Guideline for Ensuring Safety of Raw Materials and Products Containing Uranium or Thorium

(Provisional translation)

June 26, 2009

Ministry of Education, Culture, Sports, Science and Technology (MEXT)

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Chapter 1 Introduction

In the natural world, there are various radioactive materials such as those that have existed in the crust since the birth of the earth and those that have been generated by cosmic rays. These materials are called naturally occurring radioactive materials (hereinafter referred to as "NORM"). Ores that contain relatively a lot of NORM are used widely in large quantities as industrial raw materials, and also those products that are made from these materials are used in a wide range of fields and used as consumer goods by many people. Therefore, even people other than those who are occupationally exposed persons under control by laws and regulations get exposed to low dose in daily life.

Therefore, with an aim to reduce the health risk of getting exposed to unnecessary radiation at the time of handling NORM, it has been decided, as an immediate measure, to require manufacturers and importers for self management of safe handling of raw materials and products that contain uranium or thorium not subject to the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors (hereinafter referred to as "Reactor Regulation Law"), and the manufacturers and importers who are required to conduct self management and measures to be taken by them are incorporated¹ in the guidelines based on the discussions made by the Subcommittee on Safety Regulations for Research Reactors, etc. and others with reference to the report made by the General Administrative Group of Radiation Review Council in October 2003 concerning "Exemption of NORM from regulations" (hereinafter referred to as "General Administrative Group Report.")

As a matter of course, in the cases that fall under the matters prescribed by the laws and regulations concerning radiation safety such as the Reactor Regulation Law, the Laws concerning the Prevention from Radiation Hazards due to Radioisotopes and others, the Industrial Safety and Health Act and others, such laws should be followed. Even in the case where the raw materials not subject to the guidelines are used, it should be noted that such case may become subject to the laws and regulations mentioned above, if the concentrations of uranium, thorium and others may increase in the process of production.

In consideration of the status of implementation of measures to be taken by manufacturers and importers for ensuring safety, MEXT will continuously review the guidelines for improvement.

¹ The background to date is shown in Commentary 1 "Background of Guideline Preparation."

Chapter 2 Position and outline of guidelines

(1) Purpose of guidelines

To reduce the health risk of getting exposed to unnecessary radiation at the time of handling raw materials and products that contain uranium or thorium, the manufacturers and importers who are required to conduct self management and measures to be taken by them are specified concerning the following matters:

- 1 Ensure safety by reducing unnecessary radiation exposure of workers at production establishments and residents living in the vicinity.
- 2 Ensure safety by reducing unnecessary radiation exposure of users from consumer goods.

(2) Self management by manufacturers and importers

MEXT's Subcommittee on Safety Regulations for Research Reactors, etc. made discussions about a desirable safety management concerning the use of NORM in the future, and a report was prepared by the Subcommittee concerning "Desirable Safety Regulations for Test and Research Reactor Facilities, etc." in January 2005. The report suggested, concerning the safety management involved in the use of NORM, that it should be appropriate to develop guidelines with reference to the General Administrative Group Report and opinions of knowledgeable persons, rather than immediately introducing regulation under the law, and then to require manufacturers and importers who handle NORM to conduct self management based on the guidelines.

For these reasons, those companies and industries that handle raw materials and products that contain uranium or thorium, among NORM, are expected to make effective use of the guidelines for ensuring safety, including reduction in exposure to unnecessary radiation.

(3) Current state of safety regulation

The materials that contain uranium or thorium are now regulated by the Reactor Regulation Law in Japan concerning the concentration of radioactivity of radionuclide and the quantity thereof. Specifically, as for the regulatory values of uranium and thorium which are subject to utilization notification of nuclear raw materials, as shown in Fig. 1, the concentration of radioactivity of uranium or thorium is set at 74 Bq/g (370 Bq/g for nuclear raw materials in solid state), and the quantity thereof is provided for that the "total of the three times the amount of uranium plus amount of thorium" is more than 900 g. The quantity of nuclear fuel materials which are subject to utilization permission is set at more than 300 g for natural uranium or depleted uranium and more than 900 g for thorium. It is provided for that the use of enriched uranium requires permission regardless of quantity.

Therefore, raw materials, industrial products and consumer goods, which contain uranium or thorium of radioactivity concentration and quantity less than the values mentioned above, are not subject to the Reactor Regulation Law.

Fig. 1 Notification and permission of nuclear raw materials and nuclear fuel materials

Nuclear raw materials subject to utilization notification			
In the case where both the concentration and quantity of uranium or thorium exceed the following values:			
Radioactivity concentration 74 Bq/g (Solid state: 370 Bq/g)			
• Quantity Amount of uranium x 3 + amount of thorium = 900 g			
Nuclear fuel materials subject to utilization permission:			
• Natural and depleted uranium and compounds thereof Quantity in excess of 300 g			
Enriched uranium Fully subject to regulation			
• Thorium and compounds thereof Quantity in excess of 900 g			

(4) Description of guidelines

The guidelines are composed of the six steps mentioned below, including the identification of targeted manufacturers and importers, provision of information and recording (see Fig. 2). Description (1) presents the measures to be taken by targeted manufacturers engaged in the manufacturing industry, and Description (2) presents the measures to be taken by targeted manufacturers and importers of consumer goods. The details of respective descriptions are mentioned in Chapters 4, 5 and 6. The manufacturers that produce consumer goods are required to take the measures prescribed in both Description (1) and Description (2).

Moreover, among those who have permission to use nuclear fuel materials and those who made notification to use nuclear raw materials, the manufacturers that produce consumer goods or industrial products are subject to the guidelines, and they are required to take the measures prescribed in Description (1) or Description (2), in addition to the obligations prescribed by the Reactor Regulation Law.

Fig. 2 Respective steps mentioned in the guidelines

	Description (1)	Description (2)
	Measures to be taken by targeted manufacturers engaged in the manufacturing industry (See Chapters 4 and 5 for further details)	Measures to be taken by targeted manufacturers and importers of consumer goods (See Chapters 4 and 6 for further details)
Purpose	Ensure safety by reducing unnecessary radiation exposure of workers at production establishments and residents living in the vicinity.	Ensure safety by reducing unnecessary radiation exposure of users at the time of use of consumer goods (excluding interim products, etc.).
Step 1	[Identification of targeted manufacturers] Identify targeted manufacturers based on the information about the types of raw materials to be used in processing and the radioactivity concentration of uranium or thorium.	[Identification of targeted manufacturers and importers] Identify targeted manufacturers and importers based on the information about the types of raw materials contained in products and the radioactivity concentration and quantity of uranium or thorium, and on how products are used.
Step 2	[Measurement of radiation dose rate] The targeted manufacturers identified by Step 1 should measure radiation dose rates of their work environments (raw materials, wastes, products, etc.) by using survey meters.	[Measurement of radiation dose rate] The targeted manufacturers and importers identified by Step 1 should measure the radiation dose rates of consumer goods by using survey meters.
Step 3	[Evaluation of exposure dose] Calculate the exposure doses of workers and residents in the vicinity based on the results of measurement of radiation dose rates as prescribed in Step 2.	[Evaluation of exposure dose] Calculate the exposure doses of users based on the results of measurement of radiation dose rates as prescribed in Step 2.
Step 4	[Measures to reduce radiation exposure] Take necessary measures to reduce exposure doses if radiation exposure is estimated to exceed 1 mSv/year ² .	[Measures to reduce radiation exposure] Take necessary measures to reduce exposure doses if radiation exposure is estimated to exceed 1 mSv/year ² .
Step 5	[Provision of information] Provide information to the destination to which interim products, etc. are shipped.	[Provision of information] Provide and present information to consumer goods users.
Step 6	[Production of records and education] Produce and save necessary records and conduct necessary education programs.	[Production of records] Produce and save necessary records.

