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**Specification of Radionuclide Content in  
Commodities requiring Regulation for purposes  
of Radiation Protection**

**DRAFT SAFETY GUIDE  
DS161**

**INTERNATIONAL  
ATOMIC ENERGY AGENCY  
VIENNA**

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# 1. INTRODUCTION

## BACKGROUND

1.1. The *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (the BSS) [1] specify the basic requirements for protection of health against exposure to ionizing radiation, and for the safety and security of radiation sources. They are based on the recommendations of the International Commission on Radiological Protection (ICRP) [2] and regulate both '*practices*'<sup>1</sup> and '*interventions*'<sup>2</sup>. A complementary Safety Requirements publication establishes the basic requirements for the legal and governmental infrastructure that is necessary in order to implement these Standards effectively [3]. An essential component of this infrastructure is the existence of a competent national regulatory authority that has the authority to establish regulations. Such regulations shall, inter alia, define the scope of situations to be regulated for purposes of radiation protection.

1.2. Humans incur radiation doses from cosmic rays and radiation generated by x-ray apparatuses and particle accelerators, or from exposure to radionuclides, which can cause either direct irradiation from outside the body or be taken into the body and irradiate from within. Some radionuclides are primordial and they are usually referred to as 'natural', while others have been created as a result of practices and are usually termed 'artificial'. Natural radionuclides are ubiquitous in the environment and some are present from human activities. Many artificial radionuclides are also widely spread in the environment as a result of, for instance, fallout from the old practice of testing nuclear weapons in the atmosphere and routine or accidental releases from current practices. As a result of the widespread presence of radionuclides in the environment, a certain amount of radioactivity, of natural or artificial origin, is always present in substances, materials, water, foodstuffs, goods, merchandises, consumer products and, in general, in any '*commodity*'<sup>3</sup>. The specification of the radionuclide

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<sup>1</sup> A practice is defined as any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

<sup>2</sup> An intervention is defined as any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.

<sup>3</sup> The term *commodity* is an article or raw material that can be bought or sold, including water, foodstuffs, metals, concrete, soil, plastics, wood, paper, etc., as well as mixtures of substances and materials, and goods, merchandises, and consumer products made up of them.

content in commodities requiring regulation for purposes of radiation protection is essential for defining the scope of the relevant regulations for commodities.

1.3. The definition of the scope of radiation protection regulations involves consideration of situations where control is not feasible or it is unwarranted. The BSS explicitly establish three mechanisms (exclusion, exemption, clearance) to define the applicability of part or all of its provisions. The summary of these mechanisms is as follows:

- The *exclusion* of any radiation exposure that is unamenable to control through regulation;
- The *exemption* of practices (and radiation sources within practices) from regulatory requirements that otherwise would be applicable;
- The *clearance* of radioactive materials within a regulated practice from further control.

1.4. In addition, the ICRP recommendations and a number of international conventions have mechanisms that define their scope of application: for example the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (London Convention, 1972) [4] and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (the Joint Convention) [5]. A summary of these mechanisms are:

- The exemption from intervention, which involves the use of the ICRP concept of *intervention exemption levels* [4], is recommended specifically in the context of international trade in commodities;
- The exemption of material from the requirements of the London Convention, 1972 in relation to radiation protection considerations;
- The exclusion of waste that contains only naturally occurring radioactive material and does not originate from the nuclear fuel cycle from the Joint Convention.

1.5. In this Safety Guide, these mechanisms are taken into account to specify the radionuclide content in commodities which do not require regulation for purposes of radiation

protection, and can be used as one of the bases for meeting the resolution GC(44)/RES/15 of the IAEA General Conference<sup>4</sup>.

## OBJECTIVE

1.6. The objective of this Safety Guide is to specify levels of activity concentration in commodities for radionuclides, of both natural and artificial origin, below which regulation for the purposes of radiation protection in accordance with the BSS should not be required. These activity concentration levels for commodities will hereinafter be referred to as scope-defining levels. Guidance is also provided on how these levels should be applied in a regulatory context.

