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THE HISTORY OF EXEMPTION OF PRACTICES FROM REGULATORY CONTROL AND OF CLEARANCE OF MATERIALS CONTAINING RADIOACTIVE SUBSTANCES

Augustin Janssens[1]

1. Starting 1959

The history of the concept of clearance goes back a little more than 25 years. It should not be dissociated from the concept of exemption however, which is much older. The concept, albeit not the term, goes back to the first Euratom Basic Safety Standards, adopted in 1959 [1]. The scope of this Directive extended to any types of practices involving natural or artificial radioactive substances causing a health risk from exposure to ionizing radiation. Any such practices were subject to a requirement of reporting (Article 3), and in some cases, under consideration of the magnitude of the health risk, to a regime of prior authorisation. However, *reporting may not be required* (Art. 4), for practices involving radioactive material if:

a) The total activity of radioactive material is below 0.1 µCi[2] (and higher values for radionuclides with lower radiotoxicity),
b) The activity concentration is below 0.002 µCi/g, or 0.01 µCi/g for natural radioactive materials.
c) Reporting is also not required if the practice involves apparatus of an approved type in which the radioactive material is secured against contact and against leakage and the dose rate at a distance of 0.1 m from the surface of the apparatus is always below 0.1 mrem/h.[3]

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2 Ci (curie) is a unit of activity, which is now replaced by the SI unit Bq (becquerel, s^{-1}); 1 Ci=3.7 10^{10} Bq, 1 µCi=37 kBq.

3 Rem is a unit of effective dose, similar to the absorbed dose unit rad, which are now replaced by the SI units Sv (sievert) respectively Gy (gray) ; 1 Sv=100 rem, 1 Gy= 100 rad.

The radiotoxicity classification as laid down in Annex I of the Directive had a kind of rationale in terms of the coefficients of intake (dose per unit intake) and of the half-life of the radionuclides.

The above conditions remained virtually unchanged till now for (c), except that 0.1 mrem/h now reads 1 μSv/h. The criterion was also extended to other apparatus emitting ionizing radiation, except cathode ray tubes for which the dose rate should not exceed 5 μSv/h at a distance of 0.05 m. For criterion (a) there were little changes until 1996 (Directive 96/29 Euratom [2]), but for some amendments in the radiotoxicity classification of radionuclides (in Directive 84/467 Euratom [3]) and the lower boundary being rounded upwards to 5000 Bq (0.14 μCi). In the same way, for (b), the lower boundary of activity concentrations was rounded to 100 Bq/g, respectively 500 Bq/g.

The conditions for exemption hence proved very robust, despite the absence of a scientific justification (or at least it was not recorded). The system allowed to delineate the extent of regulatory control while the impact of the actual thresholds was very small, if there was any at all. The thresholds in activity concentration were high, but actually were mostly ignored in cases where they could lead to high doses. This was not always the case however, and it seems that the high value of 0.01 μCi/g has been applied to residues going back to the early days after the discovery of Ra-226. The precise circumstances of these events are unknown to the author of this paper, but they highlight the early onset of confusion between exemption from reporting and prior authorisation on the one hand, and exclusion from the scope of regulatory control on the other hand. The exemption values were not meant to apply to the disposal of radioactive waste.

2. The principles of exemption

The principles underlying the concept of exemption were laid down in a very innovating publication, co-sponsored by IAEA and NEA and published as Safety Series 89 in 1988 [4]. The purpose of this document was to recommend a policy on exemptions from the Basic Safety Standards system of notification, registration and licensing. It is now listed as obsolete in the IAEA Safety Standards series, but it is still an important document for a better understanding of the development of the concept.

Despite a definition of exemption that was the same as today's, the document considered the application of the concept to a broader range of situations, including not only the use of consumer products but also the disposal of very low level solid radioactive wastes, the discharge of very small quantities of radioactive effluent and the recycling and reuse of materials resulting from the decommissioning of nuclear facilities.

From a radiation protection standpoint two basic criteria were identified for determining whether or not a practice could be a candidate for an exemption from the Basic Safety Standards:

- individual risks must be sufficiently low as not to warrant regulatory concern; and
- radiation protection, including the cost of regulatory control, must be optimized.

The first aspect was addressed by defining a level of individual dose that could be defined as 'trivial'. The second aspect should be addressed "by using optimization analysis techniques such as cost-benefit analysis, intuitive or formal, or other methods".

With regard to the first consideration, SS89 advocated that "*it is widely recognized that values of individual risk which can be treated as insignificant by the decision maker correspond to a level at which individuals who are aware of the risks they run would not commit significant resources of their own to reduce these risks. This is a difficult question to judge, because few individuals are conscious of the magnitude of small risks and people have little opportunity to demonstrate their preferences in this field. There is likely to be a wide range of individual views on this subject and any decision is likely to leave some people feeling that they are exposed to risks calling for further control. However, there is a widely held, although speculative, view that few people would commit their own resources to reduce an annual risk of death of* 10^{-5} *and that even fewer would take action at an annual level of* 10^{-6}*. Most authors proposing values of trivial individual dose have set the level of annual risk of death which is held to be of no concern to the individual at* 10^{-6} *to* 10^{-7}*. Taking a rounded risk factor of* 10^{-2} Sv^{-1} *for whole body exposure as a broad average over age and sex, the level of trivial individual effective dose equivalent would be in the range of 10-100 µSv per year*".

The conclusion drawn was that "an individual dose, regardless of its origin, is likely to be regarded as trivial if it is <u>of the order of some tens of microsieverts per year"</u>. The document further concluded that *"because an* *individual may be exposed to radiation doses from several practices that may have been judged exempt, it is important ... that each exempt practice should utilize only a part of that criterion, and it may be reasonable for national authorities to apportion a fraction of that upper bound to each practice. Such fractionation could lead to individual doses to the critical group of the order of 10 μSv in a year from each exempt practice".* This is still today the fundamental, universally accepted, criterion for exemption.

In the context of the revision of the international Basic Safety Standards there was a meeting to discuss whether SS89 ought to be reviewed in the light of the higher risk per unit dose then (1990) recommended by ICRP in Publication 60 [5]. One of the reasons not to do so was that the translation of "a range of 10-100 μSv per year" into "of the order of 10 μSv in a year" had been very cautious and hence the new risk coefficients did not warrant a further reduction of the dose criterion.

With regard to the second criterion, applying optimization to the examination of a practice that is candidate for exemption, SS89 highlighted that "the implementation of regulatory control may be costly in terms of regulatory time and resources". A further important argument was that the cost of performing the optimization analysis may in itself outweigh the cost savings in terms of a further potential reduction in health detriment: "In such situations, the rigorous use of cost-benefit or other method of optimization analysis would not be justified".

The document concluded, on the basis of a cost of formal optimization procedures being be at least several thousand dollars and of the IAEA minimum value of the man-sievert, on a practice-related 'trivial' collective dose for exemption purposes of the order of a few man-sievert per year of practice.

A third very important criterion was that exemption was intended for sources and practices which are inherently safe. "Exemption must not be granted if there is a possibility of scenarios leading to doses in excess of those specified in granting the exemption".

