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Subject: **CORAR Comments on Draft Regulatory Guide DG-4014, Decommissioning Planning During Operations. Docket ID NRC-2011-0286.**

Reference: **Federal Register Vol. 76, No 239, December 13, 2011, Pages 77431-77432. Decommissioning Planning During Operations. Draft regulatory guide; request for comment.**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)[1]. CORAR Manufacturers and Distributors are familiar with decommissioning major licensee facilities and appreciate the opportunity to provide comments on a regulatory guide developed to assist licensees to comply with the applicable provisions of the decommissioning planning rule.

On September 6, 2011 CORAR submitted comments to the NRC on prompt remediation of residual radioactivity expressing concern that the Decommissioning Planning Rule (DPR) appeared unnecessary as thousands of licensees comply with existing decommissioning rules. The NRC's stated reason for promulgating the DPR was to prevent the creation of legacy sites, a need based on six legacy sites involving the processing of large volumes of materials containing uranium and thorium.

1. CORAR members include major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U. S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

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Add = J. Shepherd (JCS2)

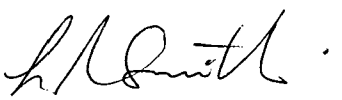
CORAR pointed out that conditions at these noncompliant sites were radically different from the majority of licensees that have never created a legacy site. We recommended that the appropriate way to address this situation was to subject similar uranium and thorium processing licensees to license conditions to prevent them becoming legacy sites. This is a practical solution because this type of operation is easily distinguishable in the license application review process. We recommended that this would be preferable to subjecting thousands of compliant licensees to additional and burdensome decommissioning regulatory requirements. Particularly since these new requirements are likely to be costly to implement and of no benefit beyond existing regulatory requirements.

We were encouraged that the NRC did recognize that the majority of licensees were unlikely to create a legacy site and could use reasonable methods to demonstrate this. However, since the new decommissioning rule requires licensees to consider subsurface surveys for residual contamination and prompt remediation during operations, licensees need guidance on how to demonstrate compliance without committing unreasonable resources. Consequently we appreciate the NRC drafting a regulatory guide to provide the necessary guidance.

However, we are disappointed to find that draft DG-4014 does not provide the guidance that material licensees are seeking. DG-4014 does assure those licensees that do not need a decommissioning plan that they are exempt from these requirements. This is because these licensees have small possession limits or handle radioactive materials only in sealed and solid forms. But there is no practical guidance for the medical community, research community, biotechnology companies or their manufacturing and distributing suppliers on practical steps they can take to demonstrate compliance to satisfy the new regulatory requirements. Licensees need explicit examples of simple methods that the licensing agency will accept to demonstrate that they are unlikely to create a legacy site. These should be provided for each type of licensed operation.

In the attached comments CORAR has made detailed recommendations on the specific guidance that is needed. We appreciate this opportunity to provide these comments and shall be glad to provide clarification and additional information.

Yours sincerely,



Leonard R. Smith, CHP
Co-chair CORAR Committee on Manufacturing Quality and Safety

Enclosure: CORAR Comments on Draft NRC Regulatory Guide DG-4014, Decommissioning Planning During Operations.

02/03/12

CORAR COMMENTS ON DRAFT NRC REGULATORY GUIDE DG-4014, DECOMMISSIONING PLANNING DURING OPERATIONS

1. **Page 2, paragraph 2, lines 5-7, "The DPR requires all licensees to establish operational practices to minimize contamination and perform subsurface radiological surveys, and sets forth new financial assurance requirements."**
Page 2, paragraph 5, lines 1-4, "The DRP requires licensees to ...perform radiological surveys to identify the extent of contamination at their sites, including the subsurface, that are reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity."

   CORAR understands that the DPR requires all licensees to minimize contamination. However, because surveys are already required in 10 CFR 20.1501, and the need to minimize contamination is required in 10 CFR 20.1406, the statement should be rewritten to explain that this continues to be a requirement, which should avoid confusing licensees. The phrase in paragraph 2, requiring all licensees to perform subsurface radiological surveys is contradicted in paragraph 5 which implies that licensees only need to do this when there is a reasonable need. The first paragraph should be modified to make it clear that subsurface surveys are only required when there is a reasonable need. Also, licensees need guidance on what circumstances the NRC considers subsurface radiological surveys to be reasonable. This should be expressed in this guide as an application of the ALARA principle and illustrated with pertinent quantitative examples. Alternatively, and perhaps more appropriately, the NRC should, as provided in 10 CFR 20.1406(a), continue to rely on the licensing process to ensure that the applicant describes the necessary operational practices and survey methods.

2. **Page 2, first subheading, "Relationship between RG 4.21 and RG 4.22"**

   This is the first time RG 4.22 is mentioned. Licensees would understand that it refers to this guide if it was indicated under the title on page 1, i.e.: "Proposed New Regulatory Guide 4.22", as has been past practice, and/or introduced in the section on "Background".

3. **Page 2, paragraph 5, lines 4-8, "The term "residual radioactivity" is defined ... as radioactivity in structures, materials, soils, groundwater, and any other media at a site resulting from activities under the licensee's control. "Significant" residual radioactivity is ..."a quantity of radioactive material that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402.""**

This is confusing to licensees. Surely the potential presence of significant amounts of residual radioactivity implies that activities are not all under the licensee's control. Perhaps the term "responsibility" is needed here instead of "control". This definition should be modified to indicate that the residual activity is the estimated quantity that remains at the projected time of decommissioning. This would then accommodate radionuclides that have half-lives up to a few years that may significantly decay by the time decommissioning is completed.

Use of the term "significant" in this context is also misleading and potentially confusing to the public. The long standing and sufficient regulatory requirement is for licensees to maintain levels of contamination in the course of ongoing operations below limits and to levels that are ALARA, and not levels that could be considered "significant."

