

From: Robert Meck *RES*
To: Bishop, Lee; Broaddus, Doug; Brummett, Elaine; Cardile, Frank; Chen, Chia; Collins, Steven; Farrand, David; Feldman, Carl; Gnugnoli, Giorgio; Huffert, Anthony; Kopsick., Deborah; Neave, John; Vazquez, Gustavo
Date: - Sun, Aug 18, 2002 2:21 PM
Subject: - Revised U.S. Comments on IAEA DS161

Dear Colleagues:

The attached comments have been significantly revised as a result of consultations with key staff at DOE, EPA, and my NRC management. They have been softened with regard to the recommendations. Substantive comments have been clarified.

NRC management would like to have a briefing by the NRC staff for the Commissioners' Technical Assistants. Thus, we must come to closure on these comments very quickly. The comments are due to our Office of International Programs during the first week of September. Because of the short time frame, I would like to set up a conference call meeting of the ISCORS Recycle Subcommittee for Wednesday, August 21, at 10:00 a.m. Please let me know by close of business Monday, August 19, if you will be participating. I'll get the appropriate number of lines according to the response.

Hal or Andy, and Mary: You are critical participants. If you cannot participate at the proposed time, please let me know alternate times. I'll reschedule.

P.S. The Excel file is for your convenience. It is the same as the Word file by the same file name.

Thanks for your cooperation.

Best regards,

Bob

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B-4

Title: Radionuclide Content in Commodities not requiring Regulation for Purposes of Radiation Protection DS161

| Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 2002 Country/Organizations: USA/NRC, DOE, EPA, DOL | | | | Resolution | | | |
|---|---|-------------------|---|------------|----------------------------------|----------|-----------------------------------|
| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 1 | General-- Applies to entire document | | SDLs for artificial radionuclides are based on clearance analyses. However, implementation of SDLs is more complex. Clearance analyses limit the concentrations of radioactivity that enter commerce from the practice. Limits are based on assessments of the doses from all subsequent diluting and concentrating processes and uses. In contrast, implementation of SDLs would allow the same concentrations to be present in any or all commodities. Generic dose assessments of SDLs have not been | | | | |

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| 1 (continued) | | | performed for radionuclides in commodities throughout general commerce as could arise in an intervention situation. Concentrating processes and exposures to many commodities could result in doses significantly greater than the dose criterion of 10 μ Sv in a year. | | | | |
| 2 | Applies to NORM SDLs | | Although the NORM SDLs are not dose based, it is problematic that some NORM SDLs applied to clearance could result in doses greater than the BSS public dose limit of 1 mSv in a year (See attached sheet.). For reasons stated in Comment 1., above, a generic SDL assessment could give greater doses. | | | | |

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| 3 | General-- Applies to entire document | | The Basic Safety Standards (BSS), a requirements document, requires authorization of a practice to meet the radiation protection principles of justification (a net benefit), optimization (ALARA), limitation of individual dose, and dose constraint. In contrast, DS161, a safety guide, prescribes a new criterion that would require a practice to be authorized, based only on the concentration of radionuclides. There is an administrative question as to whether the new "scope defining levels" (SDLs) as a requirement for authorization can be established in a guidance document. | | | | |

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| 4 | General-- Applies to entire document | | Clearance levels in units of Bq/cm ² that implement the radiological criteria for clearance are missing. A large fraction of the commodities cleared from practices only have surficial radioactivity. | | | | |
| 5 | General-- Applies to entire document | | Transportation regulations specify both the allowed surficial and mass concentrations of radioactivity, thus compatibility with SDLs is needed. | | | | |
| 6 | General-- Applies to entire document | | Waste with no intrinsic value and that can only be disposed, is not a commodity, and, thus, SDLs would not apply to it. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 7 | 1.2 | Delete reference to human activities in this sentence. Change to read. ...radionuclides are ubiquitous in the environment. | The presence of radionuclides from human activities is addressed in the next sentence. | | | | |
| 8 | 1.2/8 | In the atmosphere and from.... | clarification | | | | |
| 9 | 1.2/10 | ...of natural and artificial origin, is nearly always... | clarification and accuracy of statement needed | | | | |
| 10 | 1.2/footnote 3 | add H-3, and C-14 to list | Significant quantities of these radionuclides naturally occur on earth | | | | |
| 11 | 1.2/footnote 4 | Add: Some wastes are worthless and, thus, cannot be bought or sold, these are also included. | Clearance applies to worthless wastes that can be disposed in a landfill or incinerated. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 12 | 1.3/6 | Add sentence to bullet on exclusion: "Unamenable to control through regulation" usually means that regulation cannot be justified, i.e., no net benefit. | Clarification of principle applied | | | | |
| 13 | 1.3/10 | Add sentence: Exempted sources have such a low risk that regulation is unwarranted. | Clarification of rationale | | | | |
| 14 | 1.3/12 | Add sentence: Continuation of regulation is unwarranted due to low risk. | Clarification of rationale. | | | | |

