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Summary of the EUG event on: management, compliance and demonstration

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ERICA will provide an integrated approach to scientific, managerial and societal issues concerned with the environmental effects of contaminants emitting ionising radiation, with emphasis on biota and ecosystems. The project started in March 2004 and is to end by February 2007.

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Executive Summary

The overall objective of the event was to clarify the process of integrating an environmental assessment with management decision. The focus was on two areas of decision-making, which underpin the ERICA integrated approach, as illustrated in Figure 1 below.

1. Problem formulation, which can be defined in the Ecological Risk Assessment the first step of any risk assessment intended to identify the context and purpose of the assessment framework, involving ecological, political and societal issues related to questions being addressed;
2. Decision-making post assessment, i.e. options to choose once you have the results of the assessment.

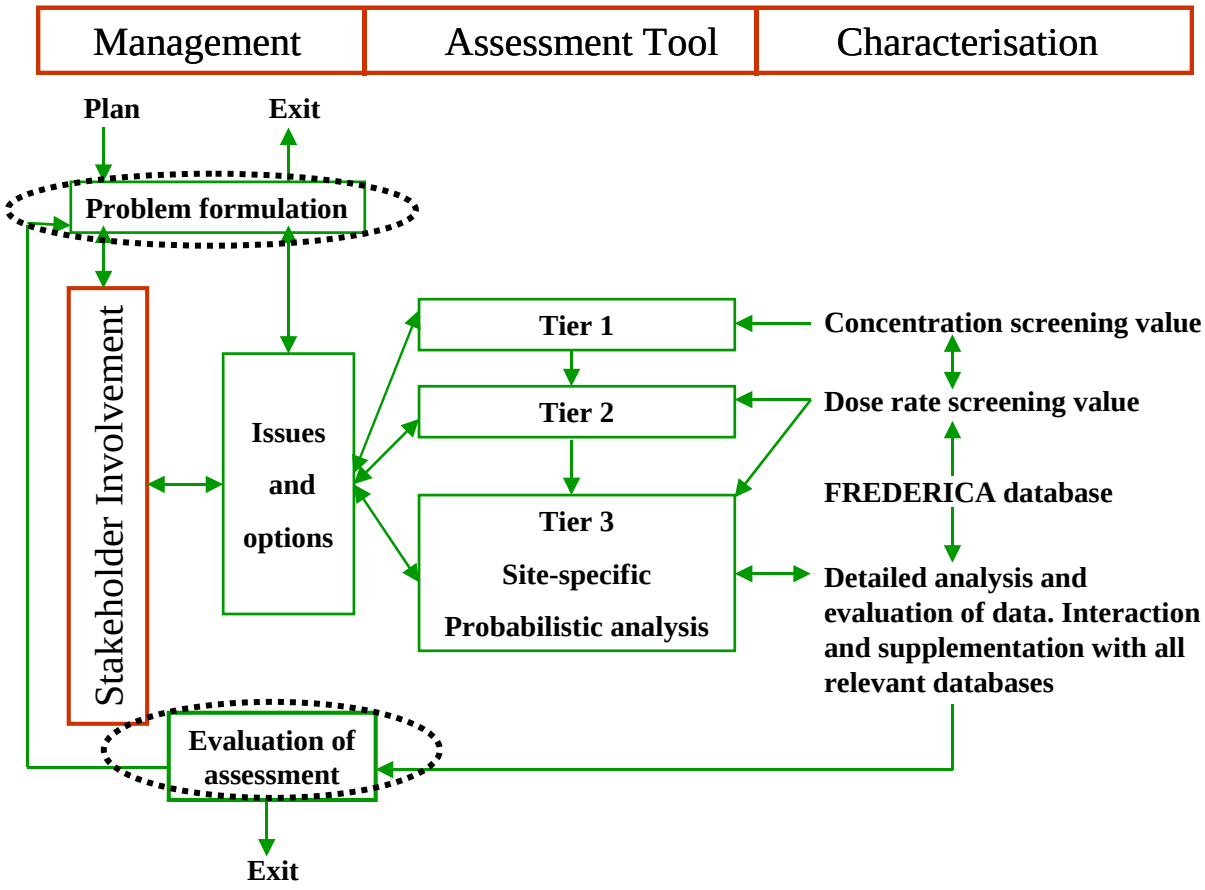


Figure 1. Overview of the ERICA Integrated Approach, outlining the interaction between assessment, risk characterisation and management.

To achieve this overall objective, three sessions were conveyed:

- Session 1. The results of a web-consultation also directed at problem formulation and decision-making post assessment, which was completed prior to the EUG event, were also analysed during the meeting.
- Session 2. Experience from EUG members, in the form of one-page summaries, was also used to supplement discussions.

- Session 3. To help review and input into the D-ERICA, i.e. the final deliverable that describes the ERICA integrated approach. For this purpose the current draft of sections on problem formulation and decision-making post assessment were distributed prior to the meeting.

Problem formulation and decision-making post assessment are closely linked and a number of external factors to the assessment will dictate the context/purpose of the assessment, as illustrated in Figure 2.

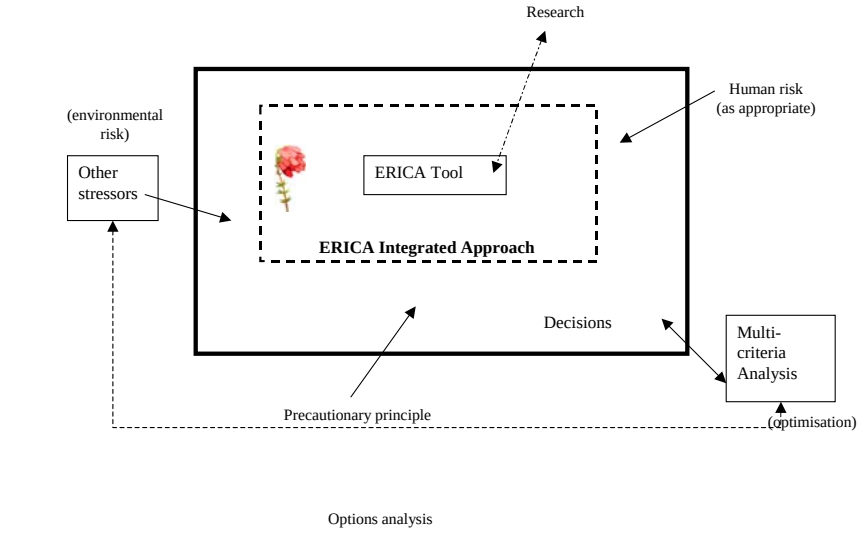


Figure 2. Illustration of factors affecting decisions – not exhaustive

General conclusions from the sessions are shown below.

- Session 1. The group suggested that "emergency situations" in the ICRP exposure situations should be replaced by "post-emergency situations", and that the purpose of biota assessments in this situation. This was explained by the fact that in an acute emergency action will be taken primarily to protect the human population. Changes in the phrasing of some of the text within problem formulation should be addressed.
- Session 2. The ERICA Integrated Approach needs to be able to deal with the impact of NORM / TENORM through the provision of underpinning data for naturally occurring radionuclides which should be included in the assessment tool.

  Numerical criteria of some form are needed, but there was no consensus on exactly what form these numbers should take or what they should be called. Observation of the ecological status of a potentially affected site is an important adjunct to any assessment based on numerical dose or radionuclide concentration criteria. A potential way forward might be for the EC to issue a guidance, rather than a legal, document, e.g. a Directive. Units should also be specified. Some of these points, will be passed on to the EC project PROTECT - Protection of the Environment from Ionising Radiation in a Regulatory Context, see www.ceh.ac.uk/protect.

- Session 3. Decision-making post-assessment should be renamed decision-aiding.

  A specific sub-section of D-ERICA should be dedicated for Tier 3 at the problem formulation giving a reminder of what the results are from the tool. Special explanation/guidance of how the benchmark could be determined would also be useful to inexperienced users.

  Once an assessment is done, it should be noted that reviewing the problem formulation and the chosen assessment criteria can help increase the confidence in the interpretation of the assessment results.

The majority of ERICA recommendations from the groups will be implemented in both the D-ERICA and the D8- "Considerations for applying the ERICA Integrated Approach" document, to be published in early 2007.

Globally, feedback of the event was positive and answers more positive than the feedback questionnaires of previous events.

Table of contents

1 Introduction

The meeting represented the fifth and last thematic EUG event to take place before the ERICA project comes to a close in February 2007.

The overall objective of the event was to clarify the process of integrating an environmental assessment with a management decision. The focus was on two areas of decision-making, which underpin the ERICA integrated approach, as illustrated in Figure 1 below.

1. Problem formulation, which can be defined in the Ecological Risk Assessment (ERA) paradigm as the first step of any risk assessment intended to identify the context and purpose of the assessment framework. This should include ecological, political and societal issues related to questions being addressed, and integrate the process of choosing appropriate assessment endpoints, identifying sources and describing the environment.
2. Decision-making post assessment, or in other words: what options are there once you have the results of the assessment?

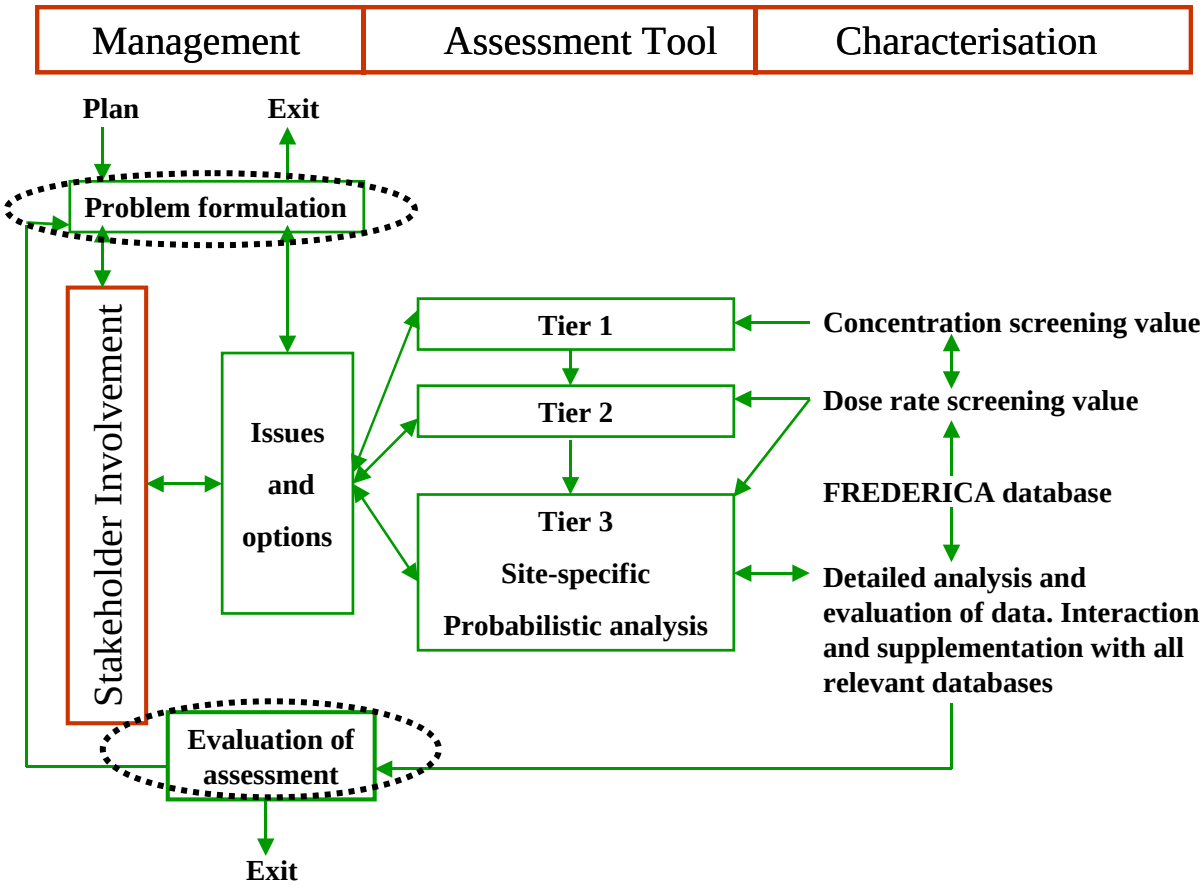


Figure 1. Overview of the ERICA Integrated Approach, outlining the interaction between assessment, risk characterisation and management.

