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Regulatory Issues Associated with Shipment of Small Quantities of Radioactive Material

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Abstract

Following decertification of the ubiquitous and simple DOT 6M specification package, radioactive materials package Shippers have been faced with the need to use Certified Type B packagings. Many DOE, commercial and academic programs have a need to ship small masses of radioactive material, where the identity of the material or radionuclides is know but the individual activity of some may not be known. For quantities which are small enough to be fissile exempt and have adequate shielding to ensure low radiation levels, these materials could be transported in a package which provides the required containment level. Because their Chalfant type containment vessels meet the ANSI N14.5 definition for leak-tight ($\leq 1x10^{-7}$ ref cm^3 air/sec), the 9975, 9977, and 9978 are capable of transporting contents requiring the highest standard of containment. The issues associated with certification of a high-integrity, general purpose package for shipping small quantities of such radioactive material are discussed and certification of the packages for this mission is recommended.

Background

Shipment of small amounts of radioactive material (RAM) is a common activity at many academic, commercial, medical and governmental sites. Some of the contents which must be shipped may not be precisely characterized, in that the identity of the material or radionuclides is know but the individual activity of some may not be known. For many such cases the quantity is sufficiently small that the materials are fissile exempt and have low radiation levels. In the past, such contents were shipped in 6M or similar specification packagings. These specification packagings are no longer approved for use. A packaging with adequate containment vessel could ship such contents, satisfying functional requirements of containment, subcriticality and shielding. A strategy is proposed that would enable shipment of small quantities of all these radioactive materials in such a packaging.

Minimal Quantity Proposal

The essential requirements for safe transport of radioactive materials (RAM) is that they be properly contained, are subcritical under all conditions, and do not expose the public, workers, or the environment to radiation dose levels greater than those permitted by the regulations (10 CFR 71) [1]. These requirements would be satisfied if such contents were limited to a quantity that was inherently subcritical (e.g., a fissile exempt amount), were shown by calculation or dose rate measurement to meet the regulatory limits, were placed in a leaktight containment vessel, and were transported in a packaging certified for larger quantities of similar materials. Because their Chalfant type containment vessels meet the highest standard of containment (leaktight, per ANSI N14.5 [1]), the 9975, 9977, and 9978 are capable of transporting any of these contents.

Contents Description

The contents allowed under this proposal would be small masses of solid radioactive material. The materials may consist of previously authorized materials with small concentrations of other actinides, fission products, decay products, and neutron activation products greater than that permitted by the authorized contents. Or, the contents may consist solely of actinides, fission products, decay products, and neutron activation products, and similar materials. Identification of these constituents may be based on process knowledge.

The contents proposed here, for the 9975, 9977 or 9978, would:

- have a total fissile material mass less than the fissile mass limits given in Tables 1 and 2, below.
- produce less than 19 w of decay-heat generation,
- have a total mass (RAM and packing materials) of no more than the certified contents weight for the packaging. (e.g., for 9975, 40 lb; for 9977, 100lb; for the 9978, 50 lb)
- be contained in a separate convenience container with an attached top,
- include less than 100 gm of plastic or other organic material,
- be solid (metal or oxide),
- contain no liquids,
- not react chemically with the containment vessel or packing, or cause corrosion; and
- not generate significant gas, other than helium from alpha decay.
- conform to the regulatory dose rate limits for a package (e.g., 2 mSv/hr at package surface).

Applicable Regulations

The regulations which control shipment of radioactive materials are contained in Titles 10 and 49 of the US Code of Federal Regulations (CFR), Part 71 and 173, respectively. The Minimal Quantity proposal conforms to the requirements of the Titles 10 and 49 [3]. Both of these parts of the Code of Federal Regulation make provision for a graded approach for shipment of small amounts of radioactive material.

Identification of Contents
49CFR 173.433(e) addresses cases where the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known. In these cases, "the radionuclides may be grouped and the lowest A1 or A2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas (for combined A1 and A2 determination). Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A1 or A2 values for the alpha emitters or beta/gamma emitters, respectively."

