Questions and Answers Regarding Increased Controls (IC) and Implementation for Licensees That Possess Radioactive Material Quantities of Concern

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I. Licensee Responses to the Increased Controls and Implementation

1. Information on how I would be required to respond to this notice when I receive it does not appear to be included with the implementing guidance. Will my response include sensitive information?

For NRC Licensees, the information on how to respond to the NRC Order requiring implementation of the increased controls are contained in the Order itself. For Agreement States Licensee, the information on how to respond will be provided separately by each Agreement State licensing organization, based on the method chosen to execute legally binding requirements. The NRC Orders are not considered sensitive information. Examples of previous Orders can be found by searching ADAMS or NRC's website.

Licensee's responses to the increased controls and information that contains licensee physical protection is considered sensitive information and shared only with those having a "need-to-know."

NRC licensees' responses to the increased controls should be marked appropriately with **"Withhold From Public Disclosure Under 10 CFR 2.390."**

Agreement State licensee's responses to the increased controls should be marked in accordance with applicable Agreement State authority for withholding of sensitive security or proprietary information.

2. Is there a process for requesting an exemption from specific increased controls?

There is a process by which a licensee may request relief from specific Increased controls, or request an extension for implementing the increased controls. The process is communicated in the language of the NRC Order or Agreements State regulatory document that requires implementation of the increased controls.

3. In responding to the Increased controls are licensees responsible to send in the details of their program to the NRC or Agreement State for approval? Could inspectors then use that approval to see if a licensee in compliance?

No, all programs will be reviewed through inspection. Licensees need to affirm compliance with the Increased controls and provide their anticipated implementation schedule. Inspectors will review the program during the inspection.

4. Can the response period and implementation period be extended, or timed to accommodate our fiscal year or the challenges of transferring or disposing of sources that are no longer in use?

The 25-day response period is adequate for communicating to the licensee's ability to be in compliance with the Increased controls. The licensee will have 180 days from issuance to implement the Increased controls. The NRC and Agreement States will consider extending the implementation date if the licensee can show good cause. Extension of time frames will be considered on a case-by-case basis. Requests for extension should be made in the initial 25-day response. Such a request should be accompanied with a time line that sets forth a

proposed schedule for implementation. Individual licensees have different fiscal years, therefore it would be impractical to time the issuance of the Increased controls to coincide with each licensee's fiscal year.

5. There are many challenges of transferring or disposing of some sources that are no longer in use, but which would trigger the implementation of the Increased controls. How can I quickly find a place that will take my unwanted sources?

The NRC does not intend to develop a new source recycling program. However, licensees or industry groups may wish to develop a system for returning and recycling larger radioactive sealed sources. If a licensee concludes that a source is no longer wanted or needed, two programs currently exist that may be able to assist you. The Conference of Radiation Control Program Directors (CRCPD) National Orphan Radioactive Material Disposition Program provides information to assist States and the NRC in the disposition of sources (such as providing a list of waste brokers and individuals who want sources). The mission of the Department of Energy's (DOE) Offsite Source Recovery Project (OSRP) is to recover and store excess and unwanted radioactive sealed sources if they are not suitable for disposal in existing radioactive waste sites. For additional information, the link to the OSRP website is: http://www.doeal.gov/osrp/. The link to the CRCPD website is: http://www.crcpd.org/orphans.asp. The link to a CRCPD document describing their program is: http://www.crcpd.org/SpecialServices&Projects/Orphan_Rad_Mat_Pgm/Announcement.pdf

6. The culture at academic and research institutions (e.g., the common sharing of keys and access cards) may make enforcement of Increased controls a difficult task.

Institution-wide changes may be necessary in response to these Increased controls. Licensees will have a period of 180 days after issuance to implement the Increased controls. The licensees can use the 180 days to address any issues at the university/hospital research and educational institutions.

7. Is there flexibility built into the Increased controls implementation process?

Yes. The Increased controls are purposely not prescriptive to allow licensees to tailor programs to their specific facility and operations. Various approaches are available to licensees to meet the objectives of the Increased controls, and that there exists no one solution to any material control challenge facing licensees. The guidance provides examples of how the Increased controls may be met. Licensees do not have to implement any of the examples in the guidance, but those examples describe acceptable approaches to implementation.

8. Do the Increased controls replace current security measures, or are they meant to enhance measures already in place?

The Increased controls are an enhancement to current health and safety requirements, and are not intended to displace current initiatives being undertaken by licensees. The intent is for licensees to evaluate their current programs, and enhance them as necessary to meet the Increased controls.

9. Will NRC or Agreement States be providing possible solutions or recommending possible vendors to assist in the implementation of the Increased controls?

The implementation guidance describes acceptable approaches for complying with the Increased controls. Due to the high variation in licensee facilities and operations, specific solutions cannot be provide. Furthermore, as a government regulatory agencies, the NRC and Agreement States cannot provide recommendations on specific commercial vendors. The guidance provides a general discussion of potential approaches to achieving compliance with the Increased controls.

10. Does the Implementing Guidance require training, who should be trained and can training already provided for radiation protection purposes suffice?

To assure full compliance and implement the Increased controls, it would be appropriate to train trustworthy and reliable staff, on a "need-to-know" basis, in accordance with the *Implementing Guidance for the Increased Controls*. Training on control measures and the Increased controls is different from training for radiation protection purposes, and employees may require additional training. As noted in the Implementing Guidance, "Assessment can be by either automated devices or trained personnel who can initiate the appropriate response. The licensee's staff should have a clear understanding of their responsibilities and limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact. Licensees should amend their training program for employees to include the licensee's procedures for implementing these Increased controls. Training should address the access control system employed and notification procedures in the event of an unauthorized access and potential malevolent activities. It should also include the process for reporting any suspicious activities to management."

11. Who should we contact to handle issues that arise regarding the Increased controls, or related issues?

There is NRC or Agreement State contact information provided in the letter transmitting the Increased controls requirements.

12. Will implementing the Increased controls be based just on possession limits or actual physical possession of material over the threshold values?

The requirement to implement the Increased controls is based on actually possessing materials that meet the threshold values identified in Table 1. Possession of quantities just below the threshold will not require implementing the Increased controls.

13. Will having two or more sources located in the same area such that the two or more sources, when added together, meet or exceed the threshold quantities require implementing the Increased controls?

If there is no additional physical barrier between the sources or devices such that someone only has to break into that area to get access to the sources or devices, then the licensee would have to implement the Increased controls, if the sources individually or collectively are greater than or equal to the quantities listed in the Table 1. With only one common barrier, the sources

or devices would be considered collocated. An example would be a High Dose Afterloader with a back up source. If the two sources were stored in the same area, they would be collocated Storing the back up source in the same area in a locked device the that could not be removed, such as a safe, or in a separate locked room could be considered additional barriers such that the sources do not require the Increased controls. Questions do arise, such as if you open the safe, are they collocated or if you are doing a source change out and, for a short period of time, have two or more sources meeting the threshold, do you have to implement the Increased controls for that time period. There is an opportunity for licensees to request exceptions to or variations of some or all of the Increased controls. Such requests will be consider if adequate justification or a proposal for achieving the same objectives as the Increased Control, is provided by the licensee.

14. Have the NRC and Agreement States considered that the draft measures letter dated November 22, 2004, could interfere with patient care?

The Increased controls, themselves, are not intended to interfere with patient care and are not prescriptive. It is the licensee's responsibility to look at the intent of the Increased controls and determine the best course of action that will provide the added security while minimizing any impact on work flow and family members' ability to provide comfort to the patient and not interfere with patient care.

15. Will Sealed Source and Device (SS&D) Registrations be made available by the NRC for use in developing a thorough plan?

The NRC has removed public access to the SS&D registry. You may contact your manufacturer and/or distributor of the source or device or your regulatory agency for information needed for regulatory compliance.

16. Can licensees perform their own vulnerability assessment and change the time requirement for detection and response listed in the Increased controls?