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| 15 | 1.4/ALL | 1.4. In addition, the ICRP recommendations and a number of international conventions have considerations that outline their scope of application. A summary of these considerations are: •The exemption from intervention, which involves the use of the ICRP concept of intervention exemption levels [6], is “ | The changes to paragraph. 1.4 are needed because 1) the word “mechanism” is incorrect in the text (no mechanisms are addressed), and 2) the 1 st bullet may be misinterpreted to indicate that the avertable dose target level of 10 mSv/a is applicable to materials not requiring regulatory control. The reference needs to be qualified to avoid misapplication of large accident cleanup strategies to low activity commercial products. | | | | |

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| 15 (continued) | 1.4/ALL (continued) | recommended specifically in the context of international trade in essential "commodities" such as food, in areas affected by significant incidents and are established for temporary emergency application. These levels are frequently referred to as "action levels" and are not considered appropriate for routine situations; •The exemption.... | | | | | |
| 16 | 1.5/ALL | | Objective should relate SDLs to exclusion, exemption, and clearance. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 17 | 1.5/3 | Delete: "for the purposes of radiation protection in accordance with the BSS" | Radiation protection in accordance with the BSS requires justification, optimization, dose limitation, and dose constraint. For the authorization of a practice. Exceeding SDLs would require authorization of a practice, and this requirement is not addressed in the BSS. Additionally, clearance of concentrations of Ra-226 or other radionuclides at concentrations that could lead to an individual dose greater than 1 mSv in a year cannot be said to be for the purposes of radiation protection in accordance with the BSS. | | | | |

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| 18 | 1.6/2 2.1/1 | Delete: "but, rather, they clarify their scopes of application in relation to commodities." | General application in relation to commodities is unanalyzed in the Safety report. Clearance calculations were performed for releases from an authorized practice. They took into account dilutions and concentration of radioactivity due to processing. In contrast, scope defining levels would allow the same level of radioactivity at any stage of industrial processing or consumer use. Doses to individuals, especially consumers, could be much greater than 10 μ Sv in a year. | | | | |

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| 19 | 1.7/3 | ADD SENTENCE: It is acknowledged that this may result in non-comparable levels for different types of commodities. Such inconsistency is warranted because of the types of radionuclides involved and the potential types of uses of the commodities in question. | Some rationale needs to be provided, so that regulatory authorities, operators, industry, etc. do not appear to be capricious in setting guidance for control of commodities. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 20 | 1.8 | This document only addresses volumetric contamination in commodities. Superficially-contaminated materials eligible for release from regulatory control are not addressed | This is a significant omission from the safety series publications list. There are significant inventories of metals and other materials that should be included in the "commodities" heading, but are excluded from the SDLs listing. | | | | |
| 21 | Table 1 | New text is needed to explain the Pb-210 and Po-210 values of 5 Bq/g | There is no explanation given for the Pb-210 and Po-210 values of 5 Bq/g | | | | |
| 22 | 3.1-3.4/all | Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides. | A full disclosure of the doses from NORM is required for an informed comparison of risk consequences with the levels for artificial radionuclides. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 23 | 3.1-3.4/all | Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides. | Low probability scenarios for clearance were assessed to ensure that doses would be unlikely to exceed 1 mSv in a year. However, some doses attributable to the SDLs for NORM for clearance exceed 1 mSv in a year. (See attached sheet.) For reasons given in Comment 1., above the doses attributable to SDL levels in many commodities could be even greater. Thus there is little support for the statement that "Doses to individuals as a consequence of the use of these scope defining levels are unlikely to exceed about 1 mSv in a year in most cases, excluding the contribution from the emanation of radon." | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 24 | 3.2/1 | Revise sentence to: "The mechanism of exclusion..." | Consistent terminology with Section 1.3 should be used. | | | | |
| 25 | 3.2/8 | Provide criteria and methods for determining "amenable to control." | The authority is left without guidance on how to determine amenability to control of exposures from materials containing radionuclides of natural origin. | | | | |
| 26 | 3.1/5, 3.5/4, 3.6I(B). | ...judged to be unlikely... | There is no indication of the criterion used to judge the probability of a 1 mSv dose in a year nor is there an indication that uniformity from nuclide to nuclide was sought in the target low probability. There is no quantitative evaluation of the probability of the 1 mSv dose. | | | | |

