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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CHAIRMAN

January 7, 2000

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

Dear Congressman Dingell:

As you know, I responded on December 20, 1999, on behalf of the Commission to the letter submitted by you and Congressmen Ron Klink and Edward Markey concerning the decision by the State of Tennessee to license the release of nickel with slight contamination from radioactive materials. I am now writing to respond to the follow-on inquiries forwarded by you and your colleagues on December 23, 1999. A response to each question is provided in the enclosure.

Let me note at the outset that the NRC takes its regulatory responsibilities under the Atomic Energy Act very seriously. We also take Congressional inquiries, such as yours, with similar serious regard. In that connection, the NRC technical staff, its legal staff, and indeed, the Commission and myself, devoted considerable time and attention in preparing our response to your letter of October 25, as well as the attached questions. In addition, NRC senior managers responsible for materials regulation, as well as officials from the NRC State Programs office and the General Counsel's office, have met with Congressional staff for discussions on the subject of your letters on two occasions, and NRC staff have also engaged in additional consultation by telephone on other occasions. Our intent is to be fully responsive to you.

Based on your December 23rd letter, we believe that some aspects of our previous response may have been misunderstood. The differences in approach between the release of slightly contaminated materials and the regulation of products in which nuclear materials have been introduced to achieve a functional purpose is in no way intended to, nor does it, result in the imposition of less protective regulation of radioactive materials in one form rather than the other. In both cases, licensee actions are subject to careful regulatory scrutiny. Viewed in this light, we understand that the main thrust of your letters relates to the fact that the NRC does not regulate both situations in the same manner.

The NRC's view is that there is a clear distinction between the unrestricted release of slightly contaminated material and the controlled distribution of nuclear material introduced into products to utilize the radioactive, physical, or chemical properties of the material. As explained by my earlier letter, in the case of release of slightly contaminated materials, the NRC and the Agreement States have typically imposed comparable restrictions by license conditions to the general effect that any radioactive contamination must be indistinguishable from background or, at the least, must be sufficiently slight as to provide adequate protection of the public health and safety. The NRC does not exercise exclusive regulatory control over such decisions and, as a result, those states (like Tennessee) that have assumed control over nuclear materials pursuant to Section 274 of the Atomic Energy Act regulate such releases. We feel this is appropriate because decisions governing the release of such materials could affect nearly every licensee;

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an effort by the Commission to regulate all such releases would undermine the Congressional determination in Section 274 to allow the states to exercise significant regulatory control over nuclear material and would result in little or no benefit to public health and safety.

Besides concerns with achieving the fundamental objectives of Section 274, there are technical differences between decisions involving unrestricted release of slightly contaminated material and controlled distribution of nuclear material introduced into products to utilize the radioactive, physical, or chemical properties of the material. The NRC has retained exclusive jurisdiction over products in which nuclear materials have been introduced to achieve a functional purpose. (Examples of such products include luminous watches, vacuum tubes, and smoke detectors.) In the case of such products, the NRC allows the presence of radioactive materials at levels or concentrations that may be much larger than would be allowed by guidelines governing the release of slightly contaminated materials if a weighing of the risks and benefits shows that the risks associated with the prospective use of the product are less than the benefits. Moreover, it would not be practically feasible to reconcentrate any residual radioactivity from released materials (such as recycled nickel), whereas products containing intentionally introduced radioactive material could be disassembled, allowing reconcentration of any discrete radioactive material in such products. The NRC has retained exclusive control because of the need to balance such risks and benefits and to provide uniform guidance. Our interpretation of the statutory and regulatory provisions governing the regulation of products reflects the practical reality that products containing nuclear materials that serve a functional purpose present different regulatory issues from those associated with the release of slightly contaminated materials. Moreover, our regulation of such products affects relatively few licensees and does not intrude significantly on the Agreement States' interaction with their licensees. The important point, however, is that both situations -- both products and released materials with slight levels of radioactive contamination -- do not escape regulatory scrutiny.