Yes, although the Increased controls do not specify time periods. Assessments have been performed by experts at a national laboratory. It is imperative that licensees quickly detect, assess and respond as stated in the Increased controls. Notification has to be made as soon as possible. If for some reason a licensee can not comply with the requirements, the licensee should inform the NRC or its Agreement State licensing authority, as appropriate, and request relief from that part of the Increased controls.

17. Should day-to-day operational increased control activities be documented, such as the coming and going of individuals requiring line-of-sight escort?

The requirement in the Increased controls is to have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material in quantities greater than or equal to Table 1 values. How to document a licensee's "Increased Controls" will be left up the each licensee and will be verified during an inspection. Having escorted individuals sign-in and out is an effective way to maintain a record of individuals having access to the material.

18. Can economic reasons be used as a means for being relieved from some of the increased control requirements?

Requests for exception, relief from, or variation of any specific requirement will be handled on a case-by-case basis. Licensees need to request exceptions or relief in their response to the Increased controls. All requests for relief must include the licensee's justification and any proposal for achieving the same objectives in lieu of those required by the Increased controls.

19. Will the Implementation Guidance carry the same regulatory force as the Increased controls themselves?

No. Guidance provides amplifying information and examples of how the Increased controls may be met, but does not impose requirements. Licensees do not have to implement any of the examples in the guidance, but those examples describe acceptable approaches to implementation.

II. Increased Controls (ICs)

A. IC 1: Controlling Access

1. Trustworthiness and Reliability for Unescorted Access Authorization

20. Are these trustworthiness and reliability requirements equivalent to those used in nuclear power plants?

No. Nuclear power plants use other more stringent requirements to determine an employee's trustworthiness and reliability (See 10 CFR §73.56 and §73.57). The NRC and Agrement States have taken a risk-informed approach for different types of licensees for trustworthy and reliability determinations for access controls.

21. Please provide further clarification regarding the trustworthy and reliability Increased Control, including suggested procedures for trustworthy and reliability determinations.

As per IC 1, to authorize unescorted access to an employee, the licensee must perform, as a minimum, verification of employment history, verification of education, and verification of personal reference checks. In addition, to the extent possible, the licensee must also obtain independent information to corroborate that provided by the employee. It is the licensee's responsibility to make a trustworthiness and reliability determination of an employee, contractor, or other individual who would be granted unescorted access to the device containing radioactive material, and it is expected that licensees will use their best efforts to obtain the information required to conduct a background check to determine individuals' trustworthiness and reliability. The sole exception is the trustworthy and reliability determination made of service providers, for which the determination may be made only by the service provider's employer (M&D licensee). The determination of trustworthiness and reliability may rely on the same or similar information evaluated by human resource personnel in their findings of employability by employers. Information previously obtained during the hiring process may be

used to support the determination, without having to re-verify that information. Licensees have the option to make a trustworthiness and reliability determination for those individuals that they deem necessary to have unescorted access, but also have the option to escort and not make the trustworthiness and reliability determination. However, if such a corroborative check becomes impossible, but the licensee concludes the individual should still be authorized for unescorted access based on other background check information, then the licensee should be prepared to provide a supporting explanation, in writing, of their efforts to obtain the necessary information.

22. Will guidance be provided on what determines trustworthiness and reliability?

No, however, IC1(b) provides the minimum basis upon which a determination may be made. Alternative sources may be used depending on the information available to the licensee. It is the licensee's responsibility to make a trustworthiness and reliability determination for an employee granted unescorted access. This is a licensee's business decision as to what criteria it uses for the bases of the trustworthiness and reliability determination.

The trustworthy and reliability determination is designed to identify past actions to help verify one's character and reputation which provide reasonable assurance of an individual's future reliability.

The following are some indicators that licensees may want to consider for what may be a trustworthiness and reliability concern:

1. Impaired performance attributable to psychological or other disorders.
2. Conduct that warrants referral for criminal investigation or results in arrest or conviction.
3. Indication of deceitful or delinquent behavior.
4. Attempted or threatened destruction of property or life.
5. Suicidal tendencies or attempted suicide.
6. Illegal drug use or the abuse of legal drugs.
7. Alcohol abuse disorders
8. Recurring financial irresponsibility.
9. Irresponsibility performing assigned duties.
10. Inability to deal with stress, or having the appearance of being under unusual stress.
11. Failure to comply with work directives.
12. Hostility or aggression toward fellow workers or authority.
13. Uncontrolled anger, violation of safety or security procedures, or repeated absenteeism.
14. Significant behavioral changes, moodiness or depression.

These indicators are not meant to be all inclusive or intended to be disqualifying factors. Licensees can a also consider extenuating or mitigating factors in their determinations.

23. Why is a trustworthiness and reliability determination necessary?

A trustworthiness and reliability determination provides the licensee reasonable assurance that the individual allowed unescorted access will not use the material for malicious purposes. The determination provides a basis upon which access cards and other such security access devices could be issued. This requirement goes beyond access control for radiation protection purposes, and further limits access to those individuals who have a legitimate need to access the material or device.

24. Can the trustworthiness and reliability requirements be avoided if there are alternative physical controls or alternative administrative controls and training?

No. All Increased controls were designed to provide a defense in depth strategy for the increased control of radioactive material in quantities greater than or equal to Table 1 values. No single measure can provide the same level of protection as all Increased controls, in total. Therefore, each of the Increased controls will require implementation. The NRC and Agreement States acknowledge that no single component can provide foolproof assurance that a loss of control will not occur.

25. How does a background check assure trustworthiness and reliability?

It is recognized that a background check cannot provide total assurance that a person granted access will not use the material for malicious purposes; however, it does provide reasonable assurance that the individual is who they purport to be, and to determine if the individual's character, reputation, and behavior is not adverse to safe operation and does not constitute an unreasonable risk to commit or aid malevolent use of radioactive sources for the protection of the public health and safety.

26. How do the NRC and Agreement States perform trustworthiness and reliability evaluations of licensees?

The NRC and Agreement states do not perform trustworthiness and reliability reviews for individuals. Currently, the process relies on the demonstrated performance of licensees to safely handle radioactive materials. Such performance is observed through the NRC and Agreement State inspection processes. It is the licensee's responsibility to determine the trustworthiness and reliability of its employees to have unescorted access to the radioactive material or device containing radioactive material.

27. What is sufficient to determine trustworthiness and reliability, and who is responsible for making the determination?

The Increased Control provides three elements (educational, employment, and personal history) needed to complete a minimal trustworthiness and reliability review; however, it may be necessary to develop additional information beyond that required in the Increased Control to provide reasonable assurance that an individual granted unescorted access to the material will not use it for malevolent purposes. There is flexibility in how to structure the process.

The ultimate responsibility for making a trustworthiness and reliability determination resides with the licensee; however, the review can be delegated to Human Resources, or other appropriate departments depending upon your organization. Information previously obtained during the hiring process may be used to support the determination, without having to re-verify that information. Licensees have the option to make a trustworthiness and reliability determination for those individuals that they deem necessary to have unescorted access, but also have the option to escort and not make the trustworthiness and reliability determination.

28. How should the trustworthy and reliable determination process for my employees be documented?

The process must be documented and must include the basis used to develop the determination for each individual (including the criteria and supporting documentation), the individual's name, and should include the date of the determination, and the name and signature of the person responsible for making the determination.

29. Does the denial of unescorted access have to be documented?

No.

30. Does the denial of unescorted access create legal liability for the licensee?

The NRC and Agreement States acknowledge that employer liability potentially exists through the process for determining trustworthiness and reliability, just as employer liability potentially exists throughout the hiring process. A finding that results in denying someone employment may be actionable on the part of the employee/employee candidate, and this is no different.

31. How can we address the unique challenges related to establishing trustworthiness and reliability for foreign nationals (anyone who is not a U.S. citizen)?

