



THE GRADED APPROACH FOR WORKPLACES IN THE CONTEXT OF THE IMPLEMENTATION OF DIRECTIVE EURATOM 2013/59

SYNTHESIS OF AN EAN AND ERPAN BRAINSTORMING MEETING

Date and place	13 th December 2018, CEPN, Fontenay-aux-Roses, FRANCE
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CONTEXT AND OBJECTIVE OF THE MEETING

The concept of a “graded approach” is commonly found in regulations and standards, e.g. in IAEA Safety Guides¹, ICRP Publications² etc. The definition of a graded approach may vary across organizations but the broad principle is that the requirements to manage an activity or practice are commensurate with the level of risk and potential hazards of the activity/practice.

More precisely, the Euratom Directive 2013/59 (EU-BSS) states that:

“Article 24”.

“Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.”

In this case, exemption, notification and authorization – which include registration and licensing – are the regulatory options under the graded approach (art. 26 to 29).

The Euratom Directive is to be implemented in national regulations by 2018. The EAN³ and ERPAN⁴ Members have decided to set up a meeting in December 13th 2018 to brainstorm on their understanding of a graded approach and experience in implementing it. To narrow the discussion, it has been decided to give a focus on the application of the graded approach for *the protection of workers in workplaces*. As starting points, four keynotes were presented that covered different activities and the resulting discussions took place between the presentations.

¹ *Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors*, IAEA Specific Safety Guide No. 22G-22, International Atomic Energy Agency, Vienna, 2012.

² For example, in *Radiological Protection against Radon Exposure*, ICRP Publication 126. Ann. ICRP 43(3) and *Radiological Protection from Cosmic Radiation in Aviation*, ICRP Publication 132. Ann. ICRP 45(1), 1–48.

³ <https://www.eu-alara.net>

⁴ <https://www.eu-alara.net/index.php/activities/sub-networks-and-working-groups/erpan.html>



1. EXAMPLES OF APPLICATION OF THE GRADED APPROACH IN BELGIUM (S. COENEN) (DOC 1).

With the implementation of the EU-BSS a list of NORM industries adapted to the Belgian context has been issued by FANC (86 industries on the list). Their respective operators are required to perform a dose assessment of their workers. The facility will then be submitted to a notification procedure (if dose exposure to the workers < 1 mSv/y) or to a licencing (if still > 1 mSv/y after mitigation measures applied).

When it comes to NORM waste, the regulatory scheme for its management, that is to say the type of treatment and type of landfill, is graded with the use of two numerical criteria:

- an activity concentration criterion (0.5 Bq/g) (derived from a dose criterion);
- and if the 1st criterion is exceeded, a second level of requirements may apply after using a dose based dose criterion (0.3 mSv/y).

Other considerations such as the presence of hazardous component in the waste and the particular acceptance criteria of the operator of the landfill are used in the decision.

For legacy sites, the graded approach uses a dose criterion expressed in dose bands (the bands are 0-0.3, 0.3-1, 1-3 and > 3 mSv/y). This is used to decide if the intervention is more or less justified and under which protective measures. It has been highlighted that social and ethical factors are also considered in the decision; notably the final use of the site is a key point (ex. industrial site vs. kindergarten).

The topic of transport was also presented. Given that more than 400,000 packages/year are crossing Belgium, FANC reported the need to efficiently exercise its regulatory control of the transport companies under its oversight. This is done with the help of a specific decision-process, which considers 11 criteria associated to a transport company and calculates a score that will determine the number of inspections per year. Most of these criteria are not directly linked with radiation protection. The decision tool was presented to peers and different forum and identified as a 'Good Practice' by IAEA IRRS team.

Discussion.

After this presentation, Mr. F. Vermeersch proposes that two main factors are the entry point of the graded approach and will then form the basis of the overall grading in the level of regulatory control and requirements that follow. He proposes that these 2 factors are the occupational exposure (normal operation) and the potential exposure (case of incident). Graphically, an activity can be positioned in a graph with the occupational exposure expressed with one axis and the potential exposure with the other axis (cf. doc. 2).

The participants agree that this approach can be used to classify (or rank) the activities in the first place. The gradation of the requirements (for the activities which are liable to them) may need further and deeper analysis.