Another objective was to help review and input into the D-ERICA, i.e. the final deliverable that describes the ERICA integrated approach. For this purpose the current draft of sections on problem formulation and decision-making post assessment were distributed prior to the meeting.

The Consortium was seeking EUG members with management experience in terms of: protection of human and or biota from radiation, or/and protection of humans and / or other species from chemical contaminants. Therefore Work Package 3 targeted this small thematic event to bring together both regulators and operators

The event was prompted by the result of the web-consultation, which took place in October 2006.

1.1 Goals of the event

The one and a half day event was divided into three sessions, with set goal for each:

- Session 1: Results from the web-consultation
  - Goal: Focus discussions on areas of difference of opinions
  - Method: Presentation of results followed by parallel sessions to consider findings and then by plenary to report findings.
- Session 2: EUG experiences
  - Goal: Capture any extra information not already addressed.
  - Method: Presentations by End-Users followed by parallel sessions to complement experiences members from each group using the received summaries. Plenary to amalgamate different views.
- Session 3: D-ERICA
  - Goal: Quality check that the aspects of the document are practical and useable.
  - Method: Brief summary of what is in the draft, then discussion on EUG expectations followed by a plenary to summarise views.

1.2 Seminar Procedures

The EUG event was run in similar fashion as many of the previous EUG events. Background material was distributed prior to the meeting; presentation(s) given in each of the three sessions to introduce the subject at hand followed by breakout group discussions and ending with a plenary to report and discuss findings. No names were attributed to the inputs throughout the event. During the group discussions, an EUG chair/rapporteur was selected by each group and two ERICA members were given the tasks of secretary/facilitator for each break-out group.

The final outcome of the event was explained at the beginning of the meeting. Two main objectives were to be achieved:

- the production of the meeting report, i.e. ERICA D7g with a summary of all discussions and presentations, as well as,
- inputting material from the discussions into two sub-sections of the D-ERICA: problem formulation and decision-making after assessment.

It was agreed that the PowerPoint presentations and background material would be available on the ERICA website.

1.2.1 Feedback related to the running of the meeting

Appendix 5 provides the results from the usual feedback questionnaire distributed to all EUG participants.

In brief, 10 EUG members provided comments. Out of 18 questions, only 4 score less than excellent collective answers, but received nonetheless positive answers.

Two participants (out of the ten who answered the questionnaire) didn't think the objectives of group discussions were clear enough. This is the less favourable score within this questionnaire. They were also doubtful about the fact that presentations adequately covered the identified topics and that enough time was available.

Globally, however, answers are positive and more positive than the feedback questionnaires of previous events.

Of particular interest are positive answers concerning the ERICA website and the timely distribution of the material prior to the event.

2 Session 1: Web-consultation

The ERICA Consortium sought EUG views related to two areas of the ERICA Integrated Approach: problem formulation and decision-making following an assessment. A simple questionnaire was designed to canvass the range of experiences of the EUG in this area and it was first distributed for comment then for providing answers prior to this EUG event.

The results from this questionnaire feed into the discussions in the Session 1. Appendix 3 provides the context to each question and details the results from the questionnaire. In brief the questions were:

1	In the draft recommendations of ICRP RP-06, three generic exposure situations have now been defined. Are there any other situations related to the protection of biota specifically which are not covered by the above exposure situations?
2	Here is a list of assessment purposes for which the ERICA integrated approach can be used. Do you envisage an assessment purpose that is missing from this list?
3	How important are the following headings (taken from the above list) to the problem formulation step for the following four assessment purposes?
4	Which assessment criteria have you used for radiation protection to biota?
5	Knowing that these will be the outputs of the ERICA Tier 3, what elements of the problem formulation will enable you to evaluate the results of the assessment?
6	Would the pragmatic approach to describe effects to individuals be acceptable to achieve this goal?
7	If - the risk is below concern/there is insufficient confidence that the risk is below concern/risk is of concern - are the proposed actions relevant, and are there others to recommend?
8a	In your opinion, which general management principles should be harmonised?
8b	Should internationally agreed no effect or exemption levels be developed?

2.1 Summary of results from the web-consultation

A total of 19 EUG members answered the following 8 questions. However some respondents skipped several questions as they felt the questions were not appropriate or that they did not feel they had the relevant expertise or experience.

The distribution of questionnaires answered, based on EUG categories, was as follows:

Regulatory	4
National advisory body	2

Academia	5
Non-governmental organisation	1
Industry	4
Consultants	3
Inter-governmental organisation	0

A number of ways forward were identified for the ERICA project and are summarised below.

2.1.1 Problem Formulation

Question 1

From the results, it is proposed to rename the three exposure situations and add additional examples to make the examples more relevant to the ERICA integrated approach. Additions in bold/italics.

Planned	***Post-Emergency***	**Existing (+ *non-conform)***
a) siting a new facility, b) b)re-assessment of the authorisation of an existing facility, c) decommissioning a nuclear facility, disposal of radioactive waste, d) remediation, ***e) NORM/TENORM,*** ***f) Clearance*** ***N.B. Applicable to both nuclear and non-nuclear***	a) accidents in nuclear facilities b) accidents in transportation of radioactive materials c) ***deliberate / malevolent uses, including terrorism***	a) exposure after an accident, b) residues from past ***or existing*** practices (not carried out within the current radiation protection standards)***non-intervention / passive remediation***

Question 2

From the results, it is proposed to add to the list of assessment purposes to illustrate the range of scenarios where the ERICA Integrated Approach can be used. Additions in bold/italics.

- General environmental protection - e.g. in Conventions
- Protection of specific ecosystems, natural resources, media and/or species
- ***Engagement with and/or*** provision of information for stakeholders
- ***Provision of information to decision-makers, e.g. as an input to cost-benefit analysis***
- ***Formulation of requirements for non-regulated activities, e.g. NORM, TENORM***
- Site selection of facility
- Planning of decommissioning and/or clean-up
- Specification and review of permits/authorisations

- Monitoring - Design or relevance of existing monitoring/surveillance programme
- ***Implementation of ISO standards***
- Emergency planning for design-basis scenarios
- Assess environmental damage following accident
- Environmental side-effects of remediation***, e.g. following accidents***

Question 3 [discussed within group discussions in session 2]

This does not show any decisive conclusion, we believe, although the table is worth going through. For example, "Specification and review of permits/authorisations" appears as the assessment purpose for which the headings seem to be least relevant. However, "Driving force" –presumably laws and regulations– appear quite relevant in this case… Similarly, Source Identification could be the relevant factor for remediation and Assessment Criteria the relevant aspect for Protection of Specific Ecosystems.

Source Identification is definitely the most relevant heading being in the first relevant half (the upper half of the table) for all 4 assessment purposes. In contrast, Stakeholder Involvement is the least relevant heading, only having some relevance for "Site selection of facility". We also observe that, according to this consultation, Assessment Criteria seem to be more relevant than Risk Characterisation.

- Discrepancy on how relevant stakeholder involvement is.
- Low driving force when dealing with environmental side effects of remediation

Question 4 [discussed within group discussions in session 2]

The majority of end-users, who answered the web-consultation, used the four proposed assessment criteria. A closer look to answers reveals that 4 end-users use all 4 criteria while 2 use none of these.

When identifying "Effects on biota" and "others" categories, end-users were prompted to list them specifically.

"Effects on biota":
- cytogenetic damages, e.g. micronuclei test, comet assay;
- biometric, size, stress enzymes, stress metabolites, DNA damage, gene expression;
- mortality, changes in reproduction, morbidity, genetic effects, adaptation;
- indirectly, by applying FASSET/ERICA method/derived limits.

"Others":
- Population growth and reproduction; average resistance to acute ionizing irradiation in experiment;
- we sometimes look at uptake or bioavailability as a complementary indicator (not a criterion).

Question 5 [discussed within group discussions in session 3]

A range of answers were given but not directly relevant to the question itself. Four end-users didn't provide an answer. As a result, views of the EUG were requested within the discussion groups.

The way forward will be to add in Section 2.1 a sub-section that informs the assessor of what Tier 3 provides as an output so that the assessor can formulate his assessment accordingly.

Question 6 [discussed within group discussions in session 2]

There is a 50-50 split in the answer. The "no" answers were supported with comments on possible ways forward, e.g. protection of the population or the ecosystem.

The pragmatic approach may therefore be to initially protect the environment/ecosystem/population through observing effects at the individual level.

2.1.2 Decision-making following an assessment

Question 7

In this table, the "no-answers" recorded in the three categories came from the same end-users.

Two relevant actions clearly stand out:

- to deny authorisation when the risk is unacceptable (after the consultation should read "of no concern"); and
- to still give authorisation when there is still insufficient confidence.

Other actions receive a comfortable majority of "relevant" scores, some being unanimously accepted as relevant.

Question 8

A number of principles to be harmonised were identified by EUG members, including:

- no effect levels;
- acceptability of risk;
- common practice; and
- similar approaches to avoid overlap.

Answers related to internationally agreed no effect and exemption levels or dose limits were globally positive. However, agreement for no effect and exemption levels appears to be more favoured than for dose limits.

Results from this question will be forwarded to the EC Euratom FP6 Coordination Action project PROTECT [Protection of the Environment from Ionising Radiation in a Regulatory Context], see www.ceh.ac.uk/protect.

2.2 Group discussions

2.2.1 Group 1

- **Question Q3. How do you define "driving force"?**

In the questionnaire, driving force was defined as "an influence that causes change, e.g. legislation". The group considered that legislation is not the only thing - often not the primary thing - that motivates

an assessment. For example, public interest may be more important than the requirement of legislation. The other factors may be more important in difficult cases. The group concluded that "driving force" is the main reason(s) for carrying out an assessment, e.g. legislation, recommendations, socio-economic factors, science etc.

During the discussion a number of points were made: The driving force can be a need to have public confidence or to maintain a good situation. Conservation legislation can be the driving force. Public interest is driving a lot of actions in environmental protection. Economic reasons are important, too. Legislation is useful for routine problems, but for difficult cases it is not enough (science is needed).

- **Q3. Why is there such a discrepancy in the answers of stakeholder involvement? Is it due to the category of people answering the questionnaire? Is it because it is limited by the current countries' legal framework?**

The group considered that procedures and precedents for site selection are currently being developed and there might already be stakeholder involvement. Site selection has a high political and public profile, which means that interest levels are high. On the other hand, assessment endpoints are a more 'academic' issue. The group thought that there has been a difference in view of who the stakeholders are: 'the public', 'experts', 'authorities' or all of these. How stakeholders have been defined affects the answers. Furthermore, the respondents might have had different stakeholders in mind at different stages of the assessment process. For instance, experts and authorities are at first building a strong project for presentation to the public. Then public inquires are carried out. On the other hand, stakeholder opinion has been the driving force in a review of permits in some cases.

It was also mentioned that among the respondents there are at least scientists, regulators and operators, who all are looking at stakeholder involvement from a different viewpoint. This may have affected the answers, too. Also the legal framework differs between the countries.

- **Q4. Discuss pros and cons of proposed "effects on biota" and "others"**

The group considered that most assessors just want an answer to "Is there a problem? - yes/no/maybe". The results of the questionnaire show preference for easy measures, such as concentrations, rather than effects on biota. Monitoring and observation were regarded by the group as a "ground truth" for models. Laboratory tests were seen to be complicated in relation to representativeness and the significance of the results under field conditions. Laboratory results should be used only in conjunction with other information, e.g. measured concentrations. The advantages of "others", including indicators, are weight of evidence (to indicate if there is a problem) and their usability for establishing guideline concentrations. However, problems were seen if guideline concentrations are too low.

The group highlighted that one should be aware of natural variability to avoid dis-conclusions (false positives). These considerations apply also to assessments dealing with combined effects of radionuclides and chemicals on biota. Radiation should not be regarded in isolation, as the cause of effect is not necessarily radiation. As a first stage in an assessment the use of radionuclide concentration levels is appropriate because they are, for instance, easier to communicate to the public than limits or benchmarks based on biological effects. Discussion on biological effects was regarded as more academic, whereas concentration levels are more useful in operational work.

