders of magnitude and with confusing and unfamiliar prefixes, as compared with the English units with which these personnel are familiar, greatly increases the possibility of erroneous conversion and, more importantly, confusion in handling RAM shipments and possible unnecessary radiation exposure to these personnel.

In our production plant, despite repeated explanations, many of our non-radiological workers who have limited educational backgrounds, have serious difficulty in dealing with SI units, although they have good understanding of and deal competently with English units:

We provide Emergency Response training to local police officers and firemen, who typically have two or four year college degrees. Our experience has been that they have an excellent grasp of the English units, but have difficulty in dealing with SI units, especially in dealing with emergency conditions which do not lend themselves to cerebral conversions. This is confirmed by the retired fire captain who does our yearly recertification of hazardous waste operations and emergency response. The difficulty found in SI conversion for emergency response personnel without using dual-units could easily result in unnecessary deaths. Conversion training costs could seriously impact Fire Department and other first responder budgets resulting in decreased responses to other types of emergencies.

As part of the installation of our devices, we also provide radiation and use training. It is interesting to note that the great majority of our customers, both in the USA and overseas, most of whom have advanced college degrees, prefer and use English rather than SI units routinely.

Transition period for conversion to exclusive use of SI units

Using the attempt to convert English to Metric units in the USA for general commerce, which has been attempted for more than 30 years with less than 10% success as a norm, a transition period of 10 years would be a minimum, with the caveat that all workers dealing with these units be trained to be competent in both algebra and mathematical notation. With the lack of educational success with the routine conversion to metric, if SI units were to be used exclusively instead of dual-units, we believe that there could be serious health and safety implications not only for QA Program Plan holders, transporters and licensees, but to the general public as well.

Summary.

The implementation of this program can result in major costs with no positive results in the enhancement of public health and safety or reduction of radiation exposure to radiation workers.

Both the NRC and Agreement States would require significant additions to personnel and budgets for the implementation to SI units only, with increased costs passed onto licensees, with no other increases in services.

We would like to ask if the NRC has interfaced with the CRCPD, heads of Agreement States, NRC Agreement States Programs for impact and cost analysis. Many of the CRCPD members, including Agreement State heads, are under the impression that this proposal only effects shipments and QA Program Plans.

Although we did not get a chance to comment on this issue before the DOT comment period was up, we ask that the DOT also consider these risks in their formulation of compatibility.

Issue 2. Radionuclide Exemption Values

Unless it can be shown that the use of the DOT exemption values have compromised Public Health and Safety these values should be referred to in Part 71. These should be applied to all domestic shipments.

For foreign shipments only the ST-1 exemption values should be adapted in part 71. This standard should not be difficult to implement for foreign shipments.

For domestic shipments the additional costs involved by adapting the ST-1 values could be justified only by possible enhancement of public health and safety related to these shipments.

The adaption of the ST-1 exemption values could create havoc for those using the current DOT values for non-transportation activities such as licensing.

To avoid burdensome and unnecessary costs for these entities, it would be necessary for the NRC to set up a protocol for specifically adapting the DOT values for these applications. Would this cost be offset by enhanced public health and safety?

Issue 3. Revision of A₁ and A₂

For the shipments we make the A₁ and A₂ values as set out in ST-1 are both well-documented and practical for transportation. There seems to be no practical alternative to the adoption of these values.

Issue 4. Uranium Hexafluoride Package Requirements

No comment.

Issue 5. Introduction of Criticality Safety Index (CSI) Requirements

No issues are envisioned in the use of two TI values for a shipment. The use of the CSI index should enhance shipment of this material with minimum burden on the shippers.

Issue 6. Type C Packages and Low Dispersible Material

Currently certified Type B packages which are used for transporting Cobalt-60 for use in process irradiators which have loadings of $\geq 100,000$ Ci. (3.7×10^{15} Bq) Co-60 would be restricted from air transport. This would result in the requirement for multiple, typically 3-10 or more shipments, replacing a single shipment under current regulations with large increases in transport costs. These are typically $\geq \$1.00$ / lb for these air shipments which usually weigh 10,000-15,000 lb.

Does increasing the number of shipments by a factor of 3 to 10 or greater really enhance public health and safety?

