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GUIDANCE NOTE NO. 2003/1.
CRITERIA FOR "CLEARANCE": CONTROLLING THE RELEASE OF SOLID MATERIALS OF VERY LOW AVERAGE ACTIVITY FOR REUSE, RECYCLING AND DISPOSAL
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1. Background

1. Radioactive materials have been generated in large quantities in the nuclear fuel cycle used for electricity generation, propulsion units, power sources and nuclear weapons. All these operations result not only in the generation of high, medium and low level radioactive waste but also generate low level radioactive waste, which includes large amounts of radioactively contaminated materials like concrete, glass and metals which may have low average levels of radioactivity. The disposal of such materials into the environment whatever their level of contamination or specific activity leads to an increase in the radiation exposure to members of the public above that received from natural background radiation and historic contamination sources e.g. weapons fallout.

2. In order to ensure the safety of members of the public and workers, all activity associated with the production, handling and disposal to the environment of radioactive materials is subject to legal controls in all developed countries through systems of

licensing and reporting. The aim of such systems has been to ensure that no member of the public may receive an exposure from any radioactive source greater than some specified amount.

The basis on which this legal absorbed dose limit is calculated is the model of the International Commission on Radiological Protection (ICRP). Governments have considered advice from the ICRP to represent the best authoritative position on the relation between radiation exposure and health. The ICRP"s most recent recommendations for a system of radiological protection are contained in their Publication 60 (1991). These take into account research into the risks of radiation exposure published up to 1990. The advice of ICRP, although not mandatory, has formed the basis of legal systems of protection in most countries of the world.

3. In Europe, all member states of the European Union (EU) are required as of May 2000 to follow Directive 96/29/EURATOM – the Basic Safety Standards (BSS) Directive (EU 1996). This gave the reference level for limits for exposure to members of the public as an effective dose of 1mSv per year. The mean level of natural background exposure gives about 1mSv per year excluding contributions from Radon gas which add about 1.4mSv if the alpha weighting factors of 20 are employed.

4. In the last 15 years there has been increasing debate among the radiation risk community of scientists and medical researchers about the health effects of very low dose radiation exposure, particularly from internal fission-product isotopes e.g. (Nussbaum and Koehnlein 1994).

This has followed a number of discoveries which have not been considered or incorporated into ICRP60. They include:

- Epidemiological evidence of cancer and other ill health in populations exposed to internal contamination by the Chernobyl accident.
- Epidemiological evidence of increases in leukaemia in children living near nuclear sites.
- Epidemiological evidence of cancer excess in adults living near radioactive contamination sources.

- Subtle genetic effects in minisatellite loci in children and animals exposed to internal contamination from Chernobyl and in experiments.
- The discovery of “genomic instability” whereby a single radiation track through a cell causes an increased level of general mutation in offspring of the cell.
- The discovery of the “bystander effect” whereby cells local to a cell which has been traversed by a radiation track also exhibit genomic instability; on a macroscopic scale, such effects show themselves as chromosome instability and aberration, a phenomenon associated with cancer.
- Theoretical arguments about multiple hits to cells (Second Event theory) the location of certain DNA seeking isotopes (Sr-90, Ba-140), transmutation, hot particle doses and Auger emitters all of which are believed to carry enhancement of hazard over the same averaged dose delivered externally.
- Experimental (cell biology and epidemiology) and theoretical falsification of the linear no threshold theory of dose response which underpins the ICRP risk model.

5. In the last ten years, with the increasing decommissioning of nuclear power stations and other nuclear sites, there has been considerable pressure for the adoption of a *de minimis* level or levels of activity below which materials are deemed to pose no health risk and may thus be classified as outside regulatory control. The release of substances of low radioactivity from licensed sites for re-use or recycling is permitted under the provisions of the EU’s BSS (Article 5.2), in which it is termed “clearance”.

The quantities of materials involved in these considerations can be very large. One decommissioning project currently being planned in the UK (Dounreay) is expected to generate 153,000 m^3 of materials which are contaminated at levels which may make them eligible for clearance. The OECD estimates that over the next few decades dismantling nuclear plant world-wide will generate 30 million tonnes of metals alone worth 10 to 15 billion dollars as scrap metal

There are four main driving forces behind proposals to permit clearance at the highest levels of incorporated radioactivity. These are:

- Removing radioactive materials from sites so that the sites may be "remediated" (meaning that the radiation levels and contamination are reduced to some acceptable target level) and sold for development thus increasing revenue for the owners of the contaminated land [1].
- Saving the owners of the licensed site or the producers of the contaminated material the costs of safe disposal.
- Providing a revenue to the owners of the material through its sale for reuse or recycling.
- Providing inexpensive material to Society for various purposes e.g. recycled steel and other metals for manufacturing, industry feedstock, ballast for roadbuilding, backfilling etc.