The document emphasised that regulatory authorities and persons in possession of exempt material must have a common understanding about what is exempted. Hence "*exemption levels are rarely, if ever, expressed in terms of individual or collective dose, since it is not practical to measure these parameters at the operational level. Rather, exemptions should be expressed in terms of derived quantities that are directly measurable so* *that compliance with the provisions of the exemption can be determined. For example, exemptions related to waste streams or recycle scrap are usually expressed in terms of concentrations of specific radionuclides*". The establishment of such derived quantities was not in the remit of this publication however.

3. The 1996 Directive

The revision of the Basic Safety Standards in the early nineties was an important milestone for the concept of exemption. The Directive was inspired by Publication 60 of ICRP [5], which introduced the distinction between processes increasing the exposure to ionizing radiation (practices) and those intended to decrease the exposure (interventions). The latter type of process related to the management of radiological emergencies and of natural radiation sources.

The 1959 and later Directives did not exclude any material or radiation source from their scope, but with regard to natural radiation sources there were actually no firm requirements. The 1996 Directive wanted to be more precise, by excluding the natural level of radiation, i.e. radiation due to radionuclides contained in the human body, cosmic radiation at ground level or aboveground exposure to radionuclides present in the undisturbed earth's crust. The purpose was not to reduce the scope of protection requirements, but rather to foster the application of the requirements to any situations that were not excluded. A detailed discussion of the subsequent inclusion of relevant exposures to natural radiation sources, first in the 1996 Directive with the concept of "work activities" rather than practices, then in the 2013 Directive [6] as part of existing or planned exposure situations, is outside the remit of this paper. Still, it is important to recognise the importance of these developments in clarifying the distinction between exclusion from the scope of the requirements and exemption from regulatory control.

The distinction between practices and interventions sharpened the scope of regulatory control and clarified the requirement of reporting (and exemption from reporting). In addition, the "Group of Experts", established under Art. 31 of the Euratom Treaty, thought that time was ripe to try and give a better scientific basis to the total activity values and activity concentration values that had been used for exemption for more than 30 years. The idea was to relate the exemption values to annual dose (from both internal and external exposure) on the basis of appropriate exposure scenarios. These were worked out in a dedicated working party of the Group of Experts, which looked into a multitude of possible situations leading to inhalation or ingestion of dispersed or spilled materials.

The dose criterion against which the calculated individual doses would be compared was the value for the individual dose taken from SS-89. Calculations were done with respect to 10 µSv/y, and the expression "of the order of" allowed to round the calculated values to powers of 10. This approach proved to work quite well and to yield total activity values (in Bq) matching properly, for some key radionuclides at least, the older values based on radiotoxicity. Calculations were performed for the long range of radionuclides already considered in earlier Directives.

The scenarios for total activity were fairly straightforward because they concerned small amounts of material and of activity. Problematic were only very short-lived radionuclides, for which one had to allow for radioactive decay prior to the materials or sources being wasted to the environment (on-site, the conservative assumption was that decayed nuclides would constantly be replaced by new deliveries), and the very long-lived radionuclides for which the scenarios had to make assumptions about the fraction of material turning into waste. None of these assumptions was truly crucial however. A more important feature of the approach was that for many scenarios one could easily imagine a more pessimistic one. The scenarios were not only within the range of normal operation, but included mishaps as well as inappropriate uses of the materials. Unrealistic scenarios were discarded, but as a further precaution it was agreed that in worst-case scenarios doses should not exceed the dose limit for members of the public (1 mSv/y). The probability of occurrence of any such scenario should be well below 1%. The scenarios related to work environments as well as to the public domain. External exposure scenarios included a small source being carried close to the body surface so that radionuclides emitting beta-rays would be affected. In addition, an organ dose criterion for skin exposure was considered, and set at 50 mSv (equivalent dose) over the contact area with the source (i.e. a few tens of cm^2).

The scenarios for deriving activity concentrations (kBq/kg) were more problematic. Indeed, infinite amounts of material invariably lead to non-trivial doses. It took a while before everyone realised that activity concentration values permitted in milk powder that was contaminated as a result of the Chernobyl accident, would yield external exposures higher than 10 µSv/year for people walking around a store. Hence the scenarios had to be restricted to “moderate amounts”. This permitted to imagine reasonable scenarios and to calculate exempt activity concentration values for the same broad range of radionuclides as for the exempt total quantities. The 1996 Euratom Basic Safety Standards Directive did not explicitly mention any restriction on the amount of material, but in the international BSS [7] a footnote referred to amounts “of the order of 1 tonne”. In the discussions on the Euratom BSS it was understood that a proper definition of “moderate amount” would depend on the scenarios and should not be a fixed value. It was agreed that such qualification could be avoided as long as it was absolutely made clear that the exemption values would not be used for the large amounts of material resulting from the dismantling of a nuclear power plant.

One important step in this clarification was the agreement with IAEA that the term “exemption” should be reserved to the Euratom concept of “exemption from reporting (or notification, in the international BSS)”, coining the term “clearance” in the context of dismantling (IAEA had spent years of efforts in the area of “exemption levels” for the purpose of dismantling). This agreement also allowed IAEA to endorse the Euratom exemption values, for which the scenarios, assumptions and parametric values had been published in Publication 65 of the Euratom Radiation Protection series [8].

4. The concept of clearance

SS89 made no clear distinction between exemption and clearance. Nevertheless, it put the latter concept clearly within the remit of practices subject to regulatory control, underlining that the regulatory authority must ensure compliance with the exemption conditions “as transfers are made from a controlled status to an exempted status” (i.e. in case of clearance, in the more recent vocabulary). The document suggests that “*The application for a licence provides the regulatory authority with an opportunity to review in advance the procedures and methods by which the licensee will assure compliance with the provisions of the exemption. The licence can contain specific provisions which also enhance compliance with the provisions of the exemption. For example, the licence can contain record keeping requirements which are subject to inspection*”.

SS89 is no longer followed on one point: it was considered that "*In the case of contaminated scrap to be recycled, the licence can specify the person or enterprise to whom the scrap can be sold. In the case of waste streams, the licence can identify a specific landfill in which the exempt wastes can be placed"*. Also Publication 43 (1988) in the Euratom Radiation Protection series [9] offered similar reflections on the concept of clearance: "The boundary at which regulatory control is relinquished is not necessarily the boundary of the licenced site". The emphasis was on the fact that the recipient of the material would be exempted from reporting and authorisation. Hence conditions could be imposed by the regulatory authority, within the licensing conditions imposed on the producer of scrap steel, for instance on the destination of the material. This is not the way we view clearance today. Indeed, in the current complex scrap recycling market it does seem adequate to follow up the destination of the material. Even if this was possible, it would imply some form of regulatory control of the recipient, to make sure the material is actually processed where it has arrived, and this seems contrary to the idea that the recipient (scrap dealer, smelter, disposal site) is exempted. The scenarios in RP43 nevertheless did not assume such form of control, and landfill scenarios for instance were included only because it could not be ruled out that materials for recycling would eventually be disposed of at municipal landfills.

Another aspect which was not immediately clear in 1988 was the application of the concept of exemption or clearance to radioactive effluent. In SS89 this application was included in the scope of exemption, but it did not provide further guidance. IAEA's TecDoc 1000 [10] applied the concept to liquids. However, in the current thinking the concept of clearance is only applicable to solid materials. This had always been the case in Euratom guidance.