## SCOPE

1.7. The scope-defining levels specify the activity concentration in commodities below which trade should not be restricted on the basis of radiation protection considerations.

1.8. The scope-defining levels do not limit the application of the BSS or any other IAEA Safety Standard but, rather, they clarify their scopes of application in relation to commodities.

1.9. Notwithstanding the scope-defining levels specified in this document, the Regulatory Authorities are empowered to:

- i. *exclude* exposures from sources of radiation as stated in the BSS [1];
- ii. *exempt* practices, and sources within practices from some or all of the requirements in the BSS [1], where exemptions should be subject to the conditions provided in the BSS, either using the criteria for exemption specified in Schedule I of the BSS, or by following the exemption levels defined in Schedule I of the BSS;
- iii. *clear* the release of materials within notified or authorized practices from further requirements of the BSS [1], subject to compliance with any clearance levels specified by the Regulatory Authority using the criteria stated in the BSS (paragraph 2.19 and Schedule I);

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<sup>4</sup> Resolution GC(44)/RES/15, inter alia, requested the Agency's Secretariat "to develop...radiological criteria for long-lived radionuclides in commodities..."

- iv. *authorize* releases or discharges into the environment from practices of effluents and other materials including solids, or authorize disposal according to the radiation protection requirements specified in the BSS (paragraphs 2.20 and 2.23 to 2.26; and
- v. *establish* intervention and action levels for purposes of undertaking protective actions in intervention situations involving substances, materials, goods, merchandises, consumer products and, in general any 'commodity', for instance using the radiation protection requirements specified in the BSS paragraphs 3.13 to 3.15 and associated appendices and schedules.

## STRUCTURE

1.10. The Safety Guide is structured as follows: Section 2 sets out the scope-defining levels; Section 3 presents the basis for deriving the scope-defining levels, which is supported by a Safety Report XXX [7] describing the methodology used; and, Section 4 provides guidance on the application of scope-defining levels with special emphasis on regulatory considerations.

## 2. THE SCOPE-DEFINING LEVELS

2.1. The scope-defining levels for radionuclide content in commodities of any type except foodstuff and drinking water are given in Table I. The list of radionuclides is limited to those radionuclides with a half-life greater than one day. For foodstuffs, the scope-defining levels to be used are given in Table II separately for foods destined for general consumption, for milk and infant foods. Table III provides scope-defining levels for drinking water.

TABLE I. SCOPE-DEFINING LEVELS FOR RADIONUCLIDES IN COMMODITIES (EXCLUDING FOODSTUFFS AND DRINKING WATER)