The NRC and Agreement States agrees that determining the trustworthiness and reliability of foreign nationals, including students, poses special challenges. An evaluation of academic and other references (i.e. transcripts, college applications, financial aid applications, etc.), can form the basis for a trustworthiness and reliability determination. A visa does not, in and of itself, provide an adequate basis for determining that the individual is trustworthy and reliable.

Background checks are required to verify and develop information that supports the basis for the trustworthiness and reliability determination. Licensees must obtain independent corroborating information to the extent possible. The Increased controls incorporate the phrase "to the extent possible" as opposed to "to the extent practical" to communicate the expectation that licensees will use their best efforts to obtain the information required. However, if obtaining such corroborative information becomes impossible, but the licensee concludes the individual should still be authorized for unescorted access based on other background check information, then the licensee should be prepared to provide a supporting explanation, in writing, of their efforts to obtain the necessary information.

32. Why was three years chosen?

A three year period was chosen based on information provided by law enforcement communities, which is not inconsistent with background investigations required for other security clearances. The 3-year employment limit is used to differentiate between a background check that develops information on the individual's character, reputation and behavior (if employed by the licensee for 3 years or less) and a background check that relies mostly on the employer's observations regarding the employee (if employed by the licensee for greater than 3 years).

A three year time period is a reasonable amount of time in which to observe an employee's actions and to establish the trustworthiness and reliability of the employee. The review and investigation for trustworthiness and reliability of an employee or candidate for employment is envisioned as a one-time event on the part of the licensee, unless other information learned following the determination could prove to influence the outcome of the initial determination.

33. How far back in time must a licensee look into a potential employee's historical information to make the trustworthy and reliability determination?

Licensees should look into a potential employee's history as far back, to the extent possible, as is necessary to satisfy themselves that sufficient information is available to meet its own criteria for the trustworthiness and reliability determination.

34. Do you have grandfather provisions for those who are long-term employees regarding trustworthiness and reliability?

All employees granted unescorted access must have a determination of trustworthiness and reliability. The level of investigation needed to develop supporting information in determining the trustworthiness and reliability of employees who have been employed for over 3 years is not the same as that required for new or recently hired individuals.

35. Are you defining three years of employment as "uninterrupted" service, or can there be breaks in service as long as he's worked for you for 3 total years?

Three years of service can be concurrent or cumulative as long as the person's work history justifies a trustworthy and reliable determination.

36. Why isn't a criminal background check required?

Licensees in some jurisdictions may not have authority to perform criminal background checks, and therefore, this was not added to the Increased controls. Licensees are encouraged to implement additional controls, which could include criminal background checks to their trustworthy and reliability determination process, consistent with applicable laws.

37. Can one institution's determination of trustworthiness and reliability for an individual suffice for another institution's assertion that trustworthiness and reliability is met, and can such information be shared among institutions?

Each institution (i.e., licensee) is ultimately responsible for determining the trustworthiness and reliability of anyone they are granting unescorted access to radioactive material in quantities greater than or equal to Table 1 values or devices containing such material through the background check requirement in the Increased Control. Licensees would need to establish their criteria on which they will base their trustworthiness and reliability determination and obtain the necessary information which substantiates their criteria. Information gathered from other sources, including information obtained for a finding of trustworthiness and reliability by another institution may be one element of the basis for making a new determination at the new institution. Your human resource and legal personnel can determine if such information may be

shared among institutions. If programs exist for other activities at a licensee's site that accomplish the same objectives as the Increased controls, licensees do not have to create a separate program for their radioactive material. Licensees will need to document how specific elements of existing programs are used to implement each Increased Control.

38. Our industry is subject to 3 different Federal background check programs: Bureau of Alcohol, Tobacco, Firearms, and Explosives, The Department of Transportation (DOT) and the NRC. All 3 have different requirements. This is very cumbersome, confusing and costly.

The process used and the information previously obtained through another background check or the hiring process may be used to support a trustworthy and reliable finding without having to re-verify the information. However, the individual responsible for the background checks must document the basis for concluding that individuals are trustworthy and reliable. The documentation may reference pre-existing records. If programs exist for other activities at a licensee's site that accomplish the same objectives as the Increased controls, licensees do not have to create a separate program for their radioactive material. Licensees will need to document how specific elements of existing programs are used to implement each Increased Control.

39. Can other individuals (e.g., contract physicians, physicists, laboratory staff, house-keeping, security staff, or other staff not actually using the device or material) be authorized unescorted access to a device or radioactive material in quantities greater than or equal to Table 1 values?

Yes. Other personnel (both licensee and non-licensee) that have job duties that require access to the room where the device is used or stored may have unescorted access to the material or device if the licensee has determined they are trustworthy and reliable and there is a need for them to have access to the material or device. The requirements restricting unescorted access are for vendors and service providers who are installing, repairing, modifying, or removing the source containing radioactive material quantities of concern from a device.

40. If a licensee has determined someone to be trustworthy and reliable, and they later betray that determination by actually taking the material for malevolent use, what actions are expected of the licensee? What liability does the licensee assume because of their background check?

The licensee is required to provide reasonable assurance that persons granted access are trustworthy and reliable, and if the licensee fails to provide that assurance, the licensee would be in violation of the Increased controls, and enforcement action will be considered. Providing assurance means that the licensee has taken reasonable efforts as required by the Increased Control to ascertain trustworthiness and reliability and documented those actions.

Once an incident occurs, the licensee is expected to implement the other elements of their documented program required by the Increased controls, and pursuant to the regulations and license conditions.

41. Could security risk assessments described in title 42 CFR 73.8 assist in achieving certain trustworthy and reliability goals? Note that current impediments to information sharing (Department of Labor restrictions) among institutions could restrict the transmittal of important information.

The "Security Risk Assessment" under title 42 CFR 73.8 could potentially serve as an element of the basis for a determination that an individual is trustworthy and reliable. Concerns that other institutions cannot share "Denial of Access" information are duly noted. The NRC is not pursuing action at this time with regard to this potential impediment to information sharing among institutions. Each institution (i.e., licensee) granting unescorted access to radioactive material in quantities greater than or equal to Table 1 values or devices containing such material is responsible for making its own determination that an individual is trustworthy and reliable, through the background check requirement in the Increased Control.

42. Can emergency first responders, such as police and fire department personnel be deemed trustworthy and reliable for the purposes of the Increased controls, without a background check?

Officials of the NRC, state radiation-protection agencies, and local law enforcement authorities are deemed trustworthy and reliable for purposes of this requirement. In the event of an emergency, such as a fire or explosion, firefighters may be granted unescorted access for the purposes of controlling the emergency situation.

43. Can the Human Resources department be designated to perform the background checks and be the repository for trustworthy and reliability determination records? If we have a process in place can we continue to use that process? Does the Radiation Safety Officer (RSO) have to be involved?

The review and/or record storage can be delegated to a licensee's Human Resources or any other appropriate department depending on its organization. Additionally, the process used and the information previously obtained through the hiring process or another background check process, may be used to support a trustworthy and reliable finding without having to re-verify the information. However, the individual responsible for the trustworthy and reliability determinations must document the basis for concluding that individuals are trustworthy and reliable. The documentation may reference pre-existing records. If security programs exist for other activities at a licensees site, that accomplish the same objectives as the Increased controls, licensees do not have to create a separate security program for their radioactive material. Licensees will need to document how specific elements of existing security programs or plans are used to implement each Increased Control. The RSO does not have to be involved just as along as the objectives of the Increased controls are met. However, because safety and security go hand-in-hand, the RSO is likely to be integrally involved in any decisions and implementation.

44. How do you handle non-disclosure of personal information other than to simply tell someone calling about employment history they worked for you from one date to another?

Verification of employment history can be one measure by which you determine a person's trustworthiness and reliability.

45. Are you attempting to determine if employees are telling the truth? If someone has a drug and alcohol problem, does that make them unreliable?