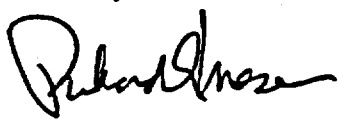
Your letter raises questions about the NRC's failure to develop a national standard for radioactively contaminated metals and materials that could find their way into consumer products. As we acknowledged in our December 20, 1999 letter, the NRC has not developed a national standard to govern the approach to be taken by the NRC and Agreement States for release of slightly contaminated solid materials, but rather has addressed the issue on a case-by-case basis. The Commission realized a need to address this area and, in June 1998, directed the staff to pursue an enhanced participatory rulemaking process. In doing so, the Commission recognized the need for input and guidance from its stakeholders. Thus, the NRC is in the process of seeking guidance from stakeholders on exactly the subject of whether a national standard should be put in place. The NRC published an issues paper concerning the release of solid materials with small amounts of radioactivity on June 30, 1999, [64 FR 35090], and has held public meetings in San Francisco, Atlanta, Chicago, and Washington, DC for the specific purpose of obtaining informed comment from those who might be affected. This spring, the staff will provide the Commission with alternatives and recommendations for how to proceed to address the control of slightly contaminated materials. In this regard, the Commission will consider the need to implement regulations that govern the release of slightly contaminated materials and any appropriate designation of compatibility for Agreement State requirements. Although there may be benefits to proceeding by way of rule -- a matter we are seeking to explore as part of these current public outreach efforts -- we believe that the Commission's long-standing case-by-case approach is consistent with the Atomic Energy Act and our regulations.

The Congress amended the Atomic Energy Act in 1959 to add Section 274, which allows a State to enter into an agreement by which the NRC relinquishes its Federal regulatory authority over State licensees, provided the State creates a regulatory program that is both adequate to protect public health and compatible with NRC's program. The sensitivity associated with the Tennessee decision to issue a license amendment authorizing the release of slightly contaminated nickel arises, as your letter notes, from the scale of operation. Section 274 does not make a distinction with respect to the scale of the activity in defining the jurisdiction relinquished to an Agreement State. Nonetheless, as noted in my earlier letter, the NRC has set criteria and established performance indicators to provide oversight of the programs of the Agreement States to ensure that the pubic health and safety is adequately protected.

In sum, we believe that we have been acting responsibly in connection with this matter. If the Congress were to conclude that, regardless of the outcome of our current efforts to seek stakeholder input, the NRC should develop a rule or national standard governing release of solid materials with volumetric or surface contamination by source, byproduct or special nuclear material, the NRC would work with the Congress to provide technical and legal advice on legislation to achieve this end. In fact, the NRC recently worked with the House Commerce Committee's majority and minority staff to draft compromise legislation that would address this issue near the conclusion of the first session of the 106th Congress. We stand ready to assist again.

I would be pleased to discuss this issue further with you at your convenience.

Sincerely,



Richard A. Meserve

Enclosure:
Responses to Questions

cc: Representative Tom Bliley
Representative Joe Barton

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CHAIRMAN

January 7, 2000

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

Dear Congressman Klink:

As you know, I responded on December 20, 1999, on behalf of the Commission to the letter submitted by you and Congressmen John Dingell and Edward Markey concerning the decision by the State of Tennessee to license the release of nickel with slight contamination from radioactive materials. I am now writing to respond to the follow-on inquiries forwarded by you and your colleagues on December 23, 1999. A response to each question is provided in the enclosure.

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an effort by the Commission to regulate all such releases would undermine the Congressional determination in Section 274 to allow the states to exercise significant regulatory control over nuclear material and would result in little or no benefit to public health and safety.

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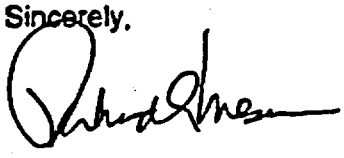

Richard A. Meserve

Enclosure:
Responses to Questions

cc: Representative Fred Upton

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CHAIRMAN

January 7, 2000

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:

As you know, I responded on December 20, 1999, on behalf of the Commission to the letter submitted by you and Congressmen Ron Klink and John Dingell concerning the decision by the State of Tennessee to license the release of nickel with slight contamination from radioactive materials. I am now writing to respond to the follow-on inquiries forwarded by you and your colleagues on December 23, 1999. A response to each question is provided in the enclosure.