2. EVOLUTION OF THE SYSTEM OF REGULATION IN IRELAND – FOCUS ON MEDICAL PRACTICES (T. KENNY) (DOC 3)

Ireland's current regulatory context requires that all users of ionizing radiation are liable to licencing, including all medical practices. For the transposition of the EU-BSS, EPA has developed a model for graded authorisation based on a risk analysis at the level of the practice. The risk analysis is based on a large array of factors including:

- documentary analysis (IAEA guidance, EU documentation, etc.),
- several radiation protection factors such as the exposed individuals, the magnitude and likelihood of the exposure etc.)
- and also considering historical data reported by the practices and EPA regulatory experience, etc.

All these factors are feeding a peer-reviewed model (scoring matrix) and the output is whether a medical practice is liable to registration or licencing (There is provision for exemption). The process is dynamic such that EPA can easily manage the list of practices liable to licencing (based on change in technology etc.)

An on-line service system (Graded Authorisation Management Information System - GAMIS) has been set up for licencing and registration and this system has a good feedback from EPA and the applicant/licensees. The more rigorous assessment and stronger inspector oversight are performed on the licence applicant, whereas the registration process is based on a set of self-declared questions. EPA assumes compliance, that is, the responsibility is with the person registered to comply with all aspects of the legislation, but a registered facility can still be inspected if necessary.

The implementation of the graded approach is referred as a 'big shift' for both the regulator and the licensees/registered. The EPA judges that the graded approach allows for a better deployment of its resources and to focus its regulatory effort on the practices with higher risk. The new system of graded authorisation will result in a move from 1740 licensees to approximately 400 with a more appropriate system of regulatory oversight being utilised for registered practices including, verification of the self-declaration through sampling, self-assessment questionnaires and inspections where relevant. Use of technology and IT systems being leveraged for this purpose.

EPA plans to elaborate several Codes of Practices (4 are planned, covering all the medical sectors) to set out its view about the new regulatory framework and help the applicants to comply with the regulatory requirements. The Codes of Practices are built with the help of medical professionals, through working groups and consultation process. Indeed, the professionals have the best insight on field-experience and what can actually work, and how to communicate it.

Discussion.

The question of the interaction between EPA and companies introducing a new practice that may need authorisation has been raised by T. Schneider. T. Kenny answers that regulatory provision are in place so the EPA can connect with the relevant Minister/Authority supervising the practice (e.g. Ministers of Defence for airport security screening). Because the list of practices liable to licencing is dynamic and flexible, it can adapt to the large (and growing) spectrum of activities.

It has also been discussed the challenge for an Authority to put, in one hand, less regulatory pressure on certain practices and, on the other hand, aims for a global improvement in radiation protection. T. Kenny answers that the improvement in radiation protection is achieved by re-balancing EPA's effort and attention on higher-risk practices. The participants agree that radiation protection for lower-risk practices can be achieved with less regulatory pressure, but this relies on the building of a radiation protection culture in the company.





3. GRADED APPROACH IN SWITZERLAND – A FEW EXAMPLES IN MEDICINE AND WORKPLACES (N. STRITT) (DOC 4)

Switzerland also faces a peculiar regulatory context, especially in the medical field because all activities using ionizing radiation to human will finally hold a licence. Companies that are sailing, doing some maintenance and performing QA on medical system using ionizing radiation are also subject according to the Swiss legislation to licence. In addition, Switzerland has not signed the Euratom Treaty, but aims to align with the EU-BSS (the revised legislation put into force in 01.01.2018 was made according to the EU-BSS).

For medical imaging practices, the grading is based on the dose to the patient, which can be low (< 1 mSv), moderate (1-5 mSv) or high (> 5 mSv).

The grading applies then to many aspects: the documentation, the type of supervision, the requisite level of education of the staff, the technical radiation protection requirements, the dosimetry etc. N. Stritt has specified that the requirements have been designed in collaboration with the professionals, and considering also the views of groups of experts (e.g. Dosimetry Expert Group), external groups and via public consultation. This does take time but is regarded essential for ensuring the graded approach is applicable in practice (and will be applied by the professionals).

Globally, the concept of graded approach shaped the work and inspections and audits planned by the regulatory bodies and inspectors since many years.

Discussion.

The case of pregnant women exposed to ionising radiation has been discussed. In Switzerland, pregnant women have the right to stop their activity with radiation if the risk is “high”. In practice, there is no cross-cutting value and discussion with management and radiation protection expert will take place. The other participants state that in some European countries, women will be asked by management to stop their activity with radiation as soon as they declare their pregnancy. The requirements for dosimeters was another opportunity to discuss the differences between countries.