The process has been developed to provide a way for licensees to have reasonable assurance of a persons true identity and that the individual's character or reputation is established to be trustworthy and reliable. Being untruthful and abuse of alcohol are indicators that may be used to deny a person's trustworthiness or reliability, but are not necessarily determinative.

46. How are we going to handle totally new hires that you put through school? How will you get all the background checks before you put him to work? Are managers subject to the same background checks?

Background checks on new hires without an employment history will require a review of their education and personal references. The background investigation for a determination of trustworthiness and reliability needs to be done before granting unescorted access to the radioactive material quantities of concern or devices containing the radioactive material, otherwise the individual may be escorted. Everyone is required to have a trustworthiness and reliability determination before being given unescorted access to radioactive material quantities of concern or to devices that contain such material. The level of investigation of the background check to develop information supporting the determination criteria is different for those employed more than three years.

47. How does the inspector judge if a licensee's program for trustworthiness and reliability checks is adequate?

When it is completed, licensees will be provided informational copies of the Temporary Instruction for inspection which gives guidance to inspectors. Generally, inspectors will verify that licensees have performed the trustworthiness and reliability determinations for those individuals granted unescorted access. This would include looking for documentation of the criteria used for those determinations and documentation of the information gathered, in the background investigation (e.g., records of phone conversations) to support that an individual meets the licensee's the criteria. Inspectors would generally not second guess a licensee's determination if the licensee has information to support its decision.

2. Trustworthiness and Reliability of Service Providers

48. Why aren't the NRC and Agreement States issuing Increased controls to all irradiator repair/service providers to have a trustworthiness and reliability determination of their service personnel?

At this time, the NRC and Agreement States are issuing Increased controls to licensees that possess their own radioactive material in quantities greater than or equal to Table 1 values and not to those that only take temporary possession of their customer's sources for radiation protection purposes while performing repairs or service. The Increased controls issued to service providers are designed to enhance control for the service providers own sources, and not for their customers' sources at the customers' facilities. The one exception is where the service provider is also a Manufacturer and Distributor (M&D) Licensee and is implementing the M&D Licensee Additional Security Measures Order of January 12, 2004. In this case, the M&D Licensee can provide certification to their customers that an individual M&D employee is trustworthy and reliable based on that Order, without its customer licensee having to go through its own process to make the trustworthy and reliable determination for unescorted access.

49. Can properly qualified service providers be considered trustworthy and reliable and granted unescorted access to the radioactive material or devices containing the radioactive material.

Yes, provided the licensee meets the requirements of IC 1. Certain Manufacturing and Distribution (M&D) Licensees implementing the NRC's January 12, 2004, Additional Security Measures (ASMs) Order, have requirements that exceed IC 1. Therefore, individuals from these M&D licensees, who are providing service at a customer's facility, need not go through the customer's process for determining trustworthiness and reliability for granting unescorted access. Rather, because the M&D licensee may already have made its own determination of trustworthiness and reliability, under the January 12, 2004, Order, for its service personnel, the M&D licensee can provide its customers with certification of an individual's trustworthiness and reliability for being granted unescorted access.

50. During a source disconnect, would trustworthiness and reliability requirements apply to the individual coming in to provide source retrieval services? What about an individual who works for another company that provides source retrieval services and they have performed trustworthiness and reliability background checks, are those checks are adequate for my company?

Yes, to both questions. Individuals without a trustworthiness and reliability determination would need to be escorted during source retrieval operations. Manufacturing and Distribution (M&D) Licensees implementing the January 12, 2004, NRC Order can provide verification of their employees trustworthiness and reliability to its customers. Some type of written communication is required from the M&D Licensee, which includes the employee's name that will be providing the service, and a statement to the effect that the employee has been determined to be trustworthy and reliable in accordance with the NRC Security Orders for M&D Licensees.

51. What type of written verification attesting to or certifying a service provider employee's trustworthiness and reliability is required from a Manufacturing and Distribution (M&D) Licensee providing the service?

Some type of written communication is required from the M&D licensee, which includes the employee's name that will be providing the service, and a statement to the effect that the employee has been determined to be trustworthy and reliable in accordance with the NRC Security Orders for M&D licensees.

52. Before a Manufacturing and Distribution (M&D) Licensee comes to a customer's facility to provide service, will the NRC provide assurance that the M&D Licensee is complying with the M&D Licensee security Order of January 12, 2004?

The M&D licensees issued and implementing the January 12, 2004, Order have notified the NRC that they are in compliance with that Order. The NRC, as part of its regulatory program will inspect these licensees to verify compliance.

53. Why do the Manufacturing and Distribution (M&D) Licensee have a more stringent standard for determining trustworthiness and reliability than these Increased Controls (ICs)?

M&D licensees' need trustworthiness and reliability requirements that are more stringent than required by these Increased controls. These requirements have been designated as Safeguards Information and will not be distributed to other licensees. M&D Licensee service providers have knowledge, tools, and access to devices that contain sources containing radioactive material quantities of concern.

54. Can vendors and service providers not associated with a Manufacturing and Distribution (M&D) License be provided unescorted access to radioactive material in quantities greater than or equal to Table 1 values at a customer facility?

No. At this time, only vendors and service providers associated with a M&D license implementing the NRC Security Order of January 12, 2004, can make a trustworthiness and reliability determination for individuals that provide service at their customer's facilities. All other vendors and service providers must be escorted by a person, from the customer's facility, who is authorized to have unescorted access to the radioactive material or device containing radioactive material. There is need for more stringent trustworthiness and reliability requirements for M&Ds relative to other licensees, based on the fact that the M&Ds are intimately more familiar with the devices containing radioactive material quantities of concern than other licensees. Vendors and service providers not associated with a M&D may also have intimate knowledge of these devices. However, they do not have possession limits that warrant the issuance of increased controls that are comparable to those issued to the M&D Licensees.

55. Are the NRC and Agreement States considering developing an alternate pathway for vendors and service providers not associated with a Manufacturing and Distribution (M&D) Licensee to have unescorted access to radioactive material in quantities greater than or equal to Table 1 values at their customer facilities?

Not at this time.

3. Controlling Access

56. Can the NRC provide examples of how to best achieve the level of unescorted access and detection given budget constraints versus risk?

Each licensee needs to develop a plan that identifies the areas where radioactive material in quantities greater than or equal to Table 1 values are located, who has access to these areas, and how to best achieve compliance with the Increased controls. The way to achieve compliance will vary for each facility. This is a business decision that the licensee needs to make.

57. Can we assume that patients can be granted unescorted access during patient treatments?

Patients who are being treated with devices containing radioactive material of concern, are usually escorted, monitored, or frequently observed by an approved individual. Access by patients who are receiving treatment with such devices should be restricted during treatment, and the licensee shall comply with the Increased controls. Patients should not be able to access areas where radioactive material quantities of concern is stored without being escorted or confronted by approved personnel.

58. Can the escorted access requirement be waived for hospitals because of the cost, and safety concerns involved in accompanying patients at all times? Exceptions are needed for emergency situations.

Licensee must comply with the Increased controls and control access of patients who are receiving treatment with devices containing radioactive material in quantities greater than or equal to Table 1 values. Escorting individuals who have not been deemed trustworthy and reliable is required, and patients being treated are usually escorted, monitored, or frequently observed by an approved individual. Licensees have the ability to identify those areas/rooms where radioactive material quantities of concern are located and may use a variety of methods to limit access, escort and monitor patients. Licensees need to determine which methods would be the most reasonable and practical for there situation. While safety and security are complimentary, security should not interfere with safety. Licensees can determine their own best practices or procedures in anticipated emergency situations.

59. Does "access control" (IC 1) require that locks for different rooms be re-keyed to different keys/combinations?

No. IC 1 requires that only approved individuals have unescorted access to radioactive material in quantities greater than or equal to Table 1 values. It is up to the licensee to determine how access will be controlled at their facility. If you are using a key based system for access to radioactive material quantities of concern, the keys should only be distributed to personnel who have a need-to-know and have been granted unescorted access. Compliance with this Increased Control can only be determined during the inspection process.