 $^{^2}$ As shown in Commentary 2 "Concept of Radiation Exposure of General Public," even if radiation exposure exceeds 1 mSv/year, clinical findings are not found with radiation doses lower than 100-200 mSv. In other words, 1 mSv/year is lower than one-hundredth of the level at which clinical findings are found, meaning the level to conduct the risk management of radiation.

Chapter 3 Definition of terms and commentary

Major terms used in the guidelines are defined as follows:

(1) Naturally occurring radioactive materials (NORM)

Naturally occurring radioactive materials (NORM) mean the generic name of earth-origin radioactive nuclides and cosmic-ray-produced nuclides, which exist in the natural world, in a general sense or in a broad sense. It is known that many nuclides other than uranium and thorium exist as NORM such as potassium-40.

(2) Natural uranium and thorium

As for uranium and thorium, several nuclides of different mass numbers exist. In the guidelines, nuclide composition is not limited unless otherwise particularly mentioned.

Many of them emit radiation and change to other elements (daughter nuclides). In many cases, these daughter nuclides are also radioactive (and create more daughter nuclides). Therefore, those that contain natural (not refined) uranium and thorium coexist with daughter nuclides.

(3) Refined uranium and thorium

Refined uranium and thorium contain almost no daughter nuclides. When refined uranium or thorium is handled, many manufacturers have permission to use nuclear fuel materials and made notification to use nuclear raw materials. However, those products, of which the concentration and quantity are less than the values prescribed by the Reactor Regulation Law as they are mixed with other materials in the process of utilization, are not subject to statutory regulations. The guidelines are prepared because it is desirable to give consideration to radiation exposure even in such case that above-mentioned products are not subject to laws and regulations.

(4) Those who are protected from radiation exposure

Under the guidelines, workers at production establishments where raw materials and products that contain uranium or thorium are handled, residents in the vicinity, and consumer goods users should be protected from radiation exposure.

(5) Specified raw materials

Under the guidelines, the specified raw materials mean the following materials that contain uranium or thorium:

(i) Ores and mineral sand

Monazite, bastnaesite, zircon, tantalite, phosphate ore, uranium ore, thorium ore, titanium ore (rutile, ilmenite, etc.) and coal ash.

(ii) Metals, glass and others added with refined uranium and thorium.

(6) Standards for radioactivity concentration³ (unit: Bq/g (Becquerel per gram)⁴)

Those materials that contain natural uranium and thorium coexist with daughter nuclides. If such materials are refined and coexisting daughter nuclides are removed, their radioactivity decreases to about one-tenth in the case where natural uranium and thorium were in the state of radioactive equilibrium. Under the guidelines, therefore, as the indicative values to guarantee that exposure doses due to raw materials, products and others are kept at 1 mSv/year or lower, 1 Bq/g is applied to those materials that contain natural uranium or thorium that can be considered being in the state of radioactive equilibrium with daughter nuclides, and 10 Bq/g to those materials that contain uranium or thorium that are refined and daughter nuclides are removed from them, and those materials that exceeds the indicative values are made subject to the guidelines.

For reference, the mass of targeted material, which is used as the denominator to calculate the concentration, should basically be the mass of raw material. In the case of consumer goods, however, each product used is applied. In the case of products composed of several parts, parts that can be roughly removed should be applied⁵.

(7) Standards for quantity of radioactivity of consumer $goods^6$ (Unit: Bq (Becquerel)⁷)

Under the guidelines, as the indicative values to guarantee that exposure doses due to the use of consumer goods are kept at 1 mSv/year or lower, the quantity of radioactivity of uranium or thorium contained in consumer goods that are used in contact with or close (within one meter) to human bodies is set at 8,000 Bq for those materials that contain natural uranium or thorium, and at 80,000 Bq for those materials that contain refined uranium or thorium, and those materials that exceeds the indicative values are made subject to the guidelines.

(8) Interim products, etc.

Under the guidelines, interim products, etc. mean primary products, semi-finished products, industrial products and by-products other than consumer goods that are processed by using specified raw materials. In the case where defective products produced in the manufacturing process are to be reused and wastes are to be recycled to manufacture other products, such products should be handled in the same manner as interim products, etc. In the case where those products that are not raw materials themselves like welding electrodes but are used in manufacturing processes, such products should also be handled in the same manner as interim products, etc.

In the case where interim products, etc. are used as raw materials in other manufacturing industries, such products may cause radiation exposure of workers at production establishments where they are processed. Therefore, the case where interim products, etc. are processed as raw materials is also made subject to the guidelines.

³ See Commentary 3 "Regarding the standards for radioactivity concentration."

⁴ Unit that represents the quantity of radioactivity contained per gram

⁵ For example, as for thoriated electrodes that are used for electric-discharge lamps, the weight of electrode

is applied in the assembly process. As for finished products, the weight of electric-discharge lamp is applied.

⁶ See Commentary 4 "Regarding the standards for the quantity of radioactivity of consumer goods."

⁷ Unit that represents the quantity of radioactivity

(9) Consumer goods

Those products that are processed from specified raw materials or interim products, etc. that are processed by using specified raw materials and that are used by ordinary households and are not further processed or not used for industrial applications should be defined as consumer goods. In addition, those products that are used for business purposes should also be defined as consumer goods. For example, home spa machines, ornaments and stone tiles used in stone spa facilities should also be regarded as consumer goods.

(10) Wastes subject to evaluation

Wastes that are produced in manufacturing process and stored within production establishments or wastes that are scheduled for final disposal as being valueless are made subject to evaluation.

(11) Radiation dose rate

Radiation dose rates should be represented by the quantity of radiation (Sv (sievert)) irradiated for a certain period of time (one hour in general) from materials that discharge radiation.

Chapter 4 Manufacturers and importers subject to guidelines

Of the details of the guidelines as mentioned in (4) of Chapter 2, Step 1 "Identification of targeted manufacturers and importers" in Fig. 2 is explained in this chapter. The flow chart to identify targeted manufacturers and importers is shown in Figs. 4 and 5.