4. **Page 2, paragraph 8, "It explicitly includes the subsurface in the radiological surveys required of all licensees by 10 CFR 20.1501(a);"**

Material Licensees have long had the understanding that contamination control applied to all locations including the subsurface. This is why there have been so few legacy sites, and none in radiopharmaceutical supplier industry.

5. **Page 2, paragraph 9, "It establishes a threshold for when residual radioactivity becomes "significant" residual radioactivity: ..."**

This "threshold" is useful as a first step in deciding when residual radioactivity is "significant". There are many other characteristics that need to be determined to complete this evaluation, including physical and chemical form and half-life. Licensees need guidance on these too. Even more important for the majority of licensees is how are they to make these determinations without involving unreasonable cost and resources and disruption of operations?

6. **Page 3, paragraph 1, "It requires all licensees to retain 10 CFR 20.1501(a) survey results with records important to decommissioning ..."**

This is not a new requirement. Historical records on conditions relevant to decommissioning are retained by licensees, including surveys. This section should emphasize that this is an ongoing requirement. It would also be useful here to indicate the time these records must be kept.

7. **Page 3, paragraph 2, lines 1-3, "Although the DPR does require subsurface surveys, it does not require the extensive site characterization and compliance surveys that are required ... in ... MARSSIM ..."**

This is a useful statement but it would be more useful to licensees if this guide listed what is required. Licensees need guidance on what practices are acceptable to the NRC for a range of commonly occurring circumstances. If the purpose of this guidance is to ensure some equity between survey results and results likely to be obtained at the end of operations wouldn't it make sense to refer to appropriate survey methodology described in NUREG-1757?

8. **Page 3, paragraph 3, lines 6 and 7, "However, the DPR does require that the results of the monitoring and surveys be included in records important to decommissioning."**

This paragraph is confusing. Does the entire paragraph apply only to nuclear power plants? Does the above sentence apply to all licensees? It always did apply to all licensees with decommissioning plans, and this should be stated.

9. **Page 3, paragraphs 4, lines 3 and 4, and paragraph 5, lines 3 and 4, "... each licensee must develop its own site specific surveillance and monitoring plan and procedures for: ... Performing surveys sufficient to determine the extent of significant residual radioactivity contamination in the site environment."**

Licensees are aware that they need to develop their own site specific plans to support decommissioning but they need this guide to explain what plans are acceptable to the NRC for at least examples of commonly occurring conditions. Licensees need guidance on whether and how to survey to meet regulatory approval. This can be addressed in the licensing process (see comment 1 above) or by describing survey methodology already accepted by NRC such as NUREG-1757 (see comment 7 above).

10. **Page 3, paragraph 7, lines 1 and 2, "Periodically evaluating the costs to remediate significant residual radioactivity to unrestricted release levels at the time of license termination."**

How can this be done for unknown residual radioactivity in inaccessible locations to meet regulatory approval?

11. **Page 3, last line, and page 4, paragraph 1, "... and so provides a risk-informed approach to implementing the DPR. The risk-informed approach to implement the DPR recognizes the need for minimizing contamination to the extent practical while at the same time not requiring definitive identification and quantification of all residual radioactivity."**

We understand that the stated intent of implementing the DPR is to provide a risk-informed approach but this guide doesn't provide the practical guidance to do this that licensees need. Since CORAR's radionuclides and radiopharmaceuticals manufacturers and distributors and their customers have never caused a legacy site and don't have the inventory, practices nor facilities that are likely to cause a legacy site there is no risk and none of the requirements in the DPR can be considered to be risk-informed.

12. **Page 4, paragraph 6, "The DPR adds a new paragraph, 10 CFR 20.1406(c), which establishes a new requirement for licensees with operating licenses to operate their facilities in a manner that minimizes the introduction of residual radioactivity into the site, including the subsurface, to facilitate remediation of the site for unrestricted use at the time of license termination."**

This is not a new requirement. Licensees have always been required to minimize and control radioactive contamination wherever it is located.

13. **Page 4, paragraph 7, lines 1-3, "The DPR also amends 10 CFR 20.1501(a) to explicitly include a requirement for radiological surveys in the subsurface necessary to evaluate residual radioactivity at licensed sites. This revised regulation retains its existing limit of "reasonable under the circumstances."**

Licensees need an explanation and specific examples of what regulatory agencies would consider to be reasonable under the circumstances. Alternatively, since license applications tend to reflect individual circumstances, a determination as to whether the surveys described in the application are reasonable should be accomplished during the licensing process.

14. **Page 4, paragraph 7, lines 3-8, "... residual radioactivity ... activities under the licensee's control ...significant amount of residual radioactivity ... that would require remediation ... to meet the unrestricted use criteria ..."**

See comment 3 above.

15. **Page 4, paragraph 8, "The new 10 CFR 20.1501(b) requires licensees to keep records ..."**

See comment 6 above.

16. **Page 5, paragraph 2,**

"1. relatively large volumes of low specific activity radioactively contaminated liquids;
2. large volumes of long-lived radionuclides;
3. large throughput;
4. liquid processes; or
5. processes that involve large quantities of solid radioactive material stored outdoors."

This guide needs to clarify what is meant by large and relatively large volumes and throughputs. For example: some CORAR members generate hundreds of liters of liquid effluent that are held in holding tanks prior to disposal to the sanitary sewer that can contain microcurie quantities of radioactive materials; the volumes of long-lived radionuclides are typically handled in the micro liter to liter range; throughput involves a few drops in thousands of individual closed vials or absorbed onto solid matrices; liquid processes involve micro liter to liter quantities most of which have half-lives under 4 days; radioactive materials are not stored outdoors. We conclude from this that the NRC would not consider any of these processes to be credible sources to create legacy sites and this is one explanation for why these licensees have not created legacy sites in over 50 years of operations.
It is conspicuous that the 5 sets of characteristics correspond to the uranium and thorium processes that resulted in legacy sites described in the NRC study.

