Consultation on ONR’s revised interpretation of ‘bulk quantities’ in the context of licensing nuclear installations for storage and disposal of radioactive matter

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Executive Summary

It is the UK government’s policy to dispose of higher activity radioactive waste through emplacement in a Geological Disposal Facility (GDF). Geological disposal involves placing radioactive waste deep underground where a suitable rock formation provides long-term protection by acting as a barrier against escape of radioactivity and by isolating the waste from effects at the surface. There is no facility currently available in the UK.

The Office for Nuclear Regulation (ONR) has no role in identifying the site for a GDF but the UK government has committed that a GDF would be subject to the requirements of the Nuclear Installations Act 1965 (NIA65) and be licensed by ONR. This licensing requirement would provide the necessary regulatory oversight to ensure that any future facility can demonstrate the high standards of safety and security required by UK law.

Our licensing framework does not currently allow licensing of disposal facilities. The UK government intends to update the law to include licensing of disposal facilities; which is one of the recommendations from the recent IAEA Integrated Regulatory Review Service Mission.

We expect that the UK government will take a similar approach to prescribing disposal as that previously taken for storage, requiring a nuclear site licence for installations designed or adapted for disposal of ‘bulk quantities’ of radioactive matter. NIA65 does not give a definition of what is meant by ‘bulk quantities’, meaning we must interpret its meaning when making licensing decisions.

This consultation relates to how we will interpret ‘bulk quantities’ when applying the revised legislation to make a decision to licence a future GDF. While addressing this matter, we are also seeking to update how we make licensing decisions relating to storage because of other recent changes to the law.

Although a licensing decision in respect of any disposal facility for higher activity radioactive waste is some years away, we consider it appropriate to progress work now to underpin such decisions to give clarity on application of the nuclear site licensing regime and provide assurance to communities potentially interested in engaging with the siting process. The consultation is entirely separate to the ongoing national siting process for a future GDF in England and Wales.
1. **Introduction**

1.1 The Nuclear Installations Act 1965 (NIA65) provides for a system of close regulatory control in which a nuclear site licence is granted to a corporate body to use a site for specified activities. The NIA65 also implements international conventions regarding nuclear third party liability.

1.2 The NIA65 precludes the installation or operation of certain nuclear facilities unless a nuclear site licence has been granted by ONR; these facilities include nuclear reactors and other installations that are ‘of a prescribed kind’.

1.3 Whilst NIA65 lists the types of nuclear installation that may be prescribed, for ONR to be able to grant a nuclear site licence, a facility must also meet the description of one of those prescribed in regulation 3 of the Nuclear Installations Regulations 1971 (NIR71).

1.4 NIA65 allows ONR to attach conditions to nuclear site licences as necessary or desirable in the interests of safety, or with respect to the handling, treatment or disposal of nuclear matter.

1.5 The 36 standard Licence Conditions (LCs) are non-prescriptive and set goals that the licensee must meet, amongst other legislative requirements, by making and implementing detailed safety management arrangements for their facilities.

1.6 ONR assesses whether a licensee has demonstrated that it understands the hazards associated with its activities and how to control them adequately. Central to this is the production by the licensee of an adequate safety case.

1.7 The safety case is the totality of documented information and arguments developed by the licensee that substantiate the safety of the facility, activity, operation or modification in question. The safety case provides a written demonstration that relevant standards have been met and that risks have been reduced so far as is reasonably practicable. The safety case is not a one-off series of documents prepared to obtain a nuclear site licence, but is a body of information that underpins all safety related decisions made by the licensee throughout its lifetime.

1.8 In addition to development of the safety case to underpin safe operations, the requirements of the LCs encompass the totality of the operator’s organisational capability and arrangements necessary to undertake its activities in accordance with the safety case.

1.9 The requirements and duties arising from the nuclear site licence are more stringent than the normal duties on employers under the Health and Safety at Work etc Act 1974 to protect the health and safety of its employees and the public because of the particular hazards associated with the nuclear industry, including the potential for accidents to cause widespread harm.
2. Nuclear Site Licensing and Bulk Quantities

2.1 Amongst the types of facility that may be prescribed, NIA65 refers to “installations designed or adapted for storing, processing or disposing of bulk quantities of radioactive matter”. The Act does not give a definition of what is meant by ‘bulk quantities’, meaning ONR, as the licensing authority, must interpret its meaning.