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| 27 | 3.2/8 | ADD SENTENCE: Some locations are naturally antagonistic to human health and can be addressed by physical isolation or restricted access; there may be little benefit from remediation. | There may be little point to remediation of naturally poisonous areas that may have high radionuclide content. The guidance should encourage controls in the form of restricted access or other physical barriers rather than leave silent the implication that a remediation is necessarily warranted. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 28 | 3.3/13 | After sentence ending: '...consideration and control." Add : "Decisions for existing, as well as future, NORM industries including fertilizers, coal ash, ores, mineral sands, and slag, need to be based on the radiological principles of justification, optimization, and dose limitation. | Provide sound guidance established by the BSS. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 29 | 3.3/13 | Revise sentence to: "Decisions on which materials should be within the system of regulatory control may be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and an evaluation of the human tolerance to health risks associated with these exposures." | For example, concentrations of non-radiological environmental toxins, such as arsenic, are regulated on the basis of health risk. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 30 | 3.3/14 | of regulatory control and the degree of such control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and on the specific national circumstances (e.g., availability of resources). | Control can be institutional as in restriction of access or translocation of affected populations. The implications of the original language are too suggestive that remediation is the sole course of action. | | | | |
| 31 | 3.4/3 | Scope defining levels for natural radionuclides are the total of the background and any added radioactivity. | The text is not clear that the total amount of a naturally occurring radionuclide is included in the SDL and not just the incrementally added amount. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 32 | 3.5/3-4 | ...with modeling considering a low ... | The indefinite article "a" is unnecessary. | | | | |
| 33 | 3.6/6 | Change to read "...selected set of exposure pathway scenarios..." | Exposure pathways were evaluated on a nuclide-by-nuclide basis. All pathways for a scenario were not added to get a total exposure dose. | | | | |
| 34 | Section 3.6, page 8 | This section should state that certain scenarios encompassed skin contamination also. | Draft Safety Report indicates that skin contamination was evaluated for metal and concrete processing (scenarios II and III), but not for typical exposure situations (scenario I) | | | | |
| 35 | Section 3.6, page 8 | This section should state that the dose basis ranged from 10 μ Sv/a to 100 μ Sv/a | Draft Safety Report section 3.3, states that values in Table 1 of the Draft Safety Guide were increased by a factor 10 to account for the conservatism in metal and concrete scenarios | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 36 | 3.8/all | Revise section to state that the calculations apply to solids cleared from a practice. Similar analyses for liquids and gases have not been performed. | There is no rationale or basis or analyses presented to support the assertions that the calculations for solids are, in fact, appropriate for liquids or gases. Counter examples might include large storage tanks or pipelines. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 37 | 4.1/1 | Change to read: "Materials and equipment [alternatively: Commodities and waste] cleared from an authorized practice with activity concentrations below the clearance levels should not be subject to regulatory controls from radiological protection considerations." | If the levels in DS161 were applied to all commodities, they would not necessarily meet the dose criterion of <10 μ Sv in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20). | | | | |

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| 38 | 4.1/3 | Delete sentence beginning, "Where commodities have an activity concentration above the scope-defining levels but below the exemption levels," or specify additional safety criteria and applied only to applied to clearance that would be required to equalize the prerequisite conditions of exemption. | Exemption can be applied at higher levels than clearance, because prerequisite conditions must be met before the exemption concentrations can be applied. These conditions are summarized as: applicable to moderate quantities, sufficiently low risk to individuals and the collective dose to be of no regulatory concern and inherently safe. | | | | |

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| 39 | 4.2/3-4 | In general, countries should coordinate their regulatory strategy and implementation with their neighboring States, including their monitoring programs for commodities, in order to avoid unnecessary nuisance alarms at boundary transfer points. | As originally worded, the sentence implied that measurement along the material flow path would not be necessary. The entrance of orphaned sources or related contaminated material either incidentally or deliberately would seem to necessitate some degree of monitoring or continuity of control measure to avoid such downstream contamination scenarios. | | | | |