- **Q6. Why the 50-50 split in answering: would the pragmatic approach to describe effects to individuals be acceptable to achieve this goal?**

The group thought that the question was whether this is a pragmatic way at showing protection has been achieved. The group considered that it depends on circumstances: the procedure is fine if concentrations are well below a level where any harm may occur ("Yes" answers). The group asked what is meant by 'appropriate' and will that change in the course of time/process of the assessment. It was concluded that the 'appropriate' will not change, because the object is protection of ecosystems as

a whole. There was concern that describing effects on individuals is the thin end of the wedge towards protecting individuals.

It was also mentioned that "achieved" does not mean "finished": once the assessment has been carried out the process will continue and further assessments may be needed. The duration of each stage of the assessment has not been defined beforehand in the tiered approach. "No" answers might have resulted from a conception that the assessment can be ceased if there is no proof of effects.

Another possible reason for the split might be that some of the questions were rather difficult to understand and the respondents might have interpreted them in different ways.

2.2.2 Group 2

- **Q3. How you define "driving force"**

It was pointed out that "driving force" is a very unclear term, one of the participants actually believed that it was the title for the other steps in the table of definitions. The group ended defining driving force as the legal/regulatory context, although one member felt that other reasons such as stakeholder interest could also act as driving force.

- Why there is such a discrepancy in the answers of stakeholder involvement?

First the group defined who is a stakeholder. Stakeholders include regulators, operators and other interest groups, not just public.

Several aspects that could influence the distribution of the responses were then identified.

- There could be differences in interpretation of the question, either how important is the stakeholder involvement or how important it should be?
- The understanding of who is a stakeholder may vary by responding EUG members; the difference could be country/culture related, or related to the interest group of the person responding.
- The origin of the regulation serving as driving force for assessment varies in different countries (there are differences in the level of implementation of relevant EU legislation in different countries); it could be either radiological/nuclear or environmental law and thus there can be different requirements related to stakeholder involvement.

It was noted that the relative amount of work that has to be done for stakeholder involvement in an assessment and subsequent decision-making compared with other efforts that are needed for assessment is not very large, but stakeholder involvement is critical for the success of the assessment.

- **Q4. Discuss pros and cons of proposed "others" and "effects on biota"**

The group noted that concentrations and dose rates are generally accepted good assessment criteria. The usefulness of other criteria depends on the assessment context, the availability of information and the case specific relevance of a given criteria.

For example for a new activity a non-specific screening evaluation using concentrations and /or dose rates was accepted as the starting point. On the contrary, for existing activities one can learn from experience; is something really happening in the environment?

It was also noted that regulation should be simple and use only 1-2 criteria that are predefined by scientific data analyses. The judgement governing the choice of indicators should be acceptability and measurability, taking into account of economic and human resources.

- **Q6. Why the 50-50 split in answering: would the pragmatic approach to describe effects to individuals be acceptable to achieve this goal?**

The group changed the question to read: Are individual effects enough to indicate protection of the environment against ionising radiation? The answers were:

- No: one should look at ecosystems/populations. Especially for existing activities a wider look is relevant. One has to consider also the effect of combined stressors.
- Yes: That's how it is done pragmatically. The starting point could be: No effects to individuals -> OK for populations. In case there are some effects to individuals, one has to look at populations.

The data availability was again recalled as a key point in the decision here.

2.3 Summary of plenary

Following the discussions of the given questions, the group discussed some of the definitions of exposure situations by the ICRP. A question was raised if consideration of emergency situations is relevant in this context. It was asked what actions one might take in reality regarding radiation protection of biota in such a situation. It was emphasised that one should be clear about the purpose of biota assessments in this situation. The group suggested that "emergency situations" should be replaced by "post-emergency situations". This was explained by the fact that in an acute emergency action will be taken primarily to protect the human population.

The two groups presented the conclusions of their discussions. A couple of comments were made in addition to the viewpoints already mentioned above:

- Regarding the ICRP "emergency situations", it was mentioned that ERICA can be used in the clean up time-scale, not in the acute phase of an emergency.
- Considering effects on biota, ERICA should have a focus on individuals instead of populations (if effects are observed on individuals, then populations should be examined).

3 Session 2: EUG experiences

Each EUG participant was asked to produce a one-page summary to inform the ERICA project. The four questions asked were:

- What is the experience in your country of managing and regulating radioactive substances compared to other contaminants?
- Does your country have any specific legislation for addressing the protection of biota from radiation?
- Does your country routinely carry out exposure assessment on biota for radiation protection purposes?
- Your experience in decision-making post assessment – what worked and did not?

3.1 EUG Presentations

Two EUG members gave talks on their experiences as operators: Ivica Prlic, Croatia, and Boguslaw Michalik, Poland. Their presentations will be posted on the EUG protected area of the ERICA website. Irene Zinger then gave a brief overview of the answers from all received summary contributions. A summary of each talk is given below.

3.1.1 Our experience as operators in Croatia

Since 1959 the Institute for Medical Research and Occupational Health (IMI) has been licensed as an Operator by the Ministry of Health for the monitoring programme of radioactive contamination of human environment in Yugoslavia (first legislative from 1947-8.). IMI publishes reports annually covering Republic of Croatia. A special situation exists in Croatia on nuclear safety as the Republic of

Croatia owns 50% of the Nuclear Power Plant, Krško, which is situated on the territory of the Republic of Slovenia.

The Article 9 of the Croatian Radiation protection law: "Systematic testing and monitoring of ionising radiation in the environment" specifically addresses biota. Priorities on Radiological and Nuclear Issues due to:

- national plan and programme for radiation;
- protection measures in the case of accidental events involving ionising radiation;
- national strategy for the protection of environment;
- Country Programme Framework (CPF) to IAEA and joint convention on the safety of spent fuel and on the safety of radioactive waste management, concern:
    - Energy and Radiation Protection;
    - Radiation Applications in Medicine;
    - Nuclear Knowledge and Education Radioecology; and
    - Nuclear Safety and Security of Radiation Sources.

Croatia is a Type B Country, under IAEA classification, i.e. radiation sources widely used in industry, medicine and research; there are no commercial nuclear reactors; the long-term treatment of low-active and mid-active nuclear waste is not solved for good only temporary solutions exist; and the residues from past industrial practices exist in form of industrial waste; problem of general environmental pollution which falls into a broad category of TENORM sites although one site has been remediated.

The monitoring programme of radioactive contamination in the human environment in Croatia, is implemented according to Commission Recommendations of 8 June 2000 - europa.eu.int/comm/energy/nuclear/radioprotection/doc/legislation/00473_en.pdf.

The only post assessment decision-making experience concerning TENORM (or any environmental radioactive pollution) we have had in Croatia is due to the remedial actions done in coal-fired power plants. IMI participates two ongoing EU-IMI Joint Research Projects:

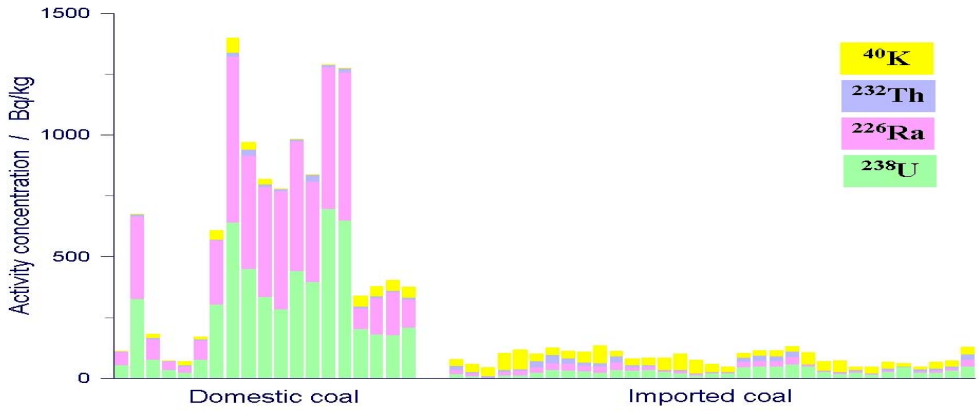
- Management and remediation of hazardous industrial wastes in the Western Balkan Countries" (INDUWASTE) EC INCO SSA CONTRACT NR. 515919 www.induwaste.eu ; &
- Assessment of environmental risk of radioactively contaminated industrial tailings" (INTAILRISK) EC CONTRACT N° FP6-509214, www.ibes.be/intalirisk/ .

Within the IAEA-RER/7/003 Project Marine Environmental Assessment of the Mediterranean Region and IAEA-RER/7/003 Project Marine Environmental Assessment of the Mediterranean Region, two areas have been studied:

- Istrian Peninsula categorised into areas with slightly elevated natural background due to layers of coal containing elevated natural radioactivity concentration - geologically "old" formations;
- Mid Dalmatian coastal region has slightly lower natural background due to younger geological formations containing mostly lime-stone.
- Case 1: Coal-fired Power Plant in Plomin

Plant waste area is 120000 m^2 with 10^9 kg of waste material. The average natural background dose rate values are between 69,1±12 $nGyh^{-1}$ and 77,9±11 $nGyh^{-1}$, compared to 104,4 ± 7 $nGyh^{-1}$ in

Zagreb. Today the coal presently used originates from South America, South Africa and Asia. The Figure below shows the differences in radionuclide content of domestic and imported coal.



The average "site-specific" background absorbed dose rate values above TENORM waste as before remediation = 312,1 ± 78,9 nGy/h; and after remediation = 3,3 ± 18,2 nGy/h.

During the restoration waste was covered with a new soil layer, which remarkably prevents ingression of rainfall into contaminated material and reduces deflation (blowing material away). The average "site specific" background dose rate value in the surrounding area is 99 ± 13 nGy/h.

A preliminary risk assessment for Plomin CFPP site was carried-out in 1996. Risk assessment was not done for any biota, and was based on ICRP. Scenarios for exposed workers and the general population were carried out with both RESRAD and PATHRAE software methods.

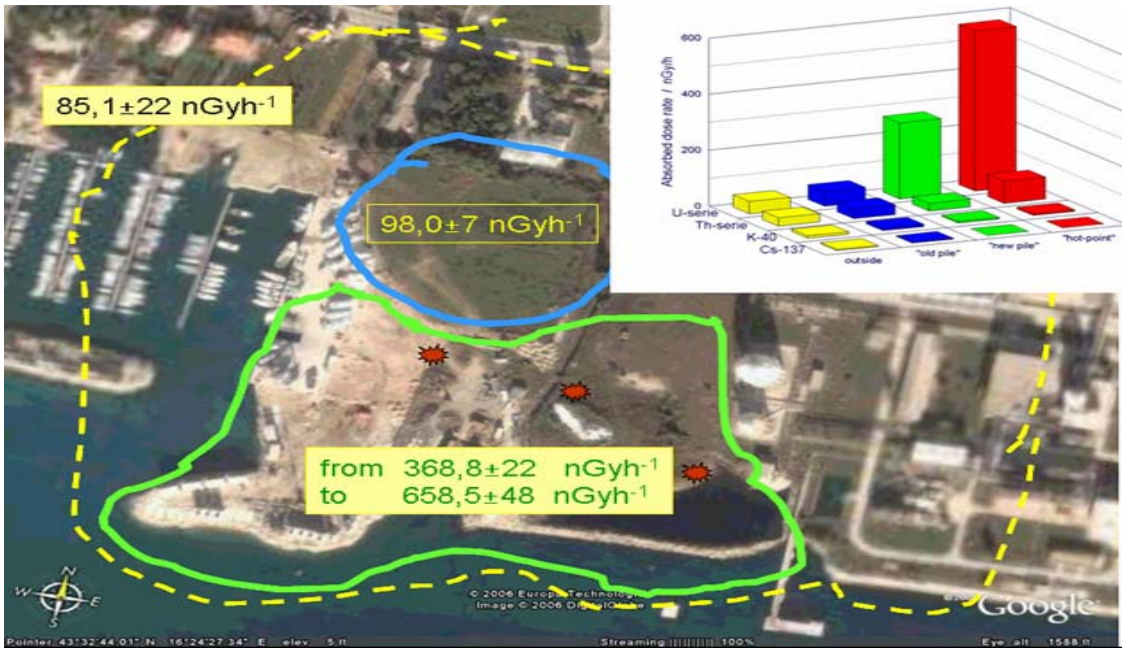
Today, the rainwater barrier and main drainage are considerably lower than the erosional and proluvial processes. The drainage collector and retention pool significantly reduce the loss of eroded terrestrial material including slag and ash into the adjacent Plomin Bay.For the Plomin Coal Power Plant Risk Assessment was done. Controlled, new coal ash and slug levelling is carried out so that now it is commercially used in cement production. The Plomin Bay was drained and cleaned – creek and fallout deposited a lot of alluvium.