It should be noted, however, that the concentration and quantity of radioactivity mentioned in this chapter serve as indicative values to guarantee that exposure doses are kept at 1 mSv/year^8 or lower and strict application thereof is not necessarily required.

(1) Targeted manufacturers engaged in the manufacturing industry

are used as raw materials and processed

The targeted manufacturers engaged in the manufacturing industry should be those manufacturers (including individuals) who possess the production establishments that satisfy Conditions 1 and 2 as described below:

Condition 1:	Production establishments where specified raw materials are used as raw materials and processed into interim products, etc. or consumer goods, or where interim products, etc. that are processed by using specified raw materials are used as raw materials and processed into other interim products, etc. or consumer goods
Condition 2:	Production establishments where specified raw materials or interim products, etc., of which the radioactivity concentration of natural uranium or thorium may exceed 1 Bq/g or that of refined uranium or thorium may exceed 10 Bq/g,

* "Specified raw materials" are defined in (5) of Chapter 3, "interim products, etc." are defined in (8) of the same chapter, and "consumer goods" are defined in (9) of the same chapter.

(i) Condition 1

The typical flows of specified raw materials and interim products, etc. are shown in Fig. 3.

Those manufacturers who process specified raw materials and interim products, etc. process specified raw materials themselves as raw materials (primary processing) in one case and process interim products, etc. that are processed by using specified raw materials as raw materials (n-th processing) in other case. The guidelines cover both of the two cases.

Interim products, etc. should include those that are recycled from wastes produced at the time of processing and reused for other processing. Manufacturers who process imported specified raw materials and imported interim products, etc. are, of course, subject to the guidelines.

(ii) Condition 2

As mentioned in (6) of Chapter 3, the specified raw materials and interim products, etc., which contain natural uranium or thorium and of which the radioactivity concentration of uranium or thorium is 1 Bq/g or lower, and which contain refined uranium or thorium and of

⁸ As for 1 mSv/year, see Commentary 2 "Concept of Radiation Exposure of General Public."

which the radioactivity concentration is 10 Bq/g or lower, are not subject to the guidelines.

It is desirable for each of the industrial associations concerned to specify the raw materials that are used in respective industries concerned and have a possibility of exceeding these radioactivity concentrations, and provide such information to their member companies.

(iii) Others

Those manufacturers who use the materials that contain uranium or thorium, of which the radioactivity concentration and quantity require notification and permission under the Reactor Regulation Law, become subject to the Act, and are required to take measures based on laws and regulations as a necessary premise. Those manufacturers subject to the Act are also required to implement the matters mentioned in the guidelines together with the measures based on laws and regulations.

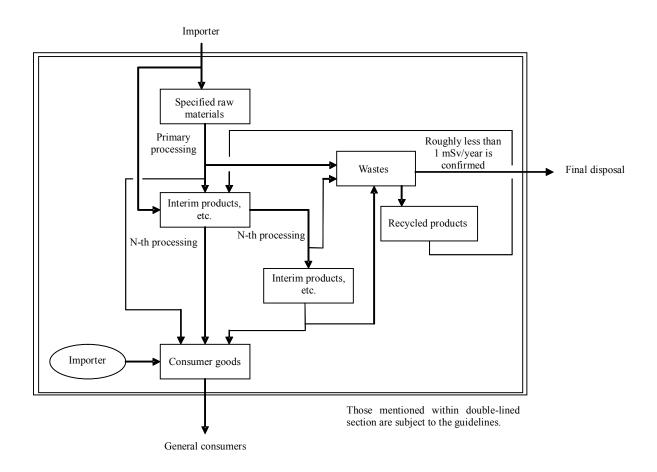


Fig. 3 Flow of specified raw materials and interim products, etc. (pattern diagram)

(2) Targeted manufacturers and importers of consumer goods

The targeted manufacturers and importers of consumer goods (excluding interim products, etc.) are those (including individuals) who manufacture or import those consumer goods that satisfy Conditions 1 and 2 as described below:

- Condition 1: Those consumer goods that are manufactured from specified raw materials or interim products, etc. that are processed by using specified raw materials or that are imported, and that are used in contact with or close (within one meter) to human bodies
- Condition 2: In the case of consumer goods that contain natural uranium or thorium, those consumer goods whose radioactivity concentration of uranium or thorium may exceed 1 Bq/g and whose quantity thereof may exceed 8,000 Bq. In the case of consumer goods that contain refined uranium or thorium, those consumer goods whose radioactivity concentration may exceed 10 Bq/g and whose quantity thereof may exceed 80,000 Bq.
- * "Specified raw materials" are defined in (5) of Chapter 3, "interim products, etc." are defined in (8) of Chapter 3, and "consumer goods" are defined in (9) of Chapter 3.

(i) Condition 1

As for consumer goods, as there is almost no possibility of radiation exposure of more than 1 mSv/year, except for the case where such goods are used in contact with or close to human bodies, only those consumer goods that are used in contact with or close to human bodies are made subject to the guidelines.

(ii) Condition 2

The quantity of uranium or thorium contained in consumer goods is much smaller than that of specified raw materials and interim products, etc. handled in large quantities on an industrial scale. Therefore, if it is obvious that the quantity of uranium or thorium is less than a certain quantity, it is considered reasonable to make such consumer goods not subject to the guidelines.

For consumer goods, therefore, the standards for the quantity of radioactivity should be stipulated, as is the case with (1) of this chapter, in addition to the standards for radioactivity concentration.

The concentration and quantity of radioactivity of consumer goods should be measured and analyzed in the shapes they are used in ordinary households.

(iii) Others

Those consumer goods that contain uranium or thorium, of which the radioactivity concentration and quantity require notification and permission under the Reactor Regulation Law, become subject to the Act, and measures based on laws and regulations should be taken as a necessary premise. Even in the case of consumer goods subject to the Act, the matters mentioned in the guidelines should be implemented together with the measures based on laws and regulations.