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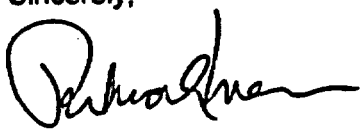

Richard A. Meserve

Enclosure:
Responses to Questions

cc: Representative W. J. Tauzin

RESPONSES TO QUESTIONS TO NRC CHAIRMAN MESERVE

QUESTION 1. In our letter dated October 25, 1999, we requested that you supply documentation to support the answers to the questions asked. We received only two documents, both of which were already in our possession. If there are any additional documents in your possession that provide support for the NRC's position that "equipment, device, commodity or any other product" containing byproduct material not specifically inserted for its radioactive purposes is not subject to the NRC's licensing requirements, please provide them.

ANSWER.

The NRC staff has not identified additional NRC documents which provide further explanation of the Commission's position in this regard. Although we have no additional documents, the Commission has consistently applied its reservation of authority under §274 c. of the Atomic Energy Act (AEA) only to the control of the distribution of commercial products, such as smoke detectors, involving the use of AEA material for its radioactive, chemical, or physical properties.

QUESTION 2. How does the NRC define "background" levels of radioactivity in Reg. Guide 1.86? Please provide all documentation for the selection of the levels set.

ANSWER.

Regulatory Guide 1.86 itself does not define background radiation, but it refers to background in Footnote b of Table 1.

The NRC definition of background radiation is provided in 10 CFR 20.1003, which states, "*Background radiation* means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. '*Background radiation*' does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission."

Background radiation may vary greatly depending on location. Further NRC guidance on determination of levels of background radiation is provided in draft NUREG-1501, "Background as a Residual Radioactivity Criterion for Decommissioning," and NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions" (attached), as well as IE Circular No. 81-07 and IE Information Notice No. 85-92, which were provided in our December 20, 1999, response.

Attachments:
1. Draft NUREG-1501
2. NUREG-1507

QUESTION 3. Has the NRC ever made an explicit finding that the levels allowed for the release of surface contaminated materials has no "adverse effect on the public health and safety"? Please provide all documentation of that finding. If no finding was made, please explain why.

ANSWER.

With respect to materials released in connection with the termination of a reactor license, the introduction to Regulatory Guide 1.86 (attached) itself states: "Section 50.82, 'Applications for terminations of licenses,' specifies the requirements that must be satisfied to terminate an operating license, including the requirement that the dismantlement of the facility and disposal of the component parts not be inimical to the common defense and security or to the health and safety of the public. This guide describes methods and procedures considered acceptable by the regulatory staff for the termination of operating licenses for nuclear reactors." IE Circular No. 81-07 discusses releases of material at levels similar to those permitted by Regulatory Guide 1.86, and states: "... the potential dose to any individual will be significantly less than 5 mrem/yr even if the accumulation of numerous items contaminated at this level is considered." Therefore, Regulatory Guide 1.86 supports the Commission's regulatory framework under 10 CFR 20.1301 by ensuring doses to members of the public are well below the 100 mrem/yr limit.

In addition, in 1992, the NRC published a summary of existing decommissioning guidance for materials facilities (57 FR 13389, April 16, 1992) (attached), which included a reference to Regulatory Guide 1.86. This 1992 notice affirmed that facilities decommissioned using the listed criteria, including Regulatory Guide 1.86, could be released for unrestricted use.

The release of slightly contaminated radioactive material by the NRC or by an Agreement State is typically by means of a licensing action. In the case of the NRC, such an action is only permitted if the NRC is satisfied that there is adequate protection of the public health and safety. The release of surface contaminated materials thus must satisfy this standard as determined on a case-by-case basis.

Attachments:
1. Regulatory Guide 1.86
2. 57 FR 13389

QUESTION 4. The NRC has promulgated in a rule the explicit levels of contamination that govern the release of buildings and land used for nuclear activities. Are there any promulgated rules for the release of solid materials? If not, please explain why the release of buildings and land, which will remain where they are left, requires a rule but the release of metals and other materials that can be placed in products far away from the source and used by unknowing consumers does not require a rule. Please provide all NRC documents supporting your position.

ANSWER.

Other than the standards in 10 CFR Part 20, Subpart K, the NRC does *not* have an existing, generally-applicable rule for levels at which solid materials may be released. The determination of whether to resolve an issue by a rule, rather than by a case-by-case licensing decision, is typically guided by consideration of regulatory efficiency. It is more efficient in general to have a rule to address frequently occurring issues or matters that affect large numbers of licensees. Rules also promote consistency. Regardless of whether an issue is resolved by rule or by case-by-case licensing decision, adequate protection of public health and safety must be assured.

