December 20, 1999

The Honorable John D. Dingell
Committee on Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Dingell:

I am responding to the October 25, 1999 letter from you and Congressmen Ron Klink and Edward Markey. In your letter, you raise a series of questions and issues relating to the release of solid materials containing low levels of radioactive byproduct material, the respective Federal and State jurisdiction over such activities, and a specific licensing action taken by the State of Tennessee, an Agreement State, involving Manufacturing Sciences Corporation (MSC). To assist in providing an integrated response, we have restated the issue as we understand it, addressed the immediate action request, explained how the Nuclear Regulatory Commission (NRC) conducts its licensing activities, explained the Agreement State program and regulatory role, and discussed the specific licensing action in Tennessee given this regulatory context.

Your letter focuses on the issue of control/release of solid materials that contain low levels of radioactive material and the proper execution of the current regulatory program. Let me first express my full agreement that additional work is needed on how we proceed to address the release of solid material and how our nation will collectively handle solid materials containing low levels of both natural and man-made radioactive material. The Commission is currently considering the issue of control of solid materials regulated under the Atomic Energy Act and has recently conducted workshops to seek public input. In addition, NRC is actively working with the Environmental Protection Agency, Department of State, and the International Atomic Energy Agency in their efforts to develop generally applicable radiological screening guidelines which may influence the import and export of contaminated materials or products.

On November 15, 1999, I provided an interim response in which I noted we are not aware of any effect on public health and safety that warrants immediate action to exercise NRC's authority to suspend all or part of the Tennessee Agreement. Our final response, which follows, and our enclosed response to the specific questions in your letter, will help explain that determination. Based on information reviewed in preparing this response, we have not identified any factors that would lead us to believe that Tennessee's action creates a public health and safety or compatibility concern warranting the exercise of NRC's authority to suspend Tennessee's Agreement. In addition, the Commission believes that the State has acted within its regulatory authority under its Agreement with the NRC, and that the State's action is not preempted by NRC's Federal regulatory program. We further understand that no release of nickel material from MSC has occurred and none is planned by MSC until the fall of 2000.

NRC's Regulatory Authority and Current Practice With Regard to Release of Material

The NRC has statutory responsibility for the protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act of 1954, as amended (AEA). The Commission's regulations that set standards for protection of the public against radiation appear in 10 CFR Part 20. These regulations limit the radiation exposure (or "dose") that a member of the public can receive from the operation and decommissioning of a NRC-licensed activity. The NRC has used public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid releases from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. As noted above, NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery, 332 U.S. 194, 203 (1947).

In applying the case-by-case approach, NRC does not consider most releases of solid material to be "disposals" authorized under Part 20 or Part 61. Instead, many such releases are authorized by specific license conditions and do not fall into one of the specific disposition categories in Subpart K of Part 20. However, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (see, e.g., §20.2001(a)(3) and §20.2005).

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92. Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see, e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material.

In the non-reactor nuclear materials license context, NRC usually authorizes the release of solid material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

As noted above, the authority for a release from a materials licensee is generally a specific provision contained in the license itself. By allowing such actions through license conditions, the NRC has provided a specific approval for such actions in lieu of applying one of the generally applicable standards of Part 20. This approach is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through case-specific measures, such as orders or license conditions.

As discussed in the issues paper, NRC's existing approach to these matters, although protective of public health and safety, does not provide a consistent, overall framework to address the disposition of solid material in the possession of NRC licensees. The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach to these issues and will continue to ensure that any actions undertaken by licensees are protective of public health and safety.

NRC Authority Over the Distribution of Certain Products to Exempt Persons

Since the advent of the Agreement State program in the early 1960s, the NRC (then Atomic Energy Commission) has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. NRC has limited its reservation of authority to the distribution of products into which radioactive material has been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties (e.g., in the operation or use of the product itself, such as use of tritium in self-luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). NRC has not reserved authority over the release of material containing low levels of radioactive material, such as the releases long authorized by NRC under the case-by-case approach described above.

Agreement State Authority

Under the AEA, the NRC has preemptive authority to license and regulate the ownership, possession, use and transfer of AEA materials - source, byproduct, and special nuclear material - and to set such standards as are necessary to protect public health in the ownership, possession, use and transfer of such materials. As a general matter, the States have authority to regulate in areas that have not been preempted by the Federal government. In the field of nuclear regulation, such State authority includes the regulation of naturally occurring and accelerator produced radioactive materials that are not subject to regulation under provisions of the AEA. Where source, byproduct, and special nuclear materials covered by the AEA are involved, Federal law generally preempts the States from regulating such material for the purposes of radiological safety. However, Section 274 of the AEA specifically authorizes the Commission to enter into agreements with States which provide for the discontinuance of NRC's authority over certain radioactive materials and the assumption of that authority by the State. In essence, these agreements lift the bar of Federal preemption and pass the NRC's authority and responsibility to regulate the materials and activities covered by the agreement to the State. The agreements do not reflect a delegation of authority. Instead, they signify the discontinuance of authority by the Commission. Once such an agreement is signed, the Commission continues to have an oversight responsibility to ensure that an Agreement State has a program for the regulation of AEA material that is adequate to protect public health and safety and compatible with that of the Commission.

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 46524) provides that, in reviewing the adequacy of an Agreement State's program, the level of protection provided by NRC's own regulatory program defines the level of protection to be achieved in Agreement State programs. For the purposes of compatibility, the Policy Statement details those aspects of NRC's regulatory program that an Agreement State's program must contain in order to ensure that the State's regulatory efforts do not create conflicts, duplication or gaps in the overall radiation protection program across the nation.

For some NRC requirements, such as basic radiation protection standards, or those that have significant transboundary implications, the Agreement State must adopt requirements that are essentially identical to those of the NRC in order to be compatible with NRC. For other NRC requirements, such as most licensing requirements, the Agreement State has the flexibility to adopt its own requirement, as long as the State's requirement meets the essential objectives of NRC's requirement. States may also establish more restrictive requirements provided they have

an adequate supporting health and safety basis and the requirements do not preclude a practice that is in the national interest.

In cases where NRC has established a specific requirement and made a determination of the degree of Agreement State compatibility, States are expected to adopt and implement the requirement in accordance with the compatibility level assignment. In those cases where NRC has not established a specific requirement, an Agreement State has flexibility and latitude to establish its own requirement, so long as the State provides adequate protection of public health and safety and its overall program is compatible with NRC's. The Adequacy and Compatibility Policy Statement specifically provides that an Agreement State has the flexibility to adopt program elements (e.g., regulations or other legally binding requirements) that are within the State's jurisdiction but are not addressed by NRC (62 FR at 46525). In reviewing all aspects of an Agreement State's program, NRC seeks to ensure the overall program for regulating AEA material is compatible and that the State's actions do not significantly affect NRC or other Agreement State programs.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric solid radioactive material. The responses indicate that, although the States vary in their approaches, the State practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses suggest that there is a need for clarification, particularly with respect to the need for some States to differentiate between the Part 20 decommissioning rule for release of land, buildings, and structures at the time of license termination, and the release of materials for unrestricted use.

The criteria utilized by States, applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach, particularly since some released materials will cross State boundaries.

Tennessee's Licensing Decision

In the particular case at hand, it is our understanding that Tennessee has approved a license amendment which will allow MSC to process and decontaminate nickel to remove radioactive contamination (please see enclosed November 19, 1999 letter from M. Hamilton to W. Travers). The amendment also allows MSC to release resulting material containing very low levels of radioactivity for unrestricted use. The level of residual radioactive material is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of public health and safety.

The NRC does not normally conduct an independent review of a specific Agreement State licensing action. However, given your concerns in this instance, NRC staff reviewed the information from Tennessee on the licensing action and independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license. Our dose analysis is conservative and shows the doses to be comparable to those calculated by MSC and reviewed by the State of Tennessee, although our analysis considered different pathways,

assumptions, and exposure groups. Our review of the Tennessee licensing action did identify some areas needing clarification or additional specific information. The staff is pursuing resolution of these matters, which include better understanding of the process Tennessee used in granting the license, the sampling and analyses that will be performed to demonstrate the release criteria are met, and the materials control by MSC to keep the total quantity of special nuclear material in its possession at any one time to quantities that can be licensed by Tennessee.

Based on the staff's review, we have not identified any issues that would lead us to believe that the action taken by Tennessee raises a significant compatibility concern. Both NRC and other Agreement States routinely approve the release of solid materials with low levels of radioactivity in accordance with current guidance or specific license provisions. Thus, Tennessee's licensing action does not differ significantly from current NRC regulatory practice in this area.

Furthermore, the Commission does not believe that the MSC license authorizing release of very low-level, slightly radioactively contaminated solid material is an activity that falls under NRC's exclusive authority to regulate the distribution of products to exempt individuals (see 10 CFR §150.15(a)(6)). The Commission has consistently applied this reservation of authority to the distribution of products (e.g., smoke detectors) involving the intentional introduction of radioactive material. Unlike the products covered by NRC's reservation of authority, there is no radioactive material intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties in the context of the MSC license. And the very low level of residual radioactive contamination in the nickel that may be released by MSC is so small that it is no longer necessary to subject the nickel to regulatory control for purposes of protection of public health and safety.

We have enclosed specific answers to each of the 45 questions that were attached to your letter.

Sincerely,

/s/ Richard A. Meserve

Richard A. Meserve

Enclosures:
1. November 19, 1999 Letter from
   M. Hamilton to W. Travers
2. Responses to Specific Questions

cc: Representative Tom Bliley
Representative Joe Barton

December 20, 1999

The Honorable Edward J. Markey
Subcommittee on Telecommunications,
Trade and Consumer Protection
Committee on Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Markey:

I am responding to the October 25, 1999 letter from you and Congressmen Ron Klink and John Dingell. In your letter, you raise a series of questions and issues relating to the release of solid materials containing low levels of radioactive byproduct material, the respective Federal and State jurisdiction over such activities, and a specific licensing action taken by the State of Tennessee, an Agreement State, involving Manufacturing Sciences Corporation (MSC). To assist in providing an integrated response, we have restated the issue as we understand it, addressed the immediate action request, explained how the Nuclear Regulatory Commission (NRC) conducts its licensing activities, explained the Agreement State program and regulatory role, and discussed the specific licensing action in Tennessee given this regulatory context.

Your letter focuses on the issue of control/release of solid materials that contain low levels of radioactive material and the proper execution of the current regulatory program. Let me first express my full agreement that additional work is needed on how we proceed to address the release of solid material and how our nation will collectively handle solid materials containing low levels of both natural and man-made radioactive material. The Commission is currently considering the issue of control of solid materials regulated under the Atomic Energy Act and has recently conducted workshops to seek public input. In addition, NRC is actively working with the Environmental Protection Agency, Department of State, and the International Atomic Energy Agency in their efforts to develop generally applicable radiological screening guidelines which may influence the import and export of contaminated materials or products.

On November 15, 1999, I provided an interim response in which I noted we are not aware of any effect on public health and safety that warrants immediate action to exercise NRC's authority to suspend all or part of the Tennessee Agreement. Our final response, which follows, and our enclosed response to the specific questions in your letter, will help explain that determination. Based on information reviewed in preparing this response, we have not identified any factors that would lead us to believe that Tennessee's action creates a public health and safety or compatibility concern warranting the exercise of NRC's authority to suspend Tennessee's Agreement. In addition, the Commission believes that the State has acted within its regulatory authority under its Agreement with the NRC, and that the State's action is not preempted by NRC's Federal regulatory program. We further understand that no release of nickel material from MSC has occurred and none is planned by MSC until the fall of 2000.

NRC's Regulatory Authority and Current Practice With Regard to Release of Material

The NRC has statutory responsibility for the protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act of 1954, as amended (AEA). The Commission's regulations that set standards for protection of the public against radiation appear in 10 CFR Part 20. These regulations limit the radiation exposure (or "dose") that a member of the public can receive from the operation and decommissioning of a NRC-licensed activity. The NRC has used public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid releases from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. As noted above, NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery 332 U.S. 194, 203 (1947).

In applying the case-by-case approach, NRC does not consider most releases of solid material to be "disposals" authorized under Part 20 or Part 61. Instead, many such releases are authorized by specific license conditions and do not fall into one of the specific disposition categories in Subpart K of Part 20. However, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (see, e.g., §20.2001(a)(3) and §20.2005).

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92. Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see, e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material.

In the non-reactor nuclear materials license context, NRC usually authorizes the release of solid material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

As noted above, the authority for a release from a materials licensee is generally a specific provision contained in the license itself. By allowing such actions through license conditions, the NRC has provided a specific approval for such actions in lieu of applying one of the generally applicable standards of Part 20. This approach is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through case-specific measures, such as orders or license conditions.

As discussed in the issues paper, NRC's existing approach to these matters, although protective of public health and safety, does not provide a consistent, overall framework to address the disposition of solid material in the possession of NRC licensees. The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach to these issues and will continue to ensure that any actions undertaken by licensees are protective of public health and safety.

NRC Authority Over the Distribution of Certain Products to Exempt Persons

Since the advent of the Agreement State program in the early 1960s, the NRC (then Atomic Energy Commission) has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. NRC has limited its reservation of authority to the distribution of products into which radioactive material has been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties (e.g., in the operation or use of the product itself, such as use of tritium in self-luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). NRC has not reserved authority over the release of material containing low levels of radioactive material, such as the releases long authorized by NRC under the case-by-case approach described above.

Agreement State Authority

Under the AEA, the NRC has preemptive authority to license and regulate the ownership, possession, use and transfer of AEA materials - source, byproduct, and special nuclear material - and to set such standards as are necessary to protect public health in the ownership, possession, use and transfer of such materials. As a general matter, the States have authority to regulate in areas that have not been preempted by the Federal government. In the field of nuclear regulation, such State authority includes the regulation of naturally occurring and accelerator produced radioactive materials that are not subject to regulation under provisions of the AEA. Where source, byproduct, and special nuclear materials covered by the AEA are involved, Federal law generally preempts the States from regulating such material for the purposes of radiological safety. However, Section 274 of the AEA specifically authorizes the Commission to enter into agreements with States which provide for the discontinuance of NRC's authority over certain radioactive materials and the assumption of that authority by the State. In essence, these agreements lift the bar of Federal preemption and pass the NRC's authority and responsibility to regulate the materials and activities covered by the agreement to the State. The agreements do not reflect a delegation of authority. Instead, they signify the discontinuance of authority by the Commission. Once such an agreement is signed, the Commission continues to have an oversight responsibility to ensure that an Agreement State has a program for the regulation of AEA material that is adequate to protect public health and safety and compatible with that of the Commission.

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 46524) provides that, in reviewing the adequacy of an Agreement State's program, the level of protection provided by NRC's own regulatory program defines the level of protection to be achieved in Agreement State programs. For the purposes of compatibility, the Policy Statement details those aspects of NRC's regulatory program that an Agreement State's program must contain in order to ensure that the State's regulatory efforts do not create conflicts, duplication or gaps in the overall radiation protection program across the nation.

For some NRC requirements, such as basic radiation protection standards, or those that have significant transboundary implications, the Agreement State must adopt requirements that are essentially identical to those of the NRC in order to be compatible with NRC. For other NRC requirements, such as most licensing requirements, the Agreement State has the flexibility to adopt its own requirement, as long as the State's requirement meets the essential objectives of NRC's requirement. States may also establish more restrictive requirements provided they have

an adequate supporting health and safety basis and the requirements do not preclude a practice that is in the national interest.

