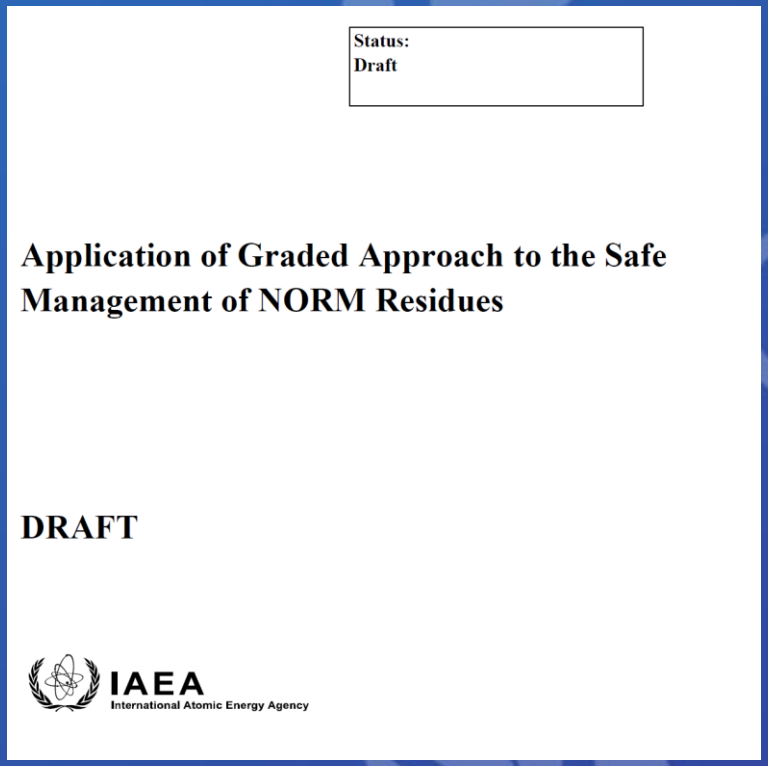
IAEA
International Atomic Energy Agency
Atoms for Peace and Development

Regulatory framework for NORM in a graded-approach



Status:
Draft

Application of Graded Approach to the Safe Management of NORM Residues

DRAFT

IAEA
International Atomic Energy Agency

IAEA
International Atomic Energy Agency
Atoms for Peace and Development

What is graded-approach ?

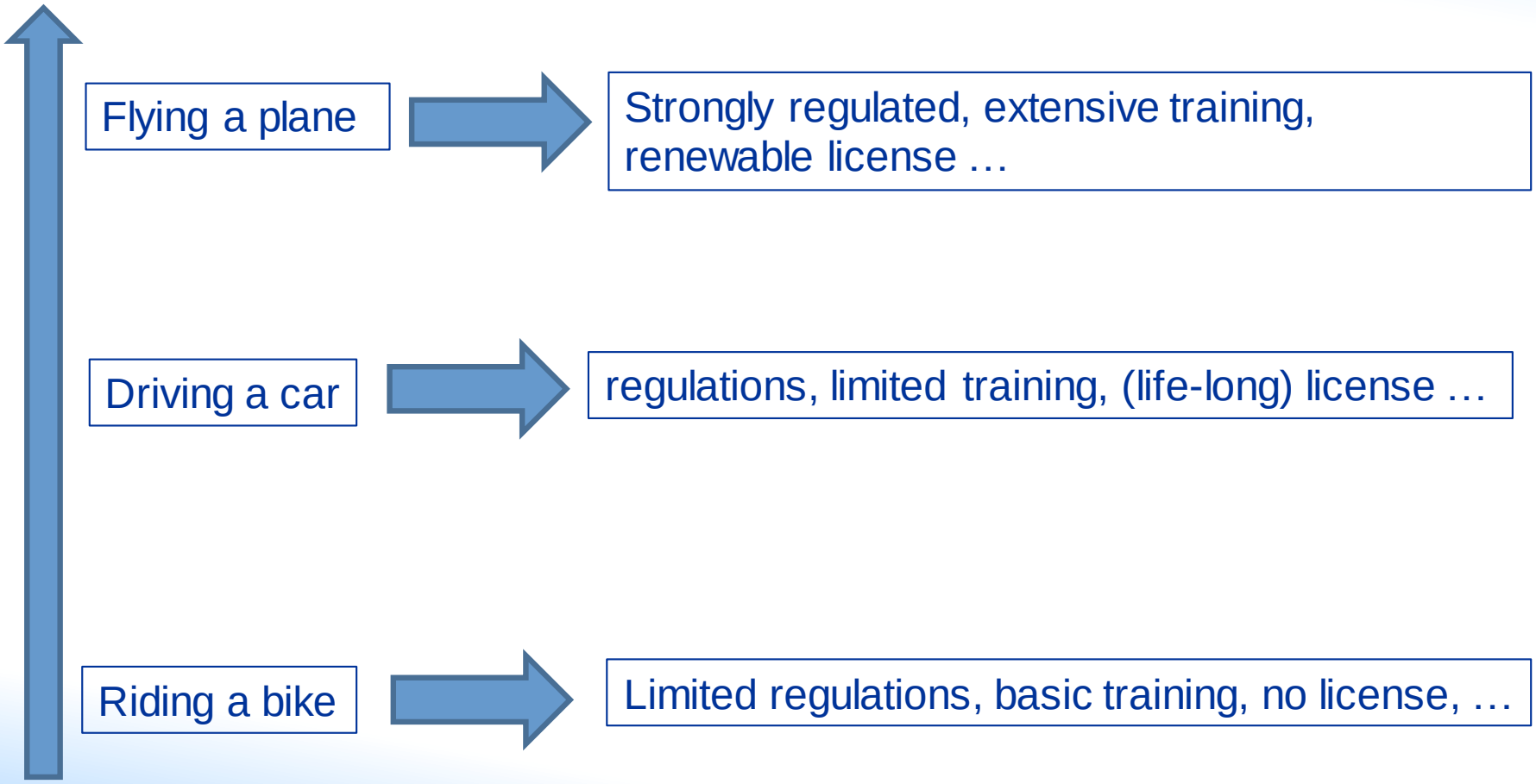
Definition IAEA Safety Glossary:

For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control." To develop a graded approach requires (i) control measures that can be applied at various levels of stringency, and (ii) a means for assessing the risks associated with the loss of control".

⇒ IAEA SSG-60: "… *the application of the requirements of planned exposure situations to NORM activities needs to* ***be commensurate with the characteristics of the NORM activity, and with the magnitude and likelihood of the exposures***

⇒ *GSR Part 1 requirement: "implementation of a* ***national policy and strategy for safety shall be subject to a graded approach*** *in accordance with the national circumstances and the radiation risks associated with facilities and activities…"*

Graded-approach is everywhere…



Why is graded-approach especially relevant for NORM ?

- Involve a large **diversity of activities** (mining, fertilizers production, water treatment,….) and **materials** (tailings, sludge, scalings,…)

- Diversity of **contamination patterns**: uranium and/or thorium in secular equilibrium or part of the decay chain (Pb-210/Po-210)
- **No acute exposure** but likelihood of chronic exposure significant without regulatory control
- **Non-radiological hazards** generally dominant
- **Multiple regulatory authorities** involved (RP, mining, environmental,…)
- Generally, industries exist **before** regulations

Process for developing a regulatory framework

a) Understanding NORM activities in the country: **Inventory**

b) Review of existing regulatory infrastructure

c) Other **prerequisites**

d) Stakeholder engagement in the development process

e) Implementation

f) Review process

NORM inventory

Which industries and / or materials may be of concern within the country ?

Two aspects:

- *Knowledge on activities and processes* of concern
  => see e.g. literature, IAEA reports,…
- *Knowledge of industries operating* within the country
  => collaboration with other ministries (e.g.ministry of economy), professional associations, direct mailing,…

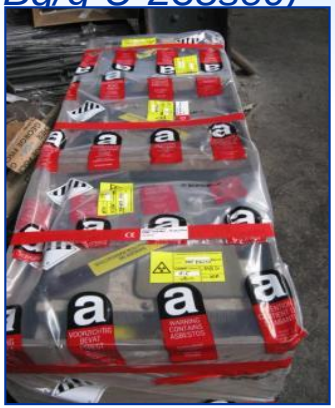
Review of existing regulatory infrastructure

Radiation protection aspects entangled with non-radiological

Who is in charge ?

⇒ Different regulators involved

e.g. NORM asbestos cement in electric circuit breakers (~ 3 Bq/g U-238sec)



⇒ Take advantage of the control mechanisms already exisiting in other regulations

⇒ Establish memorandums of understanding between all authorities involved

Or one single regulator regulates all aspects

Other prerequisites + stakeholder engagement

- Need to have ***appropriate staffing*** + sufficient ***infrastructure*** for *measurements/radiation protection expertise*

- Involve ***stakeholders*** in the development process of the regulations : what is the impact of the regulations, cost/benefits,…
- Take advice from e.g. other regulators, professional associations, workers organisations,,…

Implementation and periodic review

Implementation

⇒ Allow for transitional period, especially for existing industries

⇒ Information to operators (stakeholders meeting, mailing,…)