- Case 2: Chemical Industry - Plant – Kaštela Bay

The site is a small internal CFPP – 35 MW, with mixed TENORM and chemical pollution. The waste area is 18000 m^2, with 10^8 kg of waste material. Two waste areas include:

- an old area remediated and protected and a new one that is irregularly deposited, not under supervision and completely uncared for; and
- a new pile of slug, ash and construction waste material, which is spread in an uncontrolled manner, all over the area – including into the sea

The average "site specific" background dose rate value in the surrounding coast area is < 85 ± 22 $nGyh^{-1}$. Risk assessment has not been done for the "Kaštela" hazardous waste site.



The above Figure represents the aerial photo of the chemical plant and surrounding populated area with the local polluted areas of interest: outside yellow- surrounding populated area, blue- old remediated and protected pile, green – new, widely spread TENORM waste and red – hot spots on the new pile. Corresponding dose rate background values are also shown.

- Looking at biota

The Adriatic Sea is a closed, warm sea – very sensitive bioecological system. IMI collects research samples with mussels, pilchard and cephalopods (squid, octopus, cuttlefish) being the most suitable indicators of sea biota.

At Plomin site all natural radionuclides except ^{40}K and ^{214}Pb were below the detection limit of the instruments. The sea is not any more in direct or indirect contact with deposited material.

At Kaštela site all natural radionuclides except ^{40}K and ^{214}Pb were below the detection limit of the instruments. The presence of ^{214}Pb in some mussels samples $((5{,}2 \pm 0{,}6)E^{-1}$ Bq $kg^{-1})$ is not negligible. It indicates active ash and slug displacement on the disposal site and raising the waste level directly into the sea. The sea is in direct contact with deposited waste material.

3.1.2 Problem with ERA at post-industrial areas contaminated by enhanced natural radioactivity and heavy metals

The Upper Silesian Coal Basin (USCB) is located in the southern part of Poland and there had been 65 underground coal mines working in the area. Total outflow of wastewaters from these mines reached 900 000 m^3/day. Due to their very high salinity (sometimes higher than 200 g/l) they have caused severe damages to the natural environment. Additionally, these waters have often elevated concentrations of radium isotopes ^{226}Ra, ^{228}Ra as well as barium and other metals. This phenomenon has been recognized since the 1960's. Such waters have been found also in German coal mines and it is very well known that the oil and gas extraction industry produces saline waters with enhanced radium concentration, too.

In USCB waters with high radium concentration occur mainly in the southern and central part of the coal basin, where coal seams are overlaid by a thick layer of impermeable deposits. First investigation showed that concentration of radium in formation water is correlated with its salinity and it has been found that the behaviour of radium during transportation of radium-bearing brines in the gutters of underground galleries, settling tanks and ponds, pipelines and rivers depends mainly on chemical composition of the brines. Hence two types of radium-bearing waters have been distinguished. Waters type A contains not only radium ions but barium ions as well. Concentration of barium in these waters is at least six orders of magnitude higher than that of radium and reaches 2 kg/m^3. High barium concentrations enable co-precipitation of radium with barium sulphate when radium-bearing water type A is mixed with water containing sulphate ions, which are very common in nature. In case of radium-bearing waters type B, where barium ions are not present, concentration of radium ions is too low to enable precipitation of radium sulphate because concentration of [Ra^{2+}] *[SO_4^{2-}] does not exceed the solubility product. Due to differences in their chemical proprieties, the effect of release of radium-bearing waters type A and type B into the natural environment is completely different. Radium from radium-bearing waters type A is precipitated out in underground mine workings and in settling ponds, pipelines and little rivers. Concentration of radium in such precipitates is usually high reaching 400 kBq/kg in underground galleries and 270 kBq/kg on the surface, but the precipitation and sedimentation takes place rather close to the point where radium-bearing waters type A mix with waters containing sulphates, so that in the distance over few or several kilometres downstream from the discharge point of mine water the river water is free of radium. In contrast, radium-bearing waters type B radium is not precipitated but transported with water to large rivers. Although, concentrations of radium in bottom sediments are in this case not very high, contamination of river waters and bottom sediments is observed over a large distance even up to hundred kilometres from the discharge point.

In hard coal exploitation areas, settling ponds were used allow the Ra bearing sulphates to settle out from the underground brines. For this purpose some natural lakes or fishing ponds were adapted. This has resulted in sediments with concentrations of radium isotopes exceeding 200 Bq/kg in 25 settling ponds. The total capacity of all these settling ponds is 5 million cubic meters.

Some of settling ponds have been used for over 25 five years and during this period about 200 million m^3 of wastewaters had been discharged into them. This has resulted in 100,000 m^3 (about 150,000 tonnes) of the total amount of the suspended sediments being deposited in the pond. A significant increase in the dose rate can be observed up to 42 μGy/h near the point of inflow of waters into a settling pond.

Besides enhancement of natural radioactivity these precipitation and sedimentation processes concentrate heavy metals in the form of chlorides and sulphates.

The occurrence of enhanced natural radioactivity in Polish coalmines creates a potential radiation hazard for mining crews. In the underground mining industry in Poland, monitoring of the radioactivity of mine waters and precipitates, as well as gamma dose rates and radon progeny in air, has been obligatory since 1989. In contrast, the monitoring of the environment has not been undertaken and there is no formal regulation in place.

Now there are a lot of problems of how to assess the environmental impact of settling ponds from the point of view appropriate methods to use as well as legislation.

3.1.3 Overview of collated summaries

A total of 10 summaries were received, from seven countries:

- Croatia
- France

- Finland
- Germany
- Hungary
- Poland
- UK

The information collated show that practices throughout Europe vary greatly between countries. A brief overview of the answers for each of the four questions is given below. Please refer to the whole texts for more details. These have been posted on the EUG section of the ERICA website.

- What is the experience in your country of managing and regulating radioactive substances compared to other contaminants?
- Regulate environment for both chemicals and radioactivity
- Regulate environment for chemicals but not for radioactivity
- Regulate environment for radioactivity ”better / more strictly” than for chemicals
- Regulate biota for chemicals but not for radioactivity
- Regulate chemical impact for regulated radioactivity discharges
- Does your country have any specific legislation for addressing the protection of biota from radiation?
- Regulate for both humans and the environment
- Regulate humans, but mention environment in broad terms
- Regulate for humans but not for the environment
- Indirectly addresses protection of biota
- Does your country routinely carry out exposure assessment on biota for radiation protection purpose?
- Yes
- Yes for the purpose of food intake – i.e. follows ICRP
- Not yet but ”starting to / scope is there”
- No, only after an accident
- Your experience in decision-making post assessment – what worked and didn’t?
- Proof not enough to change regulations
- Lack of harmonisation is surfacing and need to resolve situation
- Not implement regulations adequately
- Stakeholders have greater impact than assessment results
- Wait and see attitude

A quote from one of the EUG member was of particular interest:

> ”There will always be dissension irrespective of the public consultation - thus the public consultation should aim not at gaining unrealistic consent but at creating diverse discussion with different views for the consideration of decision-makers”.

3.2 Group discussions

3.2.1 Group 1

The group discussed three topics: regulation of NORM/TENORM, criteria for protection, and how to facilitate the introduction of radiation and radioactivity into protection of the environment set within regulations.

- NORM / TENORM

Here the group noted that regulation of situations involving NORM /TENORM varied at the national level, although all noted an element of discretion on the part of the national regulators. That is to say, the criteria for regulating the use of anthropogenic radioactivity were generally quite clearly defined in a regulatory context, the regulation of activities involving NORM / TENORM was often made on a case by case basis. Factors such as the scale of operation, magnitude of the impact, and even local background in the absence of the practice may be factors in the decision.

Therefore, the group felt that decisions regarding bringing radiation impacts on biota into the regulatory process for NORM / TENORM in specific cases should properly be left to the national regulators.

However, the ERICA Integrated Approach, and tool, clearly needs to be able to deal with the impact of NORM / TENORM and the consortium should therefore ensure that the assessment tool has this capability – for example, by inclusion of all the relevant naturally-occurring radionuclides.

- Criteria for protection

Discussion in the group circulated around how ‘hard’ or ‘soft’ protection criteria should be. It was noted that the ICRP dose limit of 1 mSv per year for environmental exposure of members of the public from anthropogenic releases of radioactivity had worked well, but that there was much less uncertainty (and much more experience) of assessing doses to humans, and the consequent effects or risks, than is the case for biota.

The use of ‘dose limits’ was felt probably to be too inflexible at this stage; alternative concepts such as ‘guidance levels’ may be more helpful – however, ‘guidance levels’ may be considered too ‘soft’ by some, or alternatively become de facto ‘dose limits’ if the context of their use was not set out very clearly within the framework in which they were produced.

Overall the group agreed that numerical criteria of some form were needed, but could not agree exactly what form these should take or what they should be called.

A clear tension exists in this context from the perspective of operators, who understandably are very wary of any additional regulatory constraints, unless there is a clear scientific / safety / environmental basis for applying such constraints. Building trust between scientists, regulators and operators will be important in the effective implementation of protection criteria.

The group also noted that, for existing situations, observation of the ecological status of a potentially affected site is an important adjunct to any assessment based on numerical dose or radionuclide concentration criteria.

- Bringing radiation protection for biota into environmental regulation

In England and Wales, the view of the Environment Agency (based on their legal advice) is that the Habitats Directive already provides a legislative basis for including ionising radiation into environmental regulation.

More generally, protection of the environment is required by general principles or codes but is not the subject of specific regulations.

The group noted that the structure of national institutions may provide some barriers to the more widespread incorporation of radiation protection into environmental regulation. For example, implementation of the Habitats Directive may fall to one national agency whilst regulation of radioactive substances falls to another; England and Wales is in the advantageous position of having a single agency that deals with all aspects of environmental regulation.

A number of examples of increasing co-operation between agencies involved in different aspects of environmental regulation (including radioactive substances) were noted.

Encouraging inter-agency co-operation and a unified approach to the implementation of existing legislation (e.g. the Habitats Directive) was seen as an important way of bringing radiation protection issues into the broader regulation of environmental protection.

3.2.2 Group 2

- NORM-TENORM

The group discussed the regulation on NORM/TENORM only in the context of human radiation protection.

Finland: Regulation of NORMs in construction materials is thoroughly treated. Industrial pilings – are not regulated according to nuclear law. Industry, for example the phosphate industry, is regulated on a case-by-case basis under radiation protection law. Uranium mining and milling is regulated according to the nuclear law. Exploration (regarding radioactivity) is regulated under the radiation protection law. Detailed regulations for uranium exploration are being considered.

Croatia: Have no current law for the regulation of NORM and TENORM, but laws are being developed primarily for dealing with the current situation.

Sweden: Building materials are regulated for natural radioactivity levels. Mining tailings have been investigated. Sweden has national environmental objectives and within that the regulation of TENORM is currently being discussed including at what level it can be regulated to in comparison with regulation of artificially created radionuclides. Drinking water is also being investigated. Filters from water treatment plants have been identified as a waste and worker-exposure a problem from natural radionuclides. Individual water wells have been identified as containing water enhanced in natural radionuclides – information and advice is being given to the public.

Poland: In case of enhanced activity it should be regulated at the same level as artificial radionuclides.

Protection of the environment is a general concept included in many overall goals.

- Criteria for protection

The ICRP recommendations for the protection of the environment will not be available for 10 – 15 years. However a newly started EU project called Protect has the goal to come up with recommendations on how target values (or numbers) may be derived and, if possible to derive the target/numeric values, in two years time.

If you are under a regulatory regime based on a set of numbers to make decisions the question is will the regulations be used in an appropriate way. In a context where regulators want to just use numbers that will be given to them, then you have to be careful.

Croatia sees a need to come with some numbers.

The UK is using screening levels.

Poland: no specific dose limits – general dose limits for members of the public. No special limits for the environment.