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| 39 (continued) | 4.2/3-4 (continued) | The IAEA and other international nuclear material safety organizations should be used to harmonize the control of such commodities and the attendant transboundary interactions. | | | | | |
| 40 | 4.2/8-9 | appropriate techniques and equipment to ensure that detection levels are calibrated to detect materials having contamination at or above scope defining levels. | Original wording implies that detection equipment and techniques would result in nuisance alarms, because calibration would pick up levels below the scope defining levels. That is clearly counterproductive and constitutes poor guidance. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 41 | 4.5/all | This section appears to contradict some possible scenarios with NORM at the levels in Table I | An individual dose from the realistic scenario with the level of Ra-226 at 0.5 Bq/g yields 1.85 mSv/a. This is above the public dose limit. So, would limitation and control of occupational exposure be required just below this scope defining level? If so it would be a contradiction with the concept of scope defining level. | | | | |
| 42 | 4.6/5 | residues in the environment or vice versa. (Guidance.... | This underscores the guidance that intervention exemption or exclusion levels are not routinely appropriate for clearance of commodities. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 43 | 4.7/1 | Change to read: Deliberate dilution, as opposed to dilution that takes place in normal operations when radioactivity is not a consideration, in order to meet clearance levels ... | Distinction should be made from normal operations and processes and dilution for the purpose of meeting a specified concentration level. | | | | |

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| 44 | 4.7/3 | Change to read: "the processing of commodities containing either artificial or natural radionuclides" | While the analyses for clearance scenarios take subsequent processing of the cleared materials and the processing of resultant byproducts into account, no such analysis has been done for similar levels in all commodities. Because of endless combinations of situations for processing generic commodities, such an analysis is not feasible. See comment 20. Thus, with scope defining levels the regulatory authority cannot assure adequate public safety. | | | | |

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| 45 | 4.7/5 | ...defining levels. This may occur in cases where water recycle from sanitation systems results in re-concentration of diluted agents. In such cases... | The text was unclear as to circumstances where SDL-compliant releases could results in nontrivial impacts. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 46 | 4.7/7 | ADD SENTENCE: It should be acknowledged that what one Regulatory Authority establishes as the scope of application of these SDLs may not be acceptable to Member States to which these commodities may be exported. Again, the system of commodity control should be integrated and coordinated within and outside the borders of the Member State. | The risk that a neighboring country rejecting commodities, when the two regulatory implementations are inconsistent should be explicitly recognized in the guidance. | | | | |

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| Comment No. | Para/Line No. | Proposed New Text | Reason | Accepted | Accepted but modified as follows | Rejected | Reason for modification/rejection |
| 47 | References | Reference 13 is EC's RP-122, but the supporting Draft Safety Report references EC RP-89. Which reference is correct? | The Safety Guide and Safety Report should have similar references. | | | | |

| NUCLIDE | SDL Bq/g | Table I-IV | Low Prob Dose μ Sv | Low Prob > 1 mSv | Table I-III | Realistic Dose μ Sv | Realistic > 1 mSv |
|---------|-------------|------------|---------------------------|---------------------|-------------|----------------------------|----------------------|
| H-3 | 100.0 | 2.1E+01 | 2.1E+03 | 2.1 | 1.1E+00 | 1.1E+02 | |
| C-14 | 1.0 | 2.2E+02 | 2.2E+02 | | 1.1E+01 | 1.1E+01 | |
| K-40 | 5.0 | 3.5E+03 | 1.8E+04 | 17.5 | 1.7E+02 | 8.5E+02 | |
| Pb-210 | 5.0 | 3.4E+04 | 1.7E+05 | 170.0 | 1.7E+03 | 8.5E+03 | 8.5 |
| Bi-210 | 0.5 | 7.9E-01 | 4.0E-01 | | 4.0E-01 | 2.0E-01 | |
| Po-210 | 5.0 | 2.0E+02 | 1.0E+03 | | 1.2E+01 | 6.0E+01 | |
| Ra-223 | 0.5 | 1.2E+01 | 6.0E+00 | | 1.0E+00 | 5.0E-01 | |
| Ra-224 | 0.5 | 4.4E+00 | 2.2E+00 | | 6.9E-01 | 3.5E-01 | |
| Ra-226 | 0.5 | 7.5E+04 | 3.8E+04 | 37.5 | 3.7E+03 | 1.9E+03 | 1.9 |
| Ra-228 | 0.5 | 3.2E+04 | 1.6E+04 | 16.0 | 1.6E+03 | 8.0E+02 | |
| Th-227 | 0.5 | 2.1E+01 | 1.1E+01 | | 5.5E-01 | 2.8E-01 | |
| Th-228 | 0.5 | 4.0E+02 | 2.0E+02 | | 1.1E+01 | 5.5E+00 | |
| Th-230 | 0.5 | 1.5E+02 | 7.5E+01 | | 7.6E+00 | 3.8E+00 | |
| Th-231 | 0.5 | 6.7E-03 | 3.4E-03 | | 3.4E-03 | 1.7E-03 | |
| Th-232 | 0.5 | 1.1E+03 | 5.5E+02 | | 5.4E+01 | 2.7E+01 | |
| Th-234 | 0.5 | 2.2E-01 | 1.1E-01 | | 3.4E-02 | 1.7E-02 | |
| Pa-231 | 0.5 | 1.0E+04 | 5.0E+03 | 5.0 | 5.1E+02 | 2.6E+02 | |
| U-234 | 0.5 | 2.8E+02 | 1.4E+02 | | 1.4E+01 | 7.0E+00 | |
| U-235 | 0.5 | 2.8E+02 | 1.4E+02 | | 1.4E+01 | 7.0E+00 | |
| U-238 | 0.5 | 2.7E+02 | 1.4E+02 | | 1.3E+01 | 6.5E+00 | |