Are the increased shipping costs, which would increase overall costs per shipment to operators of process irradiators by $\geq 25\%$, justified by a program which would actually decrease public health and safety by required multiple shipments?

Because large Curie Cobalt-60 process irradiators are used for medical sterilization and/or food irradiation, besides increasing the number of radioactive materials shipments, Medicare, health insurance and other related medical/first aid/cosmetic costs (bandages and other sterile throw away items) will be greatly increased to reflect higher transportation costs for reloading these irradiators. In the case of food irradiation for the eradication of such bacteria as ecoli and salmonella, would the fledgling public acceptance of this process be destroyed because of increased costs and the presumed perception of greater risk?

Issue 7. Deep Immersion Test.

In practicality the quantities listed would be limited to irradiated fuel elements. Shipment of radioisotopes rarely, if ever, contain these amounts.

It is suggested that the present 10CFR71.61 criteria be maintained and extended to cover all packages with activity levels $\geq 10^5 A_2$ quantities with the note that this specification is more conservative than the ST-1 requirements. This should eliminate the requirement for special review and certification of US origin package designs.

For non-irradiated fuel element shipments, there should be no impact on availability and shipping costs because there are few, if any, shipments of the required quantities of this material.

With the application to B(U) packages containing A_1 special form sources are these packages exempt from this test or is this an oversight?

Issue 8. Grand fathering Previously Approved Packages

Please note that this section on the "Grand fathering" issue relates only to NRC Type B COC packages. Packages for fissile material and part 71/72 dual use packages for Spent Fuel are not included in our comments.

With reference to the various IAEA publications; Safety Series # 6, 1967 edition, ibid 1973 edition, ibid 1973 edition as amended 1979, ibid 1985 edition as amended 1990 and ST-1, 1996 edition, the date of the edition is not of significance, only the testing requirements for Type B (1969 edition) and type B(U) (subsequent editions) packages.

If a package has been certified under an earlier edition, let us say 1967 or 1973, it should be necessary only to demonstrate this package will pass any revised or additional tests as required under latest edition, ST-1 (1996), and not to recertify the entire package to permit use of the package.

Let us consider the various tests required for Type B and B(U) packages as sequentially listed in the IAEA editions.

Drop I: unchanged 1967-1996 editions.

Drop II: unchanged 1967-1996 editions.

Drop III: added 1985 edition-1996 edition.

This is actually a meaningless test for packages ≥ 500 Kg in that it has identical effect as Drop I for these packages.

For existing COC packages which exceed 500 KG mass no additional testing should be required to meet the 1985-1996 requirement.

For those packages with ≤ 500 Kg mass providing the NRC with test results or calculations proving the capability of these packages to meet this test should permit the NRC to issue a revised certificate reflecting current regulations with reference to this test.

We suggest that all packages of ≥ 500 Kg mass should be automatically "Grandfathered" in.

Thermal Test. Unchanged from 1967-1996 editions with the single exception of the addition of para.728(b) to the 1996 edition. This is not a destructive test. Calculations to show the capability of a package to meet this paragraph are simple.

All existing packages can be "Grandfathered" in using the "last two major revisions" criteria.

Providing the NRC with either test data or calculations proving that an existing COC package meets this requirement should permit the NRC to issue a revised certificate reflecting current regulations with reference to this test.

Water immersion test. Added in 1973 edition and unchanged thru 1996 edition. In fact any COC packages with metal outer surfaces or metal outer surfaces covering solid wood interiors can be easily shown to meet this requirement. Providing the NRC with either test data or calculations showing that these packages meet this requirement should permit the NRC to issue a revised certificate reflecting current regulations with reference to this test.

Because of the time required for manufacturers to test or perform the required calculations to prove that existing COC packages meet all current test requirements as discussed above, estimated at \leq one year and the time required by the NRC to evaluate this data, unknown, these packages should be "Grandfathered" in for one year plus the time required by the NRC to perform the evaluations and issue the revised certificates for all existing packages.

This would be in order because these packages have an excellent history, no documented releases of radioactive material or radiation resulting from accidental conditions of transport, and meet all current critical criteria as called out in ST-1.

Based on thousands of these types of packages which we have encountered, passing the "Water immersion test" will be no problem and ST-1, para 728(b), the additional "Thermal" test, is already accounted for by wattage limitations placed on these packages by the NRC.