Excepted Amounts
173.421 excepts radioactive materials from the packaging and labeling requirements if the amount is less that 10-2 A2 and the radiation level at the external surface of the package does not exceed 0.005 mSv/hr (0.5 mrem/hr).
(The regulatory limit for packages is 2 mSv/hr (200 mrem/hr) on the package surface.)

Low-Level Materials (10 CFR 71.14)
Section 71.14, Exemption for low-level materials, exempts a licensee from all requirements of 10 CFR 71 (except for labeling and air transport of Pu) for packages having a sufficiently low specific activity. In 71.14, this limiting amount is given for each radionuclide in Table A-2 of the Appendix to 10 CFR 71.

Alternatively (in 71.14 (b)), packages with no fissile material or meeting fissile exemption standards are similarly exempt for the requirements for a Type A quantity, or material which is Low Specific Activity (LSA) or is a Surface Contaminated Object (SCO) having an external radiation level measured at 3 m from the unshielded material or object that does not exceed 10 mSv/hr. Likewise, special form items containing Pu-244 not exceeding 20 Ci are exempt from the requirements.

In the discussion of the rule making behind 71.14, the NRC notes that "without the exempt activity for consignments value, any quantity of material that exceeded the exempt activity concentration, no matter how small, would be regulated in transport as radioactive material. The exempt consignment value is included to prevent the regulation of trivial quantities of material as hazardous material in transport."

It is worthy of note that, the criteria for LSA and SCO materials are typically specified in micro Sv/hr, or Ci, that is, in terms of count rate or dose rate. Accordingly, demonstrating that these criteria are met requires measurement of count rate or dose rate for the contents in question.

Fissile Material Exemptions
Small quantities of fissile material are addressed explicitly in 10 CFR 71.15. This section recognizes a category of contents such that, even though fissile or fissionable, the quantity present is small enough that, regardless of configuration or moderation, a nuclear criticality cannot occur. In accordance with 71.15, the materials are exempt from being classified as fissile and from meeting fissile material requirements of other Type B packages. The limits on this category include:

- No more that 2 gm of fissile material.
- No more than15 gm of fissile material in a package with at least 200 gm of nonfissile material for every gram of fissile material.
- Low concentrations of solid fissile material commingled with solid nonfissile material with at least 2000 gm or solid non fissile material for every gram of fissile material. For a contiguous solid, the ratio is 180 gm of fissile distributed within 360 kg of nonfissile material.
- Lead, beryllium, graphite and hydrogeneous material enriched with deuterium are permitted, but may not be included in the mass of nonfissile material.
- Provisions are also made for uranyl nitrate solutions having low concentrations of fissile constituents, with special limits on U-233 and 235.
- No more that 1000 gm of Pu (of which no more that 20 % is 239, 241 or combination of them).

Type A Quantity
Regulation 49 CFR 173 establishes Type A packages. The maximum activity of radioactive material permitted in a Type A package is limited to the A1 and A2 amounts listed in 49 CFR 173.435. That is, 49 CFR 173 provides a blanket contents authorization, for shipment in a Type A packaging, of any and all materials listed in the A1/A2 Tables, 173.435, provided the level of radiation is not greater than that given in the Table.

The permitted contents for Type A packages includes materials which is LSA (i.e., radioactive material with specific contents, specified as A2/gm, which is within the limits defined in 173.403). For material which meets the criteria to be classified as LSA, the actual amount of radioactive material present may exceed a Type A quantity.

Type B Quantity
Regulation 10 CFR 71 establishes Type B packages. A package whose permitted activity is greater than that permitted in a Type A package is classified as a Type B package. That is, packages containing activity in excess of the A1 and A2 amounts, listed in the A1/A2 Table (49CFR173.435 or 10 CFR 71, Appendix A) are classed as Type B. For Type B packagings, the regulations (10CFR71.33) require, in part:

The application must include a description of the proposed package in sufficient detail to identify the package accurately and provide a sufficient basis for evaluation of the package. The description must include:…

(b) With respect to the contents of the package-
1. Identification and maximum radioactivity of radioactive constituents;

2. Identification and maximum quantities of fissile constituents;
3. Chemical and physical form;
4. Extent of reflection, the amount and identity of nonfissile materials used as neutron absorbers or moderators, and the atomic ratio of moderator to fissile constituents;
5. Maximum normal operating pressure;
6. Maximum weight;
7. Maximum decay heat; and
8. Identification and volumes of any coolants.