17. **Page 5, paragraph 3, line 2, "Decommissioning regulations require licensees to remediate sites to approved release criteria for unrestricted use... without regard to the cost."**

This statement is misleading and not consistent with NRC regulations. 10 CFR 20.1402 states that residual radioactivity be reduced to levels that are as low as reasonably achievable. 20.1404 allows for the use of alternative criteria greater than the criterion in 20.1402 if doses are reduced to ALARA levels. According to the definition of ALARA, a reasonable effort to maintain doses below limits takes into account the economics of improvement in relation to the benefits of public health and safety.

18. **Page 5, paragraph 3, lines 5 and 6, "...the regulatory objective is to ensure the licensee and the NRC are aware of contamination that may create conditions that would complicate decommissioning, and possibly create a legacy site.**

This guide could ensure better licensee awareness if it included specific examples of circumstances that can create legacy sites that are relevant to most licensees. Otherwise it is not clear how the regulation or the guidance can ensure awareness.

19. **Page 5, paragraph 4, "This regulatory guide provides a risk-informed, graded approach to implementing the regulation. ...illustrated in Figures 1-3."**

We appreciate the intent but this guide seems mostly to just restate the regulation and doesn't provide the practical guidance that most licensees need. It includes statements and assumptions that are misleading and/or incorrect. It does not provide risk-informed guidance that a licensee can use. It does not explain circumstances where a licensee can decide that they do not have significant risk to justify burdensome subsurface surveillance that they can be ensured that the regulatory agency will approve.

20. **Page 7, lines 2 and 3, "The first question is whether the licensee is authorized to possess enough radioactive material to potentially create a decommissioning obligation."**

The first question in Figure 2 is "Is Site Financial Assurance Required". Figure 2 is basically a reformatted version of the narrative portion of the guidance up to this point. As configured, Figure 2 is not useful for licensees to determine what, if anything is needed to be done with regard to the DPR. Consider changing the question. We understand that the first step should be to consider the license limits. However this is only useful to provide a quick screening to exempt licensees with small possession limits. Ultimately the risk depends on the quantity and type of radioactive material on a site and the way it is processed not the license limits. Decommissioning cost estimates are based on actual activities not on license limits. Contractors who make decommissioning cost estimates commonly spend significant effort to determine the quantities of licensed material actually historically used on a site. There should be an explanation to this effect in this section.

21. **Page 7, lines 7 and 8, "... if fluids-liquids, gases, aerosols-are part of the operations at the site ..."**

The guide should confirm and explain that gases needing consideration do not include inert gases such as Ar-41, Kr-85 and Xe-133, and radionuclides with short half-lives.

22. **Page 8, Figure 2, "Have any Unplanned Releases Occurred at the Site?"**

The term "unplanned release" needs to be defined. Also, how is a licensee to respond when they do not know if there has been any unplanned releases because for example predecessors did not provide records or releases are hidden and not accessible?

23. **Page 8, Figure 2, "Are There any Fluid Processes at the Site?**

This question/decision does not properly address fluid processes that involve only short-lived radionuclides and/or inert gases. There should be additional decision making criteria in the flow chart including the following:

- Is the "fluid" component of the possession profile limited to a quantity below 30.35(d)?
- Is the "fluid" component of the possession profile limited to inert gases or radionuclides that have half-lives less than 30 days?
- If there are fluid processes, are there engineering provisions that eliminate or reduce the likelihood of environmental impact (e.g. above ground facilities, double containment of vessels, ducts and plumbing, and leak detection in liquid containment)?

If licensees with these additional criteria were not required to survey for residual radioactivity, this would eliminate most radiopharmaceutical facilities, consistent with the fact that there has yet to be a legacy site with this profile.

24. **Page 9, paragraph 2, lines 3-5, "If the licensee identifies areas that cannot be reasonably surveyed directly, it should establish surrogate monitoring (e.g., sentinel monitoring locations) on a schedule commensurate with the likelihood of significant residual radioactivity occurring there."**

Many licensees may not know what surrogate or sentinel monitoring is. Consider using different terms or explaining these terms or defining them in the glossary. Consider providing some examples.

25. **Page 9, paragraph 3, lines 1 and 2, "For many licensees, survey and monitoring requirements may be established by either license conditions or in documents specifically referenced in the license."**

It is for this reason that there is no need to prescribe surveys in the DPR if these requirements are established directly or by reference in the license and they take into account the types of operation where measures are needed to prevent unexpected environmental impairment. This also applies to other licensee Standard Operating Procedures (SOPs). Instead of or in addition to license conditions most licensees have SOPs that are not license conditions and are not specifically referenced in the license that are all subject to regulatory inspection. These SOPs may be changed expeditiously without regulatory approval. This is necessary to ensure that the licensee has the flexibility to act responsibly and efficiently.

26. **Page 9, paragraph 4, line 1, "Figure 3b shows the actions that licensees should normally follow in implementing survey and monitoring plans."**

Figure 3b is not useful to licensees because it just repeats the generic guidance elsewhere in this document reformatted into a flow chart.

27. **Page 9, paragraph 4, line 2, "Once the cause of the contamination is identified, licensees should take corrective action to minimize further contamination."**

Licensees need specific practical guidance on how to determine the cause of contamination, especially if they are unaware of contamination in inaccessible locations.

28. **Page 9, paragraph 5, lines 1-3, "The revised 10 CFR 20.1501(b) also requires licensees to record, in records important to decommissioning, the amounts and locations of subsurface residual radioactivity that may need remediation at the time of license termination."**

Licensees could benefit from guidance on how to practically and cost-effectively determine contamination in inaccessible locations in a manner approved by regulatory agencies.