| NUCLIDE | SDL | Table I-IV | Low Prob | Low Prob | Table I-III | Realistic | Realistic |
|---------|-------|------------|---------------|----------|-------------|---------------|-----------|
| | Bq/g | | Dose μ Sv | > 1 mSv | | Dose μ Sv | > 1 mSv |
| H-3 | 100.0 | 2.1E+01 | 2.1E+03 | 2.1 | 1.1E+00 | 1.1E+02 | |
| C-14 | 1.0 | 2.2E+02 | 2.2E+02 | | 1.1E+01 | 1.1E+01 | |
| K-40 | 5.0 | 3.5E+03 | 1.8E+04 | 17.5 | 1.7E+02 | 8.5E+02 | |
| Pb-210 | 5.0 | 3.4E+04 | 1.7E+05 | 170.0 | 1.7E+03 | 8.5E+03 | 8.5 |
| Bi-210 | 0.5 | 7.9E-01 | 4.0E-01 | | 4.0E-01 | 2.0E-01 | |
| Po-210 | 5.0 | 2.0E+02 | 1.0E+03 | | 1.2E+01 | 6.0E+01 | |
| Ra-223 | 0.5 | 1.2E+01 | 6.0E+00 | | 1.0E+00 | 5.0E-01 | |
| Ra-224 | 0.5 | 4.4E+00 | 2.2E+00 | | 6.9E-01 | 3.5E-01 | |
| Ra-226 | 0.5 | 7.5E+04 | 3.8E+04 | 37.5 | 3.7E+03 | 1.9E+03 | 1.9 |
| Ra-228 | 0.5 | 3.2E+04 | 1.6E+04 | 16.0 | 1.6E+03 | 8.0E+02 | |
| Th-227 | 0.5 | 2.1E+01 | 1.1E+01 | | 5.5E-01 | 2.8E-01 | |
| Th-228 | 0.5 | 4.0E+02 | 2.0E+02 | | 1.1E+01 | 5.5E+00 | |
| Th-230 | 0.5 | 1.5E+02 | 7.5E+01 | | 7.6E+00 | 3.8E+00 | |
| Th-231 | 0.5 | 6.7E-03 | 3.4E-03 | | 3.4E-03 | 1.7E-03 | |
| Th-232 | 0.5 | 1.1E+03 | 5.5E+02 | | 5.4E+01 | 2.7E+01 | |
| Th-234 | 0.5 | 2.2E-01 | 1.1E-01 | | 3.4E-02 | 1.7E-02 | |
| Pa-231 | 0.5 | 1.0E+04 | 5.0E+03 | 5.0 | 5.1E+02 | 2.6E+02 | |
| U-234 | 0.5 | 2.8E+02 | 1.4E+02 | | 1.4E+01 | 7.0E+00 | |
| U-235 | 0.5 | 2.8E+02 | 1.4E+02 | | 1.4E+01 | 7.0E+00 | |
| U-238 | 0.5 | 2.7E+02 | 1.4E+02 | | 1.3E+01 | 6.5E+00 | |