The relatively high level of exposure to radon above which a Swiss worker is considered occupationally exposed (10 mSv/y) has been put in perspective by Mrs. Gilchrist with other level of exposure (e.g. in nuclear installation). Mr. Stritt and Mr. Schneider explain that the geological context of Switzerland (numerous radon prone area and an elevated average radon concentration in building) explain why the regulator has selected this value⁵.

⁵ Which was set according to the ICRP Publication 126 “Radiological Protection against Radon Exposure”.

4. THE FRENCH GRADED APPROACH FOR THE MANAGEMENT OF RADON EXPOSURE IN WORKPLACES (S. ANDRESZ) (DOC. 5)

The management of radon in workplaces in France has evolved with the publication in 2018 of a series of decrees. The regulation is now binding to the employer/manager of *all* workplaces located in the basement/ground floor of radon prone areas⁶. The entry point is a documentary analysis and, if the situation cannot be disregarded from a radiation protection point, radon measurement shall be performed. The graded approach is implemented by using two “reference levels” (one in Bq/m³ based in measurement, one in mSv/y based on (pessimistic) scenario). Ultimately an enhanced protection system applies to some workers (but they will not be regarded as ‘workers working under ionizing radiation’).

The entering into force of this regulation is very recent and has no feedback. A potential issue is the number of workplaces entering into the scope of regulation due to the size of the radon prone area in France⁷. Most of these workplaces are from ‘outside the world of radiation protection’ so outreach and communication are at stake. Another peculiarity is that there are few providers of radon dosimeters and also few building professionals with experience in radon remediation.

The use of numbers (often seen as ‘magic numbers’ or threshold between safe and danger) and the comparison of radon exposure with other radiological exposures (e.g. normal exposures in a nuclear installation are generally far below) have also been raised in the presentation.

Discussion

The French approach is very similar to the one in the United-Kingdom (described by J. Gilchrist) and Ireland (T. Kenny), but given the geological context of these countries, most workplaces are exempted and not really entering the graded approach and concerned by protective measures (i.e. > 300 Bq/m³). C. Nuccetelli also describes the Italian experience with radon and very few workplaces are concerned (e.g. spas).

T. Schneider notes that the French approach is aiming to encompass more workplaces in the regulation, and this is very different from the Irish graded approach. Also, EPA is using assumptions of compliance which is not conceivable in France. These can be seen as cultural differences in regulation.

Most European countries have produced a map of radon but the general opinion of the participants is that a map should not be the entry point of a graded approach – especially a predictive map based on geological factors. Actual radon measurements should be considered because every building is a specific case. But it has also been raised that radon measurements are subject to large uncertainties (passive dosimeter). F. Vermeersch proposes that a graded approach can then be useful for radon measurement: from rough measurement to (if needed) more precise ones.

The general opinion of the participants is that radon shall not be managed as a standalone risk but better within the framework of the general health and safety at work, that requires employers to identify all hazards in their workplace, to assess the risk from these hazards and to put in place measures to eliminate/reduce the risk. S. Conen and F. Vermeersch concluded that radon at work could be managed in a pragmatic way, like any air chemical pollutant.

In addition, S. Conen notes that managing radon is a socio-cultural decision. To this regard, T. Kenny briefly presents the elements of the Radon Control Strategy for Ireland. The Radon Strategy surely

⁶ The list of radon prone area is provided by a separate regulatory text. The list (at communal level) is based on the geology of the area (“radon potential of the geological basement”).

⁷ The map was presented. The map is available at <https://www.irsn.fr/FR/connaissances/Environnement/expertises-radioactivite-naturelle/radon/Pages/5-cartographie-potentiel-radon-commune.aspx#.XCTFAy97TOQ>



addresses radon measurements at workplaces, but have also tackle the issue more globally, by promoting confidence in radon services, raising awareness for the general public, providing numerous advice and guidance etc.

A SYNTHESIS: AIMS OF THE GRADED APPROACH, EXPERIENCE AND ISSUES

The brainstorming meeting was an opportunity for several regulators to present their manner of implementing a graded approach for workplaces in the context of art. 24 of the EU-BSS. A large panel of workplaces and situations has been discussed during the meeting, including exposure from man-made sources and to natural sources. From the keynotes and the discussions, the following main points can be drafted.

Aims of using a graded approach.

- When applied to regulatory supervision, the graded approach is reported to allow regulators to efficiently exercise their controls based on the radiation risks of the practice under their oversight. The regulator is directing its effort to specific areas and, without compromising safety, with proportionate attention to the other ones.
- For workplaces, two dimensions can be considered as the very entry point: routine occupational exposure and exposure in case of accident, but further and deeper analysis will be needed.
- The graded approach is particularly relevant when many facilities/companies are involved and for practices involving natural sources, where the exposure are generally (but not always) very low and with no likelihood of over-exposure.
- It has been reported that the graded approach has strongly shaped the whole work of regulation and inspection.