29. **Page 9, paragraph 6, lines 4-6, " Other licensees should adjust decommissioning trust funds to reflect the necessary remediation to meet unrestricted use criteria at the time of license termination."**
Page 14, paragraph 6, Lines 7-9, "A trust fund is only one type of financial assurance instrument and might not be required of materials licensees. Those licensees subject to 10 CFR 30.35(c)(6), 40.36(a), or 70.25(d) would have a decommissioning funding plan cost estimate and would not necessarily have a trust fund."

The statement on page 9 implies that all licensees that have decommissioning plans and that are not nuclear power plants use trust funds, which contradicts the statement on page 14. CORAR does not understand the purpose of the above last sentence or what guidance it provides.

30. **Page 10, Figure 3a, "Any Unmonitored Areas in Buildings or Outside Where Spills/Leaks Could Occur?"**

How should a licensee respond to this question if they do not know if these conditions can occur? Examples of these conditions should be provided.

31. **Page 10, Figure 3a, "Any Unmonitored Areas On-Site for Effluents to Concentrate?"**

How should a licensee respond to this question if they do not know if these conditions can occur? If licensees are able to demonstrate compliance with 10 CFR Subpart D and Tables 2 and 3 of Appendix B to Part 20 (release to unrestricted areas), why would there be a cause for concern over potential concentration in the environment? Don't these limits already afford an adequate measure of radiation protection?

32. **Page 10, Figure 3a, "Revise Monitoring/Surveillance Plans as Necessary to Monitor Potentially Impacted Areas Including Subsurface"**

How should a licensee respond to this question if they do not have access to monitor these potentially impacted areas? This is particularly applicable to urban hospitals where the cost of accessing such areas can be both costly and disruptive of the hospitals mission. Also radionuclides released from nuclear medicine patients into the hospital sanitary sewer which are exempt from effluent limits are often indistinguishable from the same radionuclides that are also released into the sanitary sewer from other sources. Hospitals will need guidance on how to address this situation if the sewers were suspected to be leaking.

33. **Page 10; Figure 3a, "Verify Plans with NRC"**

This is needed only if the surveillance plan is a license condition.

34. **Page 10, Figure 3a, "Implement Defined Monitoring Program."**

How is the monitoring program to be defined? There is insufficient detail in the guidance for licensees to determine, in a practical way, a monitoring program that will enable them to work through Figure 3b.

35. **Page 11, Figure 3b, "Is Contamination Detected Greater than Action or Regulatory Limits?"**

What are the "action or regulatory limits" referred to here? These could be the limits prescribed in 10 CFR 20.1402. If so, this may not be determined without unacceptable invasive action. If so how should a licensee proceed?

They could also be the limits provided in 10 CFR Subpart D and Tables 2 and 3 of Appendix B to Part 20 (release to unrestricted areas). It could also be the case that a licensee has adequately assessed its facilities and operations to establish survey methods and action levels in its license application. In either case then, does a licensee need to proceed any further in Figure 3b if compliance can already be demonstrated?

36. **Page 11, Figure 3b, "Respond per Health & Safety or Radiation Protection Plan. Increase Monitoring Affected Areas."**

Licensees need clarification on what is intended by these plans. How should a licensee respond if they do not have access to monitor the affected area? What are the criteria for increasing or decreasing monitoring the affected area? Why is it necessary to repeatedly monitor the same area? Licensees need more specific guidance.

37. **Page 11, Figure 3b, "Record Significant Residual Radioactivity in Records Important to Decommissioning"**

How should a licensee record this if they do not have access and are unable to determine if there is residual radioactivity or are unable to quantify it?

38. **Page 11, Figure 3b, "Adjust Financial Assurance per Rules"**

How should a licensee proceed if they are unable to determine the potential decommissioning cost? Licensees need guidance on how to address these uncertainties or how they can structure the "contingency for unexpected cost increases" to provide financial assurance that is acceptable to the regulatory agency.

39. **Page 12, paragraph 3, "Section 20.1501(b) does require that licensees document the results of the surveys in records important to decommissioning."**

This guide should remind licensees that this has always been a requirement for decommissioning plans.

40. **Page 12, paragraph 4, "...if the quantity of material authorized in the license is below the amount requiring financial assurance... the DPR does not require any further action."**

This is useful to screen out licensees that are exempt from these decommissioning requirements. However, a licensee should not be required to meet the obligations of the DPR based only on the quantity of material authorized in the license. Other important factors need to be considered, including but not limited to:

- Quantities of radionuclides actually possessed
- Chemical and physical form
- Half-life
- Engineering controls to ensure containment

See also comment 23 above.

41. **Page 12, paragraph 5, " 3. Staff experience (Ref. 9) shows that fluids are the primary source of contamination beyond facility equipment."**

However, this is not relevant to decommissioning if the fluids are short-lived radionuclides and/or inert gases. It is not clear what is meant by "beyond facility equipment". Does this mean outside the area where operational equipment is normally used or does it mean that the fluids are more contaminating than equipment used to handle radioactive material? See also comment 23 above.

42. **Page 12, paragraph 6, "4. Affected licensees should review, and adjust if necessary, procedures and practices to ensure early identification of potential or actual radiological releases to the environment and take timely action to minimize the spread of radioactivity in accordance with the DPR."**

Licensees need guidance on how to determine releases to the environment when the release point and the affected area are not accessible for monitoring. This guidance appears to contradict the long accepted practice of promoting benign dispersion of effluents that might have activity concentrations that are ALARA and well within regulatory requirements including 10 CFR 20 Subpart D and Tables 2 and 3 of Appendix B to 10 CFR Part 20 (release to unrestricted areas)

43. **Page 12, paragraph 7, lines 1 and 2, "Section 20.1406(c) requires all licensees to minimize the introduction of radiological contamination into the environment."**

Other NRC regulations already mandate this (e.g. 10 CFR 20 Subpart D and Tables 2 and 3 of Appendix B to 10 CFR Part 20 (release to unrestricted areas). Licensees need guidance on whether this requirement applies to all environmental contamination or only levels that are significant for decommissioning. Licensees have historically used the ALARA principle to determine how much minimization is acceptable to the regulatory agency.