On the other hand, there are equally strong arguments made to limit the disposal of such materials either totally or on the basis of strictly controlled and low levels of specific activity and analysed specified isotopic and radioactive particle content based on concerns over:

- The huge quantities of slightly contaminated material that may be involved and the resultant collective dose increases to large populations.
- The belief that the health consequences of low dose exposure to internal man-made radioisotopes are inadequately modelled through the concept of absorbed dose owing to averaging errors.
- The perception that clearance may involve procedures that may encourage or facilitate illegal disposal of more radioactive material through dilution to the specified level or by straightforward law-breaking.

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[1] Note: Although it is the purpose of the current Guidance to limit itself to clearance rather than to explore the more complex issues of land remediation, there is an indistinct boundary between the two because materials which were present on the primordial site itself have in many cases become contaminated and may be considered for unrestricted reuse. This is known to have happened already on some UK defence establishment sites.

- The ethical position that Human Rights Ethics must take precedence over Utilitarian Ethics and that no one should be put in a position where they may be contaminated against their informed wish by a substance that carries finite risk of harm however small.

There are also pragmatic considerations. For example:

- If clearance levels are set too stringently, the cost of analysis and characterisation may exceed the value of the land or materials or the savings from not having to dispose of materials in a licensed area.
- The GMO (Genetically Modified Organisms) effect: if it became known that radioactive materials were being diluted into non-radioactive material the public would refuse to buy the items made with such material and this would provide a powerful economic reason for prospective purchasers to refuse to use such material and gain a competitive advantage.
- The increasing sophistication of the public and their NGO advisors enables them to analyse material to the same level of sensitivity as the nuclear industry or the risk agencies.
- There may be adverse political consequences of agreeing to permit clearance whether scientifically justified or based on public perception of risk.
- Future litigation may arise in the event of new science relating to low dose radiation and cancer or other ill health.

This area therefore involves a tension between those who wish to ensure the minimum exposure to members of the public and those who wish to reduce the financial burden of having to dispose of radioactive materials in a secure facility, including those who argue that the reuse of materials helps industry to meet "sustainability" targets.

For this reason, the Committee has examined the issue carefully and has made a number of observations and recommendations.

2. Political considerations

The regulation of Society in a democratic system involves forms of rules and laws which are developed with the intention of maximising the utility of all who are part of the system. In a modern formulation, complex tensions are believed to be resolved through a combination of legitimisation of government through voting and response by government and other politicians to behaviour which may be partly controlled by media and human exchange and which is accessible through polling and focus groups. Government can only be legitimate if it is competent. In areas of complex scientific issues where there may be low probability, high impact risks, proper scientific advice is crucial. A recent example of incorrect scientific advice was that given to the UK government by the scientific committee on Spongiform Encephalopathy (Mad Cow Disease). As a result of policies based on this advice, many people have now died in the UK and the UK government has learned a valuable lesson. In an example which is more relevant to the question of radioactive exposure, there has been considerable debate in the last ten years following new scientific discoveries in the field of low dose exposure, particularly from internal fission products. These include the discovery of genomic instability, the discovery of subtle minisatellite mutations in children exposed following Chernobyl and the increase in infant leukaemia in Europe in several countries in those who were *in utero* at the time of the Chernobyl fallout.

As a consequence of the atmosphere of uncertainty about low dose exposure generated by this and other evidence the UK government has set up a new committee to examine the risk model employed as a basis of its legislative controls in the area of radiation exposure. This Committee Examining Radiation Risk from Internal Emitters (CERRIE) was purposely set up in an oppositional structure with scientists from the conventional establishment opposed by scientists critical of the current risk model. Its remit is to report on the safety of the present risk model for estimating the health consequences of internal exposures. The idea is to prevent the government from making, in the area of radiation safety, mistakes like those which led to Mad Cow disease. This committee is due to report in early 2004. At the same time, the European Parliament voted in May 2001 to ask for a reassessment of the International Commission on Radiological

Protection (ICRP) risk models which were applied to estimating the consequences of the Chernobyl accident in Europe. By 2003, the ECRR Committee had completed its own deliberations on the adequacy both of the ICRP model and of its ethical base. The committee concluded that the ICRP model was unsafe and inadequate. It presented its own risk model and recommendations in January 2003 [ECRR2003]. These are the basis for the present guidance note on clearance.