2.2 When defining what constitutes ‘bulk quantities’, it is useful to consider what Parliament originally intended when the legislation was passed as it is incumbent upon ONR to reach an interpretation of ‘bulk quantities’ consistent with that intent.

2.3 Parliamentary debate on the Nuclear Installations (Licensing and Insurance) Act 1959, the forerunner to the 1965 Act, records that MPs considered initial drafting of the legislation gave rise to potential for wider application than was intended. The result being to force nuclear regulation onto sites which presented a low hazard and subsequently limited risk to the public. This was considered to be disproportionate and burdensome.

2.4 Therefore, the term ‘bulk quantities’ was added as a discriminator to exclude those lower hazard sites and ensure that the nuclear licensing regime was targeted at only those sites which represent higher hazard and risk to the public. Further details on the explanation are given in the Annex.

2.5 To underpin decisions relating to licensing of installations designed to store radioactive matter, ONR, then part of HSE, consulted on its interpretation of ‘bulk quantities’ in 2011 and again in 2012. At that time, ONR’s interpretation was limited to the storage of radioactive matter and culminated in the publication of an interim position statement in November 2012.

2.6 The current interpretation of ‘bulk quantities’ is benchmarked against numeric values for individual radionuclides derived from Schedule 2 to the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR 2001), such that a nuclear site licence will be required for the installation and operation of a storage facility if it is designed or adapted to store quantities of radioactive matter at or above 100 times the levels set out in Schedule 2 to REPPIR 2001.

2.7 This interpretation was used by ONR to inform our decision to grant a nuclear site licence to Inutec Ltd for its operations on the Winfrith site in February 2019.
3. Why is ONR revising its interpretation of what constitutes ‘Bulk Quantities’?

3.1 In our 2012 interim position statement, we committed to keep our position under review, and reconsider our interpretation if appropriate. ONR considers that there are two reasons for revising our current interpretation of what constitutes ‘bulk quantities’; these are:

- to meet an EU Directive REPPIR 2001 was revised and is now superseded by the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR 2019); and

- a need to extend our interpretation of ‘bulk quantities’ to include application to disposal to facilitate implementation of government policy for disposal of higher activity radioactive waste.

3.2 ONR is not seeking to change the risk threshold for application of nuclear site licensing in relation to storage, but the impact of the change in legislation upon our current interpretation should be considered.

3.3 When considering the high-hazard inventory of a geological disposal facility (GDF), international standards and relevant good practice, ONR and the UK government consider it appropriate that a future GDF (in England or Wales) should be subject to the requirements of the NIA65 during its design, construction and operation, and be licensed and regulated by ONR.

3.4 Whilst a licensing decision in respect of any disposal facility for higher activity radioactive waste is some years away, ONR considers it appropriate to progress work to underpin such decisions to give clarity on application of the nuclear site licensing regime and provide assurance to communities potentially interested in engaging with the siting process.
4. Bulk Quantities in relation to Storage

4.1 Current interpretation

4.1.1 In order to consider the impact of changes to REPPIR upon our interpretation of ‘bulk quantities’ in relation to storage, it is worth explaining how ONR came to its current interpretation. ONR considered three possible approaches:

- **Volume** – this does not correlate well with hazard and risk. Some radioactive waste contains very little radioactivity, and even large volumes of such waste represent very little hazard or risk, whereas even very small volumes of some higher activity waste represent a significant hazard and consequently require greater degree of control to minimise the risk. For this reason, an interpretation based on volume was discounted.

- **Potential dose uptake** – this risk is not a directly measurable quantity. Quantifying this risk depends on a number of factors including the effectiveness of control measures in place to prevent or, where that is not possible, mitigate those risks which requires specialist assessment. For these reasons, an interpretation based on potential dose uptake was discounted.

- **Total amount of radioactivity** (measured in Becquerels) – this is an easily measured quantity, and when defined by radioisotope, a correlation with risk can be determined relatively simply using standard methods. For this reason, an interpretation based on total amount of radioactivity was chosen.