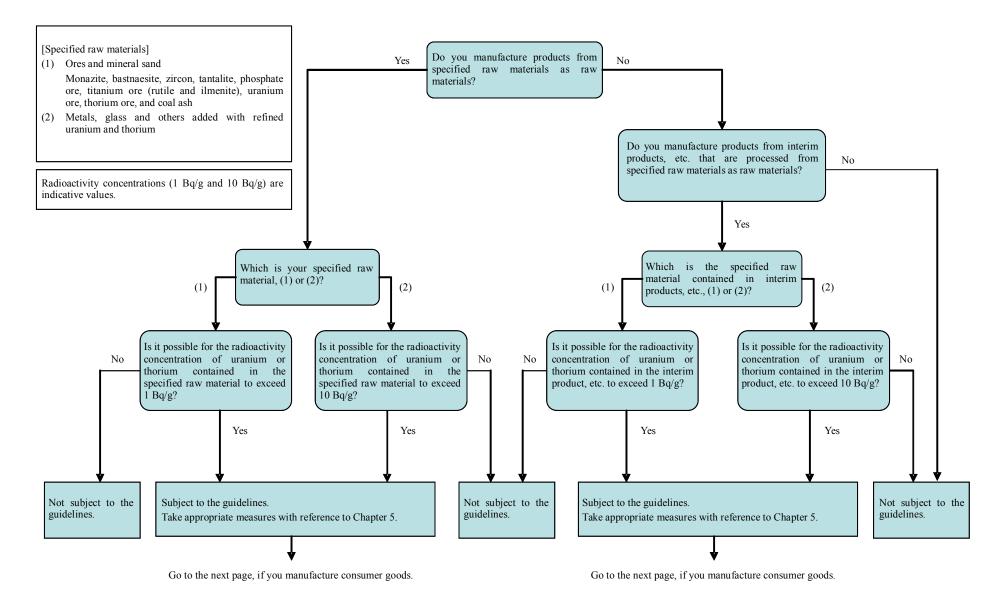


Fig. 4 Flow chart to identify targeted manufacturers engaged in the manufacturing industry

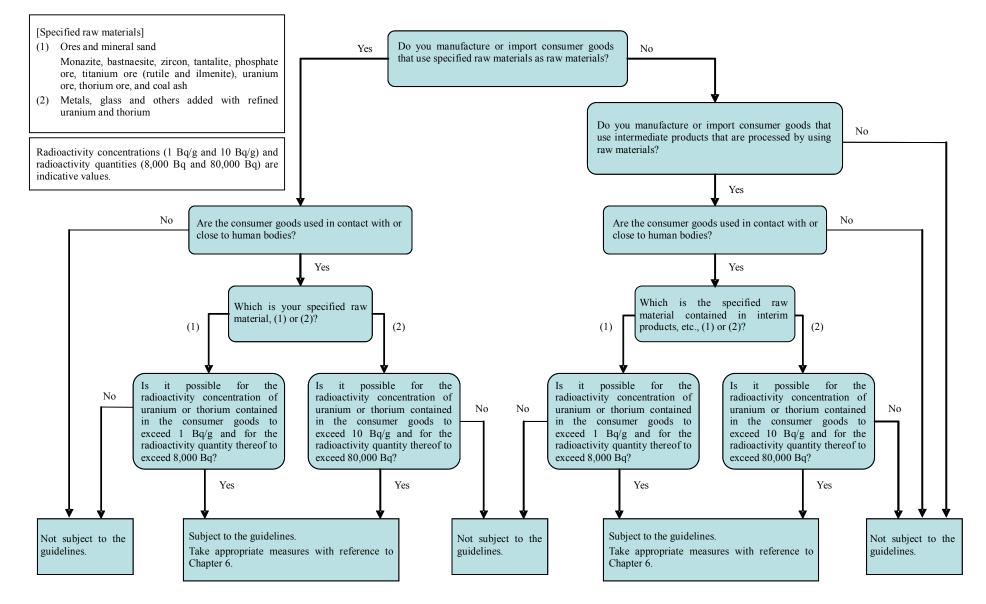


Fig. 5 Flow chart to identify targeted manufacturers and importers of consumer goods

Chapter 5 Measurement of radiation dose rates at production establishments, evaluation of exposure doses and measures for improvement

This chapter explains the measurement of radiation dose rates which is conducted by the targeted manufacturers engaged in the manufacturing industry outside the boarders of production establishments that handle specified raw materials or interim products, etc. that are processed by using specified raw materials (hereinafter referred to as "specified raw materials and others" in this chapter and the following chapters), as well as evaluation of exposure doses and necessary measures for improvement.

Specified materials and others should be handled at places where sufficient ventilation can be provided. Particularly in the case where dust can be generated, such measures as wearing appropriate protective equipment such as masks and gloves should be taken.

(1) Measurement of radiation dose rates and evaluation of exposure doses

(Step 2 and Step 3 in Fig. 2)

Targeted manufactures should conduct the measurement of radiation dose rates and evaluation of exposure doses with reference to "Appendix 1: Measurement method of radiation dose rates" and "Appendix 2: Evaluation of exposure doses."

(i) Evaluation of exposure doses of workers at production establishments

Conduct the measurement of radiation dose rates at workplaces (including waste storage places) and calculate one-year exposure doses of workers in consideration of their working hours.

(ii) Evaluation of exposure doses of residents living in the vicinities of production establishments

Conduct the measurement of radiation dose rates on the borders of production establishments and calculate one-year exposure doses of residents living in the vicinities thereof.

(iii) Frequency of measurement of radiation dose rates and evaluation of exposure doses

The frequency of measurement is once a year in principle. In the following cases, however, unscheduled measurement should be additionally conducted because of a possibility of increase in exposure doses:

- 1 Increase in the total amount of specified raw materials and others
- 2 Change in types, places of origin and suppliers of specified raw materials and others
- 3 Change in processes and specifications of equipment or products
- 4 Change in operating hours, workplaces or storage places of specified raw materials and others
- 5 Change in borders of production establishments
- 6 Changes in method of handling wastes, including specified raw materials and others

(2) Measures for improvement to reduce exposure doses

(Step 4 in Fig. 2)

In response to the results of evaluation of exposure doses as prescribed in (1) of this chapter, the targeted manufacturers should take the following measures to reduce exposure doses:

- (i) In the case where the exposure doses of workers are estimated to exceed 1 mSv/year, the following measures should be taken to keep their exposure doses at 1 mSv/year or lower:
 - 1 Reduce the amount of specified raw materials and others or products in storage
 - 2 Store wastes at several places rather than at one place
 - 3 Shorten the time of being engaged in works
 - 4 Build shields
- (ii) In the case where the exposure doses of residents living in and around the borders of production establishments are estimated to exceed 1 mSv/year, the following measures should be taken to keep their exposure doses at 1 mSv/year or lower:
 - 1 Reduce the amount of specified raw materials and others or products in storage at production establishments
 - 2 Keep places of storage or use away from the borders of production establishments
 - 3 Build shields

(3) **Provision of information**

(Step 5 in Fig. 2)

- (i) The targeted manufacturers should provide the destinations to which interim products, etc. are shipped with the following pieces of information about uranium or thorium contained in the interim products, etc. for evaluation of exposure doses and safe handling:
 - 1 Names of products and manufacturers
 - 2 Types of specified raw materials and others and places of origin (or places of processing)
 - 3 Concentration and quantity of radioactivity of uranium or thorium contained in products
 - 4 Physicochemical properties of uranium or thorium
 - 5 Cautions about handling and storage
 - 6 Other necessary matters
- (ii) When the targeted manufacturers deliver wastes under their control to third parties to dispose of them in landfills (including the case where wastes go through intermediate treatment), they should confirm that the exposure doses at such third parties do not exceed roughly 1 mSv/year⁹. In the case where the exposure doses at such third parties are estimated to exceed 1 mSv/year or cannot be evaluated, wastes should not be delivered to them.