44. **Page 12, paragraph 7, lines 2 and 3, "To do so, licensees should implement procedures and practices that minimize the occurrence of leaks and spills."**

This is also already considered in the licensing process and included in the criteria of NUREG-1556, Volume 12, where it states, "applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, ***facilitate eventual decommissioning***, and minimize, to the fullest extent practicable, the generation of radioactive waste.

45. **Page 12, paragraph 7, lines 3 and 4, "It should also have procedures and practices that will identify leaks and spills throughout the facility soon after they occur."**

This is also already considered in the licensing process and included in the criteria of NUREG-1556, Volume 12, where it states, "applicants for new licenses must describe how facility design and ***procedures for operation*** will minimize, to the extent practicable, contamination of the facility and the environment, ***facilitate eventual decommissioning***, and minimize, to the fullest extent practicable, the generation of radioactive waste. Licensees need guidance on how to proceed, especially in old facilities, when such releases are not accessible.

46. **Page 12, paragraph 7, lines 4-7, "As part of the ALARA program, licensees should have procedures to minimize to the extent practicable the spread of leaks and spills that do occur, especially when the residual radioactivity could migrate to inaccessible areas and eventually to the subsurface."**

This is already considered in the licensing process and included in the criteria of NUREG-1556, Volume 12, where it states, "applicants for new licenses must describe how facility design and procedures for operation will ***minimize, to the extent practicable, contamination of the facility and the environment***, facilitate eventual decommissioning, and minimize, to the fullest extent practicable, the generation of radioactive waste. However, licensees need guidance on how to detect sources and affected areas when they are in inaccessible locations.

47. **Page 12, paragraph 7, lines 7 and 8, "Licensees should review, and update if necessary, the actions to ensure a timely and effective response to unplanned releases of radiological material."**

Licensees have long had procedures to address loss of control issues but they need quantative guidance on unplanned releases that are inaccessible to address this new rule change. What quantities require action and what are the required actions? A definition of "uncontrolled release" is also needed in this guide.

48. **Page 12, paragraph 8, lines 1-2, "5. *Licensees should periodically conduct surveys in* accordance with 10 CFR 20.1501(a) to identify the horizontal and vertical extent of significant residual radioactivity throughout the site."**

Licensees need guidance on how they should conduct surveys when there is no evidence that there is residual radioactivity in inaccessible locations.

49. **Page 12, paragraph 8 lines 2 and 3 and Page 13, paragraph 1, line1, " As part of this identification effort, licensees may use results from a model that has been demonstrated to be representative of the physical conditions of the site."**

In addition to existing requirements in 10 CFR 20 Subpart F, licensees are already required to describe surveys conducted to ensure that contamination of the facility and the environment are minimized as part of the licensing process. Currently, approval of a license application can only be given when these surveys are performed using methodology that is appropriated for that facility and its operations. Consequently, it would now be helpful to material licensees if this guide listed and explained models that have been useful for material licensee facilities. These models should be understandable to radiation protection staff that is commonly available to material licensees. Most material licensees, such as hospitals, pharmacies and biotechnology companies, do not have staff experienced with subsurface geology or hydrology.

50. Page 13, paragraph 1, lines 1 and 2, "Licensees do not need to conduct formal, comprehensive site characterization."

Most licensees will not understand what is meant here by a formal, comprehensive site characterization. Apart from nuclear reactor sites, very few material licensees have any experience with comprehensive site characterizations that involve the subsurface. It would be helpful if this guide referenced examples of formal site characterizations that the NRC would consider unnecessary.

51. Page 13, paragraph 2, lines 1-3, "The required surveys should include, but are not limited to, the following:
a. building interiors, including in and around joints, drains, hoods, exhaust stacks, and other features that could provide pathways for residual radioactivity to concentrate or migrate to inaccessible areas,"

In addition to existing requirements in 10 CFR 20 Subpart F, licensees are already required to describe surveys conducted to ensure that contamination of the facility and the environment are minimized as part of the licensing process. Consequently, it is unlikely that material licensees would be unaware of releases from these facility components when they are fully accessible for monitoring. Licensees need guidance on how to conduct such surveys when these facilities, and/ or the pathways from them, are not accessible. Licensees should also be allowed to take into account factors that would preclude the need for monitoring as stated in previous comments 23 and 40 above.

52. Page 13, paragraph 2, lines 4-7,
"b. the soil and other media in outside areas at the facility,
c. subsurface media, especially around building footers, subsurface pipes and conduits, and below-grade tanks, and
d. ground water."

Licensees need guidance on what criteria they should use to decide on whether to monitor these facility components. These locations are typically inaccessible in urban hospitals. See also comment 51 above.

53. Page 13, paragraph 3, lines 1 and 2, "The DPR does not alter the existing requirement to conduct surveys reasonable under the circumstances to evaluate the magnitude and extent of residual radioactivity."

Considering that the licensing process and other existing regulations already address this concern, and given that virtually all material licensees have never caused a legacy site, and are unlikely to do so, most would consider it unreasonable and unnecessary to attempt to evaluate the magnitude and extent of residual radioactivity. Licensees need guidance on the circumstances the licensing agency considers surveys for residual radioactivity to be reasonable.