In cases where NRC has established a specific requirement and made a determination of the degree of Agreement State compatibility, States are expected to adopt and implement the requirement in accordance with the compatibility level assignment. In those cases where NRC has not established a specific requirement, an Agreement State has flexibility and latitude to establish its own requirement, so long as the State provides adequate protection of public health and safety and its overall program is compatible with NRC's. The Adequacy and Compatibility Policy Statement specifically provides that an Agreement State has the flexibility to adopt program elements (e.g., regulations or other legally binding requirements) that are within the State's jurisdiction but are not addressed by NRC (62 FR at 46525). In reviewing all aspects of an Agreement State's program, NRC seeks to ensure the overall program for regulating AEA material is compatible and that the State's actions do not significantly affect NRC or other Agreement State programs.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric solid radioactive material. The responses indicate that, although the States vary in their approaches, the State practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses suggest that there is a need for clarification, particularly with respect to the need for some States to differentiate between the Part 20 decommissioning rule for release of land, buildings, and structures at the time of license termination, and the release of materials for unrestricted use.

The criteria utilized by States, applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach, particularly since some released materials will cross State boundaries.

Tennessee's Licensing Decision

In the particular case at hand, it is our understanding that Tennessee has approved a license amendment which will allow MSC to process and decontaminate nickel to remove radioactive contamination (please see enclosed November 19, 1999 letter from M. Hamilton to W. Travers). The amendment also allows MSC to release resulting material containing very low levels of radioactivity for unrestricted use. The level of residual radioactive material is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of public health and safety.

The NRC does not normally conduct an independent review of a specific Agreement State licensing action. However, given your concerns in this instance, NRC staff reviewed the information from Tennessee on the licensing action and independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license. Our dose analysis is conservative and shows the doses to be comparable to those calculated by MSC and reviewed by the State of Tennessee, although our analysis considered different pathways,

assumptions, and exposure groups. Our review of the Tennessee licensing action did identify some areas needing clarification or additional specific information. The staff is pursuing resolution of these matters, which include better understanding of the process Tennessee used in granting the license, the sampling and analyses that will be performed to demonstrate the release criteria are met, and the materials control by MSC to keep the total quantity of special nuclear material in its possession at any one time to quantities that can be licensed by Tennessee.

Based on the staff's review, we have not identified any issues that would lead us to believe that the action taken by Tennessee raises a significant compatibility concern. Both NRC and other Agreement States routinely approve the release of solid materials with low levels of radioactivity in accordance with current guidance or specific license provisions. Thus, Tennessee's licensing action does not differ significantly from current NRC regulatory practice in this area.

Furthermore, the Commission does not believe that the MSC license authorizing release of very low-level, slightly radioactively contaminated solid material is an activity that falls under NRC's exclusive authority to regulate the distribution of products to exempt individuals (see 10 CFR §150.15(a)(6)). The Commission has consistently applied this reservation of authority to the distribution of products (e.g., smoke detectors) involving the intentional introduction of radioactive material. Unlike the products covered by NRC's reservation of authority, there is no radioactive material intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties in the context of the MSC license. And the very low level of residual radioactive contamination in the nickel that may be released by MSC is so small that it is no longer necessary to subject the nickel to regulatory control for purposes of protection of public health and safety.

We have enclosed specific answers to each of the 45 questions that were attached to your letter.

Sincerely,

/s/ Richard A. Meserve

Richard A. Meserve

Enclosures:
1. November 19, 1999 Letter from
   M. Hamilton to W. Travers
2. Responses to Specific Questions

cc: Representative W. J. Tauzin

December 20, 1999

The Honorable Ron Klink
Subcommittee on Oversight and Investigations
Committee on Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Klink:

I am responding to the October 25, 1999 letter from you and Congressmen John Dingell and Edward Markey. In your letter, you raise a series of questions and issues relating to the release of solid materials containing low levels of radioactive byproduct material, the respective Federal and State jurisdiction over such activities, and a specific licensing action taken by the State of Tennessee, an Agreement State, involving Manufacturing Sciences Corporation (MSC). To assist in providing an integrated response, we have restated the issue as we understand it, addressed the immediate action request, explained how the Nuclear Regulatory Commission (NRC) conducts its licensing activities, explained the Agreement State program and regulatory role, and discussed the specific licensing action in Tennessee given this regulatory context.

Your letter focuses on the issue of control/release of solid materials that contain low levels of radioactive material and the proper execution of the current regulatory program. Let me first express my full agreement that additional work is needed on how we proceed to address the release of solid material and how our nation will collectively handle solid materials containing low levels of both natural and man-made radioactive material. The Commission is currently considering the issue of control of solid materials regulated under the Atomic Energy Act and has recently conducted workshops to seek public input. In addition, NRC is actively working with the Environmental Protection Agency, Department of State, and the International Atomic Energy Agency in their efforts to develop generally applicable radiological screening guidelines which may influence the import and export of contaminated materials or products.

On November 15, 1999, I provided an interim response in which I noted we are not aware of any effect on public health and safety that warrants immediate action to exercise NRC's authority to suspend all or part of the Tennessee Agreement. Our final response, which follows, and our enclosed response to the specific questions in your letter, will help explain that determination. Based on information reviewed in preparing this response, we have not identified any factors that would lead us to believe that Tennessee's action creates a public health and safety or compatibility concern warranting the exercise of NRC's authority to suspend Tennessee's Agreement. In addition, the Commission believes that the State has acted within its regulatory authority under its Agreement with the NRC, and that the State's action is not preempted by NRC's Federal regulatory program. We further understand that no release of nickel material from MSC has occurred and none is planned by MSC until the fall of 2000.

NRC's Regulatory Authority and Current Practice With Regard to Release of Material

The NRC has statutory responsibility for the protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act of 1954, as amended (AEA). The Commission's regulations that set standards for protection of the public against radiation appear in 10 CFR Part 20. These regulations limit the radiation exposure (or "dose") that a member of the public can receive from the operation and decommissioning of a NRC-licensed activity. The NRC has used public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid releases from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. As noted above, NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery, 332 U.S. 194, 203 (1947).

In applying the case-by-case approach, NRC does not consider most releases of solid material to be "disposals" authorized under Part 20 or Part 61. Instead, many such releases are authorized by specific license conditions and do not fall into one of the specific disposition categories in Subpart K of Part 20. However, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (see, e.g., §20.2001(a)(3) and §20.2005).

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92. Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see, e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material.

In the non-reactor nuclear materials license context, NRC usually authorizes the release of solid material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

As noted above, the authority for a release from a materials licensee is generally a specific provision contained in the license itself. By allowing such actions through license conditions, the NRC has provided a specific approval for such actions in lieu of applying one of the generally applicable standards of Part 20. This approach is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through case-specific measures, such as orders or license conditions.

As discussed in the issues paper, NRC's existing approach to these matters, although protective of public health and safety, does not provide a consistent, overall framework to address the disposition of solid material in the possession of NRC licensees. The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach to these issues and will continue to ensure that any actions undertaken by licensees are protective of public health and safety.

NRC Authority Over the Distribution of Certain Products to Exempt Persons

Since the advent of the Agreement State program in the early 1960s, the NRC (then Atomic Energy Commission) has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. NRC has limited its reservation of authority to the distribution of products into which radioactive material has been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties (e.g., in the operation or use of the product itself, such as use of tritium in self-luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). NRC has not reserved authority over the release of material containing low levels of radioactive material, such as the releases long authorized by NRC under the case-by-case approach described above.

Agreement State Authority

Under the AEA, the NRC has preemptive authority to license and regulate the ownership, possession, use and transfer of AEA materials - source, byproduct, and special nuclear material - and to set such standards as are necessary to protect public health in the ownership, possession, use and transfer of such materials. As a general matter, the States have authority to regulate in areas that have not been preempted by the Federal government. In the field of nuclear regulation, such State authority includes the regulation of naturally occurring and accelerator produced radioactive materials that are not subject to regulation under provisions of the AEA. Where source, byproduct, and special nuclear materials covered by the AEA are involved, Federal law generally preempts the States from regulating such material for the purposes of radiological safety. However, Section 274 of the AEA specifically authorizes the Commission to enter into agreements with States which provide for the discontinuance of NRC's authority over certain radioactive materials and the assumption of that authority by the State. In essence, these agreements lift the bar of Federal preemption and pass the NRC's authority and responsibility to regulate the materials and activities covered by the agreement to the State. The agreements do not reflect a delegation of authority. Instead, they signify the discontinuance of authority by the Commission. Once such an agreement is signed, the Commission continues to have an oversight responsibility to ensure that an Agreement State has a program for the regulation of AEA material that is adequate to protect public health and safety and compatible with that of the Commission.

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 46524) provides that, in reviewing the adequacy of an Agreement State's program, the level of protection provided by NRC's own regulatory program defines the level of protection to be achieved in Agreement State programs. For the purposes of compatibility, the Policy Statement details those aspects of NRC's regulatory program that an Agreement State's program must contain in order to ensure that the State's regulatory efforts do not create conflicts, duplication or gaps in the overall radiation protection program across the nation.

For some NRC requirements, such as basic radiation protection standards, or those that have significant transboundary implications, the Agreement State must adopt requirements that are essentially identical to those of the NRC in order to be compatible with NRC. For other NRC requirements, such as most licensing requirements, the Agreement State has the flexibility to adopt its own requirement, as long as the State's requirement meets the essential objectives of NRC's requirement. States may also establish more restrictive requirements provided they have

an adequate supporting health and safety basis and the requirements do not preclude a practice that is in the national interest.

In cases where NRC has established a specific requirement and made a determination of the degree of Agreement State compatibility, States are expected to adopt and implement the requirement in accordance with the compatibility level assignment. In those cases where NRC has not established a specific requirement, an Agreement State has flexibility and latitude to establish its own requirement, so long as the State provides adequate protection of public health and safety and its overall program is compatible with NRC's. The Adequacy and Compatibility Policy Statement specifically provides that an Agreement State has the flexibility to adopt program elements (e.g., regulations or other legally binding requirements) that are within the State's jurisdiction but are not addressed by NRC (62 FR at 46525). In reviewing all aspects of an Agreement State's program, NRC seeks to ensure the overall program for regulating AEA material is compatible and that the State's actions do not significantly affect NRC or other Agreement State programs.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric solid radioactive material. The responses indicate that, although the States vary in their approaches, the State practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses suggest that there is a need for clarification, particularly with respect to the need for some States to differentiate between the Part 20 decommissioning rule for release of land, buildings, and structures at the time of license termination, and the release of materials for unrestricted use.

The criteria utilized by States, applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach, particularly since some released materials will cross State boundaries.

Tennessee's Licensing Decision

In the particular case at hand, it is our understanding that Tennessee has approved a license amendment which will allow MSC to process and decontaminate nickel to remove radioactive contamination (please see enclosed November 19, 1999 letter from M. Hamilton to W. Travers). The amendment also allows MSC to release resulting material containing very low levels of radioactivity for unrestricted use. The level of residual radioactive material is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of public health and safety.

The NRC does not normally conduct an independent review of a specific Agreement State licensing action. However, given your concerns in this instance, NRC staff reviewed the information from Tennessee on the licensing action and independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license. Our dose analysis is conservative and shows the doses to be comparable to those calculated by MSC and reviewed by the State of Tennessee, although our analysis considered different pathways,

assumptions, and exposure groups. Our review of the Tennessee licensing action did identify some areas needing clarification or additional specific information. The staff is pursuing resolution of these matters, which include better understanding of the process Tennessee used in granting the license, the sampling and analyses that will be performed to demonstrate the release criteria are met, and the materials control by MSC to keep the total quantity of special nuclear material in its possession at any one time to quantities that can be licensed by Tennessee.

Based on the staff's review, we have not identified any issues that would lead us to believe that the action taken by Tennessee raises a significant compatibility concern. Both NRC and other Agreement States routinely approve the release of solid materials with low levels of radioactivity in accordance with current guidance or specific license provisions. Thus, Tennessee's licensing action does not differ significantly from current NRC regulatory practice in this area.

Furthermore, the Commission does not believe that the MSC license authorizing release of very low-level, slightly radioactively contaminated solid material is an activity that falls under NRC's exclusive authority to regulate the distribution of products to exempt individuals (see 10 CFR §150.15(a)(6)). The Commission has consistently applied this reservation of authority to the distribution of products (e.g., smoke detectors) involving the intentional introduction of radioactive material. Unlike the products covered by NRC's reservation of authority, there is no radioactive material intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties in the context of the MSC license. And the very low level of residual radioactive contamination in the nickel that may be released by MSC is so small that it is no longer necessary to subject the nickel to regulatory control for purposes of protection of public health and safety.

We have enclosed specific answers to each of the 45 questions that were attached to your letter.

Sincerely,

Richard A. Meserve

Richard A. Meserve

Enclosures:
1. November 19, 1999 Letter from
   M. Hamilton to W. Travers
2. Responses to Specific Questions

cc: Representative Fred Upton

STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
NASHVILLE. TENNESSEE 37243-0435

DON SUNDQUIST
GOVERNOR

MILTON H. HAMILTON, JR.
COMMSSIONER

November 19, 1999

William D. Travers
Executive Director for Operations
Nuclear Regulatory Commission
Washington DC 20555-0001

Dear Mr. Travers:

In response to your request of November 16, 1999. I am enclosing information addressing the four points you raised concerning Manufacturing Sciences Corporation (MSC). This will supplement the copy of the March 1999 amendment to the MSC license and the supporting documentation provided to Mr. Paul Lohaus of the NRC's Office of State Programs under a cover letter &ted November 16, 1999.

I am completely committed to ensuring the health and safety of our citizens. and will continue to closely monitor this project. If you require any other materials. please contact me or the Division of Radiological Health.

Sincerely.

Milton H. Hamilton, Jr.

MHH:LEN:jhg

EXECUTIVE SUMMARY

MANUFACTURING SCIENCES CORPORATION
AUTHORIZATION TO DECONTAMINATE NICKEL FOR UNRESTRICTED RELEASE

Description of Activities Authorized by the March 1999 Amendment

The March 1999 amendment authorized, in general terms, the receipt, decontamination, sampling and survey (to determine compliance with approved unrestricted release criteria), and release of 6000 tons of decontaminated nickel. This authorization was issued following years of research and process development activities performed by Manufacturing Sciences Corporation (MSC), to develop and validate the effectiveness of its decontamination process, under license authorization issued in 1990.

In accordance with a November 15, 1999, verbal request by NRC staff, copies of the March 1999 amendment to the MSC license (originally issued on August 8, 1985) and non-proprietary referenced supporting documentation have been provided to the NRC, under a cover letter dated November 16, 1999.

Basis on Which Authorized

The basis for the March 1999 amendment was:

- Operational information submitted during the research and development phases of the project as authorized in earlier amendments which demonstrated the feasibility of the process.
- Criteria for unrestricted release based on various analyses performed by the licensee and the Division, including "Risk Analysis: Nickel Contaminated with ^{99}Tc and Uranium," submitted in support of the amendment request, and comparison to the criteria of NRC Regulatory Guide 1.86.
- The sampling plan submitted in support of the amendment request, which provided for each finished nickel ingot to be sampled and analyzed for quality control purposes during ingot production and for quality assurance purposes after production.
- The presence of an adequate radiological worker and environmental protection program as determined through the routine inspection program conducted by the Division.