Regulatory Guide 7.9
In addition to the Code of Federal Regulations, guidance on contents description for packaging is given in Regulatory Guide 7.9 (RG7.9)[4], Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material. Section 1.2.2, Contents, provides guidance that is substantially the same as the requirements of the Regulations.

This section should state the quantity of radionuclides to be transported. The description should include the following information (if appropriate):
- *identification and maximum quantity (radioactivity or mass) of the radioactive material*
- *identification and maximum quantity of fissile material*
- *chemical and physical form, including density and moisture content and the presence of any moderating constituents….*

IAEA TS-R-1
The IAEA Advisory Material for Safe Transport of Radioactive Material [5] is generally consistent with the Code of Federal Regulations. The Advisory Material describes a graded approach. For very low levels, when the risk is of no regulatory concern, the package is exempted from the regulations (Paragraph 401.3).

Paragraph 401.3 gives general principles for exemption from the regulations. These are:
(a) The radiation risks to individuals caused by the exempted practice or source be sufficiently low as to be of no regulatory concern.
(b) the collective radiological impact of the exempted practice or source be sufficiently low as to not warrant regulatory control under prevailing circumstances, and
(c) the exempted practices and sources be inherently safe, with no applicable likelihood of scenarios that could lead to a failure to meet the criteria in (a) or(b).
This is based on very low levels, e.g., 10 micro Sv/yr for normal conditions.

Similarly, Paragraph 515. provides requirements for Excepted packages in which the allowed radioactive content is restricted to such low levels that the potential hazards are insignificant.

Identification of Contents

The IAEA Advisory Material (Paragraph 405) addresses cases where the identity of the radionuclides are known, but the individual activities of some of the radionuclides are not known. In these cases, the guidance is identical to US Code of Federal Regulations. In these cases, "the radionuclides may be grouped and the lowest radionuclide value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraphs 404 and 414. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest radionuclide values for the alpha emitters or beta/gamma emitters, respectively." As noted above, 49CFR 173.433(e) provides essentially the same guidance.

External Radiation Standards

The allowable external radiation dose rates are specified in 10 CFR 71.47 to be: 2 mSv/hr (200mrem/hr) on the surface of the package. Higher dose rates are allowed for shipments under "exclusive use" conditions. Section 5.4 of RG7.9 requires description of the methods used for determination of dose rates at selected points outside of the package. The results of the analysis are summary tables that identify locations of maximum dose rates for the analysis and provide sufficient data to show that the radiation levels are reasonable and their variations with location are consistent with the geometry and shielding characteristics of the package. The results include normal and accident conditions.

Summary of Regulatory Positions

The Regulations establish criteria that provide protection for the public, workers and environment from the hazards associated with RAM. To do this, they identify the material in question and require the appropriate level of containment for it, ensure that it remains subcritical if it is fissile, and insure that the radiation dose from the package is limited to a safe level. The applicable regulations for the case of the Minimal Quantity Concept address these three basic requirements.

Material Identification

The Regulations require identification of the radioactive constituents, their maximum radioactivity and their chemical and physical form. If individual activities of some nuclides are not known, the radionuclides may be grouped, using methods specified in the regulations.

The identity of the radioactive constituents must be known sufficiently well for the A1 and A2 values to be determined. Trace level impurities that do not contribute significantly to the A1 and A2 equivalent values do not require further characterization, and are characterized as "impurities". In the words of TS-R-1, these are "sufficiently low as to be of no regulatory concern." (TS-R-1, Para 401.3)

Other aspects important to package integrity and safety must also be identified.

Containment

For all radioactive materials, the regulatory containment requirements (10^{-6} A2 per hour for NCT and an A2 per week for HAC) must be met.

Criticality
For fissile materials, the material must remain subcritical. In order to determine this, the quantity of fissile material must be known. Other aspects important to criticality safety, such as presence of moderators or reflectors, must also be identified.