 $^{^9}$ As for the time that is used to evaluate exposure doses, it is allowed to set a realistic access time and the period of 8,760 hours (24 hours x 365 days) does not need to be used at all time.

(4) Production of records and education

(Step 6 in Fig. 2)

The targeted manufacturers should produce the following records and save them:

(i) Records of measurement and evaluation

The records of measurement and evaluation should be saved with written information about the date of measurement, name of the person who made the measurement, results of measurement, and the method and results of evaluation. The records should be saved for five years.

(ii) Records of education

In the case where the exposure doses of workers are estimated to exceed 1 mSv/year and the measures prescribed in (2) of this chapter are taken, the education programs should be provided concerning the conditions of individual exposure, methods of reduction in exposure and the handling of matters that contain uranium or thorium, and the records of education should be saved. The records should be saved for three years.

Chapter 6 Measurement of radiation dose rates at the time of use of consumer goods, evaluation of exposure doses and measures for improvement

This chapter discusses the measurement of radiation dose rates at the time of use of consumer goods (excluding interim products, etc.), evaluation of exposure doses, and necessary measures for improvement, which are conducted by the targeted manufacturers and importers.

(1) Measurement of radiation dose rates and evaluation of exposure doses

(Step 2 and Step 3 in Fig. 2)

(i) Evaluation of exposure doses of users

The targeted manufacturers and importers measure radiation dose rates at the positions where consumer goods are used and calculate one-year exposure doses of users in consideration of duration of use of consumer goods in a year. If radioactivity analysis values are available, exposure doses may be evaluated by using the results of such analysis.

If consumer goods are in the form of powder and there is a possibility that such powder be inhaled, the exposure doses of inhaled powder should also be evaluated.

As for the specific methods of measurement of radiation dose rates and evaluation of exposure doses, see "Appendix 1: Method of measurement of radiation dose rates" and "Appendix 2: Evaluation method of exposure doses."

(ii) Frequency of measurement of radiation dose rates and evaluation of exposure doses

In the following cases, however, unscheduled measurement should be additionally conducted because of possible increase in exposure doses:

- 1 Change in types of specified raw materials and others used as raw materials, and places of origin and suppliers thereof
- 2 Change in composition of specified raw materials and others
- 3 Change in utilization methods of consumer goods

(2) Measures for improvement to reduce exposure doses

(Step 4 in Fig. 2)

In the case where the result of evaluation of exposure doses of consumer goods users are estimated to exceed 1 mSv/year in normal usage, the targeted manufacturers and importers should take the following measures to reduce exposure doses of consumer goods and keep exposure doses at 1 mSv/year or lower in normal usage. Even if exposure doses do not exceed 1 mSv/year, it is recommended to take such measures, when exposure doses can be reasonably and easily reduced.

- 1 Reduce the amount of specified raw materials and others that are used per unit of consumer goods
- 2 Make improvements to limit the usage of consumer goods not to allow them to be used in contact with or close to human bodies for a long period of time.

(3) **Provision of information**

(Step 5 in Fig. 2)

In the case where the results of evaluation of exposure doses of consumer goods users are estimated to exceed 1 mSv/year because of inappropriate usage such as the use thereof in excess of appropriate time, the cautions and other information prescribed below should be indicated on or attached to consumer goods. Attentions should be paid not to allow such indications to be dropped off or unreadable at the time of use. However, as for those consumer goods for which such cautions cannot be indicated, information should be appropriately known by other methods.

- 1 The fact that consumer goods contain uranium or thorium
- 2 The exposure dose per hour of use
- 3 Cautions about handling to reduce exposure doses of users, etc. (duration of use, distance between user and product, etc.)
- 4 Name of manufacturer, contact information, etc.

(4) Production of records

(Step 6 in Fig. 2)

The targeted manufacturers and importers should produce records of measurement of radiation dose rates and evaluation of exposure doses and save them. The records of measurement and evaluation should be saved with written information about the date of measurement, name of the person who made the measurement, results of measurement, and the method and results of evaluation. The records should be saved for the period until the use of targeted consumer goods is assumed to be ceased.

[Appendix 1] Method of measurement of radiation dose rates

(1) As for the equipment that is used for measurement of radiation dose rates, a calibrated energy-compensation-type Nal (TI) scintillation survey meter (detection limit is 0.01 μ Sv/h or lower) or gamma-ray measurement equipment that has equivalent performance should be selected.

(2) Measuring instruments should be read when their instrument readings become stable.

It is desirable to select the largest time constant in the case of measuring instruments whose time constants (seconds) can be changed, and read values after a lapse of time more than three times as long as the time constant.

(3) Measurements should be made twice or more (three times as a reference) at regular intervals for background and in each place of measurement, and measured values and average values thereof should be recorded. Background means a natural radiation dose rate in the place of measurement (radiation from those other than raw materials and products that contain uranium or thorium which is subject to measurement). Therefore, measurements should be made in a sufficiently distant place, where there is no effect of raw materials and products that contain uranium or thorium, from the place to measure radiation dose rates.

(4) Places for measurement should be selected in consideration of the conditions of arrangement of specified raw materials and interim products, etc. (hereinafter referred to as "specified raw materials and others"), the line of flow and access time of workers, distance and other factors.

(5) As for measurements at respective workplaces in production establishments, radiation dose rates should be measured at the positions where workers conduct their operations, if such positions are decided, or at the positions one meter distant from specified raw materials and others, manufacturing equipment, products and wastes and at the height of one meter from the floor face. Measurements should be made when operations are actually conducted in respective processes and specified raw materials and others are stored in the maximum amount of the amount slated to be used per year.

(6) As for measurements on the borders of business establishments, radiation dose rates should be measured roughly along the borders of business establishments (or places inside or outside the fences of the site where radiation dose rates can be easily measured) and at each of the measuring points set at regular intervals in proportion to the length of border at the height of one meter from the ground surface. In this case, those who make measurements should try to find the maximum value of radiation dose rate.

(7) Radiation dose rates of consumer goods should be measured at the positions where they are usually used.

(8) Net radiation dose rates should be calculated by subtracting background dose rates from

respective measured values. As for those consumer goods that are used in contact with the skin, net radiation dose rates should be calculated by subtracting background dose rates from the values that are calculated by doubling the measured values (in the case the values of radiation dose rate become negative, they are treated as zero) to take into account β ray.

(9) Those who measure radiation dose rates are not required to have any particular qualification.

[Appendix 2] Evaluation method of exposure doses

1 Evaluation of exposure doses of workers at production establishments

(1) Calculate net radiation dose rates at respective workplaces based on Appendix 1.