54. **Page 13, paragraph 3, lines 2 and 3, "It does explicitly state in 10 CFR 20.1501(a) that the subsurface must be included in these surveys."**

This statement is confusing to material licensees. It should be qualified to ensure that it does not appear to contradict the regulatory position that there may be circumstances where subsurface surveys may not be reasonable. When it is reasonable to conduct such surveys, some licensees need guidance on the appropriate frequency to meet regulatory approval.

55. **Page 13, paragraph 3, lines 4 and 5, "... therefore, licensees should survey in places where such residual radioactivity is more likely to exist."**

Is the NRC advising that other places where residual radioactivity is less likely to exist should be ignored?

56. **Page 13, paragraph 3, lines 5-7, "Licensees should also evaluate the potential for significant residual radioactivity to migrate and to concentrate such that it would not meet the release for unrestricted use criteria of § 20.1402."**

If the residual radioactivity is potentially in subsurface locations, and especially if these are inaccessible, licensees will need guidance on how to evaluate the potential for migration and/or concentration. The guidance should be structure with awareness that most licensees do not have staff that is trained in geology or hydrology.

57. **Page 13, paragraph 3, lines 7-9, "That is, if the existing significant residual radioactivity will naturally reduce to levels that meet unrestricted release criteria by the time of license termination, the DPR does not require any further action."**

Licensees are likely to be able to determine this if the natural reduction process is due only to radioactive decay. However, most licensees would need guidance on which models are acceptable to the licensing agency for determining reductions due to evaporation/resuspension and/or other benign dispersion pathways.

58. **Page 13, paragraph 3, lines 9-11, "For NRC licensees who have subsurface residual radioactivity with no current or projected groundwater contamination, a minimal, routine monitoring plan may remain in effect through license termination activities."**

Licensees will need guidance on how to determine that groundwater is unlikely to be contaminated and what "minimal" routine monitoring plan would be acceptable to the licensing agency.

59. **Page 13, paragraph 4, lines 3-5, "The DPR also places a lower bound on the amount of residual radioactivity that licensees should record: that which would require remediation at the time of license termination to meet the unrestricted release criteria of 10 CFR 20.1402."**

CORAR is aware of situations where industrial sites have been found to have residual hazardous non-radioactive materials. It appears that often these conditions are only determined when the site has been deeply disturbed during demolition or new building construction. Likewise we would expect that inaccessible subsurface residual radioactivity may only be determined during decommissioning. Licensees will need guidance on how to make these determinations prior to decommissioning especially if the site had a distant historic use by an entity that no longer exists or left no records.

60. **Page 13, paragraph 4, lines 3-5, and paragraph 5, " However, records of surveys performed that demonstrate that the residual radioactivity has not exceeded the level of significant residual radioactivity may be useful in demonstrating compliance.**
6. All licensees must document the results of the surveys required by 10 CFR 20.1501(a) in records important to decommissioning in accordance with 10 CFR 20.1501(b)."

However, this cannot be done if the licensee does not have access to determining the extent and type of residual radioactivity. In this case the licensee needs guidance on how to comply with this record keeping requirement to satisfy the licensing agency.

61. **Page 13, paragraph 6, lines 1-3, "The DPR modifies the recordkeeping provisions of 10 CFR 20.1501. It requires that licensees maintain survey results with records important to decommissioning until license termination. Licensees may do this either by physical colocation or by reference to other readily available record files."**

This guide should indicate that this decommissioning record keeping is a long standing regulatory requirement.

62. **Page 13, paragraph 7, lines 4-6, " Alternatively, a licensee should make a reasonable effort to estimate the amount of the identified residual radioactivity that would require remediation to meet the release for unrestricted use criteria of 10 CFR 20.1402 at the time it intends to terminate the license."**

Licensees need guidance and examples of what would be considered a reasonable effort to estimate the amount of residual radioactivity to satisfy the licensing agency. Since NUREG-1757 already provides the details on survey methodology and action levels suitable for screening at the time of decommissioning, it seems logical that some reference should be made to this existing guidance, particularly when the intent of the DPR is to ensure adequate assessment of potential environmental impairment when decommissioning actually occurs.

63. **Page 13, paragraph 7, lines 6 and 7, and paragraph 8, "Consideration should be given to the following:**
a. the radionuclides in the source term,
b. actual and potential migration, both vertical and horizontal,
c. dilution and natural attenuation, and
d. radioactive decay."

The first three of these considerations are likely to be impractical for most licensees and prohibitively expensive if the potential residual radioactivity is inaccessible. Licensees need guidance on how they can reasonably do this with limited resources to satisfy the licensing agency.

64. **Page 14, paragraph 2, line3, "... (ne half ...)"**

"ne" should be "one".

65. **Page 14, paragraph 5, "Licensees, ... , should adjust the decommissioning fund so that it will be sufficient to complete decommissioning at the time of license termination. If a licensee identifies residual radioactivity that would require remediation to terminate the license, it should increase the value of the fund to account for the added cost. Likewise, if a licensee elects to remediate during the operational phase of facility life, it may reduce the fund to account for remediation it has completed; the remaining fund must be sufficient to complete any remediation necessary to meet release criteria."**

Licensees need guidance on how to make these adjustments when the potential residual radioactivity is inaccessible for detection and or monitoring. Licensees need guidance on whether the contingency for unexpected cost increases can be structured to accommodate this situation especially when there is uncertainty.

66. **Page 15, paragraph 2, lines 2-5, "Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations."**

This guide does not provide methods in enough detail to be useful to licensees. Specific methods for addressing commonly occurring circumstances should already be adequately addressed by the materials licensing process (with criteria outlined in NUREG-1556) and existing regulations and NRC guidance, as discussed in our other comments. If these measures do not assure the desired level of radiation protection, then any additional methods that are needed by licensees should be detailed in this guide or referenced. If these other measure do assure the desired level of radiation protection, then the survey and monitoring requirements of the DPR, and this regulatory guidance are unnecessary.