Process Description

A complete description of the electro-refining process used by MSC to decontaminate nickel is contained in the following documentation, which is proprietary information as provided under Tennessee "State Regulations for Protection **Against** Radiation," supporting an earlier amendment request:

- "Functional Specification Full Scale Electra-refining Experiment Modification 1, April 2, **1998"**

The following is a general description of the activities authorized ancillary to the processing of nickel :

- Nickel barriers from the gaseous diffusion process are removed from the decommissioned facilities at the former **K-25** site.
- Contaminated nickel components are transported to MSC in sealed security containers.
- MSC personnel with appropriate security clearances transfer the nickel into the induction furnaces where it is melted.
- A fluxing agent is added to the melt to promote movement of contaminants into the slag.
- The nickel is poured into a mold to form a nickel anode.
- The nickel anode is processed electro-chemically to remove contaminants to meet established criteria.
- Each nickel ingot is sampled and analyzed for compliance with established criteria for quality control and quality assurance **purposes.**
- Nickel not meeting the criteria may either be reprocessed or disposed in accordance with the Division's regulations.

Description of Status of Operations Under the License

- One production-scale cell is currently being operated for experience and optimization of the process.
- Construction of the production facility has not yet begun. Current plans call for construction activities to commence early in the year 2000 and to require **about four (4)** months to complete. Facility design engineering is approximately sixty (60) percent complete.
- No nickel has been released for unrestricted use to date.
- First shipment of processed nickel is expected approximately November 2000.

REQUESTS AND QUESTIONS

FOR THE NUCLEAR REGULATORY COMMISSION

QUESTION 1. Please provide a copy of the complete agreement between the Nuclear Regulatory Commission (NRC) and the State of Tennessee issued pursuant to Section 274 (b) of the Atomic Energy Act, including any amendments issued subsequent to the original 1965 amendment.

ANSWER.

This information was submitted in our interim response letter dated November 15, 1999.

QUESTION 2. Please provide a copy of the complete license issued by the State of Tennessee to Manufacturing Sciences Corporation (MSC), including any amendments issued subsequent to the original 1965 amendment.

ANSWER.

This information was submitted in our interim response letter dated November 15, 1999.

QUESTION 3. In 1962, when the NRC first promulgated its regulations setting out agreement states' authority to regulate some aspects of byproduct material use and disposal, the Commission reserved for itself - and denied to the states - the authority to license, or exempt from licensing, the transfer of possession or control over any "equipment, device, commodity or other product containing source, byproduct or special nuclear material that could be "distribut[ed] to the general public." (10 CFR 150.15.) The reason was clearly stated:

> The uncontrolled distribution of atomic materials in products designed for distribution to the general public, such as consumer type devices and the ultimate uncontrolled release of these materials into the environment, involve questions of national policy which have not yet been resolved. It is for this reason that the Commission is retaining control over such products. (21 Fed. Reg. 1351, Feb. 14, 1962.)

Does the NRC still retain control over such products and the "ultimate" uncontrolled release of those materials? If the answer is in the negative, please explain and provide supporting documentation.

ANSWER.

NRC still maintains control over the distribution of products containing byproduct material and the ultimate uncontrolled release of those materials. However, as explained in greater detail below, the Commission has consistently applied this retention of control to products involving the

intentional introduction of radioactive material into the products to utilize the material's radioactive, physical, or chemical properties, not to materials containing very low levels of residual radioactive material.

Pursuant to 10 CFR 150.15(a)(6), NRC has reserved authority over the distribution of items containing byproduct material to persons exempt from licensing requirements. This specific reservation of authority is consistent with NRC's discretionary authority under §274 c. of the Atomic Energy Act (AEA):

> ... to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission.

Since the passage of this provision, the Commission's implementation of §150.15(a)(6) is based on the understanding that the reservation of authority to NRC applies to products involving the intentional introduction of radioactive material to take advantage of the properties of the material. The legislative and regulatory history behind these provisions, as well as decades of regulatory practice, show that it has never been the Commission's intent to reserve authority over releases of material other than those involving these types of products.

The legislative history of §274 c. itself demonstrates that the general intent of the provision was to give the Commission clear authority to retain jurisdiction, should it so choose, for those situations

where manufacturers have intentionally incorporated radioactive material into products. In the section-by-section analysis of the Senate Report for the 1958 amendment to the AEA, the Joint Committee quoted extensively from the Atomic Energy Commission's own analysis of the bill in providing the basis for enacting the last paragraph in §274 c. The language clearly shows that its intent was to address products that include the intentional introduction of radioactive material to take advantage of the radioactive, physical, or chemical properties of the material. The language in the report reads as follows (**emphasis added**):

> Under the provision, the Commission will be in a position to assure that articles containing byproduct, source, or special nuclear material will not be distributed unless they meet the Commission's minimum safety requirements, including appropriate manufacturing and processing specifications and labeling requirements. **Manufacturers of such devices as gages (sic), luminous markers, radiograph and teletherapy devices, electronic tubes, and so forth sell their products throughout the United States and in many foreign countries.** It is important to assure that controls with respect to such products should be uniform and should be uniformly applied.
>
> There is an additional reason why it is important for the Commission to continue the exercise of control over the distribution of articles containing source, by product, or special nuclear material. **As the supply of such radioactive materials, particularly byproduct materials, increases, there may be increasing proposals by manufacturers and processors to incorporate such materials in articles (such as consumer products) that receive widespread distribution.** Although it is not a

> present problem, the extent to which the widespread distribution of radioactive materials should be permitted in this country may in the foreseeable future present questions of public policy which can be resolved, and the hazards controlled, only at the Federal level.

S. Rep. No. 86-870, at 10-11(1959). In promulgating regulations to implement §274 c., the Atomic Energy Commission provided examples of the types of devices it had determined would remain under its authority for the purposes of distribution. For example, in the same notice quoted in the question, the Commission indicated that "(c)ontrol over consumer type devices, such as luminous watches would be retained by the Commission." (27 FR 1351, February 14, 1962). In addition, the draft version of the rule published for public comment in 1961 specifically listed the products that would be reserved to AEC authority (26 FR 9174, 9176, September 29, 1961). The products, listed in §150.8(e)(1)-(10) of the proposed rule, included sealed sources, thickness/density gauges, luminous paint, tracers, ceramic table ware, glassware, tungsten or magnesium thorium alloy products, aircraft counterweights, gas mantles, vacuum tubes, and welding rods. The proposed rule also contained a catch-all provision that did not specify the use of material. Nevertheless, without exception, all of the products specifically listed in the proposed rule involve the intentional introduction of radioactive material into a device or product that utilized the property of the material for a specific functional purpose. While this list of materials was not included in the final rule and the Commission at that time limited its authority to transfers of products designed for distribution to the general public, the Commission gave no indication that this change from the draft to the final version reflected an intention to expand its reservation of authority beyond products involving the intentional introduction of radioactive material.

It is clear, as pointed out in the letter and questions submitted to the Commission, that certain passages in the Federal Register notice for the final rule published in 1962, as well as language in the Commission's rules, could lead to some confusion when read out of context. However, after almost 40 years of regulatory practice in this area, the NRC, and its predecessor the AEC, have consistently applied the reservation of authority to products that involve the intentional introduction of byproduct material.

The Commission recognizes that §274 c. could be read to provide the NRC with the discretion to exercise exclusive regulatory control over a broad range of commodities containing radioactive material that may have broad national distribution and use. Moreover, material proposed for free release containing very low levels of radioactive material could be found to fall into the broad category of items over which the NRC might arguably decide to retain control. To date, however, the NRC has not made such a determination to exert exclusive authority in this area and the Commission has no plans to alter its implementation of the statutory and regulatory framework in this area. Accordingly, the Commission will continue to reserve authority pursuant to Section 150.15(a)(6) only over the distribution of products involving the intentional introduction of radioactive material.

Regulation of the distribution of products containing radioactive material to persons exempt from licensing differs in concept and practice from the release of materials for unrestricted use that contain very low levels of radioactive material. For byproduct material, NRC approves exempt distribution for a specific form, quantity or concentration of radioactive material that is contained in a product that makes use of the radioactive, physical, or chemical properties of the radioactive

material. For example, one exempt distribution product that incorporates small amounts of radioactivity is a smoke detector to detect the presence of smoke. The form, quantity, or concentration of the radioactive materials used in these products are integral to the functioning of the device. The approval of exempt distribution of such products involves regulatory decisions balancing the benefits of the intended use with the risk arising from the small amount of radioactive material introduced to the product. NRC reserves authority over the distribution of these products because of the need to undertake the balancing. No similar analysis applies to the unrestricted release of low levels of radioactive materials.

The Commission does not plan to take away the Agreement States' authority to regulate the release of slightly contaminated material for unrestricted use. Over the years, Agreement States and NRC have routinely authorized the release of low levels of slightly contaminated liquids, gases, and solids pursuant to Parts 20, 30, and 40 and Agreement State equivalent requirements, as well as through specific license conditions and guidance in cases where no generally applicable provision applies. Such releases are at levels which assure adequate protection of the public health and safety. It has never been the Commission's intent, or practice, to place itself into the position of regulating such activities conducted by Agreement State licensees. Any change of policy in this area would require pervasive involvement by NRC in specific Agreement State licensing activities. This would run afoul of one of the purposes of §274 of the AEA, which is to promote an orderly pattern of regulation between the Commission and the States in a manner which will avoid dual or concurrent regulation. Absent new information suggesting that an exclusive Federal presence is needed in this area, NRC will continue its current approach to the regulation of these activities. Of course, if the NRC were to choose to undertake a rulemaking

governing the release of solid material -- a matter on which NRC is currently seeking stakeholder advice -- the Agreement States' exercise of regulatory authority might be constrained as a result of compatibility requirements.

The NRC does seek to assure that Agreement State programs are adequate to protect the public health and safety. The NRC, with Agreement State participants, also conducts periodic Integrated Materials Performance Evaluation Program (IMPEP) reviews of Agreement States and NRC regional office programs for continued adequacy to protect public health and safety and compatibility of Agreement State programs with NRC's program. IMPEP uses a common process that is applicable to both Agreement State and NRC regional materials programs. The review areas include five common performance indicators (Status of Materials Inspection, Technical Quality of Inspection, Technical Staffing and Training, Technical Quality of Licensing, and Response to Incidents and Allegations) and six non-common review areas, as applicable, (Legislation and Program Elements Required for Compatibility, Sealed Source and Device Evaluation, Low-Level Radioactive Waste Disposal, Uranium Recovery, Regional Fuel Cycle Inspection, and Site Decommissioning Management Plan). IMPEP reviews are conducted at a frequency of between 2 to 4 years depending on the status of the Agreement State program. Periodic (approximately every 18 months) management meetings are conducted between the IMPEP reviews to determine if the status of the program may have changed. The IMPEP program is described in more detail in Management Directive 5.6 (attached).

Attachment: Management Directive 5.6

QUESTION 4. Have the questions of national policy referred to in the 1962 *Federal Register* notice been resolved? Please provide copies of any documents that support a statement of resolution.

ANSWER.

Almost 40 years of implementation in this area of regulation has demonstrated to the NRC that the jurisdictional framework set out in 10 CFR §150.15 is appropriate for addressing the issues involved. To this extent, we believe that questions concerning NRC's role in the licensing of these activities have been resolved.

QUESTION 5. In 1969, the term "general public" was deleted from 10 CFR 150.15. The rewritten section prohibited transfer of byproduct material to "all other persons exempted" from an NRC license. Did this change reduce or expand the number of persons and/or products covered by the prohibition? Please explain and provide supporting documentation.

ANSWER.

In promulgating §150.15(a)(6) in 1962 (27 FR 1351, February 14, 1962), the Atomic Energy Commission indicated that it was not implementing a “blanket reservation” of authority over the transfer of manufactured products. The Commission stated that “control of the manufacture and transfer of industrial type devices, such as thickness gauges, would be exercised by the Agreement States.” [27 FR 1351] The Commission retained control over the transfer of products designed for distribution to the general public. However, in 1969 (34 FR 6517, April 16, 1969), the Commission amended the provision to redefine the category of products covered by §150.15(a)(6) “in view of the increasing difficulty in determining whether or not such products are intended for use by the general public ....” In order to effect this change, the Commission revised the language in §150.15(a)(6) to specify that the reservation of NRC authority applies to transfers of products whose “subsequent possession, use, ... by all other persons are exempted from licensing ....” To the extent to which some products were not considered to be “intended for use by the general public” prior to the rule change, the amendment no doubt expanded the number of products covered by the rule.

QUESTION 6. Byproduct material is defined by statute as "radioactive material (except special nuclear material) that is a byproduct of the process of producing or utilizing special nuclear material." (42 U.S.C. 2014(e).) Under 10 CFR 30.71, technetium-99 is listed as a byproduct material. Since January 1, 1999, has the NRC removed technetium-99 from the byproduct material list? If the answer is in the affirmative, please provide supporting documentation.

ANSWER.

No, technetium-99 has not been removed from the list. Technetium-99 is a byproduct material as defined in NRC's regulations, and is included in 10 CFR 30.71, Schedule B. Therefore, NRC and Agreement States regulate technetium-99.

QUESTION 7. The Department of Energy has 6,000 tons of nickel barrier from its gaseous diffusion plant in Oak Ridge, Tennessee, which contains technetium-99. This contaminated material resulted from the uranium enrichment process undertaken at this plant. Is the technetium a "byproduct of the process of producing or utilizing special nuclear material"? If not, please describe what it is and provide any documentation supporting a different definition.

ANSWER.

Yes, the technetium-99 is a byproduct of the process of producing or utilizing special nuclear material. Therefore, technetium meets the definition of byproduct material in the AEA and 10 CFR 30.4: "... material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material." As you are aware, DOE is for the most part self-regulated, and thus, in most cases, NRC does not have authority over DOE activities.

QUESTION 8. MSC intends to melt the nickel barrier, remove some, but not all, of the technetium-99, and sell the resulting product to whomever wishes to purchase it. Is this nickel a product containing byproduct material as defined by 42 U.S.C. 2014(c) and 10 CFR 30.71?

ANSWER.

The nickel resulting from the MSC process will no doubt contain trace concentrations of byproduct material. However, the nickel ingots are not “products” as the term is used in 10 CFR 30.18(c) (10 CFR 30.18 references 10 CFR 30.71) and 10 CFR 150.15(a)(6). As discussed in the response to Question 3, the term “products” in these references applies to products containing byproduct material which was intentionally introduced into the product to utilize the radioactive, physical, or chemical properties of the byproduct material. The term does not apply to material released for unrestricted use which contains very low levels of radioactive material.

QUESTION 9. In its contract with BNFL, the Department of Energy has described the contaminated nickel as "process equipment" that may be recycled and released as scrap metal by MSC, an NRC-licensed facility. *(See* East Tennessee Technology Part (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A, pp. 23, 33-34.) Please explain why recycling and release as scrap metal does not constitute the "transfer" of a product containing byproduct material to exempt persons does not require a license from the NRC under Part 30.3. Please provide supporting documentation.

ANSWER.

As discussed in the response to Question 3, NRC differentiates between commercial distribution of products containing radioactive material which has been intentionally introduced to the products, and release of materials for unrestricted use which happen to contain very low levels of radioactive material. The release of material for unrestricted use is not considered by NRC to be a transfer under 10 CFR 30.3, and either NRC or an Agreement State can authorize licensees to release materials for unrestricted use. As a point of clarification, MSC is not an NRC-licensed facility; rather, it is licensed only by the State of Tennessee.