The NRC has promulgated a rule providing criteria for the release of land and buildings previously used for nuclear activities, from further licensing. This "license termination rule" added Subpart E to 10 CFR 20, Radiological Criteria for License Termination, and was published in the July 21, 1997, Federal Register (Vol. 62, pages 39058–39092) (attached). This rule provides acceptable annual all-pathway dose standards that must be met for license termination and release of previously licensed facilities. Although the rule is based on dose and

not contamination levels, the NRC has provided some conservative generic screening values, in the form of regulatory guidance, for building surface contamination (FR, Vol. 63, page 64132–64134, November 18, 1998) (attached) and for surface soil contamination (FR, Vol. 64, pages 68395–68396, December 7, 1999) (attached). These generic screening values may be used by licensees to show compliance with the dose criteria, but licensees may also use other methods (such as site-specific dose assessments) to show compliance.

The NRC is exploring whether a rulemaking to establish criteria for the release of solid materials from licensee control may be appropriate in order to provide efficiency and consistency in NRC's regulation of release of materials. The issues paper on the Release of Solid Materials at Licensed Facilities (FR, Vol. 64, pages 35090–35100, dated June 30, 1999) (attached) indicates that there are no current generally-applicable criteria in Part 20 governing control of solid materials. The issues paper further states that NRC is considering whether to initiate a rulemaking that would set specific requirements for release of solid materials. The purpose of the notice was to seek public comment on the matter.

The license termination rule was completed before the NRC launched its evaluation of the need for a rule governing the release of solid materials because buildings and lands represent the vast majority of the contaminated materials at sites undergoing decommissioning, and NRC concluded that criteria for the release of buildings and lands were the most important regulatory need for NRC's decommissioning program. Before the promulgation of the license termination rule in 1997, NRC generally addressed decommissioning issues involving buildings and lands on a case-by-case basis using regulatory guidance, just as it now evaluates releases of solid material.

Attachments:

1. FR, Vol. 62, pages 39058–39092, July 21, 1997, *Radiological Criteria for License Termination; Final Rule.*
2. FR, Vol. 63, page 64132–64134, November 18, 1998, *Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination.*
3. FR, Vol. 64, pages 68395–68396, December 7, 1999, *Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination.*
4. FR, Vol. 64, pages 35090–35100, dated June 30, 1999, *Release of Solid Materials at Licensed Facilities: Issues Paper, Scoping Process for Environmental Issues, and Notice of Public Meetings.*

QUESTION 5. On page 2 of your December 20, 1999, response letter, you indicate that the NRC requires that licensees must survey equipment and material before its release and that "if the surveys indicate the presence of AEA material above natural background levels, then no release may occur." However, the NRC apparently treats the release of radioactively contaminated solid material by a nuclear materials licensee differently, allowing such materials to be released even if AEA material is present above background levels. Please explain the justification for this differing treatment.

ANSWER.

It is correct that there is a differing treatment of reactor licensees and materials licensees. Reactor licensees are subject to a policy which does not allow material to be released if the presence of AEA material is detectable above background levels, whereas materials licensees are subject to an approval process that may result in the authorized release of material with safe (but detectable) low levels of residual radioactivity. The standard for release of material for reactor licensees and material licensees were developed at different times and under different circumstances. The basis for the difference between the two approaches is not clear. While the staff has consistently assured that its licensing decisions provided adequate protection of the public health and safety, the NRC has previously identified this as an area of its regulations requiring review. As a result, NRC is attempting to address this difference as part of its ongoing improvements in the regulatory framework for decommissioning of facilities and releases of decontaminated materials. In any event, NRC is satisfied that all current licensing decisions are providing adequate protection of the public health and safety.

QUESTION 6. On Page 4 of your response letter you note that since the advent of the Agreement State program, the NRC has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. You further indicate that the "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... (emphasis added)".

QUESTION 6(a). What if the radioactive material has been inadvertently, unintentionally or mistakenly introduced into another material? Why wouldn't the NRC also wish to reserve authority to regulate distribution of the contaminated material?

ANSWER.

The NRC did not mean to imply in its previous letter that the determination of whether a product is subject to the NRC's jurisdiction depends on the intent of the manufacturer. We cannot imagine any real-world situation in which radioactive material serving a functional purpose could be introduced into a product inadvertently or unintentionally.