There must be a parallel process, that we have numbers as targets is a clear need, but in parallel there should be optimization, always drawing the levels as low as possible. The specification of general or non-numerical goals exist, BAT, ALARA, etc. may be used instead.

How numbers are applied in specific countries depends on the regulatory system in that country. Numbers in the form of screening levels or something similar have their relevance, but the principle of setting criteria has relevance in an overall framework.

- Bringing radiation protection for biota into environmental regulation

Finland is already protecting the biota, effects on the biota versus best prevailing knowledge in the regulation regarding long term safety of disposal of spent nuclear fuel.

However the question of what do we mean by "protection of the environment" was raised. It depends on what it is that is being assessed. It is not specifically different than other types of environmental protection. Only a handful of pollutants have numbers connected with them. When they have not got numbers they are making some kind of assessment based on what is known. There is influence in general on environmental legislation – not just pollution control and not just radiation protection.

Harmonisation – is it possible to get something at the EU level? For example, guidance to consider impact of radiation on defined habitats.

ICRP is an influence; the fact that ICRP is investigating protection of the environment has influenced other countries/organisations to also investigate this problem.

3.3 Summary of plenary

The ERICA Integrated Approach needs to be able to deal with the impact of NORM / TENORM through the provision of underpinning data for naturally occurring radionuclides which should be included in the assessment tool.

Numerical criteria of some form are needed, but there was no consensus on exactly what form these numbers should take or what they should be called.

Observation of the ecological status of a potentially affected site is an important adjunct to any assessment based on numerical dose or radionuclide concentration criteria.

Encouraging inter-agency co-operation and a unified approach to the implementation of existing legislation (e.g. the Habitats Directive) was seen as an important way of bringing radiation protection issues into the broader regulation of environmental protection.

There appear to be an attitude of "passing the buck" when no numerical values are given. A potential way forward might be for the EC to issue a guidance, rather than a legal, document, e.g. a Directive. Units should also be specified.

The USA is using 1 mGy/day for the purpose of remediation. So the context has to be specified too.

4 Session 3: Chapters within D-ERICA

Irene Zinger reviewed the Table of contents of the D-ERICA document, which had been circulated for comments six months before. In addition she presented a brief outline of the current draft of Sections 2.1 and 2.7, which were also provided in advance of the meeting, dealing with problem formulation and decision-making post assessment, respectively.

4.1 Group 1

- How to devise assessment criteria to interpret the result of Tier 3 assessment

Tier 3 will provide: 1) doses (rates); 2) effects data for those dose rates; 3) probability distributions of dose (rates), and; 4) possible guidance for deriving benchmarks for a given endpoint or organism.

The key point was made was that you are likely to get fundamentally different information at Tier 3. In Tiers 1 and 2 because you are comparing to a screening value that has been set conservatively you can state with a good degree of confidence that you are unlikely to see an adverse effect in the environment and hence you can stop the assessment. With Tier 3 being open-ended and not having a comparative value (unless one is defined on the basis of the effects information – see below) you can not say with any degree of certainty that there will be no adverse effect and you might even be saying that there 'may be an effect'. Therefore you are left with a decision to make on how to define that comparative value or information on which you can make the judgement that there will be no adverse effect. Based on this it was considered that dose rates and effects information are very important pieces of information that become available at Tier 3. Furthermore it was recognised that because Tier 3 will provide the capability for undertaking probabilistic assessments you may also get information on the probability that associated with a particular effect value. Additionally, it was recognised that at Tier 3 you might instigate a monitoring programme to improve your knowledge of a given situation and that information on effects, natural background and other observations on the ecology might play a part to help 'paint the picture'.

The discussions also highlighted the importance of understanding the cost and benefits of the practice being assessed and that these costs/benefits need to feed into the discussions with stakeholders to determine the overall acceptability of the practice.

In terms of the outputs from ERICA it was agreed that the outputs from ERICA tool do not provide a decision and that the outputs of ERICA are actually to aid decision-makers to make decisions. On this basis there should be information on the input observations that are going into the tool, along with information on natural background and also a statement on the degree of confidence that a decision maker can have in the outputs from decision makers. Consequently the assessor should present the ERICA output information to a decision-maker in a format that is easily accessible and understandable but that presents the data clearly. There should also be a simple discussion on the uncertainties contained within the ERICA tool and within the outputs and there should be a recognition that the ERICA outputs should be used as inputs into multi-criteria assessment tools in order to address the costs and benefits of the practice that is being assessed.

- Decision-making post assessment

When ERICA describes the risks as acceptable and unacceptable it should try to use the following phrases instead: of concern, not of concern and it should provide information on the level of confidence to have within the assessment outputs.

With regard to the discussions around the types of information that people would like to see under the post assessment decision making heading (i.e. the management decisions that should be taken) it was decided to characterise these as being of concern, not of concern, and insufficient confidence against the planned, existing and post emergency ICRP exposure situations – as described in Session 1, Section 2.1.1.

Examples of possible conclusions, based on the results of the ERICA assessment to non-human biota.

	ICRP exposure situations		
	Planned	**Existing**	**Post-Emergency**
Risk is of concern	Say no to the practice or: Reconsider the proposal Another site Reconsider decision Perspective of other risks Would more site specific (or appropriate) data help? Are there other external over riding priorities that mean that the practice should be started?	Shut down existing practice Consider changes of current practice to re-optimise the process Consider ecological value of present site Would remediation do more good than harm? Cost benefit analysis is needed	Consider ecological value of present site Would remediation do more good than harm? Cost benefit analysis is needed
Insufficient confidence that the risk is below concern	Would more data be helpful? Or available? Ask ERICA /experts for help Proceed with additional controls imposed and review practice/assessment after defined time intervals Say no to the practice Re-iterate the assessment Undertake a multi-criteria decision analysis	Ecological restoration Consider assessment of other stressors Shut down existing practice Consider changes of current practice to re-optimise the process Consider ecological value of present site Would remediation do more good than harm? Cost benefit analysis is needed Onus of proof is on operator Proceed with additional controls imposed and review practice/assessment after defined time intervals Say no to the practice	Consider ecological value of present site Would remediation do more good than harm? Cost benefit analysis is needed Timescales and observe
Risk is below concern	Proceed but consider other factors e.g. cost, BAT, human exposure and optimisation	No intervention for biota Consider if controls for human exposure are required	Biota will be fine (don't let the people back) consider other factors

4.2 Group 2

- How to devise assessment criteria to interpret the result of Tier 3 assessment

The group agreed that assessment criteria would be case-specific at Tier 3 and would differ for new and existing situations, e.g. whether you could use existing data to do independent checks. What you need is dependent on your context. The user has to define the assessment criteria.

The group discussed the relative value of the different endpoints resulting from Tier 3 assessment. Tier 3 does not used a single number but a range of information to assist the assessor in decising the level of risk:

1. doses (rates)used most commonly;
2. effects data but noting that they are mainly for individuals not populations;
3. probability distributions of doses (rates) are important but they are dependent on expert judgment and proper communication must be achieved for acceptance; and
4. guidance for deriving benchmarks for a given endpoint or organism; this should be explained for new users at the problem formulation stage.

Both effects data and guidance for deriving benchmarks were thought to be the most helpful.

It was therefore agreed that the potential outcomes should be defined at problem formulation stage, including stakeholder views/sensitivities, what outcome (i.e. risk of concern or not) and endpoints are provided. Once the assessment is done the user can, if not certain of the results, re-visit the problem formulation and adjust if desired the criteria.

It was agreed that cost-benefit /multi-criteria decision-making analysis (MCA) was part of decision-making outside the ERICA Integrated Approach. The results from the ERICA assessment tool could be provided as an input into the MCA.

- Decision-making post assessment

The group concluded that as the ERICA Integrated Approach is not to be prescriptive, there is no real "decision-making", but rather decision-aiding considerations.

Effects on the environment can be grouped under:

- risk is below concern;
- there is insufficient confidence that the risk is below concern; or
- the risk is of concern.

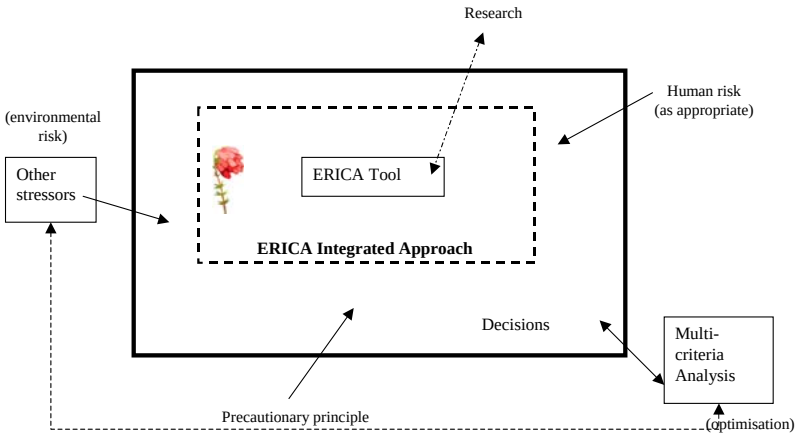
Some people felt that the precautionary principle should be mentioned when the results of the assessment indicate that a risk may be present.

The group felt that is was important to highlight that the tool can be used:

- as an aid to decision, as opposed to making decisions;
- for analysis of sensitivity;
- iteratively for:
    - optioneering (optimising)
    - modifying the criteria / endpoint, i.e. reviewing results
    - specific context – provides a broader risk characterisation (include description of how confident are the outcomes).

Therefore the nature of the effects in the environment should determine the decision to take with respect to the environment, i.e. not taking into account of other factors. Other considerations may need to be taken into account resulting in a different outcome, e.g. consider impact to humans.

The group stressed the importance of being able, once an assessment is done, to copy the results and then return to the problem formulation and review/change the assessment criteria in order to see the impact on the results. This "loop-system" will increase the confidence in the interpretation of the assessment results.



ERICA = Risk of Radioactivity on the environment (non-human biota)
- individual
- population
- non-living environment } **extrapolation**

Illustration of factors affecting decisions – not exhaustive
(Figure developed by Group 2 but reviewed in plenary)

As the ERICA Integrated approach provides guidance only, it was felt that once you get results, the assessor should give a statement/conclusion rather than recommendations.

It was also noted that decision-making under uncertainties will depend on the context and extent to which scientific/socio-political inputs determine the decision.

4.3 Summary of plenary

Decision-making post assessment should be renamed decision-aiding.

A specific sub-section should be dedicated for Tier 3 at the problem formulation giving a reminder of what the results are from the tool. Special explanation/guidance of how the benchmark could be determined would also be useful to inexperienced users.

Once an assessment is done, it should be noted that reviewing the problem formulation and the chosen assessment criteria can help increase the confidence in the interpretation of the assessment results.

5 Conclusions

A total of 19 EUG members answered the web-consultation. However some respondents skipped several questions as they felt the questions were not appropriate or that they did not feel they had the relevant expertise or experience. For this reason questions during the event were aimed at clarifying some of these points.

- Session 1

  The group suggested that “emergency situations” in the ICRP exposure situations should be replaced by “post-emergency situations”, and that the purpose of biota assessments in this situation. This was explained by the fact that in an acute emergency action will be taken primarily to protect the human population. Changes in the phrasing of some of the text within problem formulation should be addressed.

- Session 2

  The ERICA Integrated Approach needs to be able to deal with the impact of NORM / TENORM through the provision of underpinning data for naturally occurring radionuclides which should be included in the assessment tool.

  Numerical criteria of some form are needed, but there was no consensus on exactly what form these numbers should take or what they should be called. Observation of the ecological status of a potentially affected site is an important adjunct to any assessment based on numerical dose or radionuclide concentration criteria. A potential way forward might be for the EC to issue a guidance, rather than a legal, document, e.g. a Directive. Units should also be specified. Some of these points, will be passed on to the EC project PROTECT - Protection of the Environment from Ionising Radiation in a Regulatory Context, see www.ceh.ac.uk/protect.

- Session 3

  Decision-making post assessment should be renamed decision-aiding.

  A specific sub-section of D-ERICA should be dedicated for Tier 3 at the problem formulation giving a reminder of what the results are from the tool. Special explanation/guidance of how the benchmark could be determined would also be useful to inexperienced users.

  Once an assessment is done, it should be noted that reviewing the problem formulation and the chosen assessment criteria can help increase the confidence in the interpretation of the assessment results.