QUESTION 10. Is it the NRC's understanding that the nickel contaminated with technetium-99 which will be released by MSC into interstate commerce without any restrictions on use may find its way into a host of consumer products, such as tableware, orthodontic braces, caps for baby food jars, cans used for food and beverages, automobiles, intrauterine devices, hip replacement devices, and all other products that incorporate steel and/or of various types?

ANSWER.

Material that is released for unrestricted use can be used for any purpose or in any product including those listed. The criteria approved by Tennessee for authorizing such releases will ensure that the public health would be protected, regardless of use. NRC staff independently calculated potential dose consequences from release of nickel at the levels approved by Tennessee. Our dose analysis is conservative and shows the doses to be comparable to those calculated by MSC, although our analysis considered different pathways, assumptions and exposure groups.

QUESTION 11. As of January 1, 1999, by regulation (published in 10 CFR 150.1 *et seq.*), the NRC has prohibited agreement states from exempting persons from the Commission's licensing and regulatory requirements in 10 CFR Parts 30-40 who carry out the following activity: "The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter." (10 CFR 150.15.) That prohibition is repeated in 10 CFR 30.3. Has there been any regulatory revision of this prohibition since January 1, 1999? Please provide copies of any such revisions.

ANSWER.

No, there have been no revisions to these regulations containing this prohibition (10 CFR 30.3 and 150.15) since January 1, 1999.

QUESTION 12. Article III of the agreement between the NRC and the State of Tennessee incorporates the prohibition cited in 10 CFR 150.15 and 10 CFR 30.3 as a limitation on the State's authority. Has there been any revision of Article III that now allows the State of Tennessee to exempt persons from the Commission's licensing and regulatory requirements under Parts 30 and 40 who are undertaking the activities listed in 10 CFR 150.15? Please provide copies of any such revisions.

ANSWER.

No, there have been no revisions to Article III.

QUESTION 13. The MSC nickel containing the byproduct material appears to be one or more of the following: "equipment, device, commodity, or other product containing source material or byproduct material." (10 CFR 150.15.) Please describe which of the above categories are applicable to the MSC nickel. If it is the NRC's position that none applies, please explain and provide supporting documentation.

ANSWER.

As discussed in the response to Question 3, none of the categories listed in 10 CFR 150.15(a)(6) apply to the MSC nickel. The categories in 10 CFR 150.15 apply to products containing source or byproduct material where the material has been intentionally introduced in order to use its radioactive, physical, or chemical properties. Section 150.15(a)(6) does not apply to material released for unrestricted use which happens to contain very low levels of radioactive material.

QUESTION 14. Under its license amendment, the State of Tennessee has permitted MSC to transfer "possession or control" of metal containing technetium-99 to anyone who wishes to purchase or otherwise use it. Are those persons "exempt from the licensing and regulatory requirements of the Commission under Parts 30 ... of this chapter"? If they are, under what authority does Tennessee issue such a license? If the answer is in the negative, please explain and provide documentation.

ANSWER.

Yes, recipients of the metal containing technetium-99 would be exempt from licensing and regulatory requirements. As discussed in the response to Question 3, such transfers are not within the scope of the authority reserved to NRC in 10 CFR 150.15(a)(6), because MSC has not intentionally introduced the technetium-99 into the metal to take advantage of its properties. Agreement States can, and do routinely, grant authorizations for release of material containing very low levels of radioactive material for unrestricted use.

QUESTION 15. The transfer of byproduct material by NRC licensees to exempt persons is prohibited in 10 CFR 150.15 and 10 CFR 30.3 without certain licenses from the NRC itself. Is it the NRC's position that the sale or transfer of byproduct material by MSC to exempt persons is not covered by these regulations? If so, please explain and provide supporting documentation.

ANSWER.

Yes, as discussed in the response to Question 3, NRC's position is that, for byproduct material, 10 CFR 150.15 applies to transfers of material containing byproduct material which has been intentionally introduced in order to use its radioactive, physical, or chemical properties. It does not apply to authorizations to release material containing very low levels of radioactive material for unrestricted use. Therefore, the release of the material is not a transfer under 10 CFR 30.3.

QUESTION 16. NRC regulations in 10 CFR 30.14 (c) and (d) requires that anyone introducing any concentration of byproduct material into a "product or material" must have a "specific license issued by an agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction." Persons who put the material in a product "knowing or having reason to know" it will be transferred to exempt persons have a specific prohibition. This appears to cover both MSC and any subsequent purchaser of the MSC nickel who plans to incorporate it into another product or commodity, such as a carload of nickel scrap or steel or nickel products. How does the NRC or the State of Tennessee plan to determine that each one of these processors and manufacturers has a "specific license" to incorporate this material into their products? Please explain and provide supporting documentation.

ANSWER.

The NRC does not consider the MSC license to involve the introduction of byproduct material into a product. As explained in more detail in the response to Question 3, this is because MSC is not intentionally introducing byproduct material into the products to be used for its radioactive, physical, or chemical properties. 10 CFR 30.14(c) and (d) do not apply to the MSC nickel.

MSC will release material which contains very low levels of radioactive material for unrestricted use. Once the material is released for unrestricted use, there are no restrictions on how it is processed or transferred by subsequent recipients of the material. Therefore, it is not necessary for NRC or Tennessee to determine whether recipients of the metal are licensed.

QUESTION 17. 10 CFR 30.14 further limits the introduction of byproduct material in less than exempt concentrations into both industrial and consumer products to those applications in which the byproduct material is used for its radioactive purposes. This can only be done by a holder of an NRC or agreement state license. The byproduct material released by MSC will be inserted into many products by numerous persons. Will it be released only for applications in which it will be used for its radioactive purposes by licensees with “express authorization" in their license to do so? If not, please explain why these regulations do not apply and provide supporting documentation.

ANSWER.

No, the material will not be required to be released only to licensees. As discussed in the response to Questions 3 and 16, this case does not involve introduction of byproduct material into a product to be used for its radioactive, physical or chemical properties. Therefore, 10 CFR 30.14 does not apply. The material may be released for unrestricted use to unlicensed persons.

QUESTION 18. The specific license requirements for the introduction of byproduct material into a product or material - even in exempt concentrations - and the transfer of ownership or possession to an exempt person are governed by 10 CFR 32.11. These requirements are numerous and specifically provide that the material not be incorporated into any product designed for application to a human being. Are these regulations applicable to persons obtaining byproduct material from MSC? If they are not applicable to persons who obtain byproduct material from MSC, please explain why and provide documentation.

ANSWER.

No, 10 CFR 32.11 does not apply to persons receiving material which has been released by MSC for unrestricted use. As discussed in the responses to Questions 16 and 17, the radioactive material is already in the metal, and is not being intentionally introduced by MSC.

QUESTION 19. 10 CFR 32.11 specifically prohibits the introduction of byproduct material into other products that are designed "for application to a human being." Some of the potential uses for the nickel containing byproduct material are earrings, orthodontic braces, hip replacement devices and intra-uterine devices. Are these products designed for application to a human being? If not, please explain why not and provide supporting documentation.

ANSWER.

Yes, these devices are products designed for application to a human being. However, as discussed in the response to Question 16, NRC does not consider MSC to be introducing byproduct material into the products in order to use the material's radioactive, physical, or chemical properties (also see response to Question 8). Therefore, the restrictions in 10 CFR 32.11 do not apply to recipients of material which has been released for unrestricted use by MSC.

QUESTION 20. 10 CFR 32.18 establishes the requirements for obtaining a license to release byproduct material in exempt quantities for commercial distribution to a person without a license. Does MSC's license amendment allow it to release byproduct material in exempt quantities for commercial distribution to a person without a license? If the answer is in the affirmative, please explain and provide supporting documentation.

ANSWER.

No, MSC’s license does not allow it to release byproduct material in exempt quantities for commercial distribution. As discussed in the responses to Questions 3, 8, and 9, NRC does not consider the unrestricted release of material containing very low levels of radioactive material to be a commercial distribution under 10 CFR 32.18, because the byproduct material has not been intentionally introduced for use of its radioactive, physical or chemical properties.

QUESTION 21. According to 10 CFR 32.18, prior to transfer from a licensee to a person exempt from licensing, the byproduct material must be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, be identified as radioactive and to be used for its radioactive properties, cannot be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

(a) Will the MSC nickel containing byproduct material be in one of the above forms? If so, state which one and provide documentation of that form.

ANSWER.

After the decontamination process takes place, the MSC nickel will have undergone processing which results in some separation of chemical elements, thereby producing processed chemical elements. The process is described in the license amendment request submitted by MSC to Tennessee Department of Environment and Conservation (TDEC). Note, however, that the premise of this question appears to be that the MSC amendment permits a transfer of an otherwise licensable byproduct material to a person exempt from licensing. Contrary to this premise, the MSC amendment does not authorize a transfer to a person exempt from licensing, but rather permits the release for unrestricted use of material containing very low levels of radioactive material.

(b) Will the MSC byproduct material be identified as radioactive? If the answer is in the affirmative, please provide documentation of the labeling requirements or other methods of identification. If the answer is in the negative, please explain why this material is not required to be identified as radioactive and provide supporting documentation.

ANSWER.

No, the MSC license submitted in response to Question 2 authorizes the release of the material for unrestricted use because the concentration of radioactive material present in or on the material being released is so small that it is no longer necessary to subject the material to regulatory control (e.g., further licensing, registration, labeling, or notification) for purposes of protection of the public health and safety. TDEC would not exert, or expect the licensee to exert, any additional specific requirements or controls on the material. This is consistent with NRC's regulatory approach.

(c) Will the MSC byproduct material be used for its radioactive properties? If the answer is in the affirmative, please provide documentation of that use. If the answer is in the negative, please explain why this material is not required to be used for its radioactive properties and provide supporting documentation.

ANSWER.

No, in this case, there is no intent to introduce byproduct material intentionally into a product to take advantage of its properties (e.g., in the operation or use of the product itself, such as use of tritium in self luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). The very low levels of radioactive material are residual and remain with the nickel as a trace contaminant that does not have a significant effect on public health and safety. Moreover, NRC is unaware of any potential use of the MSC nickel that would involve the use of the properties of the trace amounts of radioactive material that it may contain. Accordingly, Tennessee has not required a license because the use of byproduct material in the end product will not be used for its radioactive, physical or chemical properties.

(d) Will the MSC byproduct material be incorporated into a commodity intended for commercial distribution? If the answer is in the negative, please explain and provide supporting documentation.

ANSWER.

Depending on its end use, some or all of the material resulting from MSC's operation may eventually be incorporated into a commodity intended for commercial distribution. However, as discussed in more detail in other responses, the material released by MSC does not fall into the types of products covered by 10 CFR 32.18 and does not constitute a commercial distribution under 10 CFR 32.18.

QUESTION 22. Under 10 CFR 32.18-.19, the applicant must submit, and the NRC approve, prototype labels and brochures for each container of byproduct material which include the following statements: (a) the material is exempt from licensing; (b) the label will bear these specific words: “Radioactive Material -- Not for Human Use -- Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (c) set forth appropriate additional radiation safety precautions and instructions about handling, use, storage, and disposal of the radioactive material.

Does the MSC license amendment permitting release of the DOE nickel contaminated with byproduct material mandate any of these labeling requirements? Please explain your response and provide supporting documentation.

ANSWER.

No. As discussed in the responses to Questions 9 and 20 and the responses referenced therein, the release of material containing very low levels of radioactive material does not constitute commercial distribution of a product or commodity under 10 CFR 32.18. Therefore, the labeling requirements do not apply.

QUESTION 23. As described in the MSC license amendment, does the 6,000 tons of nickel containing byproduct material to be transferred by MSC contain in total more or less than the exempt quantity of technetium listed in 10 CFR 30.71? Please explain and provide supporting documentation.

ANSWER.

The total quantity of technetium released in the entire 6000 tons of nickel would exceed an exempt quantity. The MSC license amendment authorizes release of nickel which contains an average of 3 becquerels (81 picocuries) per gram. Therefore, using the average concentration, the 6,000 metric tons of nickel could contain up to 480,000 microcuries of technetium, which exceeds the exempt quantity of 10 microcuries.

The exempt quantity limits listed in 10 CFR 30.71 are irrelevant in this case, however, because, as stated previously, the material released by MSC does not fall into the types of consumer products covered by 10 CFR 32.18 and does not constitute a commercial distribution under 10 CFR 32.18 for persons exempt pursuant to 30.18.

QUESTION 24. 10 CFR 32.19 requires that no more than 10 individual packages containing exempt quantities of byproduct material shall be contained in an outer package or sold or transferred in a single transaction to an exempt person. Does MSC's license to transfer byproduct material contain that restriction? If not, please explain and provide supporting documentation.

ANSWER.

No, the MSC license does not contain such a restriction. As discussed in the responses to Questions 9 and 20, 10 CFR 32.19 does not apply to the release for unrestricted use of material containing very low levels of radioactive material.

QUESTION 25: Is NRC Regulatory Guide 1.86 -- which the NRC is using to release surface-contaminated metal from decommissioned nuclear power plants - a regulation under the Administrative Procedure Act? What force of law does it have? Please explain and provide supporting documentation.

ANSWER.

Regulatory Guide (RG) 1.86, “Termination of Operating Licenses for Nuclear Reactors,” is not a regulation promulgated pursuant to the Administrative Procedure Act (APA). Regulatory Guides are issued to; (1) describe and make available to the public methods acceptable to the NRC staff for implementing the Commission’s regulations, (2) delineate techniques used by the staff in evaluating specific problems or postulated accidents, or, (3) provide guidance to applicants, licensees, and regulatory staff. Because Regulatory Guides are issued as guidance and not as regulations, they do not have the force of law. It is noted, however, that a Regulatory Guide does carry the force of law when the licensee has committed to adhere to the Regulatory Guide, and the commitment is included, in whole or in part, in the license of an NRC or Agreement State licensee, or the Regulatory Guide is incorporated in the regulations of an Agreement State Radiation Control program.

QUESTION 26: Regulatory Guide 1.86 cites no statutory or regulatory authority for its implementation, but in its recent issue paper, the NRC stated that Regulatory Guide 1.86 was compliant with the case-by-case reviews for alternative disposal provided for under the Part 20 regulations. (See 64 Fed. Reg. 35090, 35092, 35095, June 30, 1999.) In the AEA and in the NRC's implementing regulations, "disposal" is defined as "isolation" of a radioactive waste. *(See e.g.,* 42 U.S.C. 2021h; 10 CFR 61.2; 62.2; and 110.2.)

Please explain under what authority the NRC classified the unrestricted release of byproduct material into interstate commerce as "disposal" providing "isolation" of radioactive waste under the above-cited statute and regulations. Provide supporting documentation.

ANSWER.

With the exception of 20.2002 and 20.2003 disposals, NRC does not generally consider releases of solid material to be “disposals” authorized under Part 20 or Part 61. However, as recognized by the issues paper published by NRC in June 1999 (64 FR 35090), the releases of solid material authorized under NRC’s current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee’s control. Part 20 does not contain a definition for the term “disposal.” While the term “disposal” is defined as involving the isolation of material in the context of licensing requirements for low-level waste disposal facilities licensed under Part 61 and export licensing under Part 110, the general radiation

protection standards in Part 20 do not limit the acceptable means of disposition of material to the concept of isolation. For example, Part 20 allows transfer of material to an authorized (licensed) recipient (§20.2001(a)(1)); release of material as an effluent (§20.2001(a)(3)); and decay in storage with transfer for disposal of material according to its non-radiological properties (§20.2001(a)(2)). In many of these cases, the material disposed of is not subject to any further or continuing regulatory control.