Meanwhile also ICRP has strongly advocated against the use of the term clearance in the context of authorised discharges. In Publication 104 [11] an extensive overview is given of all developments in relation to the definition of the scope of regulatory control. With regard to clearance, this publication offers a semantic analysis of the term and its translations, and has the merit of clearly pointing at the difference between the concepts of exclusion, exemption and clearance (see Fig. 1).

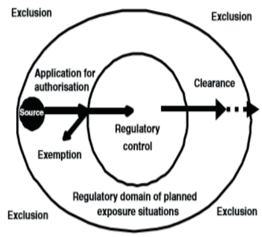

Fig.1 (extract from ICRP Publication 104):
relationship between exclusion, exemption and clearance

ICRP also rejects the term "conditional clearance" and emphasises that "clearance should only mean the complete removal of the cleared materials from regulatory control". It is now (since the 1996 BSS and the work on specific clearance levels for metals and building rubble), generally agreed that no conditions apply to cleared material (but internationally the term "conditional clearance" seems to survive until now). Any conditions should apply and be verified on-site, e.g. that items with possible re-use be destructed prior to being offered for recycling. The term "specific clearance levels" was coined later (and confirmed in the 2013 BSS [6]) in opposition to "general clearance levels" applying to any type of material and any pathway of disposal, incineration, recycling or reuse.

The 1996 Euratom Directive gave a clear definition of the concept of clearance: "values, established by national competent authorities, and expressed in terms of activity concentrations and/or total activity, at or below which radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorization may be released from the requirements of this Directive". In Article 5 it is stated that: "The disposal, recycling or reuse of radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorization is subject to prior authorization. However, the disposal, recycling or reuse of such substances or materials may be released from the requirements of this Directive provided they comply with clearance levels established by national competent authorities. These clearance levels shall follow the basic criteria for exemption and shall take into account technical guidance provided by the Community. At the time of adoption of the Directive no such guidance was already published, unfortunately, except for the single value for beta or gamma emitters proposed in RP43 [9].

The inclusion of the concept of clearance in the 1996 Euratom Directive was a crucial step. It should be noted that it received broad support only because it was non-binding; Member States could read Article 5.2 in the sense that clearance was an option they could use or not, there was no obligation to include the concept in national legislation. France, for instance, did not introduce it, even though the contribution of French experts to the development of the concept (and its translation into the term "libération") was very important.
The international BSS, in 1996, had a similar definition of clearance as in the Euratom BSS, however with no similar operational requirement as in Euratom Article 5. IAEA does not say much about the derivation of clearance levels, except that the exemption criteria ought to be satisfied, and that "clearance of bulk amounts of materials with activity concentrations lower than the guidance exemption levels may require further consideration by the Regulatory Authority". The idea that clearance levels should be lower that exemption levels was strongly encrusted in people's minds. It was feared that otherwise there would be loopholes in the regulatory system and people would, naively or malevolently, claim that cleared materials ought to be notified and regulated as soon as they were traced.

5. Clearance levels

5.1. Clearance of metals

Guidance on clearance levels for steel scrap from nuclear power stations was offered already in 1988 (Radiation Protection 43). In this early document the exemption criteria (10 μSv/y and 1 man-Sv) were in fact introduced already before their international endorsement in SS89. In this publication the concept was applied to the recycling of steel arising from the dismantling of nuclear installations. The study resulted in a single value of 1 kBq/kg, averaged over a maximum mass of 1000 kg as long as no single item exceeded 10 kBq/kg. This value applied to radionuclides emitting beta or gamma radiation. For alpha-emitters it was assumed that they arise only as surface contamination, and they are restricted to 0.04 Bq/cm^2, measured over any area of 300 cm^2. For beta-gamma emitters a distinction was made between fixed and non-fixed surface contamination, and a value of 0.4 Bq/cm^2 (taken from the IAEA transport regulations) applied to non-fixed contamination, whereas fixed contamination was included in the mass activity. The mass-activity concentration value and the surface criterion for alpha emitters were based on generic assessments of individual and collective doses from recycling and use of the materials. The scenarios for re-use of equipment (e.g. external exposure during pump repair) were not limiting, but it was conceded that in exceptional circumstances the dose to the most exposed individual from reuse might be greater than the pessimistic scenarios included in the study, without increasing the individual risk however, given the low probability of occurrence of such situations.

This first approach to the establishment of clearance levels focussed on the recycling of steel, because of the high volume of steel used in nuclear installations, an important fraction being stainless steel, and the high commercial value of such steel. A volume of 10 000 tonnes per dismantling project was assumed, and allowed for in the further calculations. Similar large volumes would arise for concrete, but this has little or no commercial value. Other metals, copper and aluminium, should also have a potential for recycling.

Hence the scene was already set for further work. In the meantime new studies had been conducted on the features of the steel recycling industries (1985-1990). In addition it was considered appropriate to have clearance levels also for aluminium and copper and different steel alloys. The work of the Article 31 Working Party on metal recycling and reuse was very much a test case for the clearance concept, which meanwhile had emerged from the Basic Safety Standards. In the same way as for the exemption values, it was pursued to have a range of radionuclide-specific values.

The approach followed for the establishment of clearance levels included the detailed identification of exposure scenarios and the careful choice of parameters: physical parameters (distribution factors), parameters related to the industrial practice (type of furnace) and to the exposure pathway (exposure time, dust concentration). A deterministic approach was followed for the identification of reference groups of the population (workers, consumers) to calculate annual doses for compliance with the 10 μSv/y criterion.

The second criterion (collective dose below 1 man-Sv) was also considered. On the one hand, the scenarios for individual dose proved to be very hypothetical, and in any circumstances affect only very few individuals, hence their contribution to collective dose would be very small. A few generic scenarios were added, assuming conservatively a broad, dispersion of radioactivity close to population centres, but these, even allowing for a very large volume of steel for recycling, would not yield an important collective dose. Hence this criterion was shown to be of no practical importance.

This work has yielded a broad range of values (for all types of metal) ranging from 1 kBq/kg (e.g., Co-60, Pu-239) to 10 000 kBq/kg (e.g. Fe-55). It was further specified that compliance with clearance levels should be demonstrated for items or batches of a few hundred kilograms. This averaging mass was chosen for coherence with the scenarios, but was also dictated by the concern that operators could be tempted to dilute low-level radioactive waste into non-contaminated material.

These thorough investigations were carried out first for different steel alloys, elaborating on the early work [9], then for copper and for aluminium. It was concluded that the values obtained for different types of metal were not so much different, so that for the sake of simplicity it was better to merge these and take the lower values.

Surface criteria were considered in a similar way. Mass and surface criteria applied simultaneously (irrespective whether the radioactive contamination is actually on the surface or in the mass), the surface criteria being the more restrictive for thick slabs. For reuse no mass clearance levels were introduced, the reason being that ingots could then be transformed directly into finished products without being mixed with other material in the furnace. No consideration was given to non-fixed contamination, which ought to be removed prior to release.

The extensive work conducted for the establishment of clearance levels for metals also allowed the development of sound rationales for the choice of scenarios and of parametric values. While the approach was still deterministic, some parameter values were tested using probabilistic methods; it was said that scenarios were “prudently realistic”. The results of the investigations were laid down in extensive technical documents [12-14].