Problem formulation and decision-making post assessment are closely linked and a number of external factors to the assessment will dictate the context/purpose of the assessment, as illustrated below.

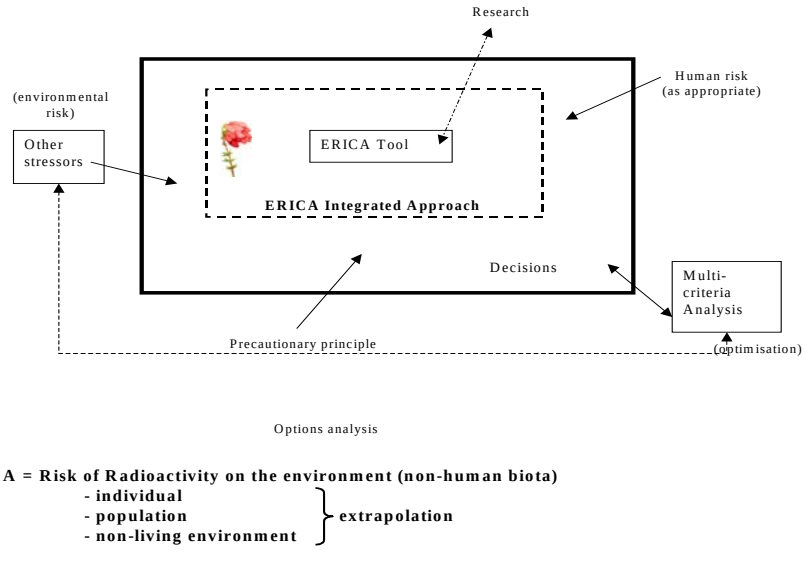


Illustration of factors affecting decisions – not exhaustive

The majority of ERICA recommendations from the groups will be implemented in both the D-ERICA and the D8- "Considerations for applying the ERICA Integrated Approach" document, to be published in early 2007.

Globally, feedback of the event was positive and answers more positive than the feedback questionnaires of previous events.

Appendix 1: Agenda

Tue. 14th	**09:00 - 12:00**	**General Welcome**	**Irene Zinger**
		Analysis of the results from the web-consultation *Goal: Focus discussions on areas of difference of opinions* *Method: Presentation of results followed by parallel sessions to consider findings and then by plenary to report findings.*	
	13:00 - 17:00	**Experiences to extract from EUG members' background material** • Our experience as operators in Croatia • Problem with ERA at post-industrial areas contaminated by enhanced natural radioactivity and heavy metals • BNGSL`s experience of meeting regulatory requirements for non-human impact assessments *Goal: capture any extra information not already addressed.* *Method: Presentations by End-Users followed by parallel sessions to complement experiences using received summaries and members in each group.*	**Ivica Prlic** **Boguslaw Michalik** **Tim Parker (cancelled)**
	17:30	Departure from the hotel	
	17:45 - 18:30	**Visit of STUK quarters in Rovaniemi**	
	19:00 - 22:30 ***Dress warm***	**Arrival at the Sirmakko Reindeer Family restaurant** - open fire cooked coffee inside the kota (kota is a traditional Lappish house, a kind of tent) and a real story about the traditional Lappish costume (things you can see of the costume about the social and economic status of the owner of the dress, etc.) - feeding the reindeers and a story about reindeer's year and husbandry - lasso throwing contest: If guests want to throw lasso they can do it with instructions and guide (a little present to the winner)	
Wed. 15th	**09:00 - 12:00**	**Presentation of the D-ERICA related to problem formulation and decision-making post assessment** *Goal: quality check that the document is practical and useable.* **Feedback and way forward**	**Irene Zinger**
	12:00 - 13:00	**Lunch**	

Appendix 2: List of participants and discussion groups

EUG members

No.	First name	Surname	Institute/ Organisation/ Company
1	Ari	Ikonen	Posiva OY (Finland)
2	Andrew	Farmer	Institute for European Environmental Policy (UK)
3	Christine	Willrodt	Federal Office for Radiation Protection (Germany)
4	Ian	Robertson	Scottish Environment Protection Agency (UK)
5	Carol	Robinson	Enviros Consulting (UK)
6	Ivica	Prlic	Institute for Medical Research and Occupational Health
7	Sanja	Milkovic Kraus	(Croatia)
8	Boguslaw	Michalik	Central Mining Institute (Poland)
9	Bela	Kanyar	University of Pannonia (Hungary)
10	Patrick	Devin	Areva (France)
11	Jaana	Pennanen	Ministry of the Environment (Finland)

Apologies from Tim Parker – BNFL (UK)

Consortium Members

No.	First name	Surname	Institute/ Organisation/ Company
1	Kirsti-Liisa	Sjöblom	Finnish Radiation and Nuclear Safety Authority
2	Virve	Vetikko	Finnish Radiation and Nuclear Safety Authority
3	Ritta	Hanninen	Finnish Radiation and Nuclear Safety Authority
4	Dina	Solatie	Finnish Radiation and Nuclear Safety Authority
5	Taina	Bäckström	Swedish Radiation Protection Authority
6	Lynn	Hubbard	Swedish Radiation Protection Authority
7	Irene	Zinger	Swedish Radiation Protection Authority
8	David	Copplestone	Environment Agency for England and Wales
9	Steve	Jones	Westlakes Scientific Consulting Ltd (UK)

GROUP	1	2
EUG	Ari Ikonen Béla Kanyár Ivica Prlic (c) Ian Robertson Patrick Devin Christine Willrodt (c)	Jaana Pennanen Michalik Boguslaw Sanja Milkovic Kraus Andrew Farmer Carol Robinson (c)
Consortium	Virve Vetikko (s1) David Copplestone (s3, f1) Steve Jones (s2, f3) Taina Bäckström (f2)	Kirsti-Liisa Sjöblom (s1, f2) Irène Zinger *(s3)* Lynn Hubbard (s2, f3) Riita Hanninen (f1) Dina Solatie (on 14th Nov. only)

c- EUG chair
f - facilitator
s - secretary
1/2/3 sessions

Appendix 3: Web-consultation questionnaire results

Analysis carried out by Partick Momal, IRSN.

A. Problem Formulation

DEFINITION. In the Ecological Risk Assessment (ERA) paradigm, problem formulation is defined as the first step of any risk assessment and is intended to identify the context and purpose of the assessment framework [1]. This should include ecological, political and societal issues related to questions being addressed, and integrate the process of choosing appropriate assessment endpoints, identifying sources and describing the environment [2].

[1] Suter, GW (1993) Ecological Risk Assessment: Lewis Publishers. [2] Moore, DRG, Biddinger, GR. (1995) the interaction between risk assessors and risk managers during the problem formulation phase. Environ. Toxicol. Chem, 14, 2013-2014.

1. In the current ICRP Recommendations (ICRP 60, 1991) the Commission has distinguished between *practices* that added doses and *interventions* that reduced doses. The principles of protection have been applied differently between the two situations. That distinction has been seen as artificial and sometimes confusing.

The Commission now intends its recommendations to be applied to all sources in the following three types of exposure situations, which address in total all conceivable circumstances:

- *planned situations* are everyday situations involving the planned operation of sources including decommissioning, disposal of radioactive waste and rehabilitation of the previously occupied land. Practices in operation are planned exposure situations.
- *emergency situations* are unexpected situations that occur during the operation of a practice, requiring urgent action. Emergency situations may arise from practices.
- *existing exposure situations* are exposure situations that already exist when a decision on control has to be taken, including natural background radiation and residues from past practices that were operated outside the Commission's recommendations.

Thus the three types of exposure situations replace in the future the previous two categories 'practices' and 'interventions'. There are some small differences in application of the system of protection between these three types of situations.

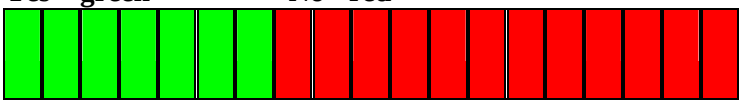
Note that in each situation, both retrospective and prospective assessments can be carried out.

Examples of assessment purposes under each ICRP exposure situation

Planned	Accidental	Existing
a) siting a new nuclear facility, b) re-assessment of the authorisation of an existing nuclear facility, c) decommissioning a nuclear facility, d) disposal of radioactive waste, e) remediation	a) accidents in nuclear facilities, b) accidents in transportation of radioactive materials	a) exposure after an accident, b) residues from past practices (not carried out within the current radiation protection standards)

In the draft recommendations of ICRP RP-06, three generic exposure situations have now been defined. Are there any other situations related to the protection of biota specifically which are not covered by the above exposure situations?

Yes – green **No - red**



If yes please list:
(answers in no particular order)

Deliberate, non-authorised releases, whether past or current.
Military or terrorist actions against nuclear facilities or those with use of radioactive materials – depleted uranium, etc
Planned: processing NORM/TENORM (materials with elevated or enhanced natural radioactivity) occurring in usually called “work activities” (Radiation protection 112, paragraph 40 Council Directive 96/29EURATOM)Existing: residues from work activities
accident in radiological facility/lab.
Planned: - Nuclear medicine waste disposal - Scientific & pharmaceutical wasteAccidental: - accidents in medicine – use of open sources in therapy (this sites are not regarded as nuclear facilities in the legislative) c) radiological accidentsExisting:a) … after any accident – radiological or nuclear– abandoned former military siteswhich are now used for public activitiesTENORM of any origin
ACCIDENTAL (or EMERGENCY ?) Malevolent use-terroristic use (may be not directly to biota, but biota may be involved)Are medical use of radionuclide also considered in the above situations? I think YES
- Under “planned”, the abandonment or release from all regulatory control of a licensed facility is missing; - Under “existing”, perhaps there should be some recognition of passive remediation as a common strategy, e.g. sometimes facilities operated under

2. Here is a list of assessment purposes for which the ERICA integrated approach can be used.

General environmental protection - e.g. in Conventions
Protection of specific ecosystems, natural resources, media and/or species
Provision of Information for stakeholders
Site selection of facility
Planning of decommissioning and/or clean-up
Specification and review of permits/authorisations
Monitoring - Design or relevance of existing monitoring/surveillance programme
Emergency planning for design-basis scenarios
Assess environmental damage following accident
Environmental side-effects of remediation

Do you envisage an assessment purpose that is missing from this list?

Yes – green **No – red** **No answer - grey**

If yes please list:
(answers in no particular order)

Site selection of a waste disposal
1. Formulate relevant requirements for NORM/TENORM industry; 2. Provision of information for decision makers; 3. investment cost-benefit analysis; 4. remediation, land reclamation efficiency and effectiveness analysis; 5. implementation of ISO 14000 standard
no - Recently there is an interest in so called “risk-based” design modifications, eg for new reactors
Radiological accidents of any kind and in any environment including indoors
Unless included in the Specification…: Safety Case of a nuclear facility (not necessarily related to licensing but could be also for e.g. internal/interim use) – this is highlighted now in the Finnish post-site-selection situation
- The concept of “adaptive management” might be worthy of special mention either as a separate item or possibly in the context of monitoring; - The concept of “engagement of stakeholders” would be more appropriate than simply “provision of information”, given the user-friendly tools and resources developed by ERICA

3. How important are the following headings (taken from the above list) to the problem formulation step for the following assessment purposes?

DEFINITIONS (taken form the Draft D-ERICA)

Driving force	An influence that causes change, e.g. legislation,
Conceptual model	Representation of the environmental system and of the physico-chemical and biological processes that determine the transport/transfer of contaminants from sources through environmental media to ecological receptors within the system.
Assessment criteria	Preparation of a procedure for summarising the results of the evaluation and takes, as input, management criteria specific to a particular environment which may influence the relative importance of different characteristics.
Risk characterisation	The synthesis of information obtained during risk assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the adverse effects likely to occur in a population or environmental compartment, together with identification of uncertainties.
Stakeholder involvement	Take into account views of stakeholders. A stakeholder is defined as anyone who has an interest in or considers themselves to have an interest in the issue and therefore it goes beyond "representatives" of groups to include "interested members of the public"
Source identification	Identify anything that may cause radiation exposure — such as by emitting ionising radiation or by releasing radioactive substances or materials — and can be treated as a single entity for protection and safety purposes.