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92 (attached). Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material.

In the non-reactor materials license context, NRC usually authorizes the release of solid material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material

using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

Two examples of case-specific releases with volumetric contamination are 5,000 tons of calcium fluoride with a low enriched uranium activity of about 3 picocuries per gram and 175,280 pounds of calcium fluoride with a natural uranium activity of about 7 picocuries per gram. There would be little or no impact to workers or members of the public from these cases. To put these releases in perspective, EPA encourages the recycling of coal ash, with a natural uranium activity level that may be an order of magnitude or more higher. Fertilizers also contain naturally occurring radioactive material at these or higher levels.

As discussed in the issues paper on this subject, NRC's existing approach to these matters although protective of public health and safety, does not provide a consistent, overall framework to address the case-by-case disposition of solid material in the possession of NRC licensees. The NRC has used the public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid effluents or discharges that may be released from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally

addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (see, e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery, 332 U.S. 194, 203 (1947).

The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach on these issues and will continue to ensure that any action taken by licensees is protective of public health and safety.

Attachments: Office of Inspection and Enforcement
Circular 81-07 and Information Notice 85-92

QUESTION 27: Is the MSC facility an NRC licensee undergoing decommissioning?

ANSWER.

No. The MSC facility is licensed by the State of Tennessee, an Agreement State and, based on information provided by Tennessee, is an active licensee. MSC is not an NRC licensee undergoing decommissioning.

QUESTION 28: In 1986, the Congress ordered the NRC to "identify methods of the disposal of low-level radioactive waste other than shallow land burial, and establish and publish technical guidance regarding licensing" of those facilities. Technical requirements for those methods are outlined in the statute. They include "site suitability, site design, facility operation, disposal site closure, and environmental monitoring as necessary to meet the performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility." (42 U.S.C. 2021 h.) (Emphasis added.)

Please explain how the unrestricted release of byproduct material into interstate commerce as an alternative method of disposal meets the “performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility" and provide supporting documentation.

ANSWER.

As discussed in the cover letter and the response to Question 26, NRC does not generally consider releases of very low levels of byproduct material to be “disposals.” Therefore, such releases are not subject to, or required to meet, the performance objectives for a licensed low-level radioactive waste disposal facility.

QUESTION 29: The resulting NRC report on alternative methods of disposal was published in December 1986. Entitled "Licensing of Alternative Methods of Disposal of Low-Level Radioactive Waste"(NUREG- 1241), the study began by stating that all "siting, design, operations, closure, and the monitoring criteria" of Subpart D (Technical Requirements for Land Disposal Facilities) of 10 CFR 61 (Licensing Requirements for Land Disposal of Radioactive Waste) should apply. Subpart D limits off-site releases of radioactive material to those which is released "to the general environment in ground water, surface water, air, soil, plants, or animals." (*See* 10 CFR 61.41.)

Please explain how the unrestricted release of byproduct material into interstate commerce is an alternative method of disposal limiting off-site release of radioactive material to those contained "in ground water, surface water, air, soil, plants, or animals." Provide supporting documentation.

ANSWER.

As discussed in the cover letter and responses to Questions 26 and 28, NRC generally does not consider releases of byproduct material to be “disposals” authorized under 10 CFR Part 61. Therefore, the technical requirements in Subpart D of this Part do not apply. In addition, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the release of solid material authorized under NRC’s current practice

resembles disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (e.g., §20.2003 and §20.2005).

QUESTION 30: 10 CFR 20.2002 allows the NRC only to license alternative forms of "waste disposal." Please explain how unrestricted release qualifies as an alternative form of waste disposal, based on definition in the statute, regulations and NRC report cited in the previous questions. Provide supporting documentation.

ANSWER.

In a few instances licensees have used the specific process set out in §20.2002 to seek approval for the disposition of material in a manner not specifically enumerated elsewhere in Part 20. The disposition of material under the §20.2002 process through release is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2005). Because 10 CFR Part 20.2002 (or compatible regulations of Agreement States) allows for the disposal of licensed material by means other than those specifically identified elsewhere in Subpart K of Part 20, the specific elements of disposal pursuant to 10 CFR Part 61, or one of the approved methods in 20.2001, do not apply, and compliance with the requirements of Part 61 is not necessary.

QUESTION 31: The 1986 alternate method report reported on five types: below-ground vaults, above-ground vaults, earth-mounded concrete bunkers, mined cavities and augured holes and specifically refers to Subpart D, 10 CFR 61. Please explain how unrestricted release of byproduct material into interstate commerce compares with the criteria applied to these listed alternate methods of disposal and provide supporting documentation.

ANSWER.

The 1986 alternate method report discusses five types of facility design that could be used to demonstrate compliance with the technical requirements in Subpart D of Part 61. These technical requirements are intended to ensure permanent isolation of waste that is required to be disposed of under the provisions of 10 CFR Part 61. As discussed in the response to Question 26, the unrestricted release of solid material containing very low levels of radioactive material is not a disposal under the provisions of 10 CFR Part 61. Therefore, technical requirements in Subpart D of Part 61 do not apply.

QUESTION 32. 10 CFR Part 20 covers all persons licensed by the Commission to "receive, possess, use, transfer, or dispose of byproduct ... material ... under Parts 30 through 35." (10 CFR 20.1002.) Is there any other section in Part 20 that exempts MSC from the requirements of Parts 30-35? If the answer is in the affirmative, please explain and provide supporting documentation.

ANSWER.

There are no sections or provisions in 10 CFR Part 20 that would specifically exempt NRC licensees from the specific licensing requirements of Parts 30-35. In this case, Tennessee has approved the release pursuant to its licensing authority. As a Tennessee (Agreement State) licensee, MSC is not subject to the requirements of 10 CFR Part 20, which applies to NRC licensees, but rather to the requirements in Tennessee regulations that are comparable with the requirements in 10 CFR Part 20.

QUESTION 33. 10 CFR 20.1302 allows for some radioactive material from the normal operations of a licensee to be released in gaseous and liquid effluents. At the boundary of the licencee's restricted area, these releases must meet certain standards. Effluent is most commonly defined as "waste material (as smoke, liquid industrial refuse, or sewage) discharged into the environment especially when serving as a pollutant." Does the NRC or the State of Tennessee have a different definition of "effluent" that would include products or commodities sold into interstate commerce? Please explain and provide supporting documentation.

ANSWER.

The NRC does not have in 10 CFR Part 20 a specific definition for the word “effluent.” Similarly, Tennessee does not have a specific definition of “effluent” in its Part 20 equivalent rule. NRC does not believe “effluents” would include products or commodities sold into interstate commerce.

Nevertheless, the NRC views release of solid materials containing very low levels of radioactivity for unrestricted use as similar to releases of radioactivity to the air or water. In each case, material with very low levels of radioactivity may be released from a licensee’s operation because the concentration of radioactive material present is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of the public health and safety. In other words, if the material meets acceptable radiological criteria for release, whether it is in gaseous, liquid or solid form, it would not be subject to any further licensing control and would be

acceptable for unrestricted use. Similarly, for each of these forms of material, monitoring would occur prior to release to ensure that the release criteria are met. A similar regulatory framework for release was codified as part of the license termination rule, issued July 21, 1997, which set forth criteria in 10 CFR 20.1402.

QUESTION 34. In its recent issues paper, the NRC stated that although Part 20 provided for the release of air and liquid effluents from licensees' operations, it was "inconsistent" because it did not have a standard for a release of solid material, presumably as an effluent.

Please explain how 6,000 tons of nickel to be sold into interstate commerce can be defined as a solid "effluent" emanating from a licensee's normal operations and released for natural dispersion at the boundary of the licensee's restricted area similar to the gaseous and liquid effluents. Provide supporting documentation.

ANSWER.

The NRC views release of solid materials containing very low levels of radioactivity for unrestricted use as similar in basis and process to releases of radioactivity to the air or water. In each case, material with very low levels of radioactivity may be released from a licensee’s operation because the concentration of radioactive material present is so small that it is no longer necessary to subject the material to regulatory control for the purposes of protection of the public health and safety.

QUESTION 35. In the same issues paper, the NRC stated that Part 20 does not have a provision for the release of solid material. This does not appear to be accurate, as 10 CFR 20.2003 allows for the disposal by release of "licensed material" into sewerage if it is "readily soluble" in water.

Please state whether this provision allows solid material to be released under certain conditions and provide supporting documentation.

ANSWER.

The provisions in 10 CFR 20.2003 are limited to allowing discharges under certain conditions, i.e., it permits a licensee to discharge licensed material into sanitary sewerage if the material is readily soluble in water (or if it is readily dispersible biological material), and if the amount and type of material meets the conditions indicated in 20.2003(a)(2), (3), and (4). For example, a researcher may pour liquid waste containing residual radioactivity down a laboratory drain provided that Part 20 limits are not exceeded.

The issues paper does note (at 64 FR 35091) that there are some NRC regulations in 10 CFR Part 20 covering the release of certain materials and lists a few of those regulations as examples. However, the issues paper also notes that there are no current overall criteria in Part 20 governing control of solid materials, and that, therefore, NRC is currently considering reexamining its approach for control of these materials in order to provide a more consistent regulatory framework.

QUESTION 36. Please explain how, under Part 20, MSC would release its solid byproduct material at the boundary of its restricted area and how it will carry out the other provisions requiring monitoring of those releases for persons "continuously present" at the boundary of the licensee's restricted area. Provide supporting documentation.

ANSWER.

Prior to any release of solid material, a licensee, such as MSC, would conduct a radiation survey of that material within the restricted area before the material leaves the licensee’s control to ensure that radioactivity concentration levels in, or on, the material meet acceptable criteria as required by the regulatory agency for unrestricted use. After surveys confirm that radioactivity levels meet these criteria, the material would be authorized for release for unrestricted use.

The radiation surveys would be similar to those required for air and liquid releases in that they would demonstrate that the material meets criteria for release. However, the surveys would not include monitoring for persons who might be continuously present at the boundary of the licensee’s restricted area, because the maximum exposure for solid materials would more likely be persons away from the site who process, handle, or use the material, rather than a person at the site boundary.

QUESTION 37: In its contract with BNFL, the Department of Energy has described the contaminated nickel as "process equipment" that may be recycled and released as scrap metal by MSC, an NRC-licensed facility. (*See* East Tennessee Technology Part (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A, pp. 23, 33-34.) Please explain how recycling and release as scrap metal qualifies as the disposal of waste. Provide supporting documentation.

ANSWER.

As discussed in the response to Question 26, NRC does not generally consider releases of solid material for unrestricted use to be "disposals." For such releases, regulatory guidance on permissible releases, such as the surface contamination limits in Regulatory Guide 1.86, ensure that any subsequent use of the material will provide reasonable assurance of protection of the public health and safety with no further need for regulatory control. Also, as discussed in the responses to Questions 9 and 27, MSC is not licensed by NRC but is licensed by Tennessee, an Agreement State.

QUESTION 38: Since 1992, has the NRC promulgated through the regulatory process under the Administrative Procedure Act an unrestricted release standard for solid material of any type that contains byproduct material in any form? If the answer is in the affirmative, please provide supporting documentation.

ANSWER.

In July 1997, NRC promulgated its final rule establishing radiological criteria for license termination (10 CFR Part 20, Subpart E). This rule codified radiological criteria for the unrestricted and restricted release of land and structures or buildings with residual levels of radioactive contamination upon license termination. This rulemaking set standards that are generally consistent with criteria applied by NRC for many years prior to the rulemaking at individual sites though the licensing process. These criteria do not apply to uranium and thorium recovery facilities already subject to Appendix A of 10 CFR Part 40. (See 62 FR 39058, July 21, 1997).

Provisions for the release of land and structures or buildings at uranium recovery facilities were amended in April 1999 (10 CFR Part 40, Appendix A, Criterion 6(6)). (See 64 FR 17506, April 12, 1999.)

None of these rulemakings bear directly on the MSC licensing action.

QUESTION 39: Based on the above response, has the NRC established a legally binding release standard for solid material of any type containing byproduct material in any other process? Please explain and provide supporting documentation.

ANSWER.

The rule changes referred to in the response to Question 38 were promulgated in accordance with the requirements of the Administrative Procedure Act and are therefore legally binding. Please see our response to Question 26 for information on current practices relating to the release of solid material.

QUESTION 40: If there are such release standards, under what statutory and/or regulatory authority did the NRC issue them?

ANSWER.

The approach discussed in response to Question 39 is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through the issuance of specific license conditions or through the promulgation of generally applicable rules. (See, e.g., §161b and §81 of the AEA of 1954, as amended).

QUESTION 41. Section 274(j)(1) of the Atomic Energy Act allows the Commission to terminate or suspend all or part of its agreement with a state if it finds that the state's program is not compliant with the statute. Section 274 (g) requires that radiation standards be "coordinated and compatible." (*See* 42 U.S.C. 2021 (g) and (j)(1).) In September of 1997, the NRC adopted its "Statement of Principles and Policy for the Agreement State Program Policy Statement on Adequacy and Compatibility of Agreement State Programs." It was published in the *Federal Register* after extensive public comment. *(See* 62 Fed. Reg. 46517, Sept. 3, 1997.)

Specifically, compatibility is defined in the policy as "program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications." (*See* "The Commission Policy," Subsection III (B).) State radiation control programs are compatible only when they do "not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis." (*See* "Compatibility," Subsection III (E).) State standards for release limits "should be essentially identical to those of the Commission, unless Federal statutes provide the State authority to adopt different standards." (*See* "Basic Radiation Protection Standards," Subsection III (E)(A).)

Several years ago the NRC attempted to establish a level of byproduct contamination "below regulatory concern" that would allow the release of solid byproduct material. In 1992, Congress ordered the NRC to halt that rulemaking. In June of this year, the NRC published in the *Federal Register* an issue paper on the release of solid materials at licensed facilities. In that paper, the Commission states that it has no specific regulatory requirements regarding release of solid material," and that it wants "to establish a regulatory framework more consistent with existing NRC requirements on air and liquid releases."

(a) Are those accurate statements as of this date?

ANSWER.

Yes. We note that, in 1992, Congress revoked two NRC policy statements concerning material “below regulatory concern”; no NRC rulemaking action had been initiated.

(b) How does the State of Tennessee have an "essentially identical" standard to one promulgated by the NRC for the release of solid material containing byproduct material when there is no standard? Please explain and provide supporting documentation.

ANSWER.

The action taken by Tennessee does not establish a “basic radiation protection standard” that is generally applicable to all licensees. Rather, Tennessee has authorized one of its licensees to release solid material containing specific concentrations of particular radionuclides through a license condition. This is consistent with case-by-case reviews and use of license conditions to address licensee requests for release of solid material, as discussed in responses to earlier questions. (See response to Question 26.) The action taken by Tennessee is consistent with case-by-case actions taken by NRC and other Agreement States for the release of solid material containing very low levels of radioactive material.

NRC has not established a “basic radiation protection standard” for the release of solid material. In cases where NRC has established a basic radiation protection standard or regulation, and made a determination of the extent to which the Agreement State program must be compatible with that standard or regulation, States are expected to adopt and implement the standard in accordance with the compatibility level assignment. In those circumstances where NRC has not established a specific standard, States have flexibility to establish their own requirement, or to develop and apply a criterion or limit applicable to a specific case, provided the States continue to provide reasonable assurance of protection of public health and safety and their activities are, in a broad sense, compatible with the Commission’s program. (See Policy Statements at 62 FR 46525, September 3, 1997 and Management Directive 5.9 (attached)).