If the material has been unintentionally introduced and the product does not take advantage of the properties of the radioactive material, the matter would be tracked like any other release of radioactive material (whether in a product or not). In such cases, the regulatory decision to be made is whether the radioactively contaminated material is safe for unrestricted use by persons exempt from the regulations. Decisions to approve release of radioactively contaminated

materials for unrestricted use can be made by Agreement States, which must have programs which are adequate to protect the public health and safety, and are compatible with NRC's regulatory program.

The risks associated with products which are distributed to take advantage of the properties of the radioactive material may be much larger than the radiological risks associated with slightly radioactively contaminated solid materials. This is particularly so in light of the fact that products containing radioactive components could be disassembled, allowing reconcentration of any discrete radioactive materials. The NRC has retained exclusive control over such products because of the need to balance the risks associated with the prospective use and the benefits. The radiological risks associated with the release of slightly contaminated solid materials, by contrast, may be less than the radiological risk from materials outside NRC control, such as concrete containing recycled coal ash.

The Commission's experience has confirmed that the distinction between materials introduced to products to utilize the properties resulting from the radioactive content and materials with slight contamination is a valid distinction that serves to focus NRC resources on regulatory matters most likely to have health and safety consequences. We are aware of no instances in which the regulated releases of materials with slight contamination has resulted in a threat to public health and safety.

QUESTION 6(b). What if radioactive material had been intentionally introduced, but not with the purpose of taking advantage of the material's radioactive, physical, or chemical properties? Why wouldn't the NRC also wish to reserve authority to regulate distribution of such radioactively contaminated materials?

ANSWER.

Such material would be regulated like any other release of radioactive contamination, whether in a product or not. The NRC would not retain exclusive jurisdiction. An explanation for the NRC's reservation of exclusive regulatory authority over products in which nuclear materials serve a functional purpose is provided in response to question 6(a).

QUESTION 6(c). What if it cannot be positively determined whether or not the material had been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties? Would the NRC reserve authority over the distribution of such materials?

ANSWER.

As stated in the response to Question 6a, we cannot imagine any real-world situation in which radioactive material serving a functional purpose could be introduced into a product inadvertently or unintentionally. The NRC's jurisdiction would not depend on the intent of the manufacturer. See Answer to Question 6(a). If NRC or an Agreement State concluded that the product was not being distributed to take advantage of the properties of the radioactive material, then the product would be considered to contain unwanted contamination. Therefore, regulatory decisions regarding its release for unrestricted use could be made by NRC or Agreement States.

QUESTION 6(d). When did the NRC first announce this policy of only reserving authority over distribution of radioactive materials that had been intentionally introduced? Please supply supporting documentation of that announcement.

ANSWER.

The AEC promulgated 10 CFR §150.15(a)(6) on February 14, 1962 (27 FR 1351) (attached). This rulemaking established the Commission's reservation of authority over certain activities of Agreement States. At that time, the AEC reserved authority over distribution of certain consumer products which involved the introduction of Atomic Energy Act material in order to take advantage of the properties of that material. While the AEC provided an example of the type of consumer products involved (luminous watches), it did not specifically indicate that the reservation involved the introduction of AEA material. However, it is our view that the types of products covered by the reservation of authority were understood at the time and that it is likely that no detailed explanation was deemed necessary. Subsequent to the promulgation of §150.15(a)(6), the Commission has consistently applied its reservation of authority under this regulation in the context of products involving the introduction of nuclear material serving a functional purpose (see, e.g., 31 FR 5315 (April 2, 1966) (Exemption of Tritium Contained in Certain Items); and 43 FR 2386 (January 17, 1978) (Exemption of Persons Using Spark Gap Irradiators Containing Cobalt-60) (attached)). The staff is not aware of more recent documents that provide more specific information regarding the scope of NRC's reservation of authority in this area.

Attachments:
1. 27 FR 1351
2. 31 FR 5315
3. 43 FR 2386

QUESTION 7. In your response, you indicate that "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." Please provide a copy of all notes, memoranda, and other documents which relate, in any way, to this review.

ANSWER.