67. **Page 15, paragraph 3, lines 2 and 3, "Licensees may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.'**

The information in this guide is mostly conceptual and provided neither in sufficient detail nor to correspond to commonly occurring circumstances to be of use to most licensees. CORAR believes that this regulatory change and the lack of suitable guidance will cause significant difficulties with regulatory inspectors. For example, one CORAR member recently decommissioned a radiochemical manufacturing facility after a major fire where about 60,000 gallons of water were passed through the affected 5 story building. In this case the licensee had considerable in-house expertise and was able to determine that multi-millicurie quantities of C-14 and H-3 had been released to the soil and groundwater under the basement below the building which was confirmed during the decommissioning process. However, the licensing agency was initially unable to determine whether other agencies had jurisdiction or applicable requirements. This forced the licensee to conservatively remove slightly contaminated materials to decontaminate far below any regulatory requirements and incur an additional and unnecessary cost of over a million dollars. Furthermore the lack of experience in the licensing agency delayed this decommissioning project over two years. Similarly, when the NRC required licensees to verify that releases to the sanitary sewer were in soluble form, the licensing agency did not have the experience to confirm compliance and it took more than a year for the licensing agency to recognize that the licensee was in compliance. Consequently CORAR is concerned that the lack of specific guidance in this guide will cause countless difficulties with regulatory inspections.

68. **Page 15, paragraph 6, lines 3-5, "The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue.**

Licensees are unlikely to understand what the NRC is referring to by "generic regulatory issues". Perhaps this could be explained and/or examples provided in the guide.

69. **Page A-1-2, paragraph 1, lines 4-6, "The first action that any licensee would have to perform would be a comprehensive review of its existing monitoring and surveillance plans."**

This appears to contradict the provision that licensees, that do not need to file a decommissioning plan and/or only possess sealed sources or short-lived radionuclides or inert radioactive gases, are exempt from further evaluations, monitoring and surveillance. However, it should be recognized, in this guide, that all licensees licensed to possess significant quantities of radioactive material have long been required to annually review their radiation protection program including radiological surveys.

70. **Page A-1-3, paragraph 1, lines 6 and 7, "The amount of funds is a function of how much radiological material the licensee is authorized to possess."**

This is reasonable as a first step for making a determination of whether the requirements of the DRP apply to a licensee. However, the decommissioning cost estimate should be based on actual site conditions and the actual quantities of radioactive material in use. This is a particularly important consideration when establishing decommissioning plans for accelerator facilities where the most significant component of residual activity in terms of remediation and cost is likely to be fixed activation of structures and equipment. See also comment 40 above.

71. **Page A-1-3, paragraph 3, lines 1-3, "If, however, regulations do require financial assurance, either by formula or by site-specific estimate, the licensee must determine if there have been previous spills or leaks during the operating history of the site."**

This guide should indicate that this is a long standing requirement.

72. **Page A-1-3, paragraph 3, lines 3 and 4, "Also, the licensee must identify the potential for such events to occur in the future."**

Licensees need specific guidance on how to comply with this requirement to satisfy the licensing agency.

73. **Page A-1-3, paragraph 3, lines 8-11, "Therefore, if fluids are part of the operations at the site, licensees should conduct a more detailed review of monitoring and survey plans to ensure that they will identify the sources and extent of future leaks or spills."**

Licensees need guidance on the quantities of fluids that require more detailed review of monitoring and survey plans to satisfy the licensing agency. Also the guide should modify this sentence to indicate those short-lived radionuclides and inert gases that do not apply. See comment 40 above.

74. **Page A-1-4, paragraph 1, lines 1-3, "Licensees should review existing plans and procedures related to identification and management of leaks, spills, aerosols, dispersible solids, and other unplanned releases."**

As outlined in NUREG-1556, applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the fullest extent practicable, the generation of radioactive waste. This description is typically part of the licensee's radiation protection program. This guide should indicate that the licensee annual review of its radiation protection programs is a long standing requirement and should include decommissioning plans and contamination management. The release of radioactive materials indicated above may not all be unplanned.

75. **Page A-1-4, paragraph 1, lines 3-6, "Licensees should pay particular attention to identifying any changes in the facility operations, such as revisions to specifications for products, addition of new products or discontinuation of previous products, and changes to the process rate since the last revision to the procedures."**

CORAR agrees with this statement but NRC does not need DPR guidance for licensees to do this. Changes to licensee facility operations involving radioactive material are required to be reviewed prior to the change. Also, typically the licensee annual review of radiation protection program acts as an additional check to ensure changes have been reviewed. This guide should indicate that these are well established requirements.

76. **Page A-1-4, paragraph 1, lines 6-12, "The review should also note any physical changes to the facility, ... These changes are not limited to those in the immediate vicinity of the process. For example, rerouted plumbing could result in irregular fittings in normally inaccessible areas; or construction of a tall building on adjacent land could alter the airborne discharge paths."**

See comment 75 above.

Regarding the examples of changes provided, the act of rerouting plumbing would require the fittings to be accessible. Secondly, the existing regulatory limitations on airborne releases (10 CFR 20 Subpart D, 10 CFR 20.1301(e) and (f)) are sufficiently conservative to negate any meteorological impact from a large building on adjacent property. Regardless, use of the EPA COMPLY code, commonly used by licensees to demonstrate compliance with 10 CFR 20.1301(e), allows accounting for variations in source terms and conditions. The construction of an adjacent tall building is unlikely to radically change this common situation.