Attachment: Management Directive 5.9

QUESTION 42. Under the agreement state policy, radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. "They should be not only effective and cooperatively implemented by NRC and the Agreement States, but also should provide uniformity and consistency in program areas having national significance."

Do the NRC, Tennessee and the other agreement states have common definitions for such words as "waste," “disposal,” “effluent,” “byproduct material," "transfer," and "release limits"? Please provide those definitions.

ANSWER.

NRC regulations include definitions of the terms “byproduct material”, “waste”, and “disposal,” for application in particular contexts. Those definitions are:

[10 CFR 150.3(c)] Byproduct material means: (1) Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “byproduct material” within this definition.

[10 CFR 61.2] Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, that is, radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste).

[10 CFR 61.2] Disposal means the isolation of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal facility.

Under the implementing procedures for the Policy Statement on Adequacy and Compatibility of Agreement State Programs, Agreement States should adopt definitions for “byproduct material” and “waste” that are essentially identical to those of NRC and adopt a definition for “disposal” that meets the essential objectives of the NRC’s definition.

All States have adopted a compatible definition for 11e.(1) byproduct material as set forth in 10 CFR 150.3(c). Six States do not include the definition of 11e.(2) byproduct material as set out in paragraph (2) of 10 CFR 150.3(c) -- the definition of “11e.(2) byproduct material.” These six States, however, do not have regulatory authority over 11e.(2) byproduct material under their

Agreements. All States, except two which have not adopted a definition of waste, have adopted a compatible definition of waste. All States, except eleven which have not adopted a definition of disposal, have a compatible definition of disposal.

The terms “effluent”, “transfer”, and “release limits” are not defined in NRC regulations and are therefore not covered in the implementing procedures.

QUESTION 43. This policy, under the authority of Section 274 (j)(1) of the Atomic Energy Act, requires that the NRC must consider suspending or terminating its agreement with agreement states if their release standards are not compatible with the NRC's and the other agreement states. Please describe the release standards for solid material containing byproduct material of the other agreement states and answer the following questions:

ANSWER.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric radioactive material. Their responses indicate that, although the approaches vary, the States' practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses appear to indicate that there is a need for clarification, particularly with respect to the need for some States to differentiate between the decommissioning rule for release of land, buildings and structures that are on sites at the time of license termination, and the release of materials for unrestricted use. We plan to communicate with the Agreement States to clarify their practices. We are aware that two other States (Washington and New York) have also received recent requests from their licenses to authorize releases of large volumes of slightly contaminated material.

The criteria utilized by States, generally applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health

and safety issue, there may be a benefit in establishing a consistent national approach. If an Agreement State promulgates requirements that are inconsistent with the compatibility designation assigned to an existing NRC rule, NRC would likely find the state's action "not compatible" under the Integrated Materials Performance Evaluation Program (IMPEP). Such a finding could result in NRC consideration of suspending or terminating its agreement with the Agreement State. Before taking such action, however, a number of steps would first be implemented. These steps would include: correspondence with the State requesting action to effect adoption of a compatible standard; a follow-up meeting at a senior management level to discuss the need to adopt a compatible standard and understand the State's basis for not adopting a compatible standard; a follow-up IMPEP review; or placement of the State's program on heightened oversight, or probation. In most cases, NRC expects that such measures, short of suspension or termination of an agreement, would effect the change necessary to achieve a compatible State standard.

(a) Is it possible for any agreement state to set a completely different standard for the release of solid material containing byproduct material? Please explain and provide any supporting documentation.

ANSWER.

In the current situation where NRC has not established a "basic radiation protection standard" applicable to all licensees for the release of solid material, Agreement States have the flexibility to establish standards, criteria or individual limits on a case-by-case basis. Generally, an Agreement State may set a different standard from other Agreement States where: (1) NRC has

not established a specific requirement, (2) the State has an adequate supporting health and safety basis; (3) the requirement does not preclude a practice that is in the national interest and is otherwise generally compatible with the Commission's program; and (4) the Agreement State continues to provide reasonable assurance of adequate protection of public health and safety.

(b) Is it possible for any or all other states to ban the import of MSC nickel released under the Tennessee license from entering their states? Please explain and provide any supporting documentation.

ANSWER.

If the nickel continues to contain detectable levels of AEA material, it is conceivable that another Agreement State, based on its authority stemming from its Agreement with NRC, could attempt to assert regulatory authority over the material and prohibit the entry into that State. As the Policy Statement indicates, a State may impose regulatory requirements for material covered by its agreement as long as it, among other things, "does not preclude a practice in the national interest without an adequate health and safety or environmental basis related to radiation protection." Given the NRC's ongoing efforts to explore the need for consistency in this area, it is premature for the Commission to conclude that the practice in question (i.e., MSC's release of nickel) qualifies as a "practice in the national interest" warranting the Commission's intervention against State actions seeking to preclude the entry of such material into their State. We note, however, that it is likely that a State's attempt to ban the import of the material would raise a host of practical implementation problems associated with the identification of the material.

It is possible that States may have authority outside the Agreement State context to ban import of MSC nickel. We have not analyzed the extent of State authority in this regard.

(c) Would such actions by other states in response to Tennessee's setting of a standard for the unrestricted release of byproduct material "create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis"? If the answer is in the negative, please explain why different state standards for release "create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis."

ANSWER.

As stated in the response to Question 41(b), NRC's policy statement on adequacy and compatibility of Agreement State programs indicates that where NRC has not established a specific standard, Agreement States have the flexibility to establish their own requirements, or to develop and apply a criterion or limit applicable to a specific case, provided that the States continue to provide reasonable assurance of protection of public health and safety and that their activities are in a broad sense compatible with the Commission's program. (62 FR 46525.) (Also see response to Question 43(b)). It can be expected that such flexibility will result in some differences between NRC and Agreement State programs, particularly where no general NRC standard exists. In addition, as explained in more detail in response to Question 43(b), the NRC will raise compatibility concerns with Agreement States if a State's regulatory action precludes a

practice in the national interest. At this time, it is premature for the NRC to determine whether the State's effort to ban an import would raise a compatibility concern.

QUESTION 44. The agreement state policy also requires that “Regulations and regulatory decisions should be based on assessments of the best available information from affected and interested individuals and organizations, as well as on the best available knowledge from research and operational experience.... The public should have an opportunity for early involvement in significant regulatory program decisions." (Subsection C (1).)

By everyone's evaluation, the unrestricted release of 6,000 tons of byproduct material into interstate commerce is a "significant regulatory program decision." The public received no notice or the opportunity to comment on the MSC license amendment. Is this in keeping with the policy statement cited above? Please explain.

ANSWER.

Generally, NRC imposes no specific requirements on Agreement States to employ any particular public notice or hearing procedures for particular licensing actions. (For mill tailings, the requirements in Section 274o of the AEA require the Agreement State to provide for an opportunity, after public notice, for written comments and a public hearing, along with several other procedural and legal review requirements). In most cases, the Agreement States follow administrative procedures dictated by the administrative laws applicable to all regulatory agencies in that state. In light of this, NRC has not generally imposed its own procedures on the Agreement

States. However, if NRC identifies adequacy problems in an Agreement State program that can be linked to procedures in the State, NRC will raise the issue with the State.

In this particular case, Tennessee staff has informed NRC staff that the MSC licensing action was reviewed and issued in accordance with Tennessee State administrative procedures. We believe that Tennessee could assert that this action is not a "significant regulatory program decision" since it addresses, for only one licensee in one specific license, the criteria that will be applied to the release of material containing very low levels of radioactive material.

In the case of NRC licensees, licensing actions involving the issuances of licenses or license amendments, including those addressing releases, would be subject to an opportunity for a hearing. Also, additional information may be provided through supporting environmental analysis for the licensing actions. However, as stated above, NRC does not require Agreement States to adopt the same procedures and, as such, differences in approach are inevitable. Specific opportunities for public participation vary among the States.

QUESTION 45. Under this policy the agreement states are required to provide the NRC with information about their regulations and license conditions. When and how did the NRC receive information concerning the MSC license amendment?

ANSWER.

When approving a new agreement, NRC reviews a State's program including regulations, licensing and inspection procedures, and other program implementation documentation to determine that the State's program is adequate to protect public health and safety and compatible with NRC's program. After an agreement is effective, as discussed in response to Question 3, NRC reviews each Agreement State program under the Integrated Materials Performance Evaluation Program (IMPEP) for continued adequacy and compatibility. As part of each review, under the common performance indicator "Technical Quality of Licensing Actions," a State is asked to identify any major, unusual or complex licenses which were issued or amended. This listing is used by the review team to identify licensing actions to review during the on-site review. The State is also asked to identify any changes made in written licensing procedures during the review period. Tennessee's last IMPEP review was conducted in 1996, and at that time, the Tennessee program was found to be adequate and compatible. The next IMPEP for Tennessee is scheduled for August 2000.

In the late March (1999) time frame, NRC staff received a press inquiry regarding the MSC licensing action. In response, NRC staff contacted Tennessee staff to obtain information on the MSC license. Subsequently, NRC staff also requested information from Tennessee on the

licensing action in connection with activities of the Release of Solid Material Working Group in order to develop background information on Agreement State activities. Staff is not aware of any specific notification by Tennessee staff to NRC that Tennessee had issued the license amendment. However, staff on the NRC Release of Solid Materials Working Group were informally contacted by Tennessee staff during Tennessee's review of the amendment request to discuss whether work being done by the Working Group could be of assistance to Tennessee. NRC staff indicated the work was in progress and the results were not yet available.

Q-26

SSINS: 6830
Accession No.:
8103300375
IEC 81-07

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

May 14, 1981

IE Circular No. 81-07: CONTROL OF RADIOACTIVELY CONTAMINATED MATERIAL

Description of Circumstances:

Information Notice No. 80-22 described events at nuclear power reactor facilities regarding the release of radioactive contamination to unrestricted areas by trash disposal and sale of scrap material. These releases to unrestricted areas were caused in each case by a breakdown of the contamination control program including inadequate survey techniques, untrained personnel performing surveys, and inappropriate material release limits.

The problems that were described in IE Information Notice No. 80-22 can be corrected by implementing an effective contamination control program through appropriate administrative controls and survey techniques. However, the recurring problems associated with minute levels of contamination have indicated that specific guidance is needed by NRC nuclear power reactor licensees for evaluating potential radioactive contamination and determining appropriate methods of control. This circular provides guidance on the control of radioactive contamination. Because of the limitations of the technical analysis supporting this guidance, this circular is applicable only to nuclear power reactor facilities.

Discussion:

During routine operations, items (e.g., tools and equipment) and materials (e.g., scrap material, paper products, and trash) have the potential of becoming slightly contaminated. Analytical capabilities are available to distinguish very low levels of radioactive contamination from the natural background levels of radioactivity. However, these capabilities are often very elaborate, costly, and time consuming making their use impractical (and unnecessary) for routine operations. Therefore, guidance is needed to establish operational detection levels below which the probability of any remaining, undetected contamination is negligible and can be disregarded when considering the practicality of detecting and controlling such potential contamination and the associated negligible radiation doses to the public. In other words, guidance is needed which will provide reasonable assurance that contaminated materials are properly controlled and disposed of while at the same time providing a practical method for the uncontrolled release of materials from the restricted area. These levels and detection capabilities must be set considering these factors: 1) the practicality of conducting a contamination survey, 2) the potential of leaving minute levels of contamination undetected; and, 3) the potential radiation doses to individuals of the public resulting from potential release of any undetected, uncontrolled contamination.

Studies performed by Sommers[1] have concluded that for discrete particle low-level contamination, about 5000 dpm of beta activity is the minimum level of activity that can be routinely detected under a surface contamination control program using direct survey methods. The indirect method of contamination monitoring (smear survey) provides a method of evaluating removable (loose, surface) contamination at levels below which can be detected by the direct survey method. For smears of a 100cm^2 area (a de facto industry standard), the corresponding detection capability with a thin window detector and a fixed sample geometry is on the order of 1000 dpm (i.e., 1000 dpm/100 cm^2). Therefore, taking into consideration the practicality of conducting surface contamination surveys; contamination control limits should not be set below 5000 dpm/100 cm^2 total and 1000 dpm/ 100 cm^2 removable. The ability to detect minute, discrete particle contamination depends on the activity level, background, instrument time constant, and survey scan speed. A copy of Sommers studies is attached which provides useful guidance on establishing a contamination survey program.

Based on the studies of residual radioactivity limits for decommissioning (NUREG-0613[2] and NUREG-0707[3]), it can be concluded that surfaces uniformly contaminated at levels of 5000 dpm/ 100cm^2 (beta-gamma activity from nuclear power reactors) would result in potential doses that total less than 5 mrem/yr. Therefore, it can be concluded that for the potentially undetected contamination of discrete items and materials at levels below 5000 dpm/100cm^2, the potential dose to any individual will be significantly less than 5mrem/yr even if the accumulation of numerous items contaminated at this level is considered.

Guidance:

Items and material should not be removed from the restricted area until they have been surveyed or evaluated for potential radioactive contamination by a qualified* individual. Personal effects (e.g., notebooks and flash lights) which are hand carried need not be subjected to the qualified individual survey or evaluation, but these items should be subjected to the same survey requirements as the individual possessing the items. Contaminated or radioactive items and materials must be controlled, contained, handled, used, and transferred in accordance with applicable regulations.

The contamination monitoring using portable survey instruments or laboratory measurements should be performed with instrumentation and techniques (survey scanning speed, counting times, background radiation levels) necessary to detect 5000 dpm/100 cm^2 total and 1000 dpm/100 cm^2 removable beta/gamma contamination. Instruments should be calibrated with radiation sources having consistent energy spectrum and instrument response with the radionuclides being measured. If alpha contamination is suspected appropriate surveys and/or laboratory measurements capable of detecting 100 dpm/100 cm^2 fixed and 20 dpm/100 cm^2 removable alpha activity should be performed.

*A qualified individual is defined as a person meeting the radiation protection technician qualifications of Regulatory Guide 1.8, Rev. 1, which endorses ANSI N18.1, 1971.

In evaluating the radioactivity on inaccessible surfaces (e.g., pipes, drain lines, and duct work), measurements at other appropriate access points may be used for evaluating contamination provided the contamination levels at the accessible locations can be demonstrated to be representative of the potential contamination at the inaccessible surfaces. Otherwise, the material should not be released for unrestricted use.

Draft ANSI Standard 13.12[4] provides useful guidance for evaluating radioactive contamination and should be considered when establishing a contamination control and radiation survey program.

No written response to this circular is required. If you have any questions regarding this matter, please contact this office.

REFERENCES

[1]Sommers, J. F., "Sensitivity of Portable Beta-Gamma Survey Instruments," Nuclear Safety, Volume 16, No. 4, July-August 1975.

[2]U.S. Nuclear Regulatory Commission, "Residual Radioactivity Limits for Decommissioning, Draft Report," Office of Standards Development, USNRC NUREG-0613, October 1979.

[3]U.S. Nuclear Regulatory Commission, "A Methodology for Calculating Residual Radioactivity Levels Following Decommissioning," USNRC NUREG-0707, October 1980.

[4]Draft ANSI Standard 13.12, "Control of Radioactive Surface Contamination on Materials, Equipment, and Facilities to be Released for Uncontrolled Use," American National Standards Institute, Inc., New York, NY, August 1978.