| Nuclide | SDL (Bq/g) | Nuclide | SDL (Bq/g) | Nuclide | SDL (Bq/g) |
|---------|------------|---------|------------|---------|------------|
| H-3     | 10         | Tc-97m  | 10         |         |            |
| Be-7    | 10         | Tc-99   | 0.1        | Pm-149  | 100        |
| C-14    | 1          | Ru-97   | 1          | Sm-151  | 1000       |
| Na-22   | 0.1        | Ru-103  | 1          | Sm-153  | 10         |
| P-32    | 100        | Ru-106  | 1          | Eu-152  | 0.1        |
| P-33    | 1000       | Rh-105  | 10         | Eu-154  | 0.1        |
| S-35    | 10         | Pd-103  | 1000       | Eu-155  | 10         |
| Cl-36   | 0.1        | Ag-105  | 1          | Gd-153  | 10         |
| K-40    | 4#         | Ag-110m | 0.1        | Tb-160  | 0.1        |
| Ca-45   | 10         | Ag-111  | 10         | Dy-166  | 10         |
| Ca-47   | 0.1        | Cd-109  | 1          | Ho-166  | 10         |
| Sc-46   | 0.1        | Cd-115  | 1          | Er-169  | 1000       |
| Sc-47   | 10         | Cd-115m | 10         | Tm-170  | 100        |
| Sc-48   | 0.1        | In-111  | 1          | Tm-171  | 1000       |
| V-48    | 0.1        | In-114m | 1          | Yb-175  | 10         |
| Cr-51   | 10         | Sn-113  | 1          | Lu-177  | 10         |
| Mn-52   | 0.1        | Sn-125  | 1          | Hf-181  | 1          |
| Mn-53   | 10         | Sb-122  | 1          | Ta-182  | 0.1        |
| Mn-54   | 1          | Sb-124  | 0.1        | W-181   | 100        |
| Fe-55   | 100        | Sb-125  | 1          | W-185   | 100        |
| Fe-59   | 0.1        | Te-123m | 1          | Re-186  | 100        |
| Co-56   | 0.1        | Te-125m | 100        | Os-185  | 1          |
| Co-57   | 10         | Te-127  | 100        | Os-191  | 10         |
| Co-58   | 0.1        | Te-127m | 1          | Os-193  | 10         |
| Co-60   | 0.1        | Te-129  | 10         | Ir-190  | 0.1        |
| Ni-59   | 10         | Te-129m | 10         | Ir-192  | 1          |
| Ni-63   | 10         | Te-131  | 1          | Pt-191  | 1          |
| Zn-65   | 0.1        | Te-131m | 0.1        | Pt-193m | 100        |
| Ge-71   | 100000     | Te-132  | 0.1        | Au-198  | 1          |
| As-73   | 1000       | I-125   | 10         | Au-199  | 10         |
| As-74   | 1          | I-126   | 1          | Hg-197  | 10         |
| As-76   | 1          | I-129   | 0.1        | Hg-203  | 1          |
| As-77   | 100        | I-131   | 1          | Tl-200  | 0.1        |
| Se-75   | 1          | Cs-129  | 1          | Tl-201  | 10         |
| Br-82   | 0.1        | Cs-131  | 1000       | Tl-202  | 1          |
| Rb-86   | 1          | Cs-132  | 1          | Tl-204  | 0.1        |
| Sr-85   | 1          | Cs-134  | 0.1        | Pb-203  | 1          |
| Sr-89   | 100        | Cs-135  | 10         | Pb-210  | 10#        |
| Sr-90   | 0.1        | Cs-136  | 0.1        | Bi-206  | 0.1        |
| Y-90    | 100        | Cs-137  | 1          | Bi-207  | 0.1        |
| Y-91    | 100        | Ba-131  | 1          | Bi-210  | 1#         |
| Zr-93   | 100        | Ba-140  | 0.1        | Po-210  | 10#        |
| Zr-95   | 0.1        | La-140  | 0.1        | Ra-223  | 1#         |
| Nb-93m  | 100        | Ce-139  | 10         | Ra-224  | 1#         |
| Nb-94   | 0.1        | Ce-141  | 10         | Ra-225  | 1          |
| Nb-95   | 1          | Ce-143  | 1          | Ra-226  | 1#         |
| Mo-93   | 1          | Ce-144  | 1          | Ra-228  | 1#         |
| Mo-99   | 1          | Pr-143  | 1000       | Th-227  | 1#         |
| Tc-96   | 0.1        | Nd-147  | 10         | Th-228  | 1#         |
| Tc-97   | 1          |         |            |         |            |

|        |     |                         |
|--------|-----|-------------------------|
| Th-229 | 0.1 | # Natural radionuclides |
| Th-230 | 1#  |                         |

| Nuclide | SDL<br>(Bq/g) |
|---------|---------------|
| Th-231  | 1#            |
| Th-232  | 1#            |
| Th-234  | 1#            |
| Pa-230  | 1             |
| Pa-231  | 1#            |
| Pa-233  | 1             |
| U-230   | 1             |
| U-231   | 10            |
| U-232   | 0.1           |
| U-233   | 1             |
| U-234   | 1#            |
| U-235   | 1#            |
| U-236   | 1             |
| U-237   | 10            |
| U-238   | 1#            |
| Np-237  | 0.1           |
| Np-239  | 10            |
| Pu-236  | 1             |
| Pu-237  | 10            |
| Pu-238  | 0.1           |
| Pu-239  | 0.1           |
| Pu-240  | 0.1           |
| Pu-241  | 10            |
| Pu-242  | 0.1           |
| Pu-244  | 0.1           |
| Am-241  | 0.1           |
| Am-242  | 100           |
| Am-242m | 0.1           |
| Am-243  | 0.1           |
| Cm-242  | 1             |
| Cm-243  | 1             |
| Cm-244  | 1             |
| Cm-245  | 0.1           |
| Cm-246  | 0.1           |
| Cm-247  | 1             |
| Cm-248  | 0.1           |
| Bk-249  | 100           |
| Cf-246  | 10            |
| Cf-248  | 1             |
| Cf-249  | 0.1           |
| Cf-250  | 0.1           |
| Cf-251  | 0.1           |
| Cf-252  | 1             |
| Cf-253  | 10            |
| Cf-254  | 1             |
| Es-253  | 10            |
| Es-254  | 1             |
| Es-254m | 1             |