Application of the graded approach.

- No two similar graded approaches were presented. The practices were also different, as well as the national regulatory context and culture. But this is a confirmation that there is no harmonized procedure and the graded approach is shaped on a case-by-case basis.
- A global scheme can still be drafted:
 - Focus on a practice or an existing exposure situation.
 - A baseline identification is (sometimes) performed to pre-select the facilities/companies to which the graded approach will apply. A baseline identification has been performed for NORM facilities and radon at workplaces. In the other cases, all the facilities/companies are *a priori* entering in the process;
 - A methodology for ranking the facilities/companies is used. In general, the facilities/companies are ranked using 3 to 4 graduations (min. 2, max. 5).
 - The grading it-self applies, proportionate to the ranking. It can consider the work/process, the documentation, the training, the dosimetry etc. and control is exercise thought approval, the level of rigor and details, the frequency etc.

Factors that can be considered.

- The factors to be considered for grading shows great variety:
 - in terms of number (from 1 criterion to many criteria);
 - exact numbers and band of values;
 - quantitative vs. qualitative criteria;
 - criteria based on measurement when other are based on assessment, derived criteria, scenarios etc.
- Radiological criteria are finally not so dominant: non-radiological criteria are also used (but not always).
- Social and ethical factors may influence the decision (especially in existing exposure



situations) and in some cases, may even supersede all the others factors (e.g. pregnant women, legacy site end-state).

Good practices.

- When many different criteria are used, decision-aiding techniques such as scoring matrices, have been used and identified as good practice.
- Easy-to-use tools that form part of the graded approach (website) show good feedback from regulators and applicant.
- The involvement of the professionals in the process is a key point to ensure the requirements are applicable in practice by the professional (and will be). Also, it makes the process more transparent.
- The transparency can also be achieved by peer-reviewing or public consultation.
- Professionals may still need support: outreach, communication, guidance documents etc. developed by the regulator in collaboration with the professionals are needed in many cases.

Potential issues

- The balance between reducing the regulatory control pressure on some facilities without compromising radiation protection is an area for discussion. This is part of the cultural difference between countries.
 - The information/data used are sometimes based on hypothesis, pessimistic scenario and predictive model. The better data quality comes from operating experience and field data.
 - Applying a graded approach in existing exposure situations (NORM, radon) has the potential to put many workplaces in the scope and hence raise specific difficulties (management, communication etc.).
 - To this regard, experience shows that the management of existing exposure situations should not be standalone and will benefit from a global approach: radiation protection requirements should be integrated with the overall health & safety requirements at work and supported by a national control strategy.
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Annexe. – Main elements of the graded approaches presented during the meeting.

	Sector/activity	Baseline identification (if any)	Criteria used for grading	Example of requirements
BELGIUM	NORM activities	List of activities (from the EU-BSS list)	Dose to the workers (1 value)	<ul style="list-style-type: none"> • Notification • Licensing
	Waste	-	<ul style="list-style-type: none"> • Dose impact (1 value) • Bq/g (1 value) 	<ul style="list-style-type: none"> • Exemption, notification, licensing • Type of treatment, landfill
	Legacy site	-	<ul style="list-style-type: none"> • Dose impact (4 bands) • Social/ethical consideration 	<ul style="list-style-type: none"> • Intervention (Y/N) • Protective measure
	Transport	-	Decision technique (scoring) using 11 criteria	<ul style="list-style-type: none"> • Number of inspections /years
IRELAND	Medical practices	-	Scoring-matrix (peer reviewed-model) using <ul style="list-style-type: none"> • Documentary analysis (International guidance, etc.) • Radiation protection criteria; • Experience, feedback etc. 	<ul style="list-style-type: none"> • Registration • Licensing
SWITZERLAND	Medical imaging	-	Dose to the patient (3 bands)	<ul style="list-style-type: none"> • Level of supervision, • Education, • Dosimetry etc.
FRANCE	Radon at workplaces	<ul style="list-style-type: none"> • Radon prone area map • Location of the workplace • Documentary analysis 	<ul style="list-style-type: none"> • Radon concentration (Bq/m³) • Radon exposure (mSv/y) 	<ul style="list-style-type: none"> • Notification • Radon zoning • Individual dosimetry etc.