(2) Confirm working hours of workers in a year at respective workplaces (including waste storage areas).

(3) Calculate exposure doses of workers in a year by multiplying the radiation dose rates calculated in (1) above by the working hours confirmed in (2) above (if the same worker conducts his or her operations at two or more workplaces, his or her exposure doses should be totaled).

(4) If the exposure doses calculated in (3) above are estimated to exceed 1 mSv/year, the measures prescribed in "Chapter 5 (2) Measures for improvement to reduce exposure doses" in the guidelines should be taken.

2 Evaluation of exposure doses of residents living in the vicinities of production establishments

(1) Calculate net radiation dose rates on the borders of production establishments based on Appendix 1.

(2) Calculate one-year exposure doses by multiplying the radiation dose rates calculated in (1) above by a realistic access time¹⁰.

(3) If the exposure doses calculated in (2) above are estimated to exceed 1 mSv/year, the measures prescribed in "Chapter 5 (2) Measures for improvement to reduce exposure doses" in the guidelines should be taken.

3 Evaluation of exposure doses of consumer goods users

The methods to evaluate exposure doses are shown below. Those who evaluate internal exposure doses should consult with specialized agencies.

(1) Method to evaluate exposure doses based on radiation dose rates

- 1 Calculate net radiation dose rates at the positions where consumer goods are used based on Appendix 1.
- 2 Estimate the duration of use of consumer goods in a year. However, the maximum duration of use in normal usage should be adopted to avoid underestimation.
- 3 Calculate one-year exposure doses by multiplying the radiation dose rates calculated in 1 above by the duration of use estimated in 2 above.

(2) Method to evaluate exposure doses based on the values of radioactivity analyses of consumer goods

If the values of radioactivity analyses of consumer goods are available (results of analyses by specialized agencies, etc.), it is allowed to evaluate exposure doses by using the following

 $^{^{10}\,}$ It is allowed to set a realistic access time and the period of 8,760 hours (24 hours x 365 days) does not need to be used at all time.

equations.

In the case of those consumer goods whose radioactivity concentrations can hardly be analyzed, it is allowed to estimate their radioactivity concentrations by calculation. However, the details of estimation should be recorded.

[Exposure dose of consumer goods used not in contact with the skin (effective dose) (Dose I)]

Dose I (mSv/year) = DEX [mSv/hour/(Bq/m²)] x C(Bq/g) x M(g) x T(hour/year) \div [D(m)]²

[Exposure dose of consumer goods used in contact with the skin (effective dose) (Dose II)]

Dose II (mSv/year) = DSKIN [mSv/hour/(Bq)] x C(Bq/g) x M(g) x T(hour/year)

Where,

DEX: Conversion factor into exposure dose (effective dose) per Bq at a place one meter away [mSv/year/ (Bq/m²)]

DSKIN: Conversion factor into exposure dose (effective dose) per Bq (mSv/hour/Bq)

- C: Radioactivity concentration in consumer goods (Bq/g)
- M: Weight of consumer goods (g)
- T: Assumed duration of use (hour/year)
- D: Distance between consumer goods and user (m)

Fig. 6 Conversion factor into exposure dose (effective dose)

Name of radioactive material	DEX	DSK IN
Thorium	1.8E-10	9.6E-09
Uranium	2.7E-10	1.3E-08

(Conversion factors derived from European Commission; Radiation Protection 65(1993))

(3) If the exposure doses calculated in (1) or (2) above are estimated to exceed 1 mSv/year in normal usage, the measures prescribed in "Chapter 6 (2) Measures for improvement to reduce exposure doses" in the guidelines should be taken.

Commentary

Commentary 1 Background of guideline preparation

In February 2003, the exemption from regulation for naturally occurring radioactive materials (NORM) was reviewed by the General Administrative Group of the Radiation Review Council, and the Group reviewed the exemption from regulation for NORM in relation to the introduction of "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (hereinafter referred to as "BSS") of the International Atomic Energy Agency (hereinafter referred to as "IAEA") and compiled a report on "Exemption of NORM from regulations" (hereinafter referred to as "General Administrative Group Report") in October 2003.

The General Administrative Group Report concluded, as a result of surveys that were made from various angles such as evaluation of radiation exposure based on the recommendations of the International Commission on Radiological Protection (hereinafter referred to as "ICRP") and the ideas presented in the European Commission's report (RP-122 Part 2) concerning the regulations on NORM and in consideration of the trends in other countries and the realities of use of NORM in Japan, that it was appropriate to clarify the measures for classifications by the state of materials and regulations appropriate to such classifications, and to apply the exemption from regulation pursuant to the characteristics of each classification. The indicative values and reference values of doses to cope with radiation exposure due to coal ash (fly ash), etc. generated by using those raw materials whose radioactivity concentrations are lower than the BSS exemption levels are clearly stated in the General Administrative Group Report as the matters to be discussed in the future.

In consideration of these points, MEXT's Subcommittee on Safety Regulations for Research Reactors, etc. made discussions about a desirable safety management in the future in relation to the use of NORM, and put together a report on "Desirable Safety Regulations for Test and Research Reactor Facilities, etc." (hereinafter referred to as "Review Meeting Report") in January 2005 with focus on those materials that contain thorium-232 series nuclides and uranium-238 series nuclides, which exceed exemption levels in BSS.

As the measures to be taken for the present, the Review Meeting Report concluded, taking it into consideration that regulations are applied in other countries pursuant to their situations and that management systems operated by industrial associations are considered effectively working, that it is appropriate to prepare guidelines with reference to the General Administrative Group Report and opinions of knowledgeable persons, rather than immediately introducing regulation under the law, and then to require manufacturers and importers who handle NORM to conduct self management based on the guidelines.

Based on the Review Meeting Report, moreover, the Subcommittee on Safety Regulations for Research Reactors, etc. developed the "guidelines for measurement of and measures for exposure doses at the time of use of matters that contain naturally occurring radioactive materials" (hereinafter referred to as "Proposed NORM Guidelines") in February 2006. However, in the process of promoting discussions about Proposed NORM Guidelines, various inputs were received from relevant organizations. As effective operation of the guidelines was found to be difficult, the Subcommittee on Safety Regulations for Research Reactors, etc. decided in July 2008 to review the contents of Proposed NORM Guidelines.

Based on the reports mentioned above and review by knowledgeable persons, the guidelines organized the specific matters for manufacturers and importers to voluntarily evaluate doses and take measures for improvements, in order to prevent workers who handle

raw materials and products that contain uranium or thorium, among those that contain NORM, and residents living in the vicinities and consumer goods users that contain uranium or thorium from radiation exposure of a certain level or higher.