The documents listed below (Attachments 1 to 7) relate to the review of the licensing action and the independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license:

1. Letter dated January 7, 2000, and report entitled "Review of the Tennessee (TN) License Approval of Release of Nickel from the Manufacturing Sciences Corporation (MSC) Facility in Oak Ridge, TN";

2. Draft letter dated December 17,1999, and report entitled "Review of the Tennessee (TN) License Approval of Release of Nickel from the Manufacturing Sciences Corporation (MSC) Facility in Oak Ridge, TN";

3. NRC staff Preliminary Dose Analysis for Clearance of Nickel from MSC dated December 16, 1999;

4. Letter dated November 19, 1999 from M. Hamilton to W. Travers;

5. Letter dated November 16, 1999 from L. E. Nanney to P. Lohaus which supplies the following information:

- TDEC Dose Calculation Note dated November 15, 1999
- Amendment 20 to R-01078-L00 dated October 1, 1999
- Amendment 19 to R-01078-L00 dated July 13, 1999
- Amendment 18 to R-01078-L00 dated April 8, 1999
- Letter from MSC to TN dated September 10, 1999
- Amendment 57 to S-01046-L00 dated July 13, 1999
- Amendment 56 to S-01046-L00 dated March 26, 1999
- Intraoffice correspondence from JMK to JCG, MHM dated March 24, 1999 with attached calculations
- Letter from MSC to TN dated February 18, 1999
- Letter from MSC to TN dated January 29, 1999
- Letter from MSC to TN dated January 18, 1999
- Letter from MSC to TN dated December 8, 1998 with attachments (the license amendment application);

6. Electronic mail correspondence between S. Sherbini and A. Huffert dated 1/3/2000-1/4/2000 regarding estimated doses.

7. Note dated December 1, 1999, from J. Blaha to Commissioners Assistants.

The information provided above may not be complete due to the unavailability of some staff during the holidays and the limited time frame for the response. We are continuing our review and will provide any additional documents and information identified which relate to your request.

QUESTION 8. On page 5 of your response, you also indicate that NRC's review identified some areas needing clarification or additional specific information and that the NRC staff was pursuing resolution of these matters with the State of Tennessee. Please explain the precise nature of the clarifications and additional information being sought. In light of the apparently incomplete information before the NRC, on what basis did you conclude that the actions taken by the State of Tennessee in this matter do not raise any concerns?

ANSWER.

Our concerns with the State of Tennessee were mainly associated with our inability to understand their processes for arriving at their conclusions on the basis of the information available to us. The areas needing clarification or additional specific information are contained in the report entitled "Review of the Tennessee (TN) License Approval of Release of Nickel from the Manufacturing Sciences Corporation (MSC) Facility in Oak Ridge, TN" which is provided in response to Question 7 as attachment 1. As indicated in the January 7, 2000 letter, staff has requested a written response from Tennessee to address the areas identified in the staff's report as needing clarification or additional information.

However, the NRC concluded that the actions by the State do not raise concerns regarding public health and safety because NRC's own independent calculations showed that the doses to members of the public resulting from release of the contaminated nickel are low and do not pose a health and safety concern. The preliminary dose analysis, dated December 16, 1999, provided in response to question 7 as attachment 3, concludes that the highest potential doses would occur to scrap yard/slag pile workers. The annual maximum doses calculated for these

critical groups are low (1-5 mrem). The potential doses from consumer products containing this material would result in doses lower than these.

QUESTION 9. In your response to question 3 in our letter, the NRC cites Section 274. c. of the Atomic Energy Act as providing the statutory authority to limit its reservation of authority to products involving the intentional introduction of radioactive material to take advantage of the properties of the material. While you state that the legislative history supports this limited use of the NRC's authority, the specific citations from the legislative history that you cite would seem to support a much broader interpretation. For example, the quoted Congressional Committee Report language cited on page 3 of your response does not differentiate between radioactive materials introduced into a product intentionally in order to exploit their radioactive, physical, or chemical properties, and other articles containing byproduct, source, or special nuclear material. On page 5 of your response, the NRC acknowledges that "the Commission recognizes that Section 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." In light of the fact that the legislative history appears to support a broader reading of the NRC's authority, why has the Commission chosen to adopt an artificially constrained interpretation of the authority conferred under this section?

ANSWER.

The AEC implemented its regulatory program in this area to address commercial products such as luminous watches, ceramic tableware, glassware, and smoke detectors. The Commission believes that there is a clear difference between these types of products and the release of slightly contaminated materials.