Attachments:
1. Reference 1 (Sommers Study)
2. Recently issued IE Circulars

Control and Instrumentation

Edited by E. W. Hagen

Sensitivity of Portable Beta–Gamma Survey Instruments

By J. F. Sommers*

Abstract: *Development of a new generation of portable radiation survey instruments and application of the "as low as practicable" (ALAP) philosophy have presented a problem of compliance with guides for radioactive contamination control. Isolated, low-level, discrete-particle beta-gamma contamination is being detected with the new instruments. To determine the limits of practicability requires, in turn, the determination of the limits of detection of these surface contaminants. The data and calculations included in this article indicate the source detection frequencies that can be expected using the new generation of survey instruments. The author concludes that, in low-population groups of discrete particles, about 5000 dis/min of beta activity per particle is the minimum level of activity per particle which is applicable for confident compliance with surface contamination-control guides. Lower control levels are possible with additional development of instruments or through high-cost changes in radiation survey and contamination-control methods. Additional analyses are required for assessment of the hazard caused by widely dispersed discrete-particle contaminants.*

The common, historical way to classify surface radioactive contamination has developed into standard definitions, limits, and control guides which, in some instances, are difficult, if not impossible, to apply.

In general, the definition of "removable" radioactive contamination must be inferred from guides[1] and regulations[2] on the significance of the quantity of radioactive materials removed. "Fixed" contamination, although not as uniquely defined, is, by inference, the radioactive contaminants that remain on a surface after the surface has been checked and found to have less than some defined removable contamination level. There are many minor variations of these definitions, but these will suffice to outline a major problem that applied health physicists have to verify compliance with radioactive surface contamination limits and guides.

In recent years the lowering of limits and the emphasis on as low as practicable[3] (ALAP) hazard control has encouraged commercial development of more sensitive survey instruments, the big improvement being detectors with thin windows. Peripheral features, such as audible alarms with adjustable set points, external speakers (instead of earphones), and selectable meter time constants, are common. However, the strong commercial competition to supply this type of instrumentation, the extreme competition for funds that could be used to improve radiation protection equipment, and the health physicists' reluctance or inability to provide adequate specifica-

*John F. Sommers received degrees in mathematics (B.A., 1948) and physics (B.S., 1950) from the University of Wyoming and was elected to the National Honorary Physics Society, Sigma Pi Sigma, in 1949. Under an AEC fellowship grant, he earned a certificate in radiological physics from the Oak Ridge Institute of Nuclear Studies for work at Vanderbilt University and Oak Ridge National Laboratory during 1950 and 1951. Since 1951, he has been associated with the Idaho National Engineering Laboratory (INEL) (formerly the National Reactor Testing Station) as technical assistant and as manager of Applied Health Physics in the safety groups of the prime contractors for AEC. At present, he is supervisor of the Radiological Engineering Section in the Safety Division of Aerojet Nuclear Company, the prime operating contractor for the Energy Research and Development Administration (ERDA) at INEL, where he is directly involved in development and application of a positive-action ALAP (as low as practicable) program for control of radiation hazards in INEL nuclear facilities.

tions have left something to be desired in quality and overall performance of many of the instruments.

Although present beta–gamma contamination-control practices are more rigorous than in the past, there is still less than complete control of low-activity low-density particulate sources within the operating areas. In a typical situation the highest density of these particles, outside of contamination-control zones, may be on the order of one detectable particle per 10^2 to 10^3 ft^2. The particles are removable beta–gamma activity, but because of the large areas involved, the multiple types of surfaces on which they are deposited, and the low area density of the particles, they are not subject to detection with any sensible frequency using the smear or wipe technique. Thus survey instruments must be used to detect and measure the activity of the removable particles.

The particles tend to be trapped and concentrated on certain types of surfaces, such as mopheads and acrylic fiber rugs. From these deposits it has been determined that the specific activities of most of the particles range from about 2×10^3 to 2×10^6 dis/min. In order to determine why the particles escape detection and control within the operating areas, experimenters devised a rigorous test to determine the expected frequency of detection of the particles using standard survey methods. The results of these experiments have shown that the main hope for improvement lies in the development of more sensitive survey instruments and portal monitors and the development and application of contamination-control methods similar to those used in facilities where the much more hazardous alpha-emitting materials are handled.

THEORY

The ability of a count-rate meter to provide reliable information for detection of small-diameter sources during surveys for radioactive contaminants depends upon a number of factors. These factors, for any given type and energy of radiation sources, are the specific activity of the sources, the influence of background radiation, the instrument time constant, the source–detector geometry, and the relative source–detector velocities. When an alarm set point is used to indicate the presence of radioactive sources, investigation shows that the sensitivity of the instrument is increased by setting the alarm set point as low as possible without causing alarms due to the fluctuations of background; the response of the count-rate meter is modified from the equilibrium count rate when source residence time under the detector is on the same order of magnitude of or less than the time constant of the meter; the count rate of the instrument increases as the source–window distance decreases; and the response of the count-rate meter increases as the source residence time under the detector window increases.

On the basis of the approximate Gaussian distribution of a count rate around the true average count rate, an alarm set point A has a probability p of being reached and causing an alarm due to an average background count rate B during a counting interval T that can be expressed as

$$A = (1 - e^{-T/\tau})(B + kT^{-\frac{1}{2}} B^{\frac{1}{2}}) \qquad (1)$$

where τ is the time constant of the count-rate meter and k is a constant that uniquely defines the probability of alarm.[4] The term $1 - e^{-T/\tau}$ (the fraction of equilibrium count rate obtained during T) is limited by design considerations of count-rate meters to the accuracy of the meter output. Most instruments have 1% (of full-scale reading) or larger accuracy limits. For this reason the value of $0.99 = 1 - e^{-T/\tau}$ has been assigned for this study. Knowing the value of τ allows solution for T, and the solution is used in the second term of Eq. 1. This solution can be thought of as the practical, constant, integrating interval observed by the count-rate meter.

The approximate response of an instrument to small-diameter sources can be calculated by defining standard survey conditions and relating them to the response characteristics of the instrument. For these calculations the velocity vector v of a flat circular window of the detector is assumed to be parallel to the surface being surveyed, and the velocity is held constant. The sources passing under the window of the detector bisect the circular projection of the window on the surface. The beta-counting efficiency of the instrument is assumed to be positive and constant when a source resides in the circular projection of the window on the surface; otherwise, the efficiency for counting the source is zero. This latter assumption may cause significant perturbations of experimental data from calculated data when source–window distances are larger than 2.5 cm. Gamma-counting efficiencies, the same order of magnitude as the beta-counting efficiencies, may also cause significant perturbation of experimental results, depending on the detector shielding configuration and effectiveness. The ideal source residence time t is assumed to be equal to the window diameter d divided by the velocity vector v. Under field conditions, t will usually be less than the ideal value

because the source velocity vector will hardly ever exactly bisect the circular window projection on the surface being surveyed.

Using the ideal survey conditions and an average background count rate B, a source with a net equilibrium count rate S will cause a count rate as large as, or larger than, A, with a probability P_i that is uniquely defined by the constant K_i when the source residence time under the window is t and the time-dependent meter response term is $1 - e^{-t/\tau}$. The count rate A can then be expressed as

$$A \leq (1 - e^{-t/\tau})\,(B + S + K_i[t^{-1/2}(B + S)^{1/2}]) \quad (2)$$

By substitution of the alarm set-point count rate A from Eq. 1 into Eq. 2 and rearrangement, the source strength is found to be

$$S \geq \left(\frac{1 - e^{-T/\tau}}{1 - e^{-t/\tau}}\right)(B + K_i[T^{-1/2} B^{1/2}]) - (B + K_i[t^{-1/2}(B + S)^{1/2}]) \quad (3)$$

Analysis of Eq. 3 shows that P_i is the probability, or time-dependent frequency, that S will cause an alarm when K_i is positive, and $(1 - P_i)$ is the probability that the alarm will be actuated when K_i is negative. Solutions for S can be obtained using selected values of K_i, B, τ, t, and T.

METHODS

In order to determine expected alarm-actuation frequencies during standard contamination surveys, experimenters established the following conditions. These conditions would also allow an experimental check of the calculated alarm-actuation probabilities that occur when the source strength, background, instrument time constants, and source residence time are changed.

Commercially available (two manufacturers) portable survey instruments were used as models for the calculations and experiments. Selectable time constants of 0.0159 and 0.159 min were calculated from the manufacturers' quoted time-response characteristics: "90% of the equilibrium count rates in 2.2 or 22 seconds." Survey velocities between 2.4 and 15 cm/sec were selected for analysis, velocities that cause the source residence times under the 5-cm-diameter detector windows to range from 0.33 to 2.1 sec. Cesium-137 sources having small diameter and low backscatter were used experimentally for verification of calculated data; these sources are counted with an efficiency of 0.1 count per beta at ½ in. from the center of 1.7 mg/cm², 5-cm-diameter windows of "pancake"-type semishielded Geiger-Mueller tubes. Extrapolation of the data to other beta emitters is a practical exercise; i.e., from Evans,[5] beta transmission factors through 3.0 mg/cm² (air plus window) were calculated and shown to be greater than 72% for betas with energy spectra having maximum-energy betas (E_{max}) greater than 0.2 MeV. Thus ^{137}Cs betas, with a mean $E_{max} \cong 0.56$ MeV, provide a beta-counting efficiency from the thin-window detectors which is typical of beta emitters with E_{max} greater than 0.2 MeV. Also, background and source size data are presented in counts per minute, so that changes in beta energies of sources and/or source–window distances can be normalized, using observed counting efficiencies, to the calculated data presented in this article.

With some manipulation of Eq. 3, a computer program was used to obtain an iterative set of solutions for S that are accurate to within 1% of the true values. The alarm set points were determined using Eq. 1. Selections of background count rates, relative detector–source velocities, and the instrument time constant were arbitrary but within the ranges chosen for investigation. Values of K_i were chosen to provide known probabilities of alarm actuation.

An extensive set of experimental data was obtained by moving calibrated sources past the detector windows at measured velocities and source–window distances to check the validity of the calculations. The same experimental setup to determine source detection frequencies was used with the audio (speaker) output of the survey meters. The use of audio output during contamination surveys is a well-known practice and will not be described further.

When the experimental and calculated source detection frequencies were compared, it became apparent that the time constants of the commercial survey instruments were not equal to specified values. Variations were noted between instruments of one model and between the different alarm set points on the other model. By measuring the buildup of the indicated count rates to 90% of equilibrium, we were able to determine the actual time constant on the instruments for any particular alarm set point.

The experimental data were obtained on an instrument that exhibited the advertised time constants. However, the poor (time-dependent response) performance of these instruments as a group has caused us to abandon the alarm set-point method for source detection under field conditions.

RESULTS

Alarm set points vs. background count rate were calculated from Eq. 1. These are illustrated in Fig. 1 for time constants of 0.0159 and 0.159 min. The k value selected, 4.89, uniquely defines the probability of an alarm being caused by a constant average background as 5×10^{-7} min^{-1}.

Figure 2 shows that the short-time-constant set point is more sensitive for source detection, even though the long-time-constant set point is the lowest. The relative difference between the two becomes less as the source residence time increases.

Figure 3 illustrates the improved sensitivity to be expected as the source residence time increases (detector velocity decreases). The set point is obtained from Eq. 1 or Fig. 1. Note that with a source residence time of 1 sec (5 cm/sec), it takes 5000 betas/min (500 counts/min) at a background of 60 counts/min to cause an alarm 90% of the time. As a practical illustration, if an individual surveys himself at 10 cm/sec, it will take about 3 min for him to survey half the surface area of his body, and the particles he discovers with a 90% confidence level will have a beta-emission rate of about 9000 per minute (900 counts/min).

Figure 4 illustrates the benefit of selecting low-background areas to perform contamination surveys. As indicated by Eq. 1, the alarm set point has to be changed each time the background changes, and, if the time constant is not dependable (known), the set point may not be correct. Changing background count rates are a common occurrence in our operations, and our inability to make time-constant determinations in the field has caused us to abandon the alarm set-point method for contamination surveys.

Figure 5 shows that the calculational method of determining source detection frequencies using the alarm set point is valid in comparison with experimental data. Both the time constant and the alarm set point were verified on the instrument used. In practice, there would be some ambiguity in the setting of the alarm owing to the crude alarm set-point dial furnished on this model instrument.

Figure 6 compares calculated alarm-actuation frequencies with experimental data on audio-output source detection frequencies at an average background of 120 counts/min and a relative surface–window velocity of 15 cm/sec. Using the speaker output method, smaller sources are detected with the same frequency that is obtained using the alarm set-point method. The improvement is about a factor of 3.

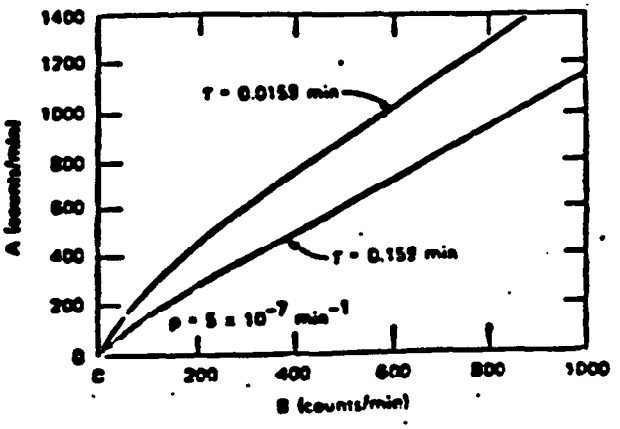

Fig. 1 Effect of background on the optimum alarm set point.

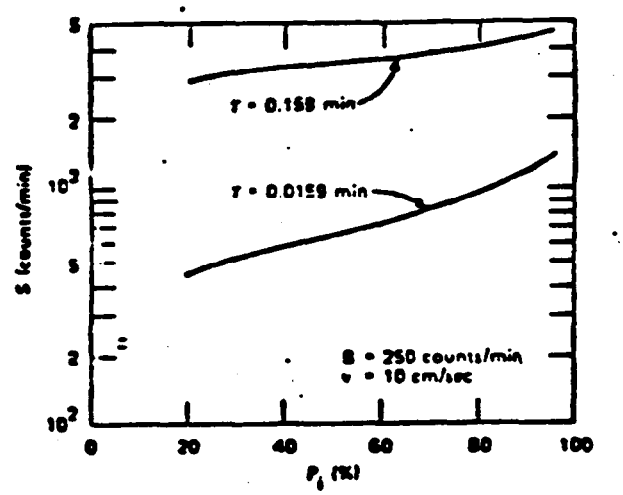

Fig. 2 Effect of instrument time constant on source detection frequency.

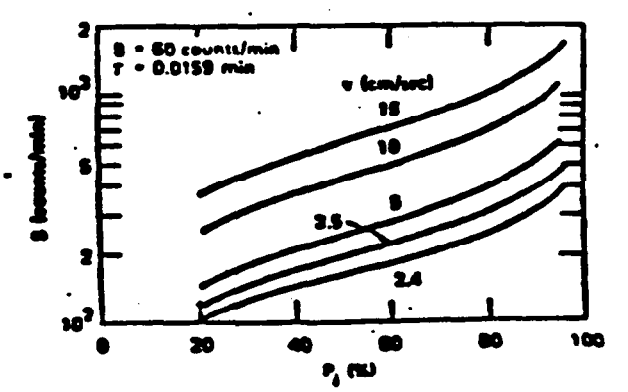

Fig. 3 Effect of probe velocity on source detection frequency.