Commentary 2 Concept of radiation exposure of the general public

(1) Dose limits and others specified by law

In the Reactor Regulation Law, dose limits on workers and the general public are specified, respectively, concerning exposure dose limits on radiation exposure of human beings. In the Reactor Regulation Law, "dose limits on occupationally exposed persons" and "dose limits on places other than supervised areas" are specified. The dose limits on occupationally exposed persons are set at "100 mSv for five years and 50 mSv for one year," and the dose limits on places other than supervised areas are usually interpreted as "dose limits on the general public" and set at "1 mSv for one year."

As for these dose limits, other countries have also introduced nearly the same regulations into their domestic laws based on the reports of ICRP and IAEA. Even in the case of lower than dose limits, doses must be reduced to the extent reasonably achievable in principle.

However, even in the case that it is higher than the dose limit (1 mSv/year), clinical findings have not been confirmed with radiation doses of lower than 100-200 mSv. In other words, this dose limit is one-hundredth or lower than the level where clinical findings can be confirmed, meaning the level to conduct risk management by radiation.

(2) Radiation exposure due to natural radiation

The exposure dose due to natural radiation is estimated at 2.4 mSv/year on average in the world (see Daily Life and Radiation as Reference Material).

This is the total of external exposure, which is caused by cosmic radiation that falls down from outer space onto the earth and terrestrial radiation and others from radioactive materials contained in soils and rocks on the ground surface, and internal exposure which is caused by respiration of radon gas in the air and ingestion of potassium-40 contained in foods.

The exposure dose standard of 1 mSv/year, which is adopted by the guidelines, is equivalent to about half of the world average of 2.4 mSv/year as exposure dose from natural radiation.

(3) Position of 1 mSv/year in the guidelines

In recent years, the following direction is presented in Japan and other countries concerning protection from NORM:

1 The General Administrative Group Report insisted that targeted exposure dose standards should be examined between $10 \,\mu$ Sv/year as the dose standard for exemption¹¹ for acts¹² and 1 mSv/year as the standard for exemption¹³ for

¹¹ Exemption for acts means that nothing subject to regulation is needed because it is not necessary to handle it as a radioactive material as the effect of radiation source thereof on health is so small that it may be ignored.

¹² Acts mean the human activities that increase radiation exposure in general.

¹³ Exemption for intervention means that intervention is not necessary because the risk of health due to exposure to radiation sources that already exist can be ignored.

intervention¹⁴.

- 2 The exemption standard for intervention of products in ICRP Publication 82 is set at about 1 mSv/year.
- 3 In the chairman's summary of NORM Symposium V (2007) hosted by IAEA, it is mentioned that "The order of 1 mSv/year, rather than 10 μ Sv/year, is desirable as the level of exemption from regulation for NORM from the viewpoint of effective utilization of regulated resources and is also generally used as the standard value for NORM."

In consideration of the above-mentioned circumstances in Japan and other countries, the guidelines adopted 1 mSv/year as the standard for exposure dose.

Commentary 3 Regarding the standards for radioactivity concentrations

IAEA's BSS has proposed a regulatory exemption value equivalent to 10μ Sv/year for materials up to one-ton order. The value for natural uranium or thorium is set at 1 Bq/g.

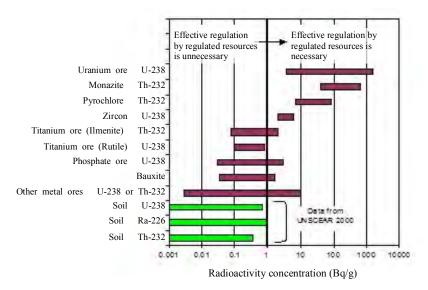
IAEA's Safety Guide No. RS-G-1.7 has proposed 1 Bq/g for natural uranium and thorium as the regulatory exemption value for materials of one-ton order or larger. This value was reported in the report for 2000 of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) as the result of survey on worldwide distribution of radioactivity concentrations of uranium and thorium in soil, and 1 Bq/g as the upper limit thereof was proposed in RS-G-1.7 as the value that needs to be reviewed for regulation of radiation protection. Moreover, it is considered unlikely for this radioactivity concentration of 1 Bq/g to exceed 1 mSv/year, except for exposure to radon.

While taking the above-mentioned international trends into consideration, the guidelines have adopted 1 Bq/g as the standard for the radioactivity concentrations of natural uranium or thorium.

For information, this value is applied to uranium series and thorium series in the state of radiation equilibrium, and represents the radioactivity concentrations (1 Bq/g) of parent nuclides of the series, i.e., uranium-238 in uranium series and thorium-232 in thorium series. As for exposure dose, the effect of daughter nuclide generated by the disintegration of parent nuclide is also taken into consideration.

As for refined uranium or thorium, on the other hand, exposure is limited to uranium or thorium only because the daughter nuclides that contribute to radiation exposure are removed, and exposure doses drastically decrease. As the standard for radioactivity concentration of refined uranium or thorium, 10 Bq/g was adopted by using the ratio of natural uranium or thorium, which is used by international organizations such as BSS, and the ratio of refined uranium or thorium (1/10).

¹⁴ Intervention means the activities that are conducted to reduce exposure to radiation that already exists.



Source: Proceedings of the 5th international symposium on naturally occurring radioactive material. IAEA. 2007

Fig. 7 Data as the grounds for radioactivity concentration of 1 Bq/g

Commentary 4 Regarding the standards for quantity of radioactivity of consumer goods

The quantities of uranium and thorium contained in consumer goods are much smaller than that of raw materials, which are handled in large quantities on an industrial scale. Therefore, if it is obvious that the quantity of uranium or thorium in consumer goods is less than a certain value, it is considered reasonable to make such consumer goods not subject to the guidelines.

The General Administrative Group Report also states that it is appropriate to make those consumer goods, whose concentrations and quantities of radioactivity exceed certain values, subject to the guidelines.

Therefore, the standard for the quantity of radioactivity contained in consumer goods was calculated based on the following ideas.

By using the equation for evaluation of exposure dose in Appendix 2 of the guidelines, the quantity of radioactivity equivalent to 1 mSv/year as the standard for the exposure dose of the guidelines was calculated. The maximum value of 8,760 hours was adopted as the duration of use on the safety side.

The results of calculation are shown in Figs. 8 and 9.

(1) Results of calculation in the case that the distance between user and product is one meter

The quantity of radioactivity that reaches 1 mSv/year for the duration of use of 8,760 hours in the distance of one meter is about 630,000 Bq for natural thorium and about 420,000 Bq for natural uranium, according to Dose I equation. Divided by the statutory radioactivity concentration of 370 Bq/g (solid), the mass of natural thorium and that of natural uranium are about 1.7 kg and about 1.1 kg, respectively. Such consumer goods that have such a large quantity and heavy mass of radioactivity and are used at a place within one meter for many hours can hardly be assumed.