TABLE II. ACTIVITY CONCENTRATION LEVELS FOR FOOD DESTINED FOR GENERAL CONSUMPTION. [8]

| Representative radionuclide           | Foods destined for general consumption (Bq/g) | Milk, infant foods (Bq/g) |
|---------------------------------------|---|---------------------------|
| $^{241}\text{Am}$ , $^{239}\text{Pu}$ | 0.01  | 0.001                     |
| $^{90}\text{Sr}$                      | 0.1   | 0.1                       |
| $^{131}\text{I}$                      | 1   | 0.1                       |
| $^{134}\text{Cs}$ , $^{137}\text{Cs}$ | 1   | 1                         |

TABLE III. ACTIVITY CONCENTRATION LEVELS FOR DRINKING WATER. [9]

| Radionuclide      | Concentration (Bq/l) or (Bq/kg) |
|-------------------|---------------------------------|
| $^3\text{H}$      | 7800                            |
| $^{14}\text{C}$   | 250                             |
| $^{60}\text{Co}$  | 20                              |
| $^{89}\text{Sr}$  | 37                              |
| $^{90}\text{Sr}$  | 5                               |
| $^{129}\text{I}$  | 1                               |
| $^{131}\text{I}$  | 6                               |
| $^{134}\text{Cs}$ | 7                               |
| $^{137}\text{Cs}$ | 10                              |
| $^{210}\text{Pb}$ | 0.1                             |
| $^{210}\text{Po}$ | 0.2                             |
| $^{224}\text{Ra}$ | 2                               |
| $^{226}\text{Ra}$ | 1                               |
| $^{228}\text{Ra}$ | 1                               |
| $^{232}\text{Th}$ | 0.1                             |
| $^{234}\text{U}$  | 4                               |
| $^{238}\text{U}$  | 4                               |
| $^{239}\text{Pu}$ | 0.3                             |

2.2. With radionuclides of natural origin, the levels apply to the parent of the relevant decay chain except in those circumstances where one decay product is unsupported, i.e. has a greater activity than its parent or where some decay products have significantly lower activities than their parent.

2.3. To apply the scope-defining levels to a material other than foodstuffs containing a mixture of radionuclides, the following simple ratio expression should be used:

$$\sum_{i=1}^n \frac{C_i}{C_{Li}} \leq 1$$

where  $C_i$  is the concentration Bq/g of radionuclide  $i$  in the material;  $C_{Li}$  is the scope-defining level in Bq/g for the radionuclide  $i$  in that material; and  $n$  is the number of radionuclides in the mixture. In the above expression, the ratio of the concentration of each radionuclide to its scope-defining level is summed over all radionuclides that leads to exposure from the mixture. If this sum is greater than one, the requirements of the BSS [1] should be applied to the material. This type of relationship may be used by national authorities in their specific guidance on application of the BSS [1] to account for situations where multiple radionuclides are present in mixtures.

2.4. For foodstuff and drinking water, the approach for determining scope-defining levels for mixtures of radionuclides should be in accordance with Codex Alimentarius [8] and WHO [9] methodology.

### 3. BASIS FOR DERIVING THE SCOPE-DEFINING LEVELS

3.1. Different approaches were used in establishing scope-defining levels for the various types of commodities. This included consideration of dose, scenarios for use, and natural radioactivity levels worldwide. These approaches are described in the ensuing sections and ref [7]. For all approaches, a basic criteria is that there is a low probability of an individual being exposed to greater than 1 mSv in a year.