5.2. Buildings and building rubble

For building rubble a similar approach was followed as for metals, but it was soon concluded that, in view of the large amounts that need to be considered, the levels in terms of mass activity concentrations would be very low. On the other hand, the use of surface criteria for reuse of

the building for non-nuclear purposes (industrial or other) was found to be a very feasible option. If the building is to be demolished then one may consider even higher surface contamination levels. For small-scale demolition works, yielding less than 100 tonnes/year, one may multiply the mass clearance levels by a factor of 10 so that they are in general of the same magnitude as for metals. This may be an option, for the disposal of activated shielding blocks in accelerator buildings for instance.
Again, as a precaution, averaging restrictions were imposed (1 m^2 for surface activity, 1 tonne for mass activity). All details on the investigations were published [15].

5.3. General clearance levels

5.3.1. RP 122

As soon as the work on building rubble was completed, rather than working on clearance levels for other types of material (plastics, etc.), it was decided to set default levels for any type of material and any release pathway.
For the purpose of setting general clearance levels it was not feasible to consider in detail all possible scenarios for any type of material. Instead, enveloping scenarios were defined to cover the different exposure pathways. The scenarios for building rubble were often the starting point of the enveloping scenarios, and it was examined whether these were suitable in other situations as well.
The general clearance levels are default values for any type of material and any destination and hence it was very appealing for Member States to introduce these promptly in national legislations.
The general clearance levels for artificial radionuclides have been published in Radiation Protection 122, Part I [16]. Part II [17] of the same publication addresses naturally occurring radionuclides (See section 6.4).

5.3.2. RS-G-1.7

In September 2000, the General Conference of IAEA requested (GC (44)/21) the Secretariat “to develop, using the Agency’s radiation protection advisory mechanisms and in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, […] radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood, and to submit them to the Board of

Governors for its approval". Work on non-comestible commodities was subsequently carried out by the Secretariat.

The IAEA undertook the establishment of such levels (originally labelled "Scope Defining Levels", SDL) for any type of commodity, which soon turned out to be a big problem. It proved impossible to define a unique set of values for any type of materials, or instance foodstuffs, building materials, metals or wood. At the same time there was a strong plea for simplification. The new levels should not add another layer to the existing exemption levels laid down in the Basic Safety Standards and to the clearance levels established in EU guidance.

Hence there was a shift from "trade in commodities" to the definition of a borderline for the inclusion in a regulatory control scheme. If there was a unique set of levels, it would indeed be appealing to consider this as a kind of "exclusion" level. Unfortunately, "exclusion" has the connotation that the regulator does not care for such situations, or worse, that he is not allowed to control these on grounds of international requirements.

After many years of difficult discussions, it was eventually agreed that the SDL's for artificial radionuclides fit in the conceptual framework of exemption, rather than exclusion, and should be regarded as the lower boundary to a graded approach of regulatory control. It was suggested that the levels established for use in making decisions on the exemption of bulk materials may also "find use by regulatory bodies as a basis for the clearance of such materials". The result of this was the publication of IAEA Safety Guide RS-G-1.7 on Application of the Concepts of Exclusion, Exemption and Clearance [18], which provides values of activity concentration for radionuclides (both of natural and of artificial origin) in bulk amounts of materials and provides guidance on their application to national and international trade in commodities.

Soon after the publication of the Safety Guide the application of the numbers to clearance became more prominent, and many people now regard these simply as clearance levels. The exemption/clearance levels proposed in RS-G-1.7 were the outcome of years of work, recorded in different TecDoc's. The final technical report consolidating this work was published a little later [19]. This publication gave an extensive overview of the levels proposed by different authors and national organisations (and by the EC), and offered scenarios for the calculation of the levels that were actually very similar to those worked out in the European work.

Hence it was no surprise that the numbers in RS-G-1.7 and in RP 122 part I were quite close. A later thorough analysis [20] on request of the EC demonstrated that the difference were substantial only for radionuclides which are of little practical interest. For those that matter, the values are the same.

6. New Basic Safety Standards

Soon after the publication of the latest general recommendations of ICRP (Publication 103, 2007 [21]) the work started to revise the international Basic Safety Standards (IBSS) as well as the Euratom Directive (EBSS) accordingly. For the Euratom BSS this was also an opportunity for a thorough consolidation of all radiation protection legislation in a single document. The work on the international and Euratom Standards proceeded in parallel and in close cooperation, so that the differences are small and can mostly be ignored; where appropriate differences are mentioned, but otherwise the analysis in this section applies to both. Differences in vocabulary are ignored (e.g. regulatory body versus competent authority are merged in the term "regulatory authority"). The Standards were adopted in 2013-2014 ([22], respectively [6]).

6.1. Graded approach

The Standards emphasize the need for a graded approach to regulatory control, allowing for the magnitude of exposures and the possible impact of regulatory control on reducing these. The graded approach is based on the pillars of notification, registration and licensing (as well as inspection) and the possible exemption from some or all of the requirements (in EBSS only exemption from notification or authorisation). Both standards offer full flexibility in the application of the graded approach, where appropriate identifying practices that only need to be notified, and others for which there is exemption from authorisation on the basis of specific levels or of an ad-hoc regulatory decision.
An important element of this approach is also that it makes provision for exemption both generically, on the basis of pre-established values, and for specific exemption by the regulatory authority (or as laid down in national legislation). Similarly, clearance can be granted by the regulatory authority either on the basis of default values for any type of material and any pathway of release, or on the basis of specific clearance levels. These can

be well above the default values, and may still prove to be very important in optimising strategies for the dismantling of nuclear installations or accelerators.

Both Standards have now introduced the general exemption and clearance values of IAEA RS-G-1.7 and have listed the same radionuclide-specific values for exempt quantities and concentrations. The IBSS do not elaborate on the concept of exemption in the main text, and merely refer to the criteria for exemption as specified in Schedule I and to *any exemption levels specified on the basis of these criteria*. EBSS allows for higher values that have been approved for specific applications and for the exemption of specific practices on the basis of an assessment showing that exemption is the best option.

The IBSS lists concentration values for the exemption of moderate amounts of material (same as in the 1996 BSS); the EBSS have incorporated the same set of values but these are not for exemption from notification but for exemption from authorisation (the information provided with a notification should allow the regulatory authority to make a judgement on the qualifier "moderate").

The Standards avoid possible loopholes in the system of regulatory control. The IBSS clarify that no notification is required for radioactive residues in the environment and that the exemption values do not apply to discharges of radioactive effluent; Euratom also introduces this idea, and extends it to materials that have been cleared. The more comprehensive framework of planned and existing exposure situations would have permitted to do without this precautionary statements, but it was no doubt felt to be important to maintain this general type of exemption explicitly, in view of the now much lower exempt concentration values, compared to those in 1996. It should also be borne in mind that there is now no longer any reason to consider exemption values as an upper boundary to clearance levels.

6.2. General exemption criteria

The general criteria for exemption in the two Standards share the prime criterion that "radiation risks … are sufficiently low as not to warrant regulatory control … so as to be of no regulatory concern"). While the IBSS add: "… with no appreciable likelihood of situations that could lead to a failure to meet the general criterion for exemption, …", this is taken up in the EBSS as "the practice is inherently safe" (same as in SS89).