4.1.2 ONR sought to link its interpretation to a value (or values) in existing legislation, and considered the radionuclide specific values provided in Schedule 2 to REPPIR 2001 to be the most appropriate. It is worth noting that there are no internationally agreed standards in relation to this matter so the use of REPPIR values represents a pragmatic approach.

4.1.3 REPPIR sets out requirements for assessment of risks and emergency preparedness where there may be off-site impact from incidents involving radioactive material, and provides a schedule of radionuclide specific values as a simple means of comparison to a dose criterion during accidental release of radioactivity from the site. If a site holds radioactivity in excess of these values, the regulations apply to that site.¹

4.1.4 ONR considers that licensing should only be necessary in cases where the total quantity of radioactivity on the site is well above the threshold at which REPPIR applies. Assessment of the REPPIR values for the radionuclides that are most relevant to the nuclear industry concluded that a multiplication factor of 100 was appropriate.

¹ REPPIR 2019 has introduced various other exclusions; but the first check regarding applicability remains comparison of the site inventory against the REPPIR values.
4.2 Revised Interpretation

4.2.1 Implementation of the emergency preparedness and response elements of the Basic Safety Standards Directive 2013, which lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation and applies learning following the Fukushima Daiichi accident, led to REPPIR 2001 being replaced by REPPIR 2019.

4.2.2 As part of this revision of the legislation, the methodology used to derive the radionuclide specific reference values was updated, commensurate with scientific evidence and international good practice, to be more realistic and remove undue pessimism. The new methodology leads to a decrease the effective dose resulting from each Becquerel (Bq) released, and therefore, even though the dose criterion in REPPIR 2019 is lower than REPPIR 2001, more activity can be released before the dose criterion is exceeded; consequently the majority of the radionuclide specific values have increased in REPPIR 2019. Further information on these changes can found here.

4.2.3 This means that if ONR continues to interpret ‘bulk quantities’ as being equivalent to 100 times the REPPIR values, an operator could hold marginally more radioactivity at its premises before ONR considered the licensing regime ought to apply.

4.2.4 However, ONR considers that the impact of these changes is not significant. Although the majority of values have increased, more than half have increased by a factor of less than 10, including many of the main radionuclides relevant to nuclear operations. Less than 1 in 10 of the values increased by a factor of over 100. Given the overall inventories on nuclear sites have contributions from multiple radionuclides the effect of a change to individual radionuclide values is reduced, thereby mitigating the overall effect of the changes.

4.2.5 Indeed, comparison of the relevant values in REPPIR 2001 and REPPIR 2019 demonstrates that ONR would have reached the same decision to recommend licensing of Inutec Ltd., thus confirming the limited impact of the revised values.

4.2.6 ONR considers it appropriate not to amend its current interpretation of ‘bulk quantities’ in relation to storage, other than to update it to reflect the recent change to the legislation i.e. REPPIR 2019.

ONR intends to interpret ‘bulk quantities’ in relation to storage as meaning:

“Quantities of radioactive matter at or above 100 times the levels set out in Schedule 1 to the Radiation (Emergency Preparedness and Public Information) Regulations 2019.”
4.2.7 In determining which “radioactive matter” (that is matter which is produced or irradiated in the course of production or use of nuclear fuel) is to be included in this calculation, ONR intends to continue to disregard:

a) any quantity of irradiated nuclear fuel since installations designed or adapted for storage of such material require a site licence by virtue of section 1(1)(b) NIA65 and regulation 3(6)(b) of NIR71;

b) in accordance with NIR71 regulation 3(6), any radioactive matter which is stored incidental to carriage; and

c) sealed sources as defined in the Ionising Radiations Regulations 2017.

4.2.8 When calculating the quantity of radioactive matter, it should be broken down where possible into individual isotopes or groups of isotopes. For groups of isotopes, the most restrictive REPPIR value should be used.

4.2.9 For a mixture of isotopes, the quantity of each radionuclide present is divided by the relevant REPPIR value to obtain the fractional contribution from each radionuclide. ONR will consider there to be a bulk quantity if the sum of these contributions exceeds one.
5. Bulk Quantities in relation to Disposal

5.1 Policy Background on Licensing of Disposal Facilities

5.1.1 As mentioned above the UK government’s policy for long-term management of higher activity radioactive waste (HAW) is for disposal in a GDF, where the waste is packaged and isolated in a series of vaults and tunnels deep underground to ensure no harmful amount of radioactivity ever reaches the surface.