3.Health Detriment Estimates

The ICRP estimation of health detriment following low dose exposures currently involves calculations which apply risk factors for fatal cancer and heritable genetic illnesses to collective doses to populations. These collective doses are themselves calculated through complex modelling based on estimating environmental dispersion, human exposure and biokinetic behaviour of the isotopic substances and their physical forms. Following the calculation of organ doses the ICRP risk model applies risk factors which are almost entirely deduced from linear extrapolations of external acute radiation exposures at high or moderate dose. This procedure has been the subject of considerable scientific criticism and more recently has been considered in some depth by this committee [ECRR2003]. The committee concluded that the methodology and modelling of internal exposure at low dose by the ICRP was wholly inadequate. In ECRR2003, the committee presented a new risk model which allowed for various enhancements of risk due mainly to the anisotropy of ionisation which may result from internal exposure to certain man made nuclides and also to sub-micron diameter hot particles. In the committee's opinion, based on epidemiological and theoretical considerations, such exposures may result in high local cell doses even in situations where average doses are very low, leading to enhancements of mutagenic efficiency. For further information on the model and its predictions for various isotopic exposures refer to ECRR2003.

4. Exposure Estimates

Current political attitudes dictate that legal constraints on the clearance of radioactively contaminated solid material will be determined on the basis of exposure estimates which use the

ICRP external irradiation model as the calculation engine, moderated by assumptions about public attitudes to tolerability of risk and further assumptions about "critical groups" of exposed persons and the pathways by which they might be exposed. In the EU there is some disagreement, for example over the recycling of metals. Here the German approach was to recommend that:

> "In the case of actinides the use made of the slag into which these nuclides pass when the scrap is melted down has proved to be dose determining." (SSK1998, sect. 4)

The response in UK was that:

> "The scenario used by SSK to derive these clearance levels is very conservative and is not applicable to the recycling, reuse or disposal of large quantities of materials in the UK" (DETR 1998, 6.3)

This difference of opinion led to differences in proposed clearance levels; in some cases they differed by more than an order of magnitude.

The activity of the material being considered is determined using a bulk analysis measurement. In the analysis of contaminated soil at Harwell in the UK 50kg bags were placed on a rotating stage and presented to a large volume scintillation counter to examine the activity and mean isotopic content. This allowed estimation of the gamma dose that a person might receive if the soil were to be used, for example, as backfill on a playground. However, the material might have within it respirable dust particles of Plutonium Oxide. The dose from Plutonium Oxide particles to local tissues varies significantly with the diameter of the particle. Particles ranging from 0.5 microns to 2 microns deliver their dose to tissue cells within a 30 micron radius. These highly localised doses range between 7.3 and more than 400,000Sv per year. (This assumes a density of 11.6, Alpha decay energy of 5.2 MeV, alpha particle range 30 microns and Relative Biological Effectiveness factor of 20). Therefore very considerable doses to local tissue may result from inhalation of sub-micron Plutonium particles. These dose regimes also involve increasing probability of multiple sequential tracks to individual cells within their repair replication cycle, which increases the probability of double strand DNA breaks and second event sequences. These lead in turn to fixed mutation and an increased probability of cancer.

Since sub-micron Plutonium particles are a common contaminant of soil, concrete and other materials that may present with low average activity, the rules for releasing such material from regulatory control or clearing such material from a nuclear licensed site may be inadequate to protect members of the public. This is particularly the case for certain predominantly alpha emitters in particulate form which do not register a gamma signal on analysis (e.g. PuO2, UO2). In passing, the committee points out that risks from particulate doses result from a definite window of local dose range which lies between very high multiple track cell killing doses and very low doses that give rise to single tracks to cells within the repair cycle time of about ten hours. The higher the specific activity of the particle constituent, the smaller the size of particle that will deliver this intermediate dose.