The prime general criterion is interpreted in both Standards as being satisfied if the effective dose incurred by any member of the public " … is of the order of 10 µSv or less in a year". In the EBSS the criterion needs to be used only to grant exemption in situations where the numerical values are exceeded. The IBSS add a criterion that "the effective dose … for… low probability exposure scenarios does not exceed 1 mSv in a year (this reflects the actual scenarios constructed so far to calculate clearance levels. The EBSS add a criterion for workers, who "should not be classified as exposed workers". This reflects the more comprehensive definition of occupational exposures in the new BSS. The 10 µSv criterion should indeed only apply to actual public exposures, which include exposures at work for which the employer or undertaking has no legal responsibility. One can now conceive of occupational exposures that are related, at least potentially, to the kind of work, but that don't need to be regulated as long as no worker needs to be classified as an exposed worker, i.e. liable to exceed the dose limit for members of the public.

It is worth noting that the criterion of collective dose (1 man-Sv per year) has disappeared in the new standards.

6.3. Clearance

Both Standards have the same general criteria for clearance as for exemption, and the default clearance levels are the same as for exemption of bulk amounts of material. The IBSS allow that the regulatory authority may specify clearance levels for specific situations, in terms of activity concentrations per unit mass or per unit surface.

Both Standards have the same general criterion for clearance as for exemption and the default clearance levels are the same as for exemption of bulk amounts of material. The EBSS refer explicitly to *specific clearance levels and associated requirements*, established in national legislation or by the regulatory authority (the available Community guidance is listed in the recital to the Directive).

The EBSS further specifies that the disposal, recycling or reuse of materials arising from an authorised practice is subject to authorisation (unless such materials are release from regulatory control). It is specified that clearance levels apply to clearance of solid materials for re-use, recycling, conventional disposal or incineration. Hence the scope of clearance is limited to solid[4] materials arising in specific situations and for specific purposes. The IBSS have a broader scope for the concept of clearance: "The regulatory authority shall approve which sources, …., within notified or authorised practices, may be cleared from regulatory control".

6.4. Criteria for NORM

The Standards address all exposure situations as defined in ICRP Publication 103 [21], while slightly departing from the definitions in this publication [23]. In the Euratom Directive as well as in the international Basic Safety Standards a planned exposure situation may relate to the introduction of a new pathway of exposure resulting from a human activity. Hence NORM industries are now managed in the same way as other practices.

There is an important difference with regard to NORM industries however: while for practices involving artificial radionuclides the general exemption criterion remains at 10 μSv/y, this is not reasonable for naturally occurring radionuclides, in view of the relatively high natural radiation background (of the order of a few mSv per year).

In RS-G-1.7 it was considered that for naturally occurring radionuclides the concept of "amenability to control" underlying the concept of exclusion would in principle apply. Eventually values were chosen at the upper end of the distribution of concentrations in soils around the world (UNSCEAR data): 1 kBq/kg for the U and Th-families and 10 kBq/kg for K-40. This approach is no longer in line with the exposure situations introduced in Publication 103 and with the resulting regulatory control of NORM industries. The Euratom approach, as laid down in RP122, Part II [17], was not so much different from the approach for artificial radionuclides, but on the basis of a dose criterion of 0.3 mSv/year. This had yielded values a factor 2 lower than those advocated in RS-G-1.7. Eventually the international consensus was to keep the values of RS-G-1.7 but also to refer to an exemption criterion of 1 mSv/y (more explicitly in the Euratom BSS than in the IBSS). The same criteria, and the same values taken from IAEA RS-G-1.7, also apply to the clearance of materials arising from regulated practices. NORM residues that are incorporated into building materials must also comply with the reference level of 1 mSv/y that now applies

4 The IBSS also specify that the activity concentration values in Table I-2 for the purpose of clearance apply to materials in <u>solid</u> form.

to a type of building material, within the framework of existing exposure situations, and must allow for drinking water criteria if there is a potential for groundwater contamination by residues from NORM industries.

6.5. Mixing and dilution

The EBSS [6] finally introduce in Art. 30.4 a very important clarification with regard to dilution of radioactive materials. This paragraph distinguishes between "deliberate dilution … for the purpose of (the materials) being released from regulatory control" and the "mixing of materials that takes place in normal operations where radioactivity is not a consideration". The former (deliberate dilution) is prohibited, the latter (mixing) may be justified and authorised, in specific circumstances, for the purpose of re-use or recycling.

This clarification lifts any doubt on the validity of the scenarios used for instance for the recycling of metals. No metalwork processes a single batch of metals from a particular origin. There is always a mix of different origins with different specifications, so as to obtain the desired metallurgic properties and quality. This fact is reflected in the use of "mixing factors" in the scenarios (often a factor 10 is assumed). On the other hand the explicit prohibition of deliberate dilution is firm enough to lift the concerns already raised in 1988 (SS89): "However, the formulation of exemptions from regulatory control should not allow the circumvention of controls that would otherwise be applicable, by such means as deliberate dilution of material or fractionation of a practice". If there was to be such dilution, this would cause collective doses to rise proportionally to the total volume of material produced, and in some scenarios also cause an increase in individual doses.

While the mixing of metals for recycling in general will occur after clearance, the mixing of NORM residues is often carried out at the point of release or in close cooperation between the producer of the residues and the producer of building materials; often such mixing will be found to be justified and authorised by the regulatory authority.

7. Societal context

The societal context of clearance policies affects their acceptance; this is in particular true for the recycling of metals, for which there are huge commercial interests, and for which the volume of materials originating from dismantling of nuclear installations is very large. The stakeholders range from consumers to different branches of industry (metal scrap dealers, metal works, processors of semi-finished products (sheets and bars), and producers of finished products. It should be borne in mind that at the level of semi-finished products the material is very well characterised; most metal works keep a sample of the smelt (ingot) for analysis (also for radioactivity) and to ensure traceability. The concerns of stakeholders have affected policies in different countries, resulting in different regulatory approaches.

7.1. Concerns of the industry

It is interesting to look into RP43 [9] and realise how optimistic one was at the time (1988) about the prospect for recycling of metals from the dismantling of nuclear installations, emphasising the high economic value of the metals. The metal industry is not so eager to receive materials from nuclear industries however. It has a "clean" image and is very sensitive to public concerns about radioactivity. A car manufacturer for instance would not wish to face the risk that the steel used in its manufacture is found to exhibit a detectable level of radioactivity. The adverse publicity of such an event would have an important economic cost. It should be underlined however that this hypothesis concerns the scrap market more than that of semi-finished or finished products, since at this stage quality can easily be assured.

With the concept of clearance there is in principle no need to ensure traceability of the released scrap metal. There should be no documentation on the origin of the material either. The scrap dealer nevertheless could request such information as part of a commercial agreement; in the same way the steel work can request guarantees from the scrap dealer, and the industry processing metal sheets can make it part of its contractual arrangements that the metal be free of contamination. The fact that the regulator is not part of this process has been claimed to be very irresponsible ("let the buyer beware").

At the same time, the industry is aware that there is no material that shows absolutely zero activity. Even though steel is a very clean product, especially primary steel, there are in the secondary steel market traces of radioactivity as a result of nuclear weapons fall-out in the 1960s, lost small sources (e.g. the Co-60 lining used in the steel furnaces) etc. A further important consideration, reflected upon in the recital of the 2013 Directive, is that "Council Regulation (EU) No 333/2011 establishes criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC on waste". In other words, scrap metals are regarded as waste as long as there is no demonstration that they satisfy all relevant quality criteria. While the metal industry was very reluctant to contribute to the development of clearance levels, the different branches would now seem to favour a common threshold, but it should be low enough not to trigger the portal monitors in scrap yards and steel works. This is all the more important in view of the need for such monitoring in order to detect the presence of orphan sources.