In the case of release of slightly contaminated materials, the NRC and the Agreement States have typically imposed comparable restrictions by license conditions to the general effect that any radioactive contamination must be indistinguishable from background or, at the least, must be sufficiently slight as to provide adequate protection of the public health and safety. The NRC does not exercise exclusive regulatory control over such decisions and, as a result, those states (like Tennessee) that have assumed control over nuclear materials pursuant to Section 274 of the Atomic Energy Act regulate such releases. We feel this is appropriate because decisions governing the release of such materials could affect nearly every licensee; an effort by the Commission to regulate all such releases would undermine the Congressional determination in Section 274 to allow the states to exercise significant regulatory control over nuclear material and would result in little or no benefit to public health and safety.

Besides concerns with achieving the fundamental objectives of Section 274, there are technical differences between decisions involving unrestricted release of slightly contaminated material and controlled distribution of nuclear material introduced into products to utilize the radioactive, physical, or chemical properties of the material. The NRC has retained exclusive jurisdiction over products in which nuclear materials have been introduced to achieve a functional purpose. (Examples of such products include luminous watches, vacuum tubes, and smoke detectors.) In the case of such products, the NRC allows the presence of radioactive materials at levels or concentrations that may be much larger than would be allowed by guidelines governing the release of slightly contaminated materials if a weighing of the risks and benefits shows that the risks associated with the prospective use of the product are less than the benefits. Moreover, it would not be practically feasible to reconcentrate any residual radioactivity from released materials (such as recycled nickel), whereas products containing intentionally introduced radioactive material could be disassembled, allowing reconcentration of any discrete radioactive

material in such products. The NRC has retained exclusive control because of the need to balance such risks and benefits and to provide uniform guidance. Our interpretation of the statutory and regulatory provisions governing the regulation of products reflects the practical reality that products containing nuclear materials that serve a functional purpose present different regulatory issues from those associated with the release of slightly contaminated materials. Moreover, our regulation of such products affects relatively few licensees and does not intrude significantly on the Agreement States' interaction with their licensees. The important point, however, is that both situations -- both products and released materials with slight levels of radioactive contamination -- do not escape regulatory scrutiny.

QUESTION 10. As indicated in Question 42, "radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. On page 2 of your response, you state, "low levels of radioactivity are detected". On page 3, you indicate that the NRC allows "the release of material with slight levels of volumetric contamination." While you provide a definition of "low levels" in your answer to Question 42, you do not provide a definition for "slight" levels. Please provide a definition for "slight levels" of contamination. In particular, please specify how this relates to low level and background levels of radiation.

ANSWER.

In the context of the December 20, 1999, cover letter and for the purposes of these questions, the terms "slight", "slightly", "low levels," and "very low levels" should be viewed as having essentially the same meaning. These levels represent contamination that is a small increment above background radiation levels, but the amount of radioactive material is so small that further regulatory control is not necessary. The response to Question 42 contained the definition of waste in Part 61 of the Commission's regulations and covers a broad range of material referred to as "low level" waste. Such waste can involve levels of radiation far higher than those associated with the release of slightly contaminated material.

QUESTION 11. According to the definitions in 10 CFR 20.1003, background radiation means "radiation from cosmic sources; naturally occurring radioactive material, including radon...". On page 2 of your response, you indicate an approach in Enforcement Circular 81-07 and Information Notice 85-92 that checks for material "above background" level. In the same paragraph, you indicate "this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected." Since background levels are defined to be an ambient level of radiation, how have levels been detected below "background level?" If some type of shielding is used in these detectors, how do new detectors shield the measured source from background ambient radiation due to sources such as cosmic rays to obtain sensitivities below background?

ANSWER.

Levels of radioactive contamination can not be detected below background radiation levels; rather, radioactive contamination must be detected in the presence of background radiation levels. Thus, radioactive contamination must be detected and distinguished from background radiation levels. In our previous response (page 2, as you mention in the question), we indicated that the fact that failure to detect radioactive material above background radiation levels does not mean that none is present. This is the case because there are limitations on detection capability. Technologically advanced detectors may have the ability to reliably detect the presence of radioactivity and to distinguish low levels of contamination from background radiation levels better than older, less technologically advanced detectors. Thus, a lower level of

contamination which may be undetectable using certain older detectors could be detectable using newer, technologically advanced detectors.