Figure 7 shows a similar comparison using a detector velocity of 3.5 cm/sec. Here, the difference in detection frequencies narrows, and the alarm set-point method becomes better than the audio detection method for the larger sources at this low survey velocity.

Figure 8 compares experimental audio-output data for three different survey velocities at 120 counts/min background. The difference in source detection frequencies is surprisingly small when compared with the alarm-actuation method. This is explained by the adaptability of the human audio response; i.e., the effective time constant (human) adapts, within bounds, to the source size that can be detected with a given survey velocity and background count rate. Note that at 500 counts/min (5000 betas/min), the source detection frequencies appear to converge at about 80%. The results shown are averages of over 100 observations per datum point from two or more experienced surveyors. The largest variations in the data occurred between individuals; i.e., the largest variables were caused by the physical and psychological conditioning

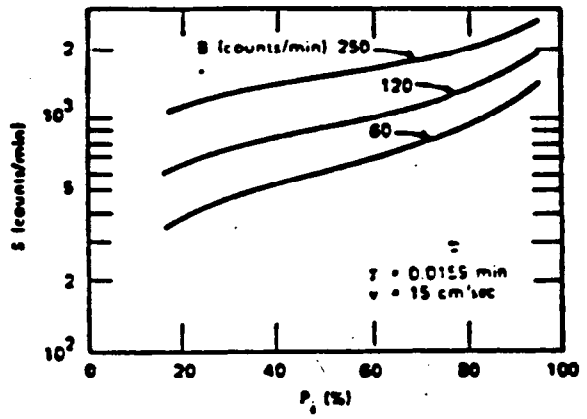

Fig. 4 Effect of background on source alarm-actuation frequency.

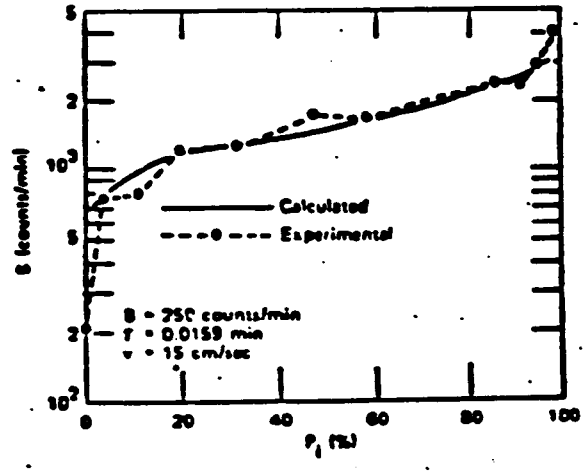

Fig. 5 Comparison of experimental and calculated data on source detection frequencies.

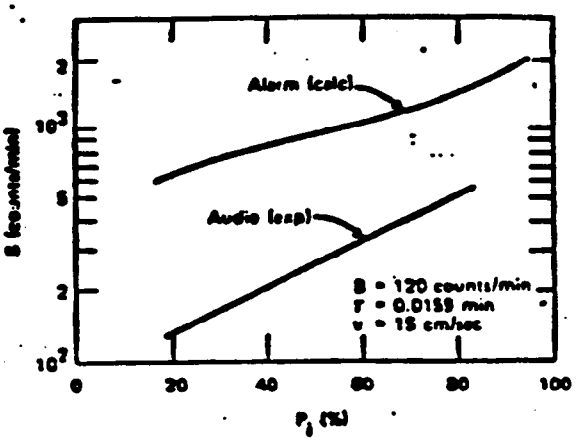

Fig. 6 Comparison of source detection frequencies using alarm set-point and audio detection methods.

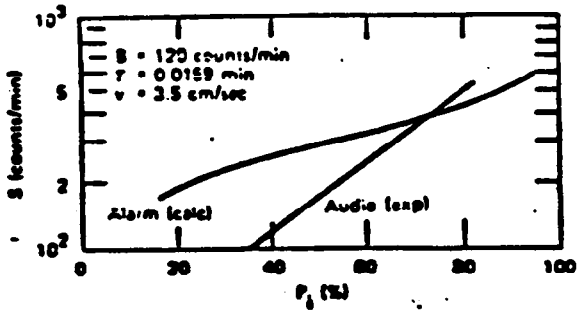

Fig. 7 Comparison of source detection frequencies using alarm and audio detection methods.

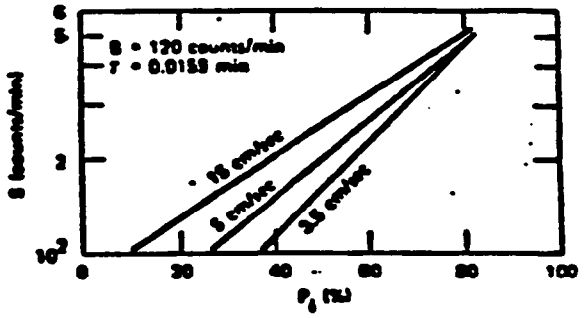

Fig. 8 Comparison of audio source detection frequencies and velocities.

of the surveyors. The lower detection frequencies have been ignored because of the statistical deviations that occurred. The time consumed to obtain reliable data at the higher detection frequencies was considerable, and, as our interest is in setting high-confidence-level control criteria, it was considered not practicable to obtain good, small source, detection-frequency statistics.

DISCUSSION AND CONCLUSIONS

A method has been shown whereby detection frequencies of small-diameter radioactive sources can be calculated for portable survey instruments that have known time constants and alarm set points. Source detection frequencies are strongly dependent upon (1) source strength, (2) survey velocities, (3) background activity, (4) detector sensitivity, and (5) the time constant of the survey meter. With activity of a large-area uniform surface, the survey velocity and the time constant of the survey meter are immaterial (within reasonable bounds). The calculations show that, even under the most rigorous conditions (survey velocities <2.5 cm/sec), small-diameter sources emitting 3000 betas/min can only be detected in low-background areas with a confidence of about 90% using the alarm set-point method. At more sensible survey velocities of 10 to 15 cm/sec, it takes sources emitting 10,000 to 15,000 betas/min to provide the same detection frequency using the alarm set-point detection method.

At the higher probe velocities investigated, source detection frequencies are larger using the audio output rather than the alarm set-point method. With small-diameter sources emitting 5000 betas/min, source detection frequency at 120 counts/min background is about 80% using the speaker output, regardless of the survey velocities between 3.5 to 15 cm/sec. With 3000 beta/min sources, the speaker detection frequency, using the slowest survey velocity (3.5 cm/sec), is only about 65%. At this velocity the alarm set-point method is as good as or better than the audio method with sources larger than 3500 betas/min. Although most of the experimental data were obtained at only one background level (120 counts/min), it is apparent that it is not practical to set contamination-control limits on discrete particles of beta–gamma activity much below 5000 betas/min if we are to have confidence in our ability to detect discrete-particle sources before they escape the contamination-control areas.

These results then pose several problems. Are the particles of beta–gamma activity that escape detection, and thus control, a health hazard of consequence? Krebs[6] and Healy[7] have presented arguments on the relative hazards of discrete-particle and small-area sources in relation to more diffuse sources. However, the data used involved higher specific activity than that of the particles we have been observing. Healy has published[8] a comprehensive resuspension hazards analysis for diffuse contaminants which is difficult to apply to the low-density particle population we observe. Good hazards analyses are needed on the resuspension of discrete particles in the size range under discussion. Development of portable instruments for surveying large areas with a practical expenditure of time and effort appears possible, but it will take time and money to design, develop, and make them commercially available. In the meantime, the advisory, standards, and regulation agencies need to look at the control guides and limits to assure that the conservatism applied using the ALAP philosophy is, in fact, *practicable* for compliance with the equipment and methods available to the industry. For this particular problem (low-density discrete particles of removable beta–gamma activity), I suggest that removable contamination be defined in two categories, "uniform" and "dispersed," and then resuspension factors applied that have some reality in the calculation of exposure hazards. This is the only way at this time that the industry has any hope for practicable compliance with contamination-control limits.

REFERENCES

1. Administrative Guide for Packaging and Transporting Radioactive Materials, ANSI-N14.1(0.1-1973, p. 7, American National Standards Institute, New York.
2. Department of Transportation, Hazardous Materials Regulations of the Department of Transportation, *Code of Federal Regulations*, Title 49, 171.397, effective Sept. 13, 1973.
3. Concluding Statement of the AEC Regulatory Staff in the "As Low As Practicable" Hearing, *Nucl. Safety*, 15(4): 443-452 (July–August 1974).
4. A. A. Jarrett, Statistical Methods Used in the Measurement of Radioactivity (Some Useful Graphs), USAEC Report AECU-262, 1946.
5. R. D. Evans, *The Atomic Nucleus*, pp. 627-628, McGraw-Hill Book Company, Inc., New York, 1955.
6. J. S. Krebs, The Response of Mammalian Skin to Irradiation with Particles of Reactor Debris, Report USNRDL-TR-67-118, U. S. Naval Radiological Defense Laboratory, September 1967.
7. J. W. Healy, A Proposed Interim Standard for Plutonium in Soils, USAEC Report LA-5483-MS, Appendix C, Los Alamos Scientific Laboratory, January 1974.
8. J. W. Healy, Surface Contamination: Decision Levels, USAEC Report LA-4558-MS, Los Alamos Scientific Laboratory, September 1971.

Attachment 2
IEC 81-07
May 14, 1981

RECENTLY ISSUED IE CIRCULARS

Circular No.	Subject	Date of Issue	Issued to
81-06	Potential Deficiency Affecting Certain Foxboro 20 to 50 Milliampere Transmitters	4/14/81	All power reactor facilities with an OL or CP
81-05	Self-Aligning Rod End Bushings for Pipe Supports	3/31/81	All power reactor facilities with an OL or CP
81-04	The Role of Shift Technical Advisors and Importance of Reporting Operational Events	4/30/81	All power reactor facilities with an OL or CP
81-03	Inoperable Seismic Monitoring Instrumentation	3/2/81	All power reactor facilities with an OL or CP
81-02	Performance of NRC-Licensed Individuals While on Duty	2/9/81	All power reactor facilities (research & test) with an OL or CP
81-01	Design Problems Involving Indicating Pushbutton Switches Manufactured by Honeywell Incorporated	1/23/81	All power reactor facilities with an OL or CP
80-25	Case Histories of Radiography Events	12/5/80	All radiography licensees
80-24	AECL Teletherapy Unit Malfunction	12/2/80	All teletherapy licensees
80-23	Potential Defects in Beloit Power Systems Emergency Generators	10/31/80	All power reactor facilities with OL or a CP
80-22	Confirmation of Employee Qualifications	10/2/80	All holders of a power reactor OL or CP architect-engineering companies and nuclear steam system suppliers

OL = Operating Licenses
CP = Construction Permit

SSIN No.: 6835
IN 85-92

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

December 2, 1985

IE INFORMATION NOTICE NO. 85-92: SURVEYS OF WASTES BEFORE DISPOSAL FROM NUCLEAR REACTOR FACILITIES

Addressees:

All production and utilization facilities, including nuclear power reactors and research and test reactors, holding an operating license (OL) or construction permit (CP).

Purpose:

The purpose of this information notice is to supplement the guidance of IE Circular 81-07 as it applies to surveys of solid waste materials before disposal from nuclear reactor facilities. It is expected that recipients will review the information for applicability to their facilities. However, this information notice does not constitute NRC requirements; therefore, no specific action or licensee response is required.

Description of Circumstance:

Some questions have arisen concerning appropriate methods of surveying solid waste materials for surface contamination before releasing them as nonradioactive (i.e., as wastes that do not contain NRC-licensed material).

Discussion:

The need to minimize the volume of radioactive waste generated and shipped to commercial waste burial sites is recognized by the NRC and industry. Some nuclear power plants have initiated programs to segregate waste generated in radiologically controlled areas. Such programs can contribute to the reduction in volume of radioactive waste; however, care should be taken to ensure that no licensed radioactive material is released contrary to the provisions of 10 CFR Section 20.301. In practice, no radioactive (licensed) material means no detectable radioactive material.

In 1981, IE Circular 81-07 was issued by the NRC. That circular provided guidance on the control of radioactively contaminated material and identified the extent to which licensees should survey for contamination. It did not establish release limits. The criteria in the circular that addressed surface contamination levels were based on the best information available at the time and were related to the detection capability of portable survey instruments

equipped with thin-window "pancake" Geiger-Mueller (G.M.) probes, which respond primarily to beta radiation. Monitoring of aggregated, packaged material was not addressed. In 1981, there was no major emphasis on segregating waste from designated contamination areas. As a consequence, large volumes of monitored wastes were not being released for unrestricted disposal. However, because of recent emphasis on minimizing the volume of radioactive waste, current practices at many nuclear power facilities result in large volumes of segregated, monitored wastes, containing large total surface areas, being released as "clean" waste.

When scanning surfaces with a hand-held pancake probe, there is a chance that some contamination will not be detected. (See the papers by Sommers,[1] for example.) There is the chance also that the total surface area will not be scanned completely. Thus, when numerous items of "clean" material (e.g., paper and plastic items) are combined, the accumulation of small amounts of contamination that have escaped detection with the pancake probe may be detected using a detector that is sensitive to gamma radiation (e.g., by using a sensitive scintillation detector in a low-background area). Such measurements of packaged clean waste before disposal can reduce the likelihood that contaminated waste will be disposed of as clean waste, then found to be contaminated after disposal. (Some operators of sanitary landfills have begun to survey incoming waste for radioactivity using scintillation survey meters which in some cases are supplemented by portable gamma-ray spectrometers.[2])

In order to preclude the unintentional release of radioactive materials, a good monitoring program like would include the following:

1. Careful surveys, using methods (equipment and techniques) for detecting very low levels of radioactivity, are made of materials that may be contaminated and that are to be disposed of as clean waste. These survey methods should provide licensees with reasonable assurance that licensed material is not being released from their control.

2. Surveys conducted with portable survey instruments using pancake G.M. probes are generally more appropriate for small items and small areas because of the loss of detection sensitivity created by moving the probe and the difficulties in completely scanning large areas. This does not preclude their use for larger items and areas, if supplemented by other survey equipment or techniques.

3. Final measurements of each package (e.g., bag or drum) of aggregated wastes are performed to ensure that there has not been an accumulation of licensed material resulting from a buildup of multiple, nondetectable quantities (e.g., final measurements using sensitive scintillation detectors in low-background areas).

The foregoing does not constitute NRC requirements; therefore, no specific action or written response is required by this information notice. If you have any questions about this matter, please contact the Regional Administrator of the appropriate NRC regional office or this office.

Edward L. Jordan, Director
Division of Emergency Preparedness
and Engineering Response
Office of Inspection and Enforcement

Technical Contacts: John D. Buchanan, IE
(301) 492-9657

LeMoine J. Cunningham, IE
(301) 492-9664

Attachments:
1. References
2. List of Recently Issued IE Information Notices

REFERENCES

[1] Sommers, J. F., (a) "Sensitivity of Portable Beta-Gamma Survey Instruments," Nuclear Safety 16 (No. 4), 452-457, July - August 1975, (b) "Sensitivity of GM and Ion-Chamber Beta-Gamma Survey Instruments," Health Physics 28 (No. 6), pp. 775-761, June 1975.

[2] Anonymous, "LA Nuclear Medicine Community Improves Radiation Monitoring at Landfills, " J. Nuclear Medicine 26 (#4), 336-337, April 1985.