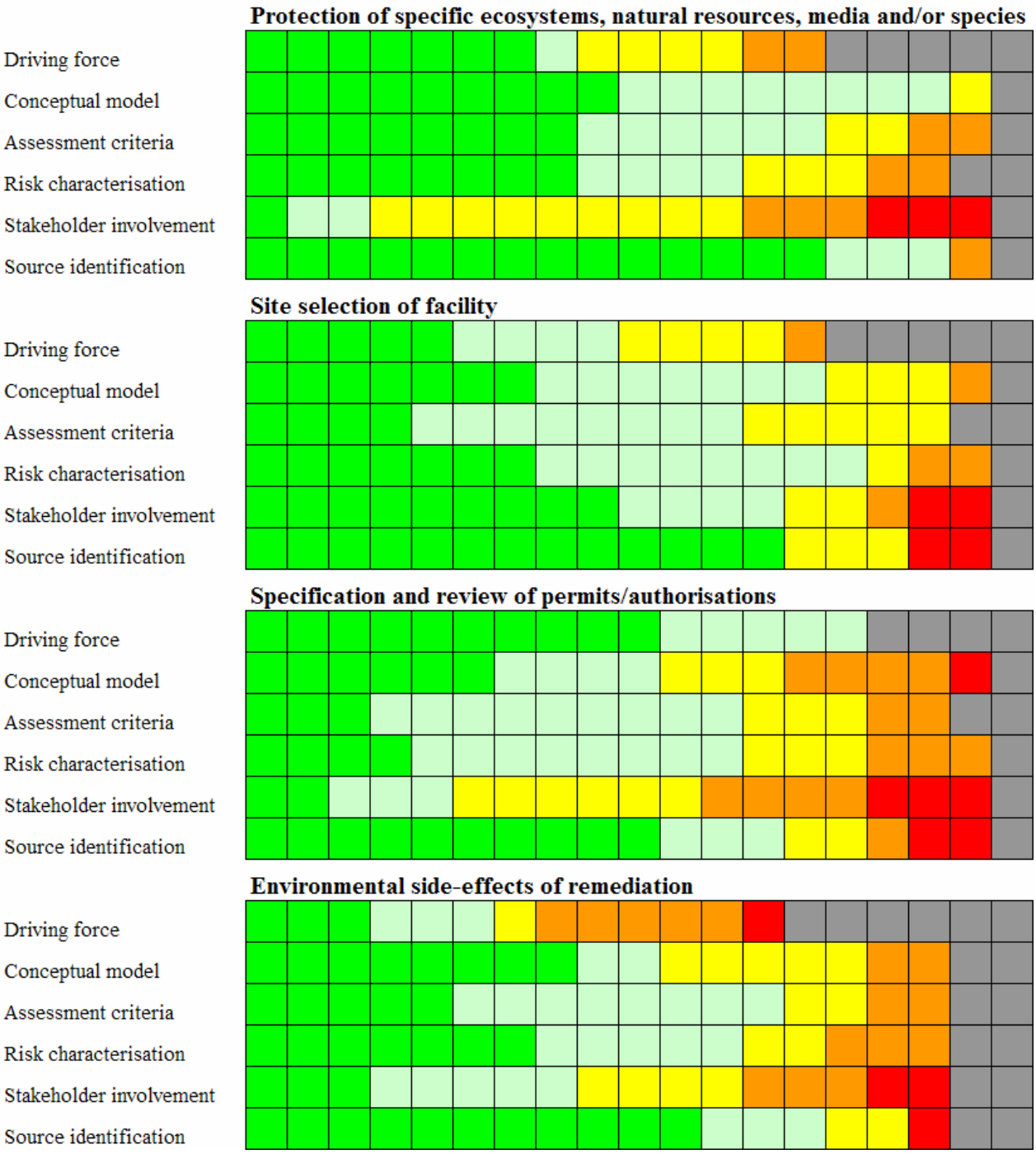
Four assessment purposes:

3a - Protection of specific ecosystems, natural resources, media and/or species
3b - Site selection of facility
3c - Specification and review of permits/authorisations
3d - Environmental side-effects of remediation

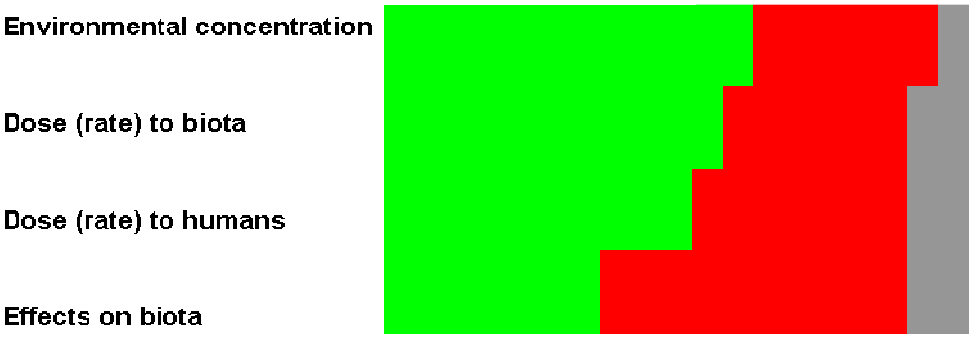
		1 (low relevance)	2	3	4	5 (high)
Driving force						
Conceptual model						
Assessment criteria						
Risk characterisation						
Stakeholder involvement						
Source identification						
Other	**List -**					

Ranked results from high to low relevance:

5 - high	4	3	2	1 - low	No answer



4. Which assessment criteria have you used for radiation protection to biota?



If "effects on biota" or "others" is chosen, list:

"Effects on biota"

- cytogenetic damages, e.g. micronuclei test, comet assay
- biometric, #, stress enzymes, stress metabolites, DNA damage, gene expression
- mortality, changes in reproduction, morbidity, genetic effects, adaptation
- indirectly, by applying FASSET/ERICA method/derived limits

"Others":

- Population growth and reproduction; average resistance to acute ionizing irradiation in experiment
- we sometimes look at uptake or bioavailability as a complementary indicator (not a criterion)

5. In the case of a complex assessment (i.e. use of Tier 3 of the ERICA tiered approach), the results of the assessment will be: doses (rates), effects data for those dose rates, probability distributions of doses (rates) and possible "guidance for deriving benchmarks" for a given endpoint or organism.

Knowing that these will be the outputs of the ERICA Tier 3, what elements of the *problem formulation* will enable you to evaluate the results of the assessment? List.

(answers in no particular order)

Risk characterisation
Inclusion and specification of the most vulnerable species, biota or compartment of the environment (e.g. soil compartment and rodents for radon exposure)
Will vary from assessment to assessment, depending on the context.
From my point of view – reliable data on radiation absorbed dose rates for biota or humans and their harmful effects. Subsequent decisions (ecological, political, medical, societal, economical, etc.) must be based on them primarily.
Dose rates and probability distributions
doses (rates), effects data for those dose rates
Risk characterisation

Among the elements of the “problem formulation”, it includes ecological, political and societal issues, notwithstanding economical issues. However, this is not an isolated decision, and it should be put in perspective together with consideration regarding protection of the population as well as other risks.
Among the elements of the “problem formulation”, it includes ecological, political and societal issues, notwithstanding economical issues. However, this is not an isolated decision, and it should be put in perspective together with consideration regarding protection of the population as well as other risks.
all of them
TRACEBILITY at all levels: environmental pathways considered, parameters used to derive environmental concentrations and related doses; how dose effectt relation was derived using which data; I wold like to have control over the validity of the output in order that if questioned by an end user/contractor I would be able to justify the result.
Driving force, Source identification, Assessment criteria
To achieve that goal, the entire assessment needs to be built very carefully and consistently; I do not see this as a matter of only problem formulation as such
- The conceptual model is critical to the global interpretation of actual risks; unfortunately most models are still too generic in terms of addressing site-specific ecological contexts; hence sophisticated quantitative results from a Tier 3 assessment are difficult to use; - Assessment criteria also often suffer from being only semi-quantitative, making it difficult to apply Tier 3 results
No answer
No answer
No answer
No answer

6. A purpose of an assessment might be to determine whether an appropriate level of protection of the environment against ionising radiation has been achieved.

Would the pragmatic approach to describe effects to individuals be acceptable to achieve this goal?	**Yes**	**No**

Yes – green **No – red** **No answer - grey**

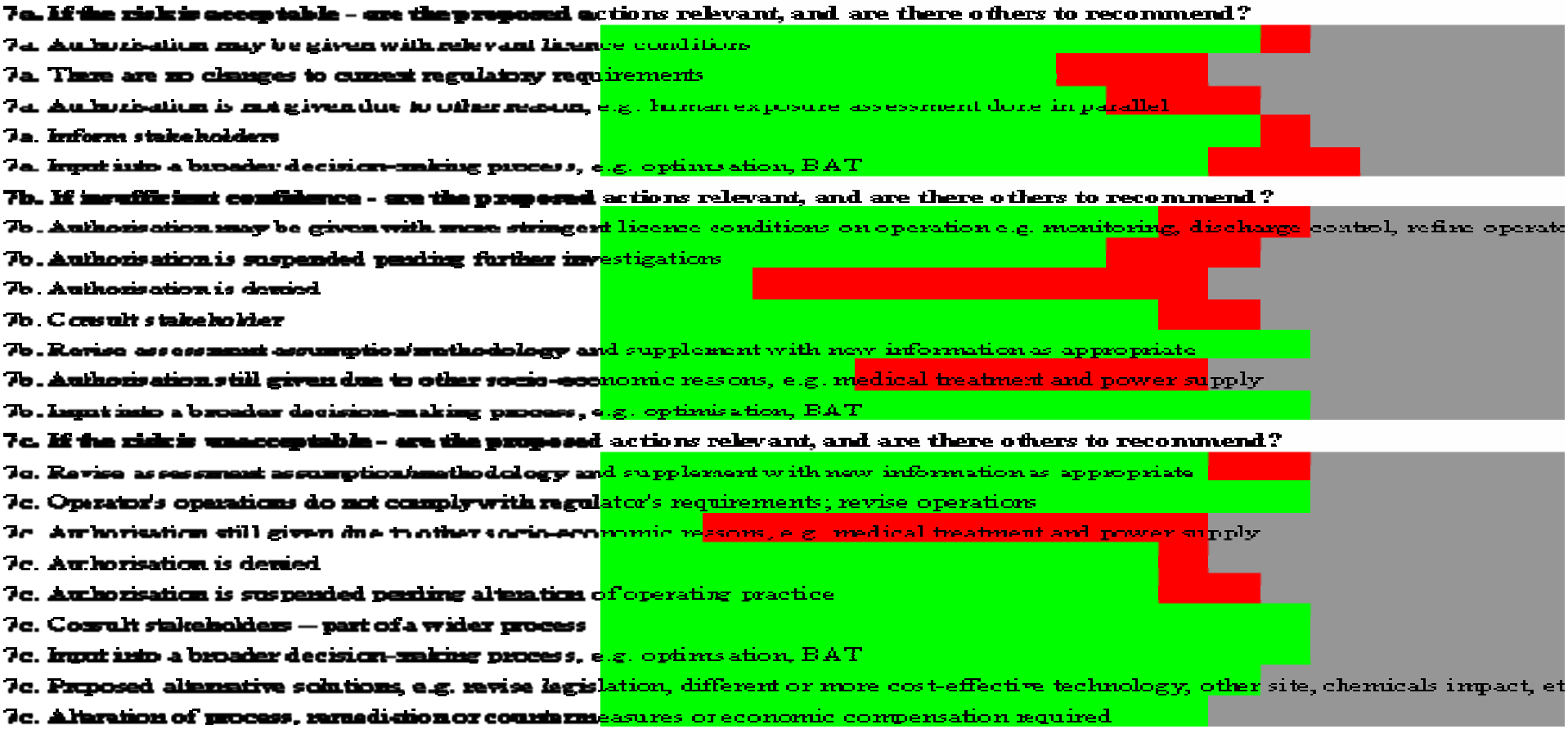
If not, what would be required?
(answers in no particular order)

That would be only one possible input and possibly not (an)/(the most) important one.
Yes - It is only first (preliminary) step in the process of establishing the appropriate level of environmental protection due to high level of variability on individual sensitivity to radioactive factors. The assessments on population level are the more suitable for this goal.
effects to individuals should be followed by analysis of possible effect to ecosystem
Protection of the ecosystem in general, as a whole.The knowledge and the observation of the environment with the eye of a naturalist/taxidermist could help to judge the relevance to carry out an assessment.
Protection of the ecosystem in general, as a whole.The knowledge and the observation of the environment with the eye of a naturalist/taxidermist could help to judge the relevance to carry out an assessment.
Estimated population-level effect
Effect on population level at least, preferably at ecosystem level, though this may not be possible or realistic to achieve. But I think the reference organism concept and the individual damage estimation may be very difficult to defend
Depends on how the effect to individuals is evaluated. The evaluation of no effect from a local observation on, may be, a poor number of subjects belonging to only some species is not a guaranty of an appropriate level of protection. The levels of “no effects” have to be results of preliminar and indepedent studies in which a large community of expert and stakeholders participated.
Yes and no, depends how the assessment has been carried out and on the details of the “pragmatic approach” and the supporting discussion

B. Decision-making following an assessment

7. Once an assessment is completed, three outcomes exist: a) the risk is below concern; b) there is insufficient confidence that the risk is below concern; or c) the risk is of concern.