5.1.2 The inventory of waste being considered for disposal to a future GDF comprises a number of categories of radioactive waste, including high level waste, intermediate level waste and some types of low-level waste. These wastes require the highest degree of containment and isolation to protect people and the environment.

5.1.3 Another potential aspect of the inventory for disposal is other highly radioactive materials, such as spent nuclear fuel and special nuclear material, that are not currently classified as waste but could be at some point in the future, if they are deemed to have no further use.

5.1.4 Consequently, an operational GDF will contain a significant radioactive inventory. However it would be in a passively safe form, packaged in highly engineered containers, deep underground so that any risks to people and the environment are minimised.

5.1.5 During the operational phase of a GDF there will be activities such as surface interim storage; unloading of waste packages from transport containers; and package handling both above and below ground, which will need to be undertaken according to prevailing nuclear safety standards.

5.1.6 Therefore, when considering the high hazard inventory of a GDF and the activities associated with its operation, international standards and relevant good practice, ONR and the UK government consider it appropriate that a future GDF (in England or Wales) should be subject to the requirements of the NIA65 during its design, construction and operation, and be licensed and regulated by ONR.

5.1.7 Currently, disposal is not prescribed by NIR71, meaning that ONR cannot grant a nuclear site licence to a site for the purposes of disposal. The UK government intends to amend NIR71 to include disposal on the list of prescribed activities, thus providing ONR with the power to grant a nuclear site licence in respect of a future GDF.

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2 Special nuclear material is that containing plutonium and or enriched uranium

3 The Low Level Waste Repository in Cumbria is a licensed nuclear site because of legacy radioactive waste stored on the site and not on the basis of LLW disposal operations.
5.1.8 ONR has advised the UK government on options for the necessary legislative amendments and expects it will take a similar approach to prescribing disposal in NIR71 as that for storage. ONR supports a qualitative approach to prescribing disposal because we consider it provides flexibility to make licensing decisions on a case-by-case basis, whilst providing a framework that gives clarity to industry and the wider public.

5.1.9 This needs ONR to consider how its interpretation of ‘bulk quantities’ may be extended to include disposal facilities.

5.2 Principles Governing ONR’s Actions

5.2.1 In considering how it should extend its interpretation of bulk quantities to apply to disposal, ONR will act in accordance with a set of principles and aims, including:

- **Transparency** – ONR’s aim is to develop a transparent basis for determining nuclear site licence applications that can be readily communicated and understood.

- **Consistency** – ONR’s aim is to develop a logical, coherent, and self-consistent approach for regulating the nuclear industry, ensuring consistency between licensing decisions.

- **Targeting** – ONR’s aim is to focus its regulatory attention on those activities that give rise to the most serious risks, or where they are least well understood.

- **Proportionality** – ONR’s aim is to develop an approach to determining nuclear site licence applications that ensures the licensing regime is only applied where necessary.

5.2.2 In applying these principles, ONR is seeking to ensure that the risks arising from a future GDF are appropriately controlled through the licensing process, whilst ensuring the licensing criteria are defined in a way that doesn’t bring low-hazard facilities into the licensing regime.

5.3 Radioactive Waste Disposal

5.3.1 When considering how ONR should interpret ‘bulk quantities’ in relation to disposal, it is useful to consider the types of radioactive waste disposal facility that it could apply to, and crucially the type of waste each facility is able to receive.
5.3.2 Protection of people and the environment in relation to radioactive waste disposal is regulated by the relevant environment regulator\textsuperscript{4}, irrespective of whether under these proposals the site will require a nuclear site licence or not. This is because ONR will regulate operation of the facility. Licensing a GDF will not impact on the environment regulators’ requirements or permitting process; we will work with the environment regulators to ensure our regulatory principles, approaches and processes are aligned. Further information on our respective roles in regulating geological disposal can be found in our publication, *Regulating geological disposal: an overview*.

5.3.3 The type and quantity of waste that can be disposed of in a particular facility is linked to its environmental safety case; in general, more hazardous waste requires more substantial containment and isolation to protect people and the environment. It follows that more hazardous waste requires more stringent controls to ensure safety during handling and disposal operations.