The identity and quantity of fissile constituents must be sufficiently well known that subcriticality can be clearly demonstrated by a criticality analysis, or be shown to be bounded by previous analyses. In practice, this requires knowledge of, or measurement of mass of fissile constituents. Contents with sufficiently low mass are considered fissile exempt. That is, if the amount is small enough that criticality cannot occur under any conditions, the content is exempt from detailed, regulatory requirements, imposed to ensure against a nuclear criticality. The regulatory criterion for categorizing such contents is mass of fissile material (71.53).

Shielding
The maximum radioactivity must be known to meet the regulatory requirements of 10 CFR 71.47 (e.g., 2 mSv/hr (200mrem/hr) on the surface of the package). This part specifies dose rates, so the acceptable level is determined by determining or measuring dose rate for the package.

RG7.9 calls for the applicant to provide information to enable understanding of the shielding arrangement so that the effects of any configuration changes in the contents on the external dose rate for the package is apparent, and to identify possible critical areas (having highest dose rate) in the shielding arrangement. This evaluation is to include the effects of HAC events on contents and shielding configuration.

Graded Approach
The Regulations provide a graded approach for small quantities of radioactive materials. This is the case for both radiation and criticality hazards. As is shown above, Contents with sufficiently low levels of radioactivity, that they are a minimal hazard, are exempt from the package performance requirements of the regulations. The regulatory criterion for categorizing such contents is radioactivity or specific radioactivity.

For example, all contents having less than an A1 or A2 quantity, as appropriate, can be shipped in a Type A package. Or, contents having less that 70 Bq/gm, or LSA with less than 10 mSv/h at hr at 3m, are exempt from 10 CFR 71 Requirements. Use of Dose Rate measurement for contents categorization is explicitly invoked by these requirements.

Minimal Quantity Concept - Comparison with Regulations
The issues for authorization of a Minimal Quantity Contents are the same as for authorization other contents for any certified packaging, and the Minimal Quantity proposal conforms in all regards to 10 CFR 71. The material must be contained, subcriticality must be ensured and radiation dose rate at the package must meet regulatory limits. In addition, the packaging must be able to withstand the NCT and HAC test conditions. As noted previously, since the amount of radioactive material is

small, compared to the previously certified contents for the proposed packages, most of these requirements are met with large margins (structural, thermal, containment, shielding, and criticality).

The proposed contents are given in Table 1.

Material Identification

For a Minimum Quantity Contents, the material to be shipped must be identified so that the radiological hazard can be determined. As discussed above, the contents must be sufficiently well characterized for the A1 and A2 values to be determined, or their amounts be small enough that they do not contribute significantly to the A1 and A2 values. That is, if included in the A1/A2 or shielding or shielding calculations, they would have no effect on the result. Examples are surface contamination of items and activated material, such as crud or sludge or other contamination on surfaces.

Typically, relatively small amounts of know materials such as “ores”, “crud”, “sludge” and similar combinations of radioactive and non-radioactive materials are identified by their generic name (ore, CRUD, sludge, debris, etc) rather than by listing each of their radionuclides separately [6]. To characterize their radiological hazard, highly active constituents (such as activation products in sludge and CRUD) would need to be identified.

This is consistent with Regulations applicable to small quantities of material. Although not specifically defined in CFR, the regulations recognize that very small amounts are not a concern. This is formalized in the exemption/exception status for small quantities described above. In the words of TS-R-1, Trace quantities of impurities are “amounts sufficiently small that they are of no regulatory concern.” That is, they do not contribute measurably to the radiation hazard of the package.

Containment

To meet the regulatory requirements outlined above, the Minimal Quantity proposal employs packagings with leaktight containment vessels that are certified for large amounts of radioactive material (e.g., the 9975, 9977 and 9978). The Chalfant type containment vessels in these packagings (which have been shown to be leaktight to the standard required for the most challenging contents) satisfy the containment requirement for all contents.