⇒ Prioritize the industries – implementation plan

Review

- New industries may emerge, processes may changes
- Gain of experience for the regulators: identification of gaps, caveats,…
- Feedback from stakeholders
- Evolution of international standards

Key-components of regulatory framework

1. Purpose
2. Scope
3. Definition of terms
4. Relevant regulatory bodies
5. Responsibilities (regulatory bodies and operator)
6. System of regulatory controls: authorizations, notification, exemption and clearance
7. Regulatory process (including regulatory criteria, inspection and enforcement)
8. Stakeholder involvement
9. Requirements on regulated facilities
10. Controls on import and export of NORM

Purpose and scope

Purpose => **why** do you regulate ?
Scope => **what** do you regulate ?

Defining the scope:

- typically, “positive” list of activities
- Or/and activity concentration (e.g. all materials > 1 Bq/g)
- …

⇒ Takes into account results of inventory;
⇒ Need to be flexible and easy to change;

Definition of terms

- Take into account existing definitions (e.g. IAEA Safety Glossary)
- Check *consistency* of definitions within the RP regulations or *other* regulations

Be careful with selection of terminology – words may have consequences (*e.g. calling NORM as "radioactive waste*");

Relevant regulatory bodies

NORM activities are of concern to ***multiple regulatory authorities*** (RP, Safety & Health, Environment,…) – *national, regional, municipal levels*…

⇒ Clearly stipulate role and responsibilities of the various authorities

⇒ *Who drives the licensing process ?*

⇒ Be aware of the role of each other – collaborate with each other

Share of responsibilities between regulatory body and operators

Who is in charge of what ?

e.g. if dose-assessment necessary, is it performed by operator, regulator, certified expert,… ?

Levels of approval for e.g. work protocol, residue management procedures

⇒ *Who may approve ?*

- operator
- radiation protection expert
- regulator

⇒ Depends on the potential impact of the procedure

Authorizations, notification, exemption and clearance

Level of regulatory control proportionate to the risk

Licensing

Registration

Notification / Exemption from authorisation

Exemption from all control

Scope

Risk

Authorizations, notification, exemption and clearance

a) **Exemption**: from *all* or *some* aspects of regulatory controls

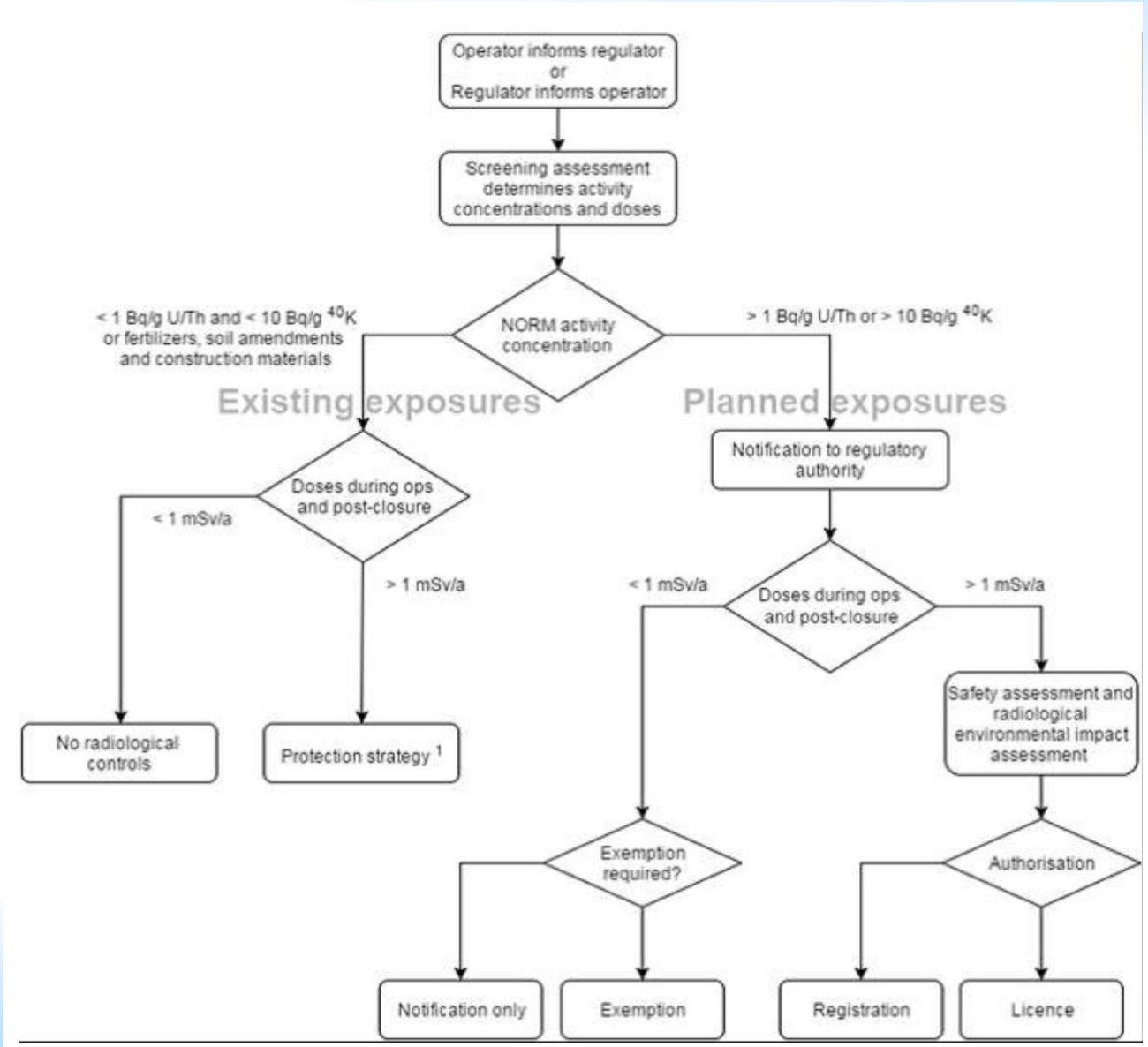
⇒ On basis of dose-assessment or operational criterias (activity concentration, dose-rate,…)