Consequently, public health and safety would not be compromised if these packages are "Grandfathered" in as recommended above.

On the other hand public health and safety could be seriously compromised if these packages are not Grandfathered" in. Because no packages exist which are currently certified to meet ST-1 and which are capable of transporting the thousands of Irradiators and Calibrators containing Type B quantities of radioactive material currently existing in US universities, hospitals, DOD, DOE and industrial facilities, each of these facilities will be unable to ship these type B quantities and become de-facto a long-term high level REPOSITORIES for these type B quantities of RAM.

Is it the intention of the NRC to instantaneously create thousands of long-term REPOSITORIES for large (Type B) quantities of RAM? In my opinion the creation of these REPOSITORIES is not in the interest of public health and safety or of the licensees who possess this material.

The Orphan Source Program, which CRCPD, the USNRC, Agreement States and the USDOT have been working on for the past several years could be placed in jeopardy. Orphan Sources with \geq Type A₁ or A₂ quantities are shipped in the types of Type B packages under question. Have these Program participants been notified of the potential impact of adoption of ST-1? It is our opinion that cessation of Type B quantities of RAM under the Orphan Source Program (which includes abandoned sources) will seriously impact public health and safety.

Some waste shipments contain greater than Type A₁ or A₂ quantities and are shipped in the types of Type B packages under question. Have waste program participants (brokers, licensees and their regulators) been notified of the potential impact of adoption of ST-1? It is our opinion that cessation of Type B quantities of RAM in these packages (which includes abandoned and orphaned sources) will seriously impact public health and safety. Is it the intention of the NRC to instantaneously create thousands of long-term REPOSITORIES for large (Type B) quantities of RAM destined for land disposal as waste?

The two-year frequency of reviewing and updating ST-1 is somewhat impractical. Typical time to design, fabricate and test a package to meet a revised ST-1 specification is greater than two years followed by the time required by the NRC to evaluate and issue a certificate for the package. If calculations rather than testing are presented to the NRC, this evaluation time must precede fabrication.

Consequently designing a new package and obtaining certification therefore will probably require greater than the two year ST-1 revision periods. No manufacturer is likely to make the investment in designing a new package if it is probable that the package requirements for certification will materially change during the design/fabrication/certification period rendering the package obsolete and of no value prior to initial use.

Issue 9. No comment.

Issue 10. No comment.

Issue 11. No comment.

Issue 12. Special Package Approvals.

"Large Objects fall into three categories (as a minimum):

1. Reactor Vessels which contain very large quantities of radioactive material.
2. Miscellaneous materials such activated shielding material or building material removed from decommissioned Cyclotrons, Accelerators etc., which may contain Type B quantities of RAM.
3. Irradiators typically used for research which contain type B quantities of RAM and were fabricated prior to current shipping regulations which are to be shipped for decommissioning.

Revising part 71 to include Category 1, Reactor Vessels, incorporating the risk-informed basis used for the Trojan shipment is feasible; however the adoption of a "Special Arrangement" provision may be more expedient because of the various of types of these Vessels which must be addressed, i.e. those from Power and those from Research reactors.

Revising part 71 to include Category 2 would be difficult because of the variables and associated risks involved.

As discussed at the public meeting, revision of part 71 to include Category 3, old Irradiators to be shipped for decommissioning, should be excluded from this rule making. There are many Cobalt-60 and Cesium-137 irradiators, originally used for research, which are located in the US. Many units of this type have no package markings, or these markings have been removed. Unlike reactor vessels, there are normally no drawing packages available for these units, many of which were one-of-a-kind, rendering a "Special Package Approval" impossible by the NRC.

The majority of the original manufacturers of these packages are now extinct; most were AEC licensees and AEC records, especially for transportation criteria, may be unavailable. These should be subject for possible consideration for a future rule making.

These joint NRC/DOT reviews and "Exemption Certificates" should be provided at no cost to the requester, otherwise the problems and endangerment of public health and safety as discussed previously, especially with concerns to orphan sources, will again be a result of this adoption into Part 71. Currently shippable packages under DOT exemption could become orphan sources.

It should be noted that the DOT exemption review process has worked very well and to our knowledge there has been no release of RAM from the sealed sources during a transportation accident for an exempt shipment. Additionally, it should be noted that historically there have been no reported releases of either radioactive material or excessive radiation from these old packages resulting from accidents in transport although large numbers of shipments were made in these packages.