60. Self contained irradiators have shown themselves to be very safe for day to day use without operators having access to the radioactive material. Controlling access to the radioactive material is generally much easier than controlling access to the irradiator. Are the Increased controls expected to address access to the radioactive material or to the irradiator?

In order to address potential malevolent intent, the Increased controls were drafted to control access both to the radioactive material and to the irradiator. When used properly with no malicious intent, the devices are inherently safe.

61. Can the requirements in IC 1 (for controlling access) be eliminated because it seems to be overly burdensome? The radioactive source cannot be easily accessed for the some types of devices (e.g. blood irradiators, panoramic

irradiators with less than 10,000 curies, teletherapy devices, gamma knife devices, and afterloader units). Only specifically trained individuals utilizing specialized equipment could exercise sufficient physical control over these sources to present a risk of theft, sabotage, or malevolent use. What is the likelihood that a Co-60 source could be removed from its housing?

The NRC has engaged the expertise of national laboratories who have shown that these devices may be vulnerable under certain scenarios. It is for this reason that the Commission has determined that certain enhanced security measures are necessary in the current threat environment.

62. Does unescorted access only apply to the storage area?

No. It applies to all areas where there is radioactive material of concern or devices containing the radioactive material.

63. Do the individuals on an oil rig who actually manipulate the tools, but are not employed by us, have to be approved individuals under the Increased Control?

No, as long as there is an approved individual on the rig escorting these individuals.

64. What should we do if one of our trucks (working under the Increased controls) breaks down and must be towed to a shop for repairs and we are not allowed into the repair shop bay?

You must still meet the requirements of the Increased controls. Your authorized user could lock the truck, remain at the shop and keep visual contact with the truck in order to control and maintain constant surveillance of licensed material (as already required by the regulations) to ensure that the sources/tools are not removed. Alternatively, you could remove the device from the truck and keep it in your possession until you can have the sources returned to your facility or the original truck is repaired.

65. Why are the access controls required when most of the Increased Control duplicates regulation, license condition, guidance, or the licensee's own safety procedures addressed for health and safety.

Current regulatory requirements for security and access controls focus on safety to assure appropriate control of the radioactive material and proper use of devices containing the radioactive material to meet the standards for protection against radiation. They were not developed for protecting against determined individuals intent on malevolent use of radioactive materials. The purpose of the Increased controls is to enhance existing security requirements to reduce the risk of malevolent use. The NRC and Agreement States consider safety and security to go hand-in-hand and that existing licensees' radiation safety procedures and current business practices can be readily adapted to meet the access controls.

B. IC 2: Monitoring, Detecting, Assessing, and Responding

1. Local Law Enforcement Agency (LLEA) Coordination

66. Could radiation detection meters, connected to a silent alarm, be used to alert local law enforcement of an attempted theft of radioactive material?

Yes, radiation meters could be a means to detect theft of radioactive material depending on the configuration of shielding surrounding the radioactive source. However, Increased controls were designed to provide a defense in depth strategy for the control of radioactive material in quantities greater than or equal to Table 1 values and the NRC expects licensees to consider all possible scenarios when developing and implementing a plan for the increased controls.

67. What if the LLEA declines to participate in the plan to respond to incidents due to lack of staffing, resources, etc?

Lack of cooperation by an LLEA, if it occurs, will be handled on a case-by-case basis.

68. Is the licensee required to keep the LLEA responders trained in radiation protection?

In order to assure that the LLEA can appropriately determine the priority of its response they need to have an understanding of the potential consequences associated with theft or sabotage of the radioactive material of concern. For the LLEA to know how best to respond, they need to know something about the potential hazards, and would therefore need to have some radiation protection education. The training of your LLEA is suggested in guidance, but not required by the Increased controls. The amount and frequency of radiation protection training needed is a matter to be coordinated between the licensee and the LLEA.

69. Can you clarify what you mean by assistance from LLEA? For example, is a single officer with radio backup sufficient or is an entire SWAT Team necessary?

The LLEA will respond as appropriate to the event based on their understanding of the situation and potential consequences. As indicated in the Increased controls Implementing Guidance, one of the purposes of establishing liaison with the LLEA is to provide them with an understanding of the potential consequences associated with malevolent use of the radioactive material of concern so that they can appropriately determine the priority of its response. The LLEA response is needed for offsite coordination, in the protection of the public health and safety, to mitigate potential consequences of malevolent use of radioactive material.

70. Does the required pre-arranged plan with the LLEA, (2.b. of enclosure 1) require something beyond what is currently required of licensees?

The Increased controls are an enhancement to current security requirements, and do not relieve current security measures being undertaken by licensees, including LLEA coordination. Depending on each licensee's existing measures, the Increased controls may or may not require additional action.

71. What information must be reported to what organization (NRC, Agreement State, LLEA), and under what circumstances?

In response to the Increased controls, you will be communicating with the NRC or Agreement State regulatory agency, as appropriate, and coordinating with the LLEA. Reports shall be made in accordance with ICs 2 and 3. This does not preclude you from making other reports as required by other State or local laws. Information regarding your physical protection of radioactive materials related to these Increased controls can be given to the LLEA, without violation of the information protection requirements in IC 6.

72. Does the NRC intend to require the responder to have firearms, or will non-lethal weapons suffice? As an example, some security staff do not carry firearms and a LLEA response might not meet the timeliness requirement.

The requirement for an armed response is not to prevent unauthorized access, but to respond to and disrupt an actual or attempted theft, sabotage or diversion of radioactive material. Adversaries could be well armed individuals. A private security force does not substitute for a LLEA. The LLEA will respond as appropriate to the event.

73. Can an on-site proprietary professional security force with trained and armed officers be considered as the LLEA?

An on-site armed force can serve as the initial licensee response. However, arrangements with off-site LLEA shall still be established, and the off-site LLEA shall be notified immediately of incidents, in case additional assistance is needed, and so that the LLEA can assess the potential for off-site impacts and the need to notify other agencies.

74. With respect to dealing with the LLEA, is it the licensee's responsibility to make arrangements with agencies beyond the local level?

It is the licensee’s responsibility to make arrangements with the LLEA that has responsibility for response to potentially malevolent events. When coordinating with LLEA, licensees should use this opportunity to also coordinate with the local Fire department.

75. What coordination is required with the LLEA for work on temporary job sites?

The NRC expects that licensees would coordinate with their established LLEA point of contact, who may be in the best position to communicate with another LLEA. Alternatively, licensees may call 911.

76. Is there some method in place whereby the LLEA may become informed about radioactive materials and our possession of such materials/devices?

The level of knowledge, experience and interest of LLEA will be varied. The Federal government through the Department of Homeland Security (DHS) is actively working with LLEA to improve their awareness and response across a wide field of threats by providing information, training, and funds. In your coordination efforts with the LLEA, information you

provide will add to, and help reinforce, your LLEA's knowledge regarding radioactive materials, their use, and potential risk associated with its malevolent use.

77. For a licensee who sets up a program with their LLEA, how do you handle informing LLEA when you cross county or state lines when going to a temporary job site?

IC 2.b only requires coordination with the LLEA for a pre-arranged plan to respond to an incident at the licensee's facility. Coordination with the LLEA in when crossing county or state lines of jurisdiction is not required. However, for IC 2.a, licensees need to know how to, and must request assistance from, the LLEA at temporary job sites. Licensees could coordinate with their established LLEA point of contact, who may be in the best position to communicate with another LLEA or to advise licensees on best practices. Alternatively, licensees may call 911.

78. Should notification to the LLEA be made by a radiographer at a temporary job site if a device is stolen from the temporary job site?

Yes. Licensees need to know how to request assistance from the LLEA at temporary job sites. Procedures following a theft at a temporary job site should be documented in your response plan.

79. When contacting the LLEA, is it necessary to contact the Hazardous Materials division? Would it be appropriate to give LLEA a diagram of my facility?