5.3.4 In the UK it is only currently possible to dispose of the least hazardous radioactive waste, i.e. the Very Low Level Waste (VLLW) and Low Level Waste (LLW) categories. Presently, this waste can be disposed of to a small number of permitted landfill sites or dedicated low level waste disposal facilities, such as the Low Level Waste Repository in Cumbria or the Dounreay Low Level Waste Disposal Facility in Caithness\textsuperscript{5}.

5.3.5 Whilst approximately 95% of the UK Radioactive Waste Inventory (RWI) by volume is in the VLLW and LLW categories, this accounts for well below 1% of the actual total amount of radioactivity contained within UK radioactive wastes.

5.3.6 All higher activity radioactive waste, i.e. those in the Intermediate Level Waste (ILW) and High Level Waste (HLW) categories, are currently safely stored on nuclear sites pending availability of a suitable disposal route, such as a future GDF.

5.3.7 ONR’s approach to licensing of disposal facilities should be sufficiently flexible to enable application to any type of disposal facility, by being based on the hazard associated with operating any proposed disposal facility and the potential risk to the public.

5.4 Options for Consideration

5.4.1 By considering the wording and intentions of NIA65, ONR has identified two options for a revised interpretation of ‘bulk quantities’ to facilitate decisions in relation to licensing of installations for storage and disposal of radioactive matter.

\textsuperscript{4} In England, the Environment Agency; in Scotland, the Scottish Environment Protection Agency; and in Wales, Natural Resources Wales.

\textsuperscript{5} The Dounreay LLWDF is only available for use by the Dounreay site, and adjacent MoD Vulcan Naval Reactor Test Establishment.
These options are:

- a single interpretation that applies to both storage and disposal; or
- two separate but related interpretations; one each for storage and disposal.

We have examined the pros and cons of the above options and the section below sets out why ONR favours the second option, however we are seeking to elicit comments on our proposals from interested parties through this public consultation before finalising our views.

5.5 ONR’s Proposed Approach

ONR’s proposed approach to defining ‘bulk quantities’ of radioactive matter in relation to disposal is to pursue a separate interpretation to that for storage.

Whilst a single interpretation of ‘bulk quantities’ that applies to both storage and disposal could appear to give clarity on the threshold at which nuclear operations are considered to represent an extraordinary hazard; it fails to recognise the differences in operation of a disposal facility compared with those of a storage facility.

Typically, there are significant differences between physical properties of radioactive waste in storage compared with those ready for disposal. Owing to the way radioactive waste is packaged for disposal to ensure long-term environmental safety, operations associated with disposal are typically lower risk, particularly for lower hazard radioactive waste. Similarly, processing of special nuclear materials to put these beyond use prior to disposal will lower their overall hazard.

A single interpretation would not allow for differentiation between physical properties of radioactive materials or waste held in a storage facility compared with a similar quantity placed in a disposal facility or the differences in safety measures implemented within these facilities.

ONR does not consider the operations conducted at VLLW or LLW disposal sites to represent a hazard or risk to the public of ‘an extraordinary nature’ to require these to be subject to the nuclear licensing regime. ONR therefore considers that its interpretation of ‘bulk quantities’ in relation to disposal should be set at such a level so as to exclude these types of disposal facility.

Assessment of the total radioactive inventory that VLLW and LLW facilities are permitted to dispose revealed that despite only accepting lower hazard waste, the large volumes of such waste result in total inventories exceeding 100 times the REPPIR values.
5.5.7 If ONR were to interpret ‘bulk quantities’ in relation to disposal as equivalent to storage, as set out under Section 4.2, low hazard VLLW and LLW disposal facilities would be inadvertently subject to the nuclear site licensing regime.

5.5.8 It is important to note, that the current VLLW and LLW disposal sites have been operating safely for many years and are adequately regulated under existing legislation and there would be no additional benefit in applying the nuclear site licensing regime to these sites.

5.5.9 ONR considers that to do so would be disproportionate to the risks associated with operating these sites thus place a disproportionate regulatory requirement on these facilities, against current government policy, and be contrary to Parliament’s original intent for licensing nuclear installations.