Issue 13. Expansion of Part 71 QA Requirements ...

10CFR72 relates to Licensing requirements for Independent Storage of Spent Nuclear Fuel and High-level Radioactive Waste only. Issue 13 should only relate to the "Dual-purpose" use of these casks for transportation as well as for storage.

Consistency of QA provisions between parts 71 and 72 should be maintained for dual purpose casks used for storage and transportation of Spent Nuclear Fuel and High-level radioactive waste only.

The following notes are offered for consideration.

The distinction has never been made by the NRC Transportation Branch between the part 71/72 packages used to transport/store for spent fuel, and the Part 71 packages used to transport sealed and "Special Form" radioactive sources as well as other radioisotopes used by both Medical and Industrial entities, and the relative RISKS associated with transportation of these categories of packages. The associated non-reactor licensable activities (Parts 20, 21, 30, 39, 40, 70 and 73 as referenced in part 71) have vast differences between fuel, sealed sources, radio pharmacy, etc., and the risks relative to shipments by these activities, which are completely distinct from spent or irradiated fuel.

We find it interesting that Part 71 and 72 dual cask uses have no cross reference to Part 50 reactor licensees. We suggest that all other licensee types be specifically exempted from participation in Nuclear Power Specific QA activities with this proposed implementation of ST-1. We would like to ask the NRC to carefully consider the cross references in Part 71 for non-reactor activities.

Many holders of part 71 QA programs and COC certificates design, manufacture, maintain and ship only sealed and "Special Form" sources, radio pharmaceutical isotopes, etc. containing radioactive material. This group is not involved in and has no interest in either Part 71 irradiated fuel or Part 72 spent fuel casks or shipments thereof, or with casks for fissile material.

and Issue 14. Adoption of ASME Codes.

The NRC's justification for including ASME Codes, ASME inspections and stamps is based upon problems found during QA/QC inspections performed at manufacturers/users of part 71/72 spent fuel transportation casks. As an extension of a Part 50 licensee QA/QC program, the extension ASME code for the transport and storage of fuel element casks only is not unreasonable.

However, we suggest that the adoption of ASME Codes for 71/71 dual-use spent fuel packages should not be applied to other packages, based on "Risk analysis" comparing Irradiated Fuel Elements" with radioactive sources doubly encapsulated in SS with welded closures and certified to meet the "Special Form" requirements of 10CFR71.75 and .77 and other types of Medical/Industrial packages.

The relative "Risk Factor" for the contained material must be reflected in the requirements for the shipping package. Shipping packages for radionuclide capsules are generally in the form of an inner shielded containment which contains the capsule. This inner containment contains the biological shielding, lead or lead equivalent, contained in an all welded steel containment with substantial wall thickness, typically 1/4" minimum. This inner containment in turn is packaged in an outer containment (overpack) which provides the impact and thermal shielding.

Broaching welds on the outer containment (overpack) by the impact (Drop) tests, if the outer surface is metal, is of consequence only if this would lead to decreased thermal resistance for the subsequent thermal test. Broaching welds on the inner containment is unlikely because the overpack is the impact shield designed to crush sufficiently to reduce deceleration to the inner containment. Even if an inner weld were broached, the lead shielding (worst case) would not be compromised because the thermal shielding in the overpack combined with the heat capacity of the inner containment retains the temperature of the inner containment to below the melting point of lead.

In consequence of the above observations, it should be concluded that the requirement for the ASME welding specification should be applied to part 72 packages to be carried over to part 71 for shipping.

Likewise it should be concluded that the ASME welding specification should NOT be applied to shipping packages for sealed radioisotopic sources.

The ANSI standards for this type of inner containment, and the conditions of 10CFR 71, Subparts E, F & H, plus 36 Subpart C are based on established ANSI, ISO and other radiation related standards. In our opinion, these 10CFR reference standards for sealed sources and radiation related activities are more appropriate and effectual for the packaging and shipment of non-fuel radioactive materials. These activities are not associated with nuclear reactor components in any manner and should not be subject to the risks of reactor and fuel activities.

Issue 15. Adoption of Changes, Tests and Experiments Authority

Issues 16 through 18. No comment.

Comments written by:


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