Each LLEA will assign the appropriate person or section to work with you. Depending an the size of your facility and the location of the at-risk material providing a facility plan to LLEA may be appropriate. The purpose of coordinating with the LLEA is to provide them with the information they feel is necessary to do their job in responding to, potential malevolent acts involving lost, stolen, or missing radioactive material quantities of concern from your facility.

80. Since facilities are also broken in to in order to obtain equipment other than radioactive materials, do licensees need to notify the LLEA and the NRC Operations Center or the Agreement State Regulatory Agency every time there is a break in?

IC 2.a requires that the licensee's response to any actual or attempted theft, sabotage, or diversion of radioactive material quantities of concern or of the devices shall include requesting assistance from the LLEA. IC 2.d requires licensees to notify the NRC Operations Center at (301) 816-5100 or, for Agreement State licensees, the appropriate Agreement State regulatory agency, after initiating appropriate response to any actual or attempted theft, sabotage, or diversion of the radioactive material. So, the licensee's decision whether to call the police and the NRC or Agreement State, depends on what area the licenses determines needs to be controlled for access to the radioactive material and its assessment of the unauthorized access. A licensee's assessment and response to an intrusion alarm in the business office section of its facility could be entirely different to its assessment and response to an intrusion alarm in the radioactive materials storage area.

81. Can local law enforcement agencies (LLEAs) have access to the Increased controls (ICs) and Licensee's physical protection information? What are the LLEAs responsibilities for protecting this sensitive information?

LLEAs can have access to the Increased controls and licensee's physical protection information if the licensee determines that they have a need for the information to conduct official business. State, local, or other law enforcement authorities are members of occupational groups deemed to be trustworthy and reliable by virtue of their employment status and are used to handling law enforcement sensitive information.

2. IC 2, Questions Specific to Portable and Mobile Devices

82. Does this mean all trucks will need an alarm system?

If the truck is left unattended with sources that meet the Increased controls's criteria, licensees must have a way to monitor and immediately detect, assess, and respond to actual or attempted theft, sabotage, or diversion of the radioactive material or of the devices.

83. How do you handle a situation where you leave a camera at another licensee's or customers facility, one who provides security for their site (i.e. federal facility) who is responsible for security? What about a client such as a refinery where you leave a camera on site, who provides security there and how do we assess if theirs is good enough?

Licensees who possess the radioactive material are responsible for the security and control of their own material and need to meet the Increased Control requirements whether at their own or a customer's facility. If a licensee chooses to store devices at its customers' facilities, they may consider their customer's physical protection program for meeting the intent of one or more of the Increased controls. There must be a clear understanding of the roles and responsibilities of the licensee and its customer, and what features of the customer's security and control program are to be relied on to meet the Increased controls. Licensees should assess the customer's security and control features being relied upon against its own program for implementing these Increased controls.

Particular attention should be given to IC 1 and limiting unescorted access to as few as possible of the customer's personnel and whether the customer has a process for determining trustworthy and reliable individuals. The requirements for IC 2, to monitor and immediately detect, assess, and respond to any actual or attempted theft, sabotage, or diversion of radioactive material quantities of concern or of the devices, will also need to be satisfied. Clear roles, responsibilities and methods need to be defined for communicating with the licensee, assessing the incident, and summoning the appropriate responder including requesting assistance from the LLEA.

84. Can you put an intrusion alarm system on a radiography truck? What about field stations; who must meet the requirements for security and immediate detection?

Yes, an intrusion alarm system can be put on a radiography truck or any vehicle. The Licensee and their authorized user has to meet the requirements of the Increased controls at field stations and at all off-site locations.

85. What about the cost for alarming all radiography trucks, temporary storage sites, remote locations, etc? Aren't these costs now prohibitive for licensees? Don't you think that you may damage the radiography industry by thrusting excessive, and potentially costly security requirements upon them?

The NRC and Agreement States did consider costs and identified performance-based Increased controls that are effective but not cost prohibitive or overly burdensome. The NRC and Agreement States consider that licensees are already implementing much of these Increased controls for radiation protection purposes and that existing practices and procedures can be easily adapted for preventing and mitigating malevolent uses. The performance-based approach gives licensees flexibility to develop effective programs tailored to the unique features of each licensee's facility and operations that can meet the intent of the Increased controls.

3. Miscellaneous

86. Many of the devices are located in facilities that are staffed 24/7. Would Increased controls be required for such situations?

As discussed in the workshops, the licensee would still be required to implement the Increased controls but, the 24/7 staffing may be able to be taken credit for in meeting some of the Increased Control requirements. Having staff that can challenge anyone clearly not having any business near the device while at the same time being able to call for assistance should be considered as part of the licensee response.

87. What about a medical facility using personnel for monitoring where people are moving about constantly and may not be watching the area under access controls. How is this area maintained?

The licensee can use any number of methods. However, the method must meet the time requirement identified in the Increased Control. The Increased Control requires that the licensee respond immediately to any actual, or attempted theft, sabotage, or diversion of radioactive material quantities of concern. An intrusion detection system linked to a monitoring facility is one method of achieving compliance. However, the use of trained personnel can also be implemented. The adequacy of a licensee's method to comply with Increased controls can only be determined during an on-site inspection. No one method of access control and monitoring may be right for all licensees.

88. Would implementation of an area monitor connected to a silent alarm, key-card access to the area, and a video monitoring system be effective in meeting the Increased controls?

The adequacy of a licensee's method to comply with Increased controls can only be determined during an on-site inspection. The Increased controls were created in a manner which will allow licensees flexibility in choosing methods which work best when applied to their specific circumstances. It is not only important to choose the appropriate method of monitoring, detecting, and assessing but to assure that there is a dependable means in place to transmit information between and among the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.

89. Does a licensee have to use an intrusion detection system linked to an on-site or off-site monitoring facility?

No. The licensee can use any number of methods. However, the method must meet the time requirement identified in the Increased controls. The Increased Control requires that the licensee respond immediately to any actual, or attempted theft, sabotage, or diversion of radioactive material. An intrusion detection system linked to a monitoring facility is one method of achieving compliance. However, the use of trained personnel can also be implemented. The adequacy of a licensee's method to comply with Increased controls can only be determined during an on-site inspection.

90. Can IC 4 (physical barriers) be used to control access and prevent an unescorted individual from entering the room where the radioactive source is located?

IC 4 is not primarily intended to provide access control but it can. IC 4 provides additional delay in removing a portable or mobile device from the facility. For portable and mobile devices, delay barriers are required in addition to the access controls required by IC 1. Without additional delay barriers, a portable or mobile device could be removed from a facility before the licensee has the ability to assess and respond to unauthorized access.

91. Can a less rigorous monitoring system be put in place during the routine workday when trustworthy and reliable staff must secure the area and are not present for direct surveillance?

Effective detection and monitoring can be accomplished in many different ways and tailored to facility operations. Detection and monitoring requirements can be met through use of personnel, electronic devices, or visual monitoring. Personnel would have to be determined to be trustworthy and reliable, have a need to know, be trained in the security procedures, have reliable communications, and be capable of meeting the immediate detection requirements. Electronic devices must be capable of alerting nearby trained facility personnel. Visual monitoring must be capable of also alerting trained personnel.

92. Do licensees have to visually distinguish (e.g., badges) all individuals who have not been granted unescorted access?

No, this is not a requirement. Colored badges may be appropriate for a larger organization, while visual recognition may be appropriate in a smaller one. Using magnetic keys in place of some form of visually distinguishing individuals would not be acceptable in terms of meeting the intent of the Increased controls implementing guidance. Magnetic keys control access, but do not identify individuals.

93. How can licensees prevent those individuals who have criminal intentions from gaining access to the radioactive material or device?

The Increased controls are not intended to stop determined adversaries, intent on malevolent actions, from gaining access to the radioactive material. Rather, the Increased controls provide

reasonable assurance that (1) individuals having unescorted access to the radioactive material are trustworthy and reliable and (2) licensees have a reliable means to rapidly identify events of potential malevolent nature and can have prompt police response to mitigate high consequences.