Shielding

Shielding evaluations, which will bound many other contents, have been performed for a wide range of isotopes, for the 9975, 9977 and 9978. Some isotopes are sufficiently active, or emit high energy radiation that even small amounts will produce a radiation dose rate in excess of the regulatory limits. For such nuclides, the Minimum Quantity proposal will employ qualified shielded content containers which ensures that the regulatory limits for package radiation level are satisfied. A standard case analysis for a Shielded Container and package will be performed. In addition, to ensure that the regulatory requirements are met, the external radiation dose rate will be measured at the

shielded container before it is loaded into the package. For this case, the measurements will be compared with the standard case analysis applicable to the contents, to confirm the measured dose rate is consistent with the analysis and limits are met for the maximum dose locations on the package, as identified by the analysis.

One approach for performing the standard case analysis is the determination of dose rate for a unit amount (e.g., 1 Ci) of the bounding group of radionuclides. The dose rate thus calculated could be scaled to establish the dose rate for known content mass or used to confirm the mass of contents from a measured dose rate. The analysis could determine limiting masses for worst case isotopes, for the applicable Shielded Container. Other isotopes can be grouped under the worst case isotopes by range of energy of photons or neutrons. In this way, proposed contents can be related to appropriate, bounding shielding analyses.

Table 1. Example Requirements for Contents

Contents	**Packaging Configuration**			
	3013	**Food-Pack Can**	**Hex-Can**	**Shielded Container**
Example Content	NA	• If ≤ 0.0018 grams ^{232}U. • Maximum 100-g plastic. • Aluminum pellets or foil for packing.	NA	• If > 0.0018 grams and ≤ 0.0101 grams ^{232}U or determined by dose-rate measurements. • The Shielded Container and aluminum convenience can manufactured per listed Addendum drawings are required. • PCV spacers replaced by Shielded-Container honeycomb spacers manufactured per the listed Addendum drawing
All	19 watts maximum radioactive decay heat rate less than 1000 ppm other radionuclides (unless otherwise stated) less than 100 ppm other inorganic impurities with total mass less than 0.1 weight percent (unless otherwise stated) PCV bottom spacer required 44.4 lb maximum content weight (radioactive contents, product cans, spacers, Shielded Container, etc.)			

Criticality

The identity and amount of fissile isotopes and other materials important to criticality safety, such as moderators and reflectors must be known. A bounding criticality assessment has been performed for two cases of contents. These supplement the regulatory "fissile exempt" categorization to include highly active Actinide Isotope, not addressed in the Regulation. The results are summarized in Table 2.

Table 2. Allowed Contents Envelopes

Material	Mass Limit	
	Type 1	Type 2
Special Actinide Isotopes[a] ^{242m}Am, ^{243}Cm, ^{245}Cm, ^{247}Cm, ^{249}Cf, ^{251}Cf	5 grams	<1000 ppm
All other RAM	5 grams	100 grams
Total RAM	5 grams	100 grams
Light Elements and Impurities	5 grams	50 grams
Total Content	10 grams	150 grams

[a] The characteristics of these special actinides are not as well established as for other, more common fissile isotopes. Accordingly, a larger safety factor is employed for these contents.

Discussion of Minimal Quantity Issues

In discussions between the SARP Applicant and the Technical Reviewers of the minimum quantity proposal, the acceptability of the packaging with respect to most regulatory compliance issues has been accepted. For example, with respect to Containment, the regulatory requirements are met. With respect to Criticality, the proposed approach is fully consistent with, and a refinement of the "fissile exempt" provisions of the regulations. With respect to structural and thermal issues, the Minimum Quantity contents are bounded by existing, certified contents.

The issues which remain subjects of discussion are identification of contents and the means of insuring regulatory dose rate requirements are met.

Contents Identification

Identification of the mass of each radionuclide within the content is required to determine the radiological hazard, as characterized by the A1 and A2 values, and the radiation exposure (source term) for regulatory compliance. Chemical compatibility and stability of the Content with the Packaging must also be demonstrated.

Contents identification has been discussed in depth above. The contents authorized under the Minimum Quantity proposal will conform to the regulatory requirements and established practice. Where the identity of the radionuclides present are known but the individual activities of the various isotopes are not known, the A1 and A2 values will be determined as specified in 49 CFR 173.433. For naturally occurring materials, such as "ore" and for LSA materials, the contents conform to the applicable regulatory requirements. For material such as CRUD, sludge and debris, the source material will be evaluated on the basis of the bounding constituent. For such material, this is typically assumed to be Co-60. An example of this is treatment of CRUD deposits on spent fuel. This approach to contents identification is also consistent with the treatment of impurities in authorized contents for certified packagings.