## NATURAL RADIONUCLIDES IN COMMODITIES, OTHER THAN FOODSTUFFS AND DRINKING WATER

3.2. The concept of exclusion, as described in the BSS, relates to the amenability of exposures to regulatory control rather than to the actual magnitude of those exposures. Exclusion applies to the exposure itself, rather than the source of the exposure, because a radiation source can produce various types of exposure in a variety of situations, some of which may be amenable to restrictions while others may not. Exclusion mainly addresses exposures from natural sources, which comprise the vast majority of those experienced by most individuals. Some exposures from materials containing radionuclides of natural origin should be regarded as amenable to control.

3.3. Examples of excluded exposures given in the BSS are those from naturally occurring radionuclides, such as potassium-40, in the body, from cosmic radiation at ground level, and exposures notably from "unmodified concentrations of radionuclides in most raw materials" [1]. The reference to unmodified concentrations points to the fact that processing some raw materials, which may have typical normal concentrations of radionuclides of natural origin, may lead to products or wastes that have higher values or give rise to exposures that should not be excluded from regulatory control. The reference to exposure from most raw materials suggests that exposure to some raw materials themselves should not be subject to exclusion. Thus, whatever the cause of the exposure - through enhancement of the radionuclide content during processing or simply because the material has an intrinsically relatively high radionuclide content - the Regulatory Authority should recognize that there are some industries using naturally occurring radioactive materials where attributable exposures warrant consideration and control. Decisions on which materials should be within the system of regulatory control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides.

3.4. The scope-defining levels for naturally occurring radionuclides in commodities other than foodstuff and drinking water have been selected from the upper end at the worldwide distribution of natural activity concentration levels [1, 10]. 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. A fuller description of the approach used is given in the Safety Report XXX [7].

## ARTIFICIAL RADIONUCLIDES IN COMMODITIES, OTHER THAN FOODSTUFFS AND DRINKING WATER

3.5. The scope-defining levels for artificial radionuclides in commodities other than foodstuffs and drinking water have been set by application of the criteria established in the BSS [1]. A relevant criterion for scope-defining levels is that doses to individuals should be of the order of  $10\mu\text{Sv}$  in a year, with a modeling considering a low probability of the dose to any individual approaching  $1\text{mSv}$  in a year.

3.6. Many studies undertaken at a national or international level have derived radionuclide specific levels for clearance of solid material [11- 13]. The results presented in this document draw upon the extensive experience gained in undertaking these studies and independent calculations performed by the Agency [7]. Four sets of calculations were undertaken to determine the scope-defining levels for artificial radionuclides in solid materials. Briefly the calculations were based on evaluation of the following selected set of scenarios encompassing external radiation, dust inhalation and ingestion (direct and indirect):

- I. Scenarios representing typical exposure situations for all materials containing artificial radionuclides:
  - (A) Using realistic parameter values, concentrations were derived using a dose criterion of  $10\mu\text{Sv}$  in a year;
  - (B) Using low probability parameter values, concentrations were derived using a dose criterion of  $1\text{mSv}$  in a year.
- II. Scenarios to represent processing and use of metals containing artificial radionuclides derived using a dose criterion of  $10\mu\text{Sv}$  in a year;
- III. Scenarios to represent processing and use of concrete containing artificial radionuclides derived using a dose criterion of  $10\mu\text{Sv}$  in a year.

3.7. The scope-defining levels for solid commodities containing artificial radionuclides were selected as the lowest values calculated from scenarios I, II and III. The details of these calculations are provided in the Safety Report XXX [7].

3.8. The calculations for solids excluding foodstuffs were considered appropriate for liquids (other than drinking water). In the case of gases, the Schedule I values of the BSS [1] should be used. These values are considered to be appropriate for adoption as scope-defining levels.