94. How can a single individual, such as a medical technologist assigned to be an escort, be capable of preventing an incident or even raising an alarm in the event that the unapproved individual is armed and intent upon malevolent use of radioactive material in quantities greater than or equal to Table 1 values.

There may be no prevention for a well-thought out determined plan to gain unauthorized access. The Increased controls provide requirements to control access, monitor, detect, assess, and respond. Each licensee may determine which methods will work the best for their specific facility.

95. How do you protect against an insider threat?

The Increased controls require that access to radioactive material in quantities greater than or equal to Table 1 values be limited to only approved individuals. A licensee may grant unescorted access to an individual, but may limit or restrict certain information concerning such things as security system codes and other items regarding the physical protection of the radioactive material. Access to vital information should be limited. This may not prevent a determined insider. However, there should be an increased awareness among licensee staff to report anything unusual or unexpected.

96. Should the radiation safety office/officer be involved in what can be viewed as a security issue?

Although they may not be the experts in security issues, the radiation safety office/radiation safety officer should be involved from the stand point that they provide valuable insight regarding the radioactive material involved and potential safety significance. The radiation safety office/radiation safety officer can provide coordination to ensure that all Increased controls are being implemented and not compromising safety.

97. What is an escort's responsibility and should an escort perform body searches?

There are no specific requirements other than maintaining line of sight contact and any assigned responsibilities under IC 2 or other safety duties. These procedures should be tailored to each facility's operations. Licensees should consider limiting the number of people assigned to an escort so as not to decrease the escort's effectiveness in completing other assigned safety and security responsibilities. The overall goal is to control access to radioactive material in quantities greater than or equal to Table 1 values and limit access to only approved individuals who require access to perform their duties. Individuals who have not been approved must be escorted.

98. Shouldn't device features be considered or given credit for providing some access control?

The Increased controls were written with full awareness of the features of the device, as well as the quantities of licensed material contained in the device. The Increased controls were designed to provide a defense in depth strategy for the protection of radioactive material in quantities greater than or equal to Table 1 values. No single control can provide the same level of protection as the combination of all the Increased controls. Therefore, each of the Increased controls will have to be implemented.

99. Do well-logging sources or radiography sources get stolen as frequently as gauges?

Information in the Nuclear Materials Event Database indicate that radiography sources are not stolen as often as portable gauges.

100. Would the use of a security guard to periodically check areas to ensure they are secure meet the requirement of "immediate detection?" Why would a 15 minute response not be adequate for response to an alarm? Is there any other way to monitor than to have an alarm system?

While trained individuals can be used to monitor, and immediately detect, assess, and respond as required by the Increased controls, periodic checks and/or a 15 minute response time by individuals would not meet the immediate detection requirement. The Increased controls were created in a manner which will allow licensees flexibility in choosing methods which work best when applied to their specific circumstances. It is not only important to choose the appropriate method of monitoring, detection, and assessment, but to assure that there is a dependable means in place to transmit information between and among the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder. Trained individuals can be used to fulfill the requirements of the Increased controls, but licensee implementation must consider the need for implementation that meets Increased Control requirements 24 hours per day, 7 days per week.

101. Couldn't someone monitor cell phone communications, etc., in a licensee's communication plan for monitoring?

Yes. They could also monitor police radios. A dependable means to transmit information about an unauthorized intrusion does not need to be a secure means of communication (i.e., encryption is not required). This is why backup communications (i.e., land line, auto dialers, cellular phones, pagers, and radios) are required.

102. When someone reports a source lost or missing, what is the response of the NRC or Agreement State?

Once an incident occurs, the licensee is expected to implement the appropriate elements of their documented plan, pursuant to the Increased controls. The NRC and Agreement States monitor the situation to assure that appropriate actions are being taken to locate the missing

source. As required by the National Response Plan, the NRC notifies other Agencies and coordinates Federal resources if needed. Similarly, Agreement States would notify NRC and other State Agencies and coordinate State resources if needed. In addition, the licensee is responsible for reporting pursuant to 10 CFR 20.2201, or applicable Agreement State regulation.

103. What is meant by assessment by automated devices?

Depending on the security system, layout of control areas, and sensors, automated devices or systems may be programed to automatically summon LLEA assistance, in response to an intrusion alarm, without having a licensee think through what the alarm may mean and deciding whether to call the police. The assessment has been done in advance by the licensee with a preset security system response to alarms from one or more detectors.

C. IC 3: Transportation Requirement

104. Does IC 3.a.1 apply to all modes of transportation?

IC 3.a.1 applies to domestic highway and rail shipments of radioactive materials of concern. Security during marine and air transport is covered by the U.S. Coast Guard Maritime Transportation security regulations and the U.S. Transportation Security Administration security regulations, respectively. The Increased Control has been revised accordingly.

105. How can the rules be fairly applied concerning transport, when a common carrier can transport without an alarm for immediate detection, versus when a licensee carries a source and has to have an alarm, etc., to meet ICs 1 & 2?

As required by IC 3.a, a common carrier must use a package tracking system, assure trustworthiness and reliability of their drivers, maintain constant control and/or surveillance and have the ability to immediately summon a response. An alarm system is only one way to maintain constant control and provide an immediate response.

106. The requirements of ICs 3.a and 3.b for use of common carriers appear to be less stringent than ICs 1 and 2. Can licensees, who transport their own radioactive materials opt to implement ICs 3.a and 3.b instead of ICs 1 and 2 for transportation.

No. Many licensees use their vehicles differently than common carriers and any differences in the Increased controls account for this while achieving the same objectives. While both the NRC and the DOT have regulatory authority for radioactive materials, DOT [now also the DHS, Transportation Security Administration (TSA)], has traditionally regulated the common carriers of radioactive material. DOT regulations require certain carriers to have security plans, but do not specify all the particular attributes of IC 3 for the security plan. The intent of IC 3 is for licensees to use those carriers that have security plans, required by DOT regulations, that have the particular attributes which achieve the same objectives as ICs 1 and 2. Because not all carriers may be required at this time to have security plans, IC 3 allows flexibility for licensees to choose any carrier that can meet the requirements of the Increased Control. The NRC, DHS, TSA and DOT are working towards having seamless security of radioactive material in quantities greater than or equal Table 1 values across the different regulatory jurisdictions, and

which is consistent with the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources.

107. Do shippers who hire Class A, etc., drivers have a trustworthiness and reliability program in place?

When licensees are “shippers” of radioactive material they must implement the requirements of the NRC’s regulations, security Orders, and Increased controls. Common carriers employed by “shippers” to transport hazardous materials must follow applicable DOT, TSA, and DHS regulations. The security threat assessment required for a commercial drivers' license with a hazardous materials endorsement, needed by common carriers, would satisfy the Increased Control to assure the trustworthiness and reliability of drivers.

108. Who will provide carrier information to licensees? Who is responsible?

Licensees are responsible for obtaining documentation from a carrier certifying that it can meet and will implement the requirements of IC 3.a.

109. What do you do about carriers who subcontract work to other carriers who go to locations that the original carrier does not travel to?

Licensees are responsible for obtaining documentation from a carrier certifying that it can meet and will implement the requirements of IC 3.a., including work subcontracted to other carriers.

110. What if during the first 180 days you are unable to get information meeting the Increased Control from the carrier, what do you do?

If a licensee is unable to work with a carrier to implement the requirements of IC 3.a for its shipment or is unable to find another carrier in time, then the licensee will need to notify the NRC or Agreement State, as applicable, and seek relief from the specific requirement. The request shall provide the licensee’s justification for seeking relief from or variation of any specific requirement, a proposal for achieving the same objective, or a schedule for achieving compliance. Documentation from a carrier need not be obtained within the 180 implementation period, but would be needed by the time the shipment is made.