Improvement in detection capability may be achieved in a variety of ways, but mainly by using more sophisticated instrument set-ups and more elaborate detection and analysis techniques. These methods include the use of: (1) sophisticated detectors and signal analysis electronics, (2) shielding, (3) an increased number of samples and (4) increased counting times.

QUESTION 12. Why does the NRC apparently think that it is more important to regulate the presence of low levels of radioactive materials intentionally introduced into luminous watches, ceramic tableware, glassware, vacuum tubes, and smoke detectors, but it is not important to regulate radioactive nickel that could end up in such products as tableware, caps for baby food jars, cans used for foods or beverages, automobiles, earrings, orthodontic braces, hip replacement joints, and intra-uterine devices?

ANSWER.

Some products, such as vacuum tubes and smoke detectors, involve the introduction of AEA material into the products to achieve a functional purpose and enter the public domain as finished products. Nickel, on the other hand, because it is a raw material and not a product, enters the public domain as a raw metal and can be used in making a variety of products. The NRC's view is that there is a clear distinction between the unrestricted release of slightly contaminated material and the controlled distribution of nuclear material introduced into products to utilize the radioactive, physical, or chemical properties of the material. This distinction is enough to justify regulating the two types of material differently. For an explanation of the rational for the difference, see response to question 9.

Nevertheless, both classes (products and raw materials) enter the public domain under appropriate degrees of regulatory oversight. In both cases, the assurance for public health and safety is based on the assessments that are completed before the licensing action is completed that authorizes the distribution or release.

QUESTION 13. Why does the NRC apparently believe that the intent of the licensee with respect to introduction of a radioactive material into a consumer product is apparently the critical determinant of whether the product should be regulated by the NRC, rather than the presence of the radioactive material in the product itself?

ANSWER.

The intent at the time of introduction is not the critical determinant. The determinant is whether the licensee is distributing a finished product, designed to take advantage of the radioactive, physical, or chemical properties of the nuclear material to consumers, or whether the licensee is releasing from control slightly contaminated solid materials. The NRC has retained exclusive jurisdiction over products in which nuclear materials have been introduced to serve a functional purpose. The NRC does not exercise exclusive jurisdiction over the release of slightly contaminated materials.

QUESTION 14. Under section 274 c(4) of the Atomic Energy Act, do you believe processors of byproduct material require a license to release or transfer this material to an exempt person?

ANSWER.

As a general matter, persons who possess and use byproduct material must have an NRC or an Agreement State license, unless possession of the byproduct material is exempt from licensing requirements (e.g., smoke detectors) or the material has been otherwise released for unrestricted use. In addition, persons seeking to distribute or transfer products containing byproduct material serving a functional purpose to persons exempt from the regulations must also obtain a separate distribution license from NRC.

The release of byproduct material for unrestricted use is not considered by NRC to be a distribution or transfer of byproduct material. For example, MSC is licensed by the State of Tennessee to possess and use byproduct material. MSC's releases are authorized under that license, and are neither considered transfers of byproduct material nor distribution of products to persons exempt from the regulations.

QUESTION 15. In your response to question 3, you refer to language in S. Rept. 86-870 that indicates the intent of the subsection of section 274 was to "address products that include the intentional introduction." This language refers to manufacturers of radioactive material. However, no restriction is made on the specific products that the Commission may regulate for producers and processors of nuclear material. However, in section 274 c(4), the:

"Commission is authorized by rule, regulation or order to require 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."

Is it your opinion that the Commission should not consider MSC to be a processor of the byproduct material? Please explain why MSC is considered a manufacturer and not a processor of this material.

ANSWER.

In implementing the reservation of authority in §274 c., it does not appear that the AEC intended to draw a distinction between the way in which manufacturers are treated for the purposes of the statute and the way in which the terms "processors" or "producers" are addressed. Accordingly, we do not attach significance to the fact that, in the cited background material, the word "manufacturers" has been used in some cases without additional reference to the words "processors" or "producers."

In the context of §274 c. and 10 C.F.R. §150.15(a)(6), NRC does not consider MSC to be a processor over which NRC has reserved authority because MSC's planned activity does not involve the introduction of AEA material into a product for the purposes of utilizing the properties

of that radioactive material. Similarly, NRC does not consider MSC to be a "manufacturer" over which this agency has reserved authority.