#### FOODSTUFFS AND DRINKING WATER

3.9. The generic intervention exemption levels for foodstuffs established in the Codex Alimentarius [8] are intended to apply in international trade following a nuclear accident during the first year following the accident. The Codex Alimentarius Commission, through a joint project of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), had provided these levels. They were derived on the basis of an individual dose criterion of 5 mSv in a year, on the assumption that the entire diet consists of foodstuffs containing these levels of radioactivity. However, on a protracted timescale, and under normal circumstances, only a very small fraction of the food being traded internationally would be expected to contain such maximum levels of radioactivity. Owing to the extremely conservative assumptions adopted, it is most unlikely that the application of these levels will result in a dose to an individual greater than a small fraction of 1 mSv in a year [8]. Consequently, the Codex Alimentarius values should be used in the absence of revised Codex values during the first year and in subsequent years in the context of the unrestricted trade of foodstuff.

3.10. The World Health Organization (WHO) has published guidelines for Drinking Water Quality [9]. These are based on a dose criterion of 0.1 mSv in a year from an adult drinking 2 liters of water per day. The dose criteria, and the assumption used for the amount of water consumed, would make these guidelines also suitable for determining the scope-defining levels for use in the context of the unrestricted trade of water.

## 4. APPLICATION OF THE SCOPE-DEFINING LEVELS

### IMPLICATIONS FOR TRADE

4.1. Trade in commodities with activity concentrations below the scope-defining levels should not be subject to regulatory controls from radiological protection considerations. Such commodities should be permitted to be traded freely. Commodities with activity concentrations above the scope-defining levels should be subject to the requirements of the BSS.

4.2. The scope-defining levels established in this document apply to day-to-day national and international trade. Compliance with the scope-defining levels should be verified at the first point of entry into trade. In general, it should not be necessary for each and every country to set up its own routine measurement programme solely for the purpose of monitoring commodities. In cases where there are reasonable grounds for believing that the scope-defining levels may be exceeded, arrangements should be made to determine the actual levels either by obtaining the information from the supplier or by measurement. The scope-defining levels may provide an input for determining the design requirements for monitoring equipment that might be used to detect the presence of commodities requiring regulation.

4.3. Any restrictions made on materials with radionuclide content below the scope-defining levels, such as action by customs organizations at national borders to prohibit the entry of such materials to limit their utilization, should not be attributed to radiation protection considerations.

### APPLICATION TO CLEARANCE

4.4. A particular implication of the values of the scope-defining levels is that they can also be used for clearing materials from practices, i.e., for determining whether regulatory controls should be lifted or removed. Any material within a practice containing radionuclides of either natural or artificial origin below the scope-defining levels should be regarded as candidate for clearance.

## IMPLICATIONS FOR OCCUPATIONAL EXPOSURE

4.5. The scope-defining levels are not intended to constrain in any way the international requirements for the limitation and control of occupational exposure, which are established in the BSS, particularly in its Appendix I. Guidance on the application of the BSS to occupational exposure was provided in Safety Guide RS-G-1.1 [14].

## IMPLICATIONS FOR PUBLIC EXPOSURE FROM PRACTICES AND INTERVENTIONS

4.6. The scope-defining levels are not intended to constrain in any way, the international requirements for the limitation and control of public exposure, which are established in the BSS, particularly in its Appendix III. Specifically, the scope-defining levels are not intended to be applied to the control of radioactive discharges of liquid and airborne effluents from authorized practices, or to radioactive residues in the environment. (Guidance on authorization of liquid and airborne effluents discharges and reuse of contaminated land is provided elsewhere [15][16].) Furthermore, scope-defining levels should not be used as part of the basis for making decisions concerning introducing or withdrawing protective actions in intervention situations.

## IMPLICATIONS FOR PROCESSING MATERIAL

4.7. Deliberate dilution in order to meet the scope defining levels should not be permitted without the prior approval of the Regulatory Authority. Furthermore, it should be noted that the processing of commodities containing natural radionuclides below the scope-defining levels could produce concentrations of these radionuclides, which are above the scope-defining levels. In such cases, the processing operation should be considered to be a practice in the meaning of the BSS [1]. Any resulting commodities that will be traded freely should meet the scope-defining levels.

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