That said, material licensees typically do not possess sufficient radioactive material inventories in a chemical or physical for and with half-lives long enough to cause a significant environmental impact. For example maximum annual public dose due to airborne emissions from a major radiochemical manufacturing facility in an urban location is unlikely to exceed 100 µrem which is 0.1 % of the regulatory limit. Licensees have long been required to address changes of this nature, and this too is required to be addressed in the annual radiation program review. Also, environmental releases of this magnitude have never had any decommissioning consequences. Any licensee with an unusual potential for significant off-site impact from environmental releases can be subject to license conditions to ensure controls are sufficient and promptly updated

77. **Page A-1-4, paragraph 2, lines 4 and 5, "In this review, licensees should identify any areas of the site not currently monitored regularly for radiological contamination."**

These areas are typically classified as non-affected areas in MARSSIM and as such are not relevant to decommissioning. However, radionuclides and radiopharmaceuticals manufacturing licensees do usually monitor adjacent unaffected areas during operations and decommissioning, but it should not be a routine requirement.

78. **Page A-1-4, paragraph 2, lines 5-11, "In addition to "under-" sources, leaks and spills onto interior or exterior surfaces may migrate through floor joints, cracks, failed seals, or through porous media to other areas. Some of these areas may not be readily accessible for direct observation. In these cases, licensee should consider alternatives to identify potential contamination, such as use of remote sensors and robotics."**

The use of remote sensors and robotics to identify potential contamination in inaccessible locations is likely to be prohibitively expensive for most material licensees and not justified by the negligible risk.

79. **Page A-1-4, paragraph 2, lines 16-20, "Likewise, airborne effluents may precipitate and concentrate in some pattern because of the local meteorology, such as prevailing wind direction and speed, and relative humidity. Licensees should identify these potential locations and include them in survey and monitoring plans."**

See comment 76 above. Material licensees typically do not have a realistic potential for significant environmental impact from airborne releases and would not need to address this in a decommissioning plan.

80. **Page A-1-5, paragraph 1, lines 1-4, "At the time of license termination, 10 CFR Part 20, "Standards for Protection against Radiation," Subpart E, "Radiological Criteria for License Termination, "requires licensees to remediate existing residual radioactivity above release levels without regard to cost.**

See comment 17 above.

81. **Page A-1-5, paragraph 1, lines 4 and 5, "Therefore, licensees must have a sufficient monitoring plan to identify the complete extent of contamination at that time."**

This may not be necessary if the entire material is disposed as LLRW. For example when periodically updating licensed operations and facilities, radionuclides and radiopharmaceuticals manufacturers frequently decide to dispose the entire facility as LLRW because the cost of surveillance and decontamination and the cost of loss in business during the time it takes to complete these tasks is typically greater than the cost of waste disposal.

82. **Page A-1-5, paragraph 1, lines 6-9, "The goal of the DPR is to encourage licensees to develop plans that will identify contamination as it occurs rather than wait until license termination..."**

NRC does not need the DPR and this guidance to accomplish this goal. This can be accomplished by the licensing process (as outlined in NUREG-1556) and existing regulations that require on-going minimization of contamination. Also this is assured because licensees are currently required to survey and monitor facilities and operations to demonstrate compliance with existing limits on releases to unrestricted areas. If NRC is not comfortable with the adequacies of existing regulatory requirements, it should address this concern by adding rigor to the current licensing and inspection processes, rather than by adding duplicative rulings that add no value.

83. **Page A-1-5, paragraph 2, "For licensees that do not have significant residual radioactivity because they possess small amounts of short-lived radioactive material or sealed sources, the staff does not expect significant changes to the existing monitoring and health and safety programs."**

This also applies to material licensees with large amounts of short-lived radionuclides and radionuclides that are inert gases. Also virtually all other licensees, including those with large amounts of long-lived radionuclides, are unlikely to have significant residual radioactivity. The only exceptions to this are the few licensees that processed large volumes of uranium and/or thorium. CORAR's position is these licensees and others with similar processes can be easily identified and specific controls required as license conditions. This would be much more preferable than requiring subsurface surveillance and monitoring for thousands of licensees that have never caused a legacy site and are unlikely to do so in the future.

84. **Page A-1-5, paragraph 3, "For licensees with subsurface residual radioactivity but no ground water implications, a minimal, routine monitoring plan may be sufficient through operations."**

Licensees need guidance on what "minimal, routine monitoring plan" would be acceptable to the licensing agency. This guide should have examples of adequate plans for commonly occurring circumstances.

85. **Page A-1-5, paragraph 4, lines 1 and 2, "Licensees other than those described above should enhance the existing programs to include areas of potential contamination not previously identified."**

Licensees need guidance on how to determine these areas

86. **Page A-1-6, paragraph 2, lines 1 and 2, "So long as there are no readings above the limits specified in the plans, the DPR does not require any additional actions."**

See comment 35 above. Licensees are unlikely to understand what limits there are in plans that are being referred to here. It would be helpful if these limits were listed here.

87. **Page A-1-6, paragraph 3, lines 1 and 2, "If the results of the sampling are above the specified limits, the licensee should respond according to the site health and safety plan."**

See comments 35 and 86 above. The specified limits should be listed or referenced here.

88. **Page A-2-8, paragraph 1, lines 1 and 2, " Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control."**

See comment 3 above.

89. Page A-2-8, paragraph 1, lines 2 and 3, "This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation.

Licensees need clarification on what is meant by "unlicensed sources". Does this mean quantities that are exempt from licensing? If so, these exempt quantities are so small they must be irrelevant to decommissioning. It would help if these unlicensed sources were listed and/or described.

90. Appendix A-1 to DG-4014

There are other NRC regulations that have relevance to the DPR and this guidance, as indicated in our comments above. These should be included in Appendix A-1 or at least considered in this guidance as we have considered them in our comments:

- 10 CFR 20.1406 (a) and (b), "Minimization of Contamination"
- 10 CFR 20 Subpart D—Radiation Dose Limits for Individual Members of the Public
- 10 CFR 20.1401, "Alternate Criteria for License Termination"
- 10 CFR 20, Appendix B, Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage, Table 2.