Fig. 8 Quantity of radioactivity that reaches 1 mSv/year in the distance of one meter

	Unit	Thorium	Uranium
Exposure dose	mSv/y	1.0	1.0
Conversion factor	mSv/h/(Bq/m2)	1.80E-10	2.70E-10
Quantity of radioactivity	Bq	634,196	422,797
Duration of use	h/y	8,760	8,760
Distance from the product	М	1	1

(2) Results of calculation in the case of use in contact with human bodies

According to the results of calculation by Dose II equation in the case of use in contact with human bodies, the quantity of radioactivity that reaches 1 mSv/year for the duration of use of 8,760 hours is 11,891 Bq for natural thorium and 8,781 Bq for natural uranium.

Fig. 9 Quantity of radioactivity that reaches 1 mSv/year in the case of use in contact with human bodies

	Unit	Thorium	Uranium
Exposure dose	mSv/y	1.0	1.0
Conversion factor	mSv/h/Bq	9.60E-09	1.30E-08
Quantity of radioactivity	Bq	11,891	8,781
Duration of use	H/y	8,760	8,760
Distance from the product	М	In contact with human bodies	In contact with human bodies

(3) Conclusion

Judging from the results of two calculations above, there is no possibility of exposure to consumer goods, which exceeds 1 mSv/year, except for those consumer goods that are used in contact with or close to human bodies.

Therefore, those consumer goods that are used in contact with or close to human bodies and whose quantity of radioactivity of natural uranium or thorium exceeds 8,000 Bq are made subject to the guidelines.

In the case of refined uranium or thorium that contains no daughter nuclide, those consumer goods whose quantity of radioactivity is more than ten times as much or 80,000 Bq for the reasons of Commentary 3.

Commentary 5 Handling of refined uranium or thorium

Metals, glass and others with refined uranium or thorium added to them are included in the definition of "specified raw materials" in the guidelines.

Refined uranium and thorium are nuclear fuel materials, and the handling of more than a certain quantity of them is subject to legal control.

As many of the processes to add refined uranium or thorium to metals and glass use a large quantity and need permission, they are subject to statutory regulations. On the other hand, in the case where the concentrations and quantities of radioactive materials contained in products manufactured under statutory regulations are less than the regulatory values of concentration or quantity, such products may not be subject to statutory regulations. Even in such case, however, if the concentration of refined uranium or thorium is higher than 10 Bq/g, it is decided to make them subject to the guidelines.

Uranium and thorium under statutory regulations are handled in controlled areas, and sufficient consideration is given to radiation exposure control of workers. However, those products whose values of concentration or quantity of radioactive materials are less than statutory regulations (such as thoriated tungsten, uranium glass, etc.) are handled in the same way as ordinary goods, and it is not recognized that radioactive materials are contained in them.

In the case where those that contain uranium or thorium are handled continuously inside and outside a controlled area, it is possible to conduct the management required by the guidelines by sharing available measuring instruments and measurement data of radiation. On the other hand, in the case where those products whose values are less than statutory regulations are shipped to other companies, necessary information should be provided to help the evaluation of exposure doses and safe handling at the destinations.

Commentary 6 Evaluation of dose exposure from wastes

Rather than disposing of all wastes, recycling them as raw materials or for other applications leads to reduction in consumption of natural resources and environmental loads. Recycling of wastes has become increasingly important.

Under the guidelines, those who produce wastes should be responsible for the evaluation of wastes in storage. When wastes are delivered to other companies for recycling, necessary information for evaluation of exposure doses is required to be provided to the companies to which the wastes are delivered. When wastes are delivered with an aim to landfill disposal as industrial waste (including the case where wastes go through intermediate treatment), as those who produce wastes confirm that exposure doses does not exceed roughly 1 mSv/year, those who dispose of industrial wastes are not subject to the guidelines and, therefore, are not obliged to evaluate exposure doses.

Commentary 7 Conditions of use of specified raw materials

Many of the specified raw materials stipulated in (5) of Chapter 3 are used as raw materials of various products as the materials inherently have the characteristics of valuable resources. As a result, radioactive materials are contained in some of them. On the other hand,

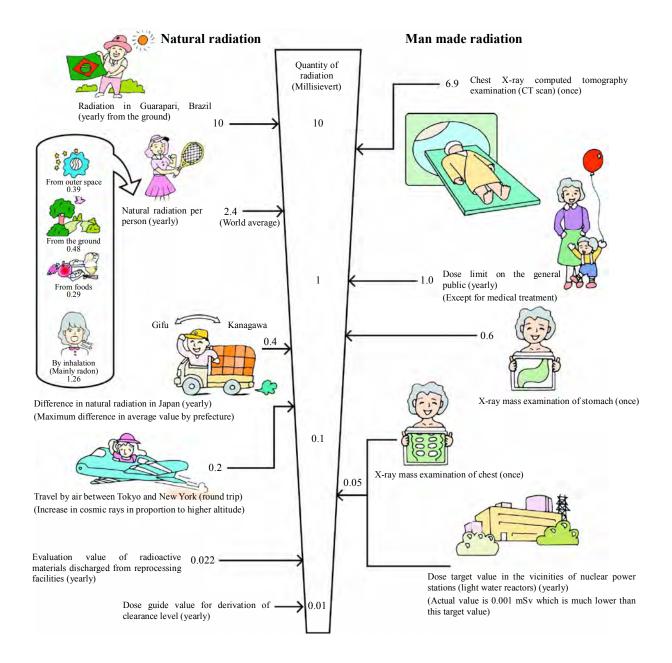
radioactive materials are contained intentionally to use radiation or used as-is in some cases. The forms of utilization of specified raw materials are as follows:

Specified raw materials	Industrial products (By-products)	Consumer goods
Monazite	Powder admixture	Negative ion products Textile products: bedding, underclothes, waistcloths, socks, negative ion sheets Accessories: bracelets and wristbands Home spa machines and catalysts for exhaust mufflers of automobiles
Bastnaesite ¹⁵	Classified powders and abrasives	Sandpaper and polishing powder
Zircon	Firebricks, casting sand and glazes for ceramics	Electronic materials and glass
Tantalite	Tantalum alloy and high corrosion-resistant materials	Electronic components
Phosphate ore	Ammonium phosphate and gypsum	Fertilizers and building materials
Titanium ores (rutile and ilmenite)	Pure titanium materials, titanium alloys and titanium oxide	Titanium metal products Paints and pigments, printing ink, resin colorants, rubber colorants, chemical fiber colorant and paper finishing agents
Coal	Clinker and fly ash	Cement
Refined uranium	Glazes and glass coloring agents	Cloisonne ware accessories, ceramic wares and glass products
Refined thorium		Gas lamp mantles, optical lenses, camera lenses, tungsten welding electrode bars and high-intensity discharge lamps

Fig. 10 Form of utilization of specified raw materials

¹⁵ Bastnaesite is rarely used at present.

[Reference Material: Daily Life and Radiation]



Source: "Collection of Nuclear Power Drawings 2007"