7.2. Orphan sources

The application of the concept of clearance must allow for an important societal issue, the need to detect and manage the presence of orphan sources in scrap metal. While cleared materials should not be regarded as orphan sources, a practical detection policy cannot distinguish between radiation emitted by the one or the other. It is necessary to avoid false alarms, either due to natural radiation sources or to material that has been cleared. The implications of this issue are now clearly established, both in binding Euratom legislation (BSS) on the one hand, and a non-binding international Code of Conduct on the other hand.

7.2.1. Euratom legislation

The EURATOM Directive on the control of high-activity sealed radioactive sources (HASS) and orphan sources [24] intended to keep control of such sources and to prevent them from becoming "orphan sources". Nevertheless, orphan sources may still be around in the EU or imported into the EU. The new Basic Safety Standards Directive, incorporating the HASS Directive, thus "addresses the need for recovery of orphan sources and [it] should be instrumental in preventing sources being incorporated in scrap metal and causing contamination". The term "contamination" should be understood in relation to the levels of activity concentration defining the borderline of regulatory control: levels for exemption, below which materials are not subject to controls, and levels for clearance that allow materials to be released from regulatory control. Hence there is a direct link between the policy for managing orphan sources or contaminated scrap metal and the policy for clearing materials arising from the dismantling of nuclear installations. The definition of orphan sources in the HASS Directive in fact already referred to the concept of exemption: "orphan source means a radioactive source which is neither *exempted* nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation".

While the recital of the new Euratom Directive [6] refers to the EU legislation on scrap metals, it makes the link with regulated release of radioactive material: "Measures need to be taken to prevent the accidental melting of orphan sources as well as *to ensure compliance of metals released from nuclear installations, for instance during their dismantling, with clearance criteria*".

7.2.2. Code of Conduct

IAEA had dealt with the issue in a Specific Safety Guide [25]. In 2010, the IAEA initiated the development of a Code of Conduct [26][5]. It was intended to "harmonize the approaches of Member States in relation to the discovery of radioactive material that may inadvertently be present in scrap metals and semi-finished products subject to transboundary movement, and their safe handling and management to facilitate regulatory control".

The initiative was prompted by the fact that "In spite of the efforts made to improve the safety and security of the radioactive sources that may pose a significant risk to individuals, society and the environment, such sources may still inadvertently be incorporated into scrap metal. Furthermore, radioactive material in unsealed form may be present in scrap metal, either as radionuclides of natural origin or for reasons of inadequate control of radioactive material used in nuclear or industrial facilities". Despite the industries' reluctance to accept any radioactivity in their product, the occurrence of metals containing radionuclides that have been released from, or that are exempted from, regulatory control is not the result of "inadequate control of radioactive material". Hence, the document introduced a definition of "radioactive material", meaning a radioactive source, or other material with an <u>activity concentration</u>

5 The Code of Conduct is a non-binding document ; while the current draft was published by IAEA in 2014, it must be noted that it has still not received a unanimous political support from the Board of Governors.

above the relevant value given in Annex I, for purposes of trans-boundary movement of consignments or, within its territory, as specified by the regulatory authority. The values in Annex I are relevant extracts from RS-G-1.7 (indeed, while calculations have been performed for a broad range of radionuclides, only few of these may be relevant to trade in metals):

Radionuclide activity concentration (kBq/kg)

Am-241, Ag-110m, Co-60, Cs-137, Pu-238, Pu-239, Zn-65	0.1
Cm-244, Ir-192, Nb-95, Sr-90, Tc-99, Tl-204, Zr-95, each radionuclide in the uranium and thorium decay chains	1
K-40	10
Ni-63	100
Pm-147	1000

The Code of Conduct puts responsibilities on the State, regulatory bodies and industries. The metal recycling industries "*should ensure, to the extent practicable, that the following are undertaken with respect to each consignment:*

(a) If there is a history of consignments from specific exporting facilities containing radioactive material, a more thorough investigation for the presence of radioactive material than would normally be the case;

(b) A review of the radiation monitoring report provided by the exporting facility. If no such report has been provided, a more thorough investigation for the presence of radioactive material should be undertaken than would normally be the case".

The radiation monitoring report should contain, where appropriate, the following information:

- Identification of the exporting facility (name, address, telephone number, etc.);
- Identification of the importing facility (name, address, telephone number, etc.);
- (unique) Identifier of the consignment that has been monitored;
- Type and quantity of scrap metal and/or semi-finished products in the consignment;
- Details of the radiation monitoring carried out, e.g., instruments used and readings obtained; position of the monitoring equipment relative to the consignment;

- Background and investigation levels used;
- Name, signature and position of the appropriately trained person who carried out the monitoring;
- Statement that radioactive material was not discovered in the consignment prior to dispatch;
- Date and place of monitoring.

The requirement to have a monitoring report hence is also relevant for the recycling of metals from dismantled nuclear installations. While, in principle, metals can be released on the basis of specific clearance levels, a shipment would be accepted by the metal industry only if the average concentration in the conveyance is below the general clearance levels, or if the scrap conveyance is accompanied by a document explaining the origin of the material and precise content of the shipment.

7.3. Consumer interests

The concept of clearance should allow large volumes of materials arising e.g. from dismantling of nuclear installations, with no, or very slight, levels of contamination, to be released for recycling or reuse. From a regulatory perspective, one could deal with materials below clearance levels as if they were not radioactive. Unfortunately, even very low levels of radioactivity can easily be detected. Whenever even very low levels of radioactivity, especially in connection with daily life ("table-spoon scenario") receive media attention, this may however give rise to huge public concern.

The picture is not the same in all countries, and in part this reflects different historical contexts, in particular on how the concept was applied in the early days, for instance on the legacies from the beginning of the 20th century. Communication on exemption and clearance has not always been adequate either. The US policy suffered from public and political perception of the term "below regulatory concern" [27]. As a result, the NRC Commission officially withdrew the policy in June 1993. Actually any regulator remains "concerned" about all exposures implying a health risk, but it should not be excessively involved in minor risks. In legal terms, this can be well expressed by the Latin expressions *de minimis not curat praetor* (as opposed to exclusion being *de minimis non curat lex* [11]). Latin, even less so the shortcut "*de minimis*", does not help communication with the general public however! At a very early stage of the development of international guidance, for the translation of “de minimis” in English language the term “trivial” was preferred to “negligible”, which was a fortunate choice since the latter term would seem to have the same connotation as “below concern”.

A number of NGO’s have campaigned against the concepts of exemption and clearance as laid down in Directive 96/29/EURATOM. One of the most striking arguments is that clearance is a means for nuclear industry to get rid of radioactive waste. Careful reading of the Directive as well as of Community guidance would make it overwhelmingly clear that this is not the case. Anyway, in total, the amount of radioactive substances released to the environment on the basis of clearance is small compared to the authorised discharge of radioactive effluents, not to speak about the amounts that have been released in accidental situations.