b) **Notification**: lowest level of regulatory control – no need of specific RP measures but periodic review of activity may be necessary

c) **registration**: lowest level of authorization – risk may be controled or monitored by simple measures

d) **licensing**: risk of significant exposure almost certain – specific conditions needed to keep exposure under control

Placement criteria: activity concentration or dose



Inspections & enforcement

- *Frequency, scope* of inspections proportionate to risks
- May be triggered by incident, changes in operations,…

Positive side-effects:

- Raise awareness of operators and workers
- Build practical knowledge and expertise within regulatory body
- Feedback from inspections to be used in review process of regulations

Maintenance of authorization through life-cycle of facility

Periodic review of dose-assessement and/or authorization conditions (e.g. validity of authorization limited in time)

Moreover:

- Clear requirements with respect to *transfer of ownership* (insure transfer of liabilities to the new owner)
- Requirements with respect to *bankruptcy* situation
- Requirements with respect to *termination* of activity: release criteria for the site, decommissioning plan,…

Requirements on regulated facilities

Topics area where requirements may be imposed:

(not all are always relevant !)

- Management arrangements
- Procedures
- Record keeping
- Training and education
- Provision of equipment and facilities
- Resources – personnel
- Resources – financial provision
- Worker Dosimetry
- Characterization of residues
- Safety assessments
- Residue management plan
- Environmental monitoring
- Clearance arrangements and discharge limits i.e. Allowed disposal routes and disposal limits

Requirements on regulated facilities

	Notification Only	Registration	Licensed
Management system	not required	simple management system	Full management system covering requirements of IAEA GSR Part 2
Procedures	not required	limited set of procedures - not necessarily reviewed by the regulator	Detailed procedures. Reviewed by regulator - including revisions.
Reporting	Only for significant changes (in raw materials or processes). And/or renewal of notification at a specified frequency.	Specific data reported at a specified frequency	extended reporting of activities at a specified frequency
Record Keeping	only to document compliance with notification	required for a limited set of data and procedures	required for an extended set of data.
Training and Education	not required	Basic NORM awareness training	extended training including refreshers training at specified interval

Requirements on regulated facilities

	Notification Only	Registration	Licensed
Characterization of Residues	Limited number of measurements. May be based on a screening criteria.	Quantitative analysis necessary. Number of measurements limited to what is necessary to support the dose-assessment.	Quantitative analysis necessary, possibly by certified laboratories. Extensive set of measurements. Detailed sampling protocol to be approved by the regulatory body.
Environmental monitoring	not required	limited (e.g. random sampling - low frequency)	Detailed monitoring programme with justification of sampling points and parameters; baseline monitoring, if applicable
Safety Assessments	either not required or based on simple, qualitative arguments or preset criteria	screening assessment based on conservative exposure scenarios	detailed assessment
Residue Management Plan	Not required	limited description (e.g. table with categories of residues, quantities, disposal route)	Detailed description including justification of the choice of the disposal route, provisional assessment of quantities to be produced in the future (including from decommissioning), etc.

IAEA
International Atomic Energy Agency
Atoms for Peace and Development

Thank you!