The Minimum Quantity contents specification, given above, allows only contents that are stable and chemically compatible with the packaging (not chemically reactive or corrosive). In addition, the contents specification requires that the radiological material be contained in a convenience container. The convenience container must also be corrosion resistant and chemically compatible with the contents and the packaging. For questionable contents, a highly corrosion resistant material, such as Alloy 22, could be used for the convenience container.

Package Radiation Dose Rate

For shipment under the SGQ approach, the contents activity would be compared with the limiting contents determined from the reference shielding analyses for the Shielded Container. This will show that the Shielded Container will provide sufficient shielding. After placing the contents in the Shielded Container, and before it is loaded into the packaging, the dose rate would be measured on the surface of, and one meter from the Shielded Container. The criterion would be that the Shielded Container surface dose rate must meet the regulatory limit of 2 mSv/hr (200 mrem/hr) and 0.1 mSv/hr (10 mrem/hr) at the surface and at one meter, respectively (higher limits are permitted for exclusive use shipments). The resulting external dose rate for a package loaded with a Shielded Container evaluated in this way is assured of having an external dose rate less than the regulatory limit. This approach is consistent with the use of activity and dose rate as criteria in the regulations (both 49 CFR 173 and 10 CFR 71) for evaluation of radioactive material present.

Shielding Analysis

It is recognized that the use of dose rate measurement alone does not provide full understanding of the radiation field emanating from a packaging. As noted, an analysis enables evaluation of effects of shifting of contents in shipment and identifies the critical areas of the package surface (if any) having highest dose rates. A shielding analysis provides insight into predicting the shielding behavior of the package. Accordingly, the position from the regulatory review perspective is that a shielding evaluation must be performed. For contents addition to a certified package, on a case-by-case basis, the reference shielding analysis shows that the shielding design is able to provide adequate shielding so that the regulatory limits are met for the proposed contents. As discussed above, for the SGQ concept, this can be achieved by analysis of bounding content cases. This provides a basis for comparison with the measured dose rate at time of shipment, and would identify any critical areas for dose rate measurement.

Structural Issues

The most challenging structural issue for the Minimal Quantity contents are the shielded containers. Since photon shielding is a product of materials density, shielded containers are necessarily heavy. The Shielded Containers for the SGQ Contents are well within the loads tested and analyzed for the packages addressed in the proposal. Structural analysis of the shielded containers themselves has been performed to confirm that they maintain structural integrity and shielding under NCT and HAC conditions for all impact orientations.

Conclusions and Recommendation

The concept of shipment of Minimum Quantities of radioactive materials in high integrity, leaktight packagings, as a generic class, without separate contents amendments:

- Meets packaging safety requirements of containment, subcriticality and shielding.
- Is consistent with applicable regulations (49 CFR 173 and 10 CFR 71)
- Is highly desirable from operational and economic standpoint for DOE and other users with a need to ship such materials.
- Is based on the regulatory precedents which recognize that small amounts of material do not represent a significant hazard.

The requirements and practices/strategies outlined here address the questions raised in discussions with the regulatory reviewers of the concept.

It is recommended that contents amendments for contents conforming to the Minimum Quantity content description given here be sought for the 9975, 9977 and 9978 packagings.

CONTRACT NUMBER

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DISCLAIMER

REFERENCES

1. Title 10, United States Code of Federal Regulations, Part 71, *Packaging and Transportation of Radioactive Material* (10 CFR 71), 2005.

2. American National Standard for Radioactive Material - Leakage Tests on Packages for Shipment, ANSI N14.5, American National Standards Institute, Inc. (1997).

3. Title 49, United States Code of Federal Regulations, Part 173, - *Shippers-General Requirements for Shipments and Packagings*, Sub Part 1 – Class 7 (Radioactive) Materials (49 CFR 173), 2005.

4. Regulatory Guide 7.9,Rev. 2, *Standard Format and Content for Part 71 Application for Approval of Packaging for Radioactive Material*, U.S. Nuclear Regulatory Commission, 2005.

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