In a system that is based on the paradigm of a linear relationship between stochastic risk and dose, without a threshold (“LNT”), there would seem to be no room for a concept of trivial individual doses. Some campaigns [28] link their opposition to the concept of clearance to arguments that low levels of radiation exposure might even be much more harmful than acknowledged by ICRP. Whether or not the LNT paradigm of the radiation protection system is valid or not in the region of very low doses, the mere fact that it is assumed that there is no threshold dose below which there would be no radiation detriment makes it easy for NGO’s to argue that the concept of exemption or clearance is unethical. Hence it is unfortunate that there is no clear guidance in ICRP recommendations on this subject. Publication 104 was important in giving a thorough overview of related developments, but it was late in offering any guidance that would have had an impact on the regulatory implementation of the concept. It also failed in offering guidance on how trivial individual doses fit in the overall radiation protection system. ICRP had never given much advice on these concepts. In Publication 60 [5] section 7.8 was devoted to “Exclusion and Exemption from Regulatory Control”. It referred to the international guidance on this matter [4], but it neither referred explicitly to the 10 µSv value nor discussed a possible radiological basis for it. In earlier versions of Publication 103 [21] a value of 10 µSv was considered for a while as a lower boundary to the range of reference levels or constraints that should be taken into consideration; eventually in Table 5 of Publication 103 the lower range is simply defined as "1 mSv or less". A search for "trivial individual doses" in Publication 103 only yields sentences to the effect that it should be avoided to calculate a number of deaths based on collective dose from trivial individual doses.

It would be welcome if future recommendations of ICRP would shed more light on the radiological basis of exemption and clearance as part of a more thorough discussion of the concept of "tolerability of risk". The author's view is that while individual doses are regarded as "acceptable" only if they are the result of optimised protection, there should be a region of very low individual doses and low collective dose where no formal optimisation is warranted, and hence such low doses would be deemed *a priori* acceptable, or trivial.

7.4. Regulatory approaches

The dismantling of nuclear installations (and other facilities such as hospital accelerators) gives rise to very large volumes of materials, most of which are not contaminated (or activated). In some cases the absence of contamination can be assumed from the nature of the premises and from records demonstrating there has been no incident causing contamination ("zoning" concept). It is not always possible to demonstrate the absence of radioactivity simply from records however; in many cases it is necessary to rely on measurements. The concept of clearance is therefore very important for the management of such materials.

In terms of public perception, the "zoning" approach is appealing. A priori, any materials released for recycling or reuse show no radioactive contamination at all. The clearance levels then are merely an upper bound for use whenever there is a need to demonstrate by measurement that the level of contamination is below the decision threshold. In some countries there is an option to remove uncontaminated materials from the regulatory control applicable to clearance, but the decision threshold was chosen to be an order of magnitude lower than the clearance levels.

While the new Euratom BSS still do not impose on Member States to introduce a clearance policy, and different options can indeed be considered, a harmonised approach and transposition of the Directive would be very beneficial. In addition, the explicit requirement on transparency of regulatory decisions in the Directive should foster the harmonisation.

8. Conclusions

The concepts of exemption and clearance have gone through a long history of fine-tuning and clarification, and now seem to be very mature and well imbedded in the international standards and in most national legislations. Below are listed some of the most prominent features that result of this development, as well as of further challenges that need to be addressed:

- Clearance is tightly embedded in the regulatory supervision of authorised practices.
- Cleared materials are not subject to the requirements of the standards and hence, from a radiation protection point of view, there is no need for traceability of cleared materials.
- Nevertheless, the societal context, in particular the need for radiation monitoring of scrap metal to uncover hidden sources, calls for appropriate documentation; the existence of such documentation should also allow Stakeholders to be involved whenever this is warranted (e.g. for workers in metal works receiving materials from nuclear installations).
- While specific clearance levels are still very important at the point of release of the materials, international trade in commodities will refer to the general clearance (and exemption) levels. The values incorporated in the IAEA Code of Conduct, once internationally accepted, may prove to be a more important factor than national clearance levels.
- While there is now good guidance for the recycling or reuse of scrap metal and for the reuse or demolition of buildings, there is a need to develop clearance levels for materials going to ordinary landfills or to incinerators, as well as for criteria exempting the recipients from further requirements; these should be developed at national level however, since there is no transboundary impact.
- General clearance levels have been derived only in terms of mass activity concentration values; doing the same for surface activity concentrations, in particular for non-fixed contamination, remains a challenge.
- There is need to address emergency exposure situations; the Fukushima accident prompted a lot of questions, for instance on the application of transport regulations, which still need to be resolved at international level; it is not clear whether the dose criteria for exemption should apply or whether reference levels for emergency or post-accidental

existing exposure situations are applicable; exposure scenarios should consider separately different groups in the population (workers in shipyards, customs, handling of containers and members of the public).

- The criteria for exemption and clearance of NORM materials will shed new light on the overall criteria, and possibly help with their perception.
- Public acceptance will depend on successful and transparent regulatory surveillance; on the other hand regulators must bear in mind that one of the main benefits of clearance is to alleviate the regulatory burden; there is also no point in being overly concerned about strict compliance with the clearance levels, they do not deserve the same status as limit values.
- Address release of contaminated sites: these often released on the basis of the exemption/clearance criteria, but there may be situations in which there is contradiction between the constraints applied to the operation of a facility and the criteria for the release of regulatory control; the fact that materials from a released site can also be carried elsewhere are often cause of confusion with the concept of clearance.

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6 At the time of adoption of the first basic standards, the EU comprised only six Member States, and english was not among the Community languages.

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EURATOM (NUCLEAR FISSION RESEARCH AND TRAINING) WITHIN THE ENERGY UNION (EU ENERGY MIX POLICY)

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The European Union (EU, 28 Member States, combined population of over 500 million inhabitants) is a major player in the world of nuclear fission. In 2013, a total of 131 units (including 18 Russian-designed VVER units in 5 States) were operable in half of the EU Member States. At the end of 2013, they represented a total installed electricity capacity of 122 GWe net and a gross electricity generation of 833 TWh (i.e.: 27 % of gross electricity production in the EU). It should also be noted that 4 reactors are under construction (1 in Finland, 1 in France and 2 in Slovakia), 19 reactors are planned (6 in Poland, 4 in the UK, 2 in Hungary, 2 in the Czech Republic, 2 in Romania, 1 in France, 1 in Lithuania and 1 in Bulgaria) and 15 reactors are proposed.

Research, innovation and education are at the heart of the Euratom Treaty [1] (Rome, 1957), dedicated to peaceful applications of nuclear fission. One of the main objectives of the Euratom Treaty is to contribute to the

1 Consolidated version of the *Treaty establishing the European Atomic Energy Community* (Euratom) OJ C 327, 26.10.2012: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012A/TXT (in general, summaries of EU Legislation: http://eur-lex.europa.eu/browse/summaries.html)

sustainability of nuclear energy by developing and sharing appropriate knowledge, skills and competences in nuclear fission and radiation protection. Euratom programmes[2] consist in end-user driven projects in selected topics, gathering the best research organisations and structured as follows:

- research and innovation (R&I) projects which contribute to generating advanced knowledge and scientific understanding of interest to industrial applications
- education and training (E&T) projects, including continuous professional development, which contribute to developing skills and competences.