Research within the International Atomic Energy Agency, the EU and the UK leading to the derivation of Clearance criteria analysed possible exposure routes, including the generation of inhalable dust from landfill disposal, the crushing of aggregates and the smelting of metals and the subsequent use of slag and dust in a wide variety of commercial products. The committee is gravely concerned that the methodology employed has led to a large underestimation of hazard. This concern arises from two factors: first, the fact that the mass of material generally assumed to be the “averaging volume” for characterisation is of the order of one tonne, which would allow for enormous inhomogeneity of specific activity; second, the fact that the health impact of inhaled “hot” or “warm” particles is one of the scientific uncertainties awaiting resolution.

5. Current Practice

The current practice (or proposed practice) in Europe and the US is that all solid materials must be surveyed before release or certified free for release from legislative control. Since the Euratom 96/29 transposition in Europe in May 2000, the European Member States have had discretion to set threshold concentrations below which release of materials is permitted, with no condition on their subsequent fate. Information on practice in most EU states is not available to the committee at the present time, since the European Commission has not delivered on an undertaking given in October 2000 that " … a country by country overview of the implementation of the Basic Safety Standards, in particular with regard to the concept of clearance …….. is a top priority …" (EC 2000).

Average concentrations are known to have been proposed, based on assumptions about the relative radiotoxicity of specific isotopes. In DETR 1999, for example, isotopes were assigned to three groups with Clearance values ranging between 0.1 and 100 Bq/g. Ultimately, however, the UK Government decided to retain the long-standing non-isotope specific value of 0.4 Bq/g for all anthropogenic nuclides. This is a potential source of confusion since this value of 0.4 Bq/g is embodied in an Order (the Substances of Low Activity Exemption Order, or SoLA) which allows exemption from control under the Radioactive Substances Act 1993. By custom and practice it has been extended to permit waste disposal, and more recently *de facto* clearance and the remediation of contaminated land. The word "clearance" is not officially used in UK. In passing the committee notes with concern that there has been some unacceptable interpretation of this SoLA rule in site remediation, e.g. at Harwell in Oxfordshire where historic levels of contamination have been used as a baseline for the remediation process rather than the level of radioactivity which would be present on the site if no nuclear work had ever been carried out there.

In the USA, the current situation appears to be that all materials must be surveyed and only allowed to be released if the amount is "below the level that is considered protective of public health and the environment" (10CFR Part 20). It is not clear if this guide relates to clearance of large quantities of material from licensed sites. However, the dose limit that appears to be employed as a defining limit for exposure from these sources in all cases is 10μSv (1mrem) per year from any single source of exposure.

6. Anisotropy: molecular, atomic and particulate sources

One problem faced by regulators with regard to clearance and release is that of anisotropy of contamination of bulk solids. This is less of a problem with metals than with soil and concrete or other similar materials although there may be surface contamination problems. For example, soil and concrete may show very low levels of gamma activity when examined with a survey meter, and may show very low levels of contamination when 1 kg is analysed by radiochemical methods. However such solids may (indeed almost certainly will) contain micron sized hot particles and as such will, according to the models of the committee, represent a serious health hazard. The same is not the case for molecular or atomic sources which are uniformly dispersed in the material in question.

7. Ethical considerations

The present ethical underpinning of the risk framework of the ICRP as it is transposed into law in Europe and the US is firmly based in the principles of Utilitarianism which have been transmuted into what is now termed cost-benefit analysis. The committee has discussed this at some length in its recent report (ECRR2003) where it has pointed out that modern ethical considerations have rejected Utilitarianism in favour of Human Rights based arguments. The failure of Utilitarianism results from its inability to equally distribute utility, both wealth and "illth". Thus a Utilitarian ethic tolerates practices which confer advantage on some sections of Society at the expense of others on condition that the practice increases the general level of utility integrated over the whole of Society. Rights based arguments, on the other hand, begin with the assumption that all individuals have inalienable rights, believed to be self-evident truths. A major right is deemed to be the security of the person (this is enshrined in the UN Declaration of Rights) and the release of radioactive materials into the environment represents a clear infringement of this right since such materials contaminate the bodies of members of Society and carry a small but finite chance of causing serious illnesses like cancer. On this basis, discharges of radioactive materials to the environment represent an unethical practice, an infringement of human rights and must not be permitted under International Law.