This is dependant on the pre-defined problem formulation set criteria. In each case, the assessor can recommend possible actions.



[ERICA]

8 At the Stavern EUG Consensus Seminar, participants reached consensus on a number of areas, including the two following management issues.

Harmonisation of the general principles for management of the protection of the environment for all contaminants
General management principles should be harmonised for all contaminants including radioactive substances, leading to a 'multi stressor' approach in the future. However, implementation will vary. There should be a general aim to develop a common best practice, and not adopt inappropriate principles in radioecological management.

The need for internationally agreed dose limits for protection of non-human species
There is a need for international harmonisation in the area of environmental protection. This might be achieved through less restrictive instruments than dose limits. Internationally agreed 'no effect' or exemption levels in combination with generic assessment guidance might be sufficient. Having harmonised approaches may facilitate interaction with stakeholders and addressing trans-boundary effects. Regional flexibility, which allows the setting of more stringent standards, is important.

8a. In your opinion, which general management principles should be harmonised? List.

(answers in no particular order)

Precautionary and proportionate principles.
Internationally agreed no effect or exemption levels would be helpful, as well as internationally agreed assessment procedures for the protection of the environment with the provision for setting more stringent standards on a national level. A general harmonisation of management principles seems pretty utopic to me.
It is at the level of the general overall approach, and in developing best practice.
Unification of sampling and other procedure of gathering of primary data as far as possible; comparative assessment of toxic effect of radioactive and non-radioactive substances; general principles of dose estimation, statistical analysis, etc.
General risk assessment approach (not necessarily details of methodology); stakeholder involvement.
Risk to human health; risk for ecosystems
European waste catalogue, radioactive waste classification system, carcinogenic and mutagenic agents list.
Principle of risks hierarchy. The risk has to be taken into account in proportion of its significance and has to lead to a reasonable management taking into account economical and social considerations.
Principle of risks hierarchy. The risk has to be taken into account in proportion of its significance and has to lead to a reasonable management taking into account economical and social considerations.
Process for selection of VECs; protection of populations (not individuals); tiered approach; implementation of risk based monitoring and/or mitigative measures
criteria, methodology, parts of parameter values to be used

Similar approach to environmental pathways and prediction of environmental concentrations; similar approach to derivation of dose effect relationship; similar approach to targets (will reference organism concept be considered or evaluation at population or ecosystem level; if reference organism concept accepted use of same reference organisms); similar approach to risk characterisation; similar approach to decision making (e.g. standardized tiered approach); system for comparing and adding risks in a multiple stressor situation should be set up and accepted.
Unified legislation/legislative compliance with a common best practice
There should be a general aim to develop a common best practice. So we should harmonize the best practice for a basic multi stressor set of contaminants including radioactive substances
The idea of no effect levels, by considering the most sensitive species which are present in the context considered, that is for different local ecosystems. These levels have to be the result of a strict cooperation work of a large (in discipline and in experience) participation of experts which have also to include knowledge of the different current reality of possibly all the countries.
All – it is stupidity leading to big confuses and low confidence to develop/maintain different principles in any area where there is potential overlap
- A common definition of ”acceptable” risk is the main problem area and it is not as straightforward to define as it would appear; most importantly, it is not just a matter of defining the magnitude of the risk in terms of effects on mortality, reproduction, etc., e.g. as in defining quantitative limits for a deterministic or stochastic effects on individuals. Risk in the real world usually comes down to more fundamental issues of ecological context, e.g. in terms of the long-term nature of impacts on a spatial and temporal scale, the ”value” of the species affected, the exact number of individuals or populations affected, the resiliency of the biological community, etc.

8b. Should internationally agreed no effect or exemption levels be developed?

8b. Do you agree that there should be internationally agreed dose limits for the protection of non-human species?

Appendix 4: List of questions for group discussions

Session 1. Questionnaire results

Q3

- How do you define "driving force"?
- Why is there such a discrepancy in the answers of stakeholder involvement? Is it due to the category of people answering the questionnaire? Is it because it is limited by the current countries' legal framework?

Q4. Discuss pros and cons of proposed "others" and "effects on biota"

"Effects on biota":

- cytogenetic damages, e.g. micronuclei test, comet assay
- biometric, size, stress enzymes, stress metabolites, DNA damage, gene expression
- mortality, changes in reproduction, morbidity, genetic effects, adaptation
- indirectly, by applying FASSET/ERICA method/derived limits

"Others":

- Population growth and reproduction; average resistance to acute ionizing irradiation in experiment
- we sometimes look at uptake or bioavailability as a complementary indicator (not a criterion)

Q6. Why the 50-50 split in answering: would the pragmatic approach to describe effects to individuals be acceptable to achieve this goal?

Session 2. EUG experiences

- Regulation of NORM-TENORM. Trend is to treat them in the "exiting" situation but there is a shift towards incorporating them within "planned". How are they treated in your country; and views on how to regulate them?
-
- What criteria would you envisage to be used for protecting specifically the environment from ionising radiation, e.g. no effect and exemption levels, dose limits, baring in mind the forthcoming ICRP recommendations on reference animals and plants?

- As most countries appear not regulate specifically for the protection of the environment (or biota?), what do you think is needed for your country to begin this process?

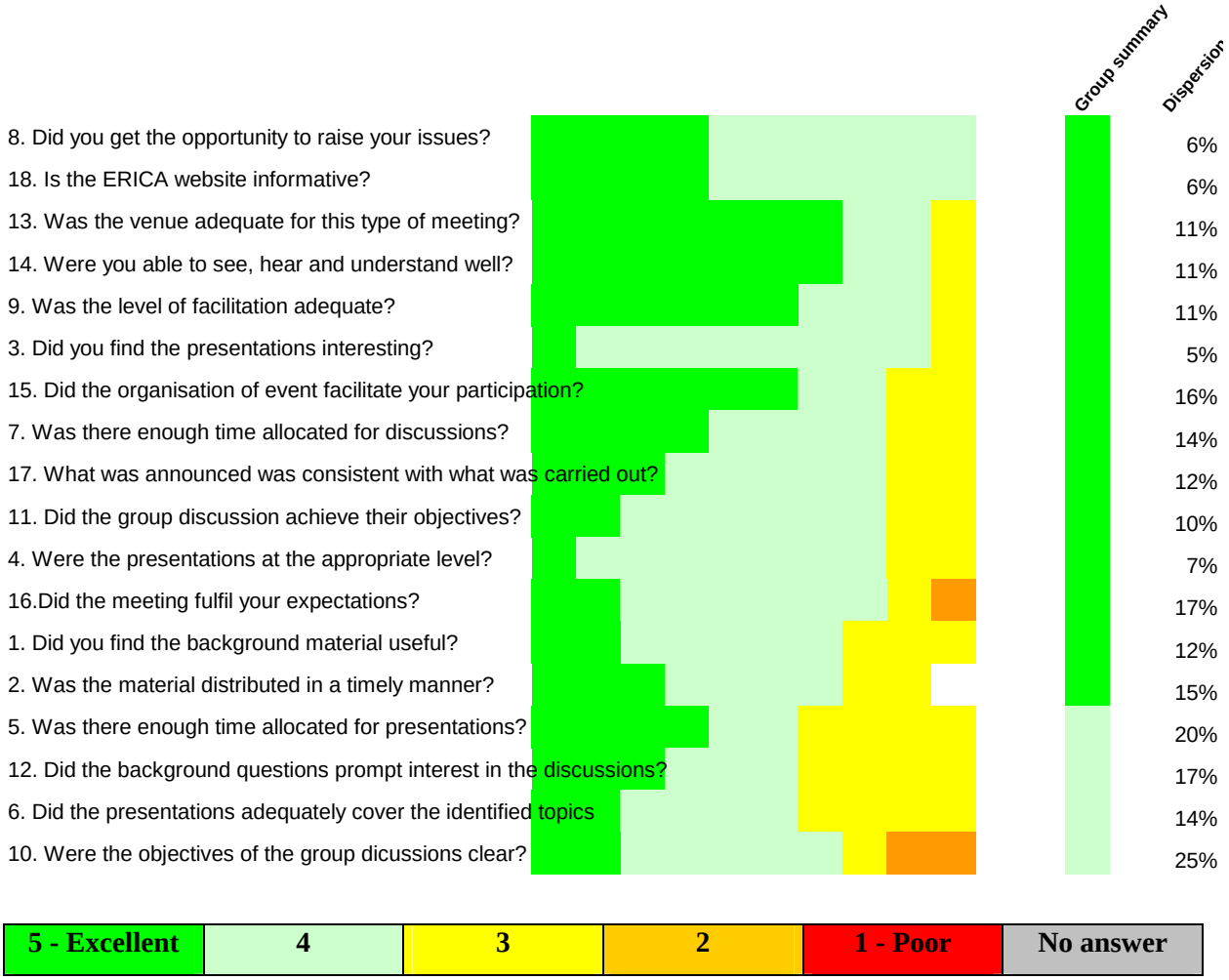
Session 3. D-ERICA

- Section 2.1. How can you devise assessment criteria to interpret the result of Tier 3 assessment. Tier 3 will provide:
  - ◊ doses (rates),
  - ◊ effects data for those dose rates,
  - ◊ probability distributions of doses (rates), and
  - ◊ possible "guidance for deriving benchmarks" for a given endpoint or organism.

- Section 2.7. What would people like to see under– decision-making post assessment?

Appendix 5: Feedback questionnaire

Here is the analysis of the 10 EUG feedback questionnaires, as always carried out following each EUG event. Analysis carried out by Partick Momal, IRSN.



Interpretation of results

Out of 18 questions, only 4 score less than excellent collective answers, but received nonetheless positive answers. These 4 items are:

5. Was there enough time allocated for presentations?

12. Did the background questions prompt interest in the discussions?

6. Did the presentations adequately cover the identified topics

10. Were the objectives of the group discussions clear?

Two participants (out of the ten who answered the questionnaire) didn't think the objectives of group discussions were clear enough. This is the least favourable score within this questionnaire. They were also doubtful about the fact that presentations adequately covered the identified topics and that enough time was available.

Globally, however, answers are positive and more positive than the feedback questionnaires of previous events.

Of particular interest are positive answers concerning the ERICA website and the timely distribution of the material prior to the event.

List of individual comments (not in any given order)

Preparation

- It was distributed well before hand

Plenary sessions

- Mining presentation very much longer than necessary – should have been forced to focus (but difficult!)
- Not enough discussion about the scientific and technical topics / We are not legitimate to discuss about these thematics / presentations by EUG members was very interesting [comment repeated under group discussions and general feedback]
- It might have been more helpful to focus on exactly how decisions are made, so seeing how ERICA would fit in – i.e. problems and opportunities

Group discussions

- Too heavy questions
- The questions for discussions were rather ambiguous – not clear whether direct views or evaluation of questionnaire results necessary.
- The first group discussions could have been a bit more focused, but later discussions very good
- Not enough discussion about the scientific and technical topics / We are not legitimate to discuss about these thematics / presentations by EUG members was very interesting

Organisation

- Evening event appropriate and interesting
- Very good!

General feedback

- I would have liked more input and discussion of problem formulation
- Not enough discussion about the scientific and technical topics / We are not legitimate to discuss about these thematics / presentations by EUG members was very interesting