Originally, in the late 1950's, the Euratom Treaty proposed nuclear power plants (NPPs) as part of the solution to the energy crisis in Western Europe. It should be noted that, already at that time, security of energy supply was a concern (e.g. oil crisis due to the closure of the Suez Canal in 1956). Severe accidents with many casualties in the fossil energy sector (in particular, in coal mines) were also a concern. Similar concerns today still exist in the energy sector not only in the EU but world-wide. Today's energy policies are facing even bigger challenges because of two new socio-economic requirements:

(1) decarbonisation of the global economy (connected to climate change concerns) and
(2) easy access to affordable energy for all (connected to global population growth).

Of course, in the nuclear energy sector, three severe accidents happened. Lessons however were drawn world-wide, in particular in the EU, which organised the "stress tests" in all European NPPs following the Fukushima Daiichi accident of 11 March 2011 (Great East Japan Earthquake, Tohoku's coastline, magnitude 9). These "stress tests" were defined by the European Commission (EC) as *targeted reassessments of the safety margins of nuclear power plants* and were developed by the *European Nuclear Safety Regulators' Group* (ENSREG). It should be noted that many non-EU countries also conducted comprehensive nuclear risk and

2 EC DG Research and Innovation / Euratom: http://ec.europa.eu/research/energy/euratom/index_en.cfm

safety assessments based on the EU "stress test" model. These include Switzerland and Ukraine (both of which fully participated in the EU "stress tests"), Armenia, Turkey, the Russian Federation, Taiwan, Japan, South Korea, South Africa and Brazil.

Euratom works in synergy with its own institutional laboratories (i.e.: DG Joint Research Centre /JRC/)[3] and with national programmes in the EU Member States concerned with applications of nuclear fission and ionising radiation. This is also done in association with international organisations dedicated to nuclear fission developments, such as the IAEA (*International Atomic Energy Agency,* Vienna) and the OECD/NEA (*Organisation for Economic Co-operation and Development / Nuclear Energy Agency,* Paris). Equally important is international collaboration with research laboratories outside the EU frontiers (industrialized countries as well as emerging nuclear energy countries).

Fission technologies can be transmitted to the next generations only within the framework of a responsible strategy regarding waste management and/or recycling of fissile and fertile materials. In this context, Euratom research and training programmes insist, in particular, on the implementation of geological disposal for spent fuel and high-level radio-active waste and/or on Generation-IV developments aiming at efficient resource utilisation and waste minimisation. Safety improvements in Generation-II (e.g. related to long-term operation) and in Generation-III (e.g. related to severe accident management) are also addressed. As regards radiation protection research, the emphasis of Euratom programmes is on better quantification of risks at low dose and how they vary between individuals (of particular interest in radio-diagnosis and radio-therapy).

The focus on sustainability in Euratom programmes goes together with a better governance structure in the decision making process (i.e.: more openness, participation, accountability, effectiveness and coherence). Special efforts are dedicated to a common nuclear safety and radiation protection culture, based on the highest achievable standards. Also important is public information and engagement in energy policy issues,

3 EC DG JRC - the European Commission's in-house science service (science hub): https://ec.europa.eu/jrc/

notably in connection with nuclear decision making (*nuclear energy is the energy that generates most emotion per MWh produced !*). These soft issues are all related to lessons learned from conducting the above "stress tests" in the 131 nuclear units in the EU.

Euratom research, innovation and education programmes bring together – within so-called "European Technology Platforms" - the major stakeholder groups of nuclear fission and radiation protection, namely:

- research organisations (e.g. from public and private sectors)
- systems suppliers (e.g. nuclear vendors, engineering companies)
- energy providers (e.g. electro-nuclear utilities and industrial heat suppliers)
- *technical safety organizations* (TSO) associated to nuclear regulatory authorities
- academia and higher education and training institutions dedicated to nuclear
- civil society (e.g. policy makers and opinion leaders), interest groups and NGOs.

The above stakeholder groups are instrumental in the design of the Euratom strategy, especially under the current EU Horizon-2020 programme of research and innovation (2014 – 2020). They also foster the scientific community to participate in collaborative projects wherever appropriate (Euratom collaborative projects usually involve up to 10 organisations and have a duration of up to 4 years). It is clear that, in this collaboration, the participating TSOs strictly keep their prescribed role, powers and independence as a support to the national regulators in decision making. Non-EU research organisations are also welcome to join Euratom projects provided that their scientific contribution brings a clear added value and that they pay for their own participation.

Euratom is not isolated in the European Energy policy[4]. Nuclear fission is part of the European energy mix, together with renewable and fissile energy sources (Article 194 of Lisbon Treaty, 2007). The EU energy strategy over the current decade is defined in the "EU Energy Roadmap 2050" (issued in 2011) which proposes five scenarios towards a low-carbon economy,

4 EC DG (Directorate General) ENER activities related to Nuclear safety; Radioactive waste and spent fuel; Radiation protection; Decommissioning of nuclear facilities; Safeguards to avoid misuse; Security (physical protection): http://www.Euratom.org/ and http://ec.europa.eu/energy/en/topics/nuclear-energy

based on a balance between sustainable development, security of supply and industrial competitiveness. Two messages are important for the European nuclear fission community at the horizon 2050. Firstly, one of the five "decarbonisation scenarios" is based on a 20 % share of electricity generation by nuclear fission, which represents an equivalent capacity operating of 127 GWe, to be compared to today's total nuclear generation of 122 GWe. Secondly, the general conclusion for all "decarbonisation scenarios" is that electricity will play a much greater role than now (almost doubling its share in final energy demand, from 21 % today to 40% in 2050).

More recently, another important step was made in the European Energy policy, namely: the launch of the "Energy Union Package" (February 2015, EC president Jean-Claude JUNCKER, 2014-2019). One of the Objectives is "An Energy Union for Research, Innovation and Competitiveness" (Section 2.5). Here are two excerpts:

- *putting the EU at the forefront of ... all innovative energy technologies ..., including ...the world's safest nuclear generation, is central to the aim of turning the Energy Union into a motor for growth, jobs and competitiveness.*
- *The EU must ensure that ... it maintains technological leadership in the nuclear domain, including through ITER, so as not to increase energy and technology dependence.*

Not surprisingly, the above statement goes together with a number of recently revised Euratom Directives (i.e.: legally binding legislation for Member States in the EU) that all go in the same direction, specifically driven by the lessons drawn from Fukushima:

- a high-level "Nuclear Safety Objective for Nuclear Installations" avoiding radio-active releases (the most stringent safety goal in the world at the time being)
- instigation of topical peer reviews by competent regulatory authorities every six years (focussing on safety issues)
- obligation to ensure transparency of regulatory decisions and operating practices, as well as obligation to foster public participation in the decision making process
- requirement for role, powers and independence of national regulatory authorities in decision making
- establishment of a strong safety culture (a number of indicators are also provided)

- obligation to obtain, maintain and further develop expertise and skills in nuclear safety, in particular, through a special effort on education and training.

Finally, as far as future is concerned, Euratom is aiming at continuously improving the collaboration between scientific research community and policy makers. In fact, a new way of “developing / teaching science” is emerging in the EU, closer to the needs of the end-users, i.e.: society and industry. As a result, a strong scientific foundation is being established to support decision making in regulatory and/or industrial organisations, based on confirmed facts and research findings stemming from “Best Available Science”.

TOWARDS MORE SCIENCE BASED POLICIES