7. Exposures resulting from the procedures associated with clearance.

Any procedures involved in clearance of contaminated nuclear sites will inevitably involve the possibility of releases of radioactivity to the environment. The committee is particularly concerned about inadvertent releases of contaminated dust, aerosols and gases to the environment occurring as a result of procedures associated with removal of contaminated material and movement within or outside nuclear licensed sites with a view to re-use or re-cycling. In addition, the final disposal in landfill or through destruction or corrosion of contaminated material cleared from nuclear sites must inevitably add to the radiation burden of the population.

8. Committee's Recommendations on clearance of materials from radioactively contaminated nuclear sites.

Regulators are referred to the recent report of the ECRR where models for calculating the health effects of exposures are given together with principles and recommendations for best practice in limiting exposures to members of the public and workers to ionising radiation. On the basis of these and considerations specific to the clearance of material from contaminated nuclear sites the committee recommends:

1. The committee has considered and rejected the employment of dose-based models for calculating thresholds owing to the difficulties relating to modelling dispersion, exposures and health risks.

2. Because of the quantities involved, and for other reasons outlined above, clearance from nuclear sites is not permitted under any circumstances. No material originating from a nuclear site may be released from regulatory control. Nuclear sites are to be made safe using the best available technology and are to remain closed, fenced, secured, guarded, protected and surrounded by prominent notices drawing attention to the presence of hazardous materials.

3. The committee is sympathetic to the arguments of small users regarding the need for practical regulations which do not

excessively hinder their actions whilst also protecting the health as far as possible of members of the public. Accordingly for small quantities of contaminated materials originating from such users a practical exemption threshold for release from regulatory control will be 25Bq/kg for all anthropogenic isotopes so long as they are uniformly distributed at the molecular or atomic level.

4. All such material destined for release from regulatory control must be analysed radiochemically and defined in terms of constituent isotopes and tested for the presence of radioactive particles using photographic emulsions, CR39 plastic or other best appropriate technology.

5. Release of material containing hot spots, hot particles or particulate material with specific activity more than two standard deviations from the mean activity of the bulk material is not to be permitted under any circumstances. Such material is to be packaged or sealed in some way so as to minimise release of any particles to the environment and stored above ground in a licensed facility.

6. There may be no intentional dilution of radioactive material into non radioactive or low level radioactive material in order to achieve any threshold for release.

7. Pre-existing and historic contamination of material destined for release (e.g. from weapons fallout and accidental releases) must be established in terms of defining what would exist in the material in the absence of any addition originating from processes carried out by the applicant (s) or their predecessors.

References

DETR 1998 Derivation of UK Unconditional Clearance Levels for Solid Radioactively Contaminated Materials DETR Report No. DETR/RAS98.004

DETR 1999 Consultation Paper: The Radioactive Substances Act 1993: Implementing the Revised Basic Safety Standards Directive Euratom 96/29 Department of the Environment Transport and the Regions March 1999

EC 2000 personal communication from European Commission Directorate General Environment Directorate C.1 Radiation Protection to Dr C. Lucas MEP; reference ENV.C.1/AJ/sfo D(2000) 520566

ECRR 2003, *2003 Recommendations of the European Committee on Radiation Risk: Health Effects of ionising Radiation Exposure at Low Doses for Radiation Protection Purposes* Brussels 2003 (Aberystwyth: Green Audit)

EU (1996), Council Directive Euratom 96/29 of 13 May 1996 laying down basic safety standards for the protection of workers and the general public against the dangers arising from ionising radiation". Brussels: Official Journal of the EC L159 Vol 39

Nussbaum RH and Koehnlein W (1994) "Inconsistencies and Open Questions regarding low-dose health effects of ionising radiation." *Environmental Health Perspectives* 102(8) 656

OECD 1996 Organisation for Economic Co-operation and Development (OECD) Nuclear Energy Agency's Co-operative Programme on Decommissioning of Nuclear Installations Task Group study of problems and possible criteria associated with the recycling and reuse of metallic materials resulting from decommissioning.)

SSK 1998 Strahlenschutzkommission (SSK) des Bundesministerium fur Umwelt, Naturschutz und Reaktorsicherheit Heft 16 (1998): Clearance of Materials Buildings and Sites with Negligible Radioactivity from Practices subject to Reporting or Authorisation: Recommendation of the Commission on Radiological Protection. ISSN 0948-308X