5.5.10 Whilst the Secretary of State is able to exempt certain facilities from the requirement for a nuclear site licence, an exemption to NIA65 has never been implemented. Furthermore, such exemptions would place administrative burden on these sites, the regulators and the government to explain, with no additional benefit, existing assessment and justifications that have resulted in extant arrangements. ONR therefore considers it more efficient to determine an interpretation of ‘bulk quantities’ that avoids including such sites in the first place.

5.5.11 ONR therefore considers it appropriate to interpret ‘bulk quantities’ in the context of storage and disposal differently, setting a higher threshold for licensing of a site for disposal purposes.

5.5.12 The UK RWI data shows that the inventory for disposal to a GDF, in terms of radioactivity content, is very much greater than that destined for VLLW and LLW disposal sites. This enables a clear differentiation on the basis of the REPPIR values to be made, and provides for clarity and simplicity in the context of licensing of disposal sites.

5.5.13 ONR assessment concluded that some VLLW disposal sites could eventually hold total radioactive inventories equivalent to over 100,000 times the REPPIR values. However, assessment of the UK RWI data for the various categories of radioactive waste that comprise HAW concluded that in each case, the inventory exceeded 1,000,000 times the REPPIR values.

5.5.14 Setting an interpretation in relation to disposal at 1,000,000 times the REPPIR values ensures that the nuclear site licensing regime would apply to any future GDF, whilst providing a sufficient buffer above the operating VLLW and LLW sites to avoid their inclusion even allowing for their future expansion. ONR considers this to be the most appropriate and proportionate approach to licensing of radioactive waste disposal facilities.
ONR intends to interpret bulk quantities in relation to disposal as meaning:

“Quantities of radioactive matter at or above 1,000,000 times the levels set out in Schedule 1 to the Radiation (Emergency Preparedness and Public Information) Regulations 2019.”

5.5.15 When calculating the quantity of radioactive matter, it will be broken down where possible into individual isotopes or groups of isotopes. For groups of isotopes, the most restrictive REPPIR value should be used.

5.5.16 For a mixture of isotopes, the quantity of each radionuclide present is divided by the relevant REPPIR value to obtain the fractional contribution from each radionuclide. ONR will consider there to be a bulk quantity if the sum of these contributions exceeds one.
6. Questions

6.1 Do you think ONR’s proposed interpretations are easy to understand? If not, which parts are not easy to understand and why?

6.2 Do you think ONR has considered appropriate criteria in developing its approach? If not, what other criteria do you think we could consider, and why?

6.3 Do you agree that ONR has adhered to its stated principles of good regulation? If not, please tell us why.

6.4 Do you have any other comments on ONR’s proposed approach?
7. ANNEX – Origin of the Term ‘Bulk Quantities’

The ‘Notes on the Nuclear Installations (Licensing and Insurance) Act, 1959’ gives the following explanation as to why the phrase ‘bulk quantities’ was introduced.

“On second reading Mr Richard Fort suggested that the scope of section 1(1)(b) as originally drafted was unnecessarily wide (Commons, 9.2.59, col. 900). The paragraph was therefore amended in Committee (Standing Committee B, 21.4.59, cols. 9-18) with a view to excluding as far as possible the types of installation to which there was no question of extending the Act. Processes ancillary to the production of atomic energy but giving off no radioactivity, such as the manufacture of graphite blocks or beryllium cans, do not require the imposition of the kind of controls and obligations contemplated in the Act. Nor does the treatment, storage or disposal of radioisotopes in small quantities or of the less radioactive types. Such operations could have been covered by Regulations under the Bill as originally drafted, though there was no intention of exercising the power in their case.”

Further detail is derived from a statement by Mr Maudling (Standing Committee B, 21.4.59, cols 10-11):

“….The third category is installations for “the storage, processing or disposal of nuclear fuel or of bulk quantities of other radioactive matter…” The point is to cover only the assembly of such quantity of radioactive matter as can be of danger which ought to be dealt with by the licensing system. By bringing in the words “bulk quantities” we have met the point made in the house and in another place that the Bill could be applied to places where radionuclides are kept in very small quantities and therefore where no real danger was involved. The purpose of the Amendment should commend itself to the Committee. It ensures that the fusion process is covered but it ensures that the Bill does not cover certain processes or activities not of themselves of a dangerous character and therefore not needing to be licensed.”