111. Licensees should not be responsible for the internal security program of private carriers. How do I verify and document that a carrier employs the appropriate security measures?

Licensees do not have to inspect carriers’ security programs to verify the security measures. Licensees need only obtain documentation from the carrier that attests to the fact that its security plan meets the requirements off the applicable IC 3.a and contains a commitment that those requirements will be applied to the licensee’s shipment.

112. What do we do if our contract carriers do not meet the criteria in the Increased controls?

You would not be able to use them to transport sources under the Increased controls. By working with the industry and the carriers, the NRC and Agreement States expect "qualified" carriers to indicate that they meet the criteria of the Increased controls.

113. Will the NRC develop an accreditation process or provide an "approved" list of those carriers that meet the requirements of IC 3.a?

The NRC does not intend to establish such a program nor can it recommend companies to perform services. However, licensees and industry groups may develop a system for identifying and certifying carriers that meet the requirements of the Increased controls and then share that certifying documentation with group members or customers.

114. Why isn't the DOT inspecting the carriers security plans instead of having licensees having to assure that carrier's security plans meet the requirements of 49 CFR 172 Subpart I?

The DOT does verify through inspection that carriers have security plans in accordance with 49 CFR 172 Subpart I. However, the security plan requirement may not apply to all carriers. Furthermore the attributes specified in IC 3.a are not all specifically identified in DOT's regulations and therefore, may not be included in all carriers' security plans. The Increased Control allows licensees the flexibility of approving the use of carriers that may not be required to have a DOT security plan, but can apply the attributes specified in the Increased Control for a licensees shipment.

115. Which licensee is responsible for investigating and reporting the loss of radioactive material in transit, the shipping licensee or the receiving licensee?

As required by IC 3.a, the shipping licensee that is transferring and arranging the shipment of radioactive material to another licensee is responsible for initiating an investigation with the carrier if the radioactive material does not arrive by the pre-arranged expected time of delivery. If the carrier can not locate the shipment and ascertain that it still has control over the radioactive material within the prescribed period, then the shipping licensee must report the missing shipment of radioactive material. As required by IC 3.d, the licensee receiving radioactive material needs to coordinate with the supplier to know when to expect the delivery to assure security when it arrives. Although the shipping licensee is responsible for seeing that the radioactive material gets to its destination in a timely fashion, the receiving licensee must coordinate with the shipping licensee to have an understanding of what notifications, if any, the shipping licensee needs. The NRC expects a clear understanding between the shipping and receiving licensees to assure the successful and timely transfer of radioactive material.

116. For IC 3.b, why can't the NRC issue Orders now to cover the shipment of radioactive materials greater that 100 times the quantities in Table 1, instead of waiting until 90 days before a shipment to notify the NRC? Alternatively, why can't the NRC require licensees to identify whether they are likely to meet that threshold in their response to the proposed Increased controls.

The NRC has a separate Order for additional security measures for the transportation of Radioactive Material Quantities of Concern (RAM QC). The ASMs are Safeguards Information - Modified Handling (SGI-M) and have limited distribution to those licensees that are likely to ship radioactive material in quantities greater than 100 times the quantities in Table 1 (i.e., licensees that have a need to know). Although this group of licensees may possess RAM QC quantities, stakeholder feedback at the workshops indicated that they are more likely to be the recipients of these quantities of material rather that shippers. Stakeholders also indicated that M&D licensees who will be implementing the RAM QC Order are more than likely the ones that will be making the return shipment of this material for their customers. Therefore, the RAM QC ASM Order will only be provided to those licensees in this group who have a demonstrated need to know based on the 90-day advanced notification of a need to ship such quantities.

117. For IC 3.b, which licensee is responsible for notifying the NRC 90 days prior to shipment radioactive material greater the 100 times the quantities in Table 1, the shipping licensee or the receiving licensee?

The shipping licensee that is transferring and arranging the shipment of radioactive material to another licensee (receiving licensee) is responsible for notifying the NRC 90 days before an expected shipment, unless the licensee is already implementing the ASM Order for the RAM QC. The RAM QC ASM Order is to be implemented by January 2006.

118. Is IC 3 applicable when I transfer a source or device to a different building?

Whenever radioactive material in quantities greater than or equal to Table 1 values is being transferred, the shipment must comply with applicable Increased Control requirements. If the transfer is accomplished within the licensee's controlled area, the movement of the radioactive material is not exempt from the Increased controls. IC 3 applies if the licensed radioactive material is being transferred from one licensee to another and the shipment is made by a common carrier by road or rail. A new building or an interim location must also have the security required by the Increased controls.

119. We have a great deal of trouble tracking our sources when they are "clearing Customs." We have been unable to get information regarding any type of tracking system that U.S. Customs may be using. Will the NRC provide us with assistance in dealing with US Customs with regard to tracking our sources once they are in the domain of Customs?

The Increased controls are not intended to require tracking of sources through Customs. IC 3 only requires the use of carriers that implement a package tracking system. Licensees may consider the sources to be secure while going through the Customs process. The NRC, in developing a National Source Tracking System, interacts with the DHS, Customs and Border Protection and will pass on this concern.

120. Are source manufacturers, including radiography source manufacturers, responsible for, and must they comply with, the Increased controls when shipping sources to licensees like me?

Yes. When M&D Licensees are shippers of radioactive material they must implement the requirements of the NRC's Order for ASMs dated January 12, 2004.

121. Are notifications of shipments not received when expected treated as Sensitive Unclassified Information that is NOT publicly disclosed? If a licensee calls the NRC Operations center, will that not be entered as an Event Notice and be made public?

The NRC is considering whether to make this type of information publicly available.

122. Do you need package design changes to approved DOT transport containers so that you can secure them to a truck, given that at present you can not modify these containers if you want to be in compliance with DOT requirements?

Yes modifications to a DOT or NRC transportation package design need to be approved by the competent authority. Security and safety should complement each other. Security should not interfere with safety.

D. IC 4: Physical Barriers for Portable and Mobile Devices

123. If sources are stored in one room, does that mean aggregate quantities?

Footnote 3 to Table 1 provides that radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

124. Can 1/8 inch wire cables be used to secure a radiography camera instead of chains? Is the lock then more of a vulnerability than the cable?

A heavy-duty twisted steel wire cable may be used to secure portable and mobile devices. Ideally the wire should be such that it can only be removed with a heavy duty cable cutter (e.g., thickness greater that a No. 10 wire - 1/8 inch or 2 mm). Any system is only as effective as its weakest component therefore other components of the securing mechanism need to have similar strength such that it would require a heavy duty bolt cutter for removal (Typically, Tensile Force: 2,000 lbf and Shackle cutting force test: 4,000 lbf). Regulatory Guide 5.12 "General Use of Locks in the Protection and control of Facilities and Special Nuclear Materials" may provide some useful information. Other references include: NUREG/CR-5929, Locking Systems for Physical Protection and Control; NUREG-0274, part 5, Catalog of Physical Protection Equipment, book 2, Volume III, Entry Control Components; Army Regulation 190-11, Physical Security of Arms, Ammunition and Explosives; and Department of Energy (DOE) M 5632.1C-1, Manual for Protection and Control of Safeguards and Security Interests.

125. If you lock a radiographic camera in a trailer at a job site, and the source is locked in side the trailer, how do you secure the trailer?

How a trailer could be immobilized or secured to add a delay factor would depend on the size of the trailer and its location. This may be accomplished by a variety of physical controls including: protective storage enclosures, trailer hitch locks, wheel locks, hardened chain and lock, removing the wheels, or deflating the tires.

E. IC 5: Documentation and Document Retention

126. When a device/source is removed from a license (or when a licensee falls below greater-than Table 1 quantities) may the licensee destroy or transfer to the NRC the security documentation required by IC 5?

There is no requirement to maintain documentation when the quantity of radioactive material falls below the Table 1 threshold criteria. At that time, all security documentation should be appropriately destroyed. No transfer of documentation to the NRC is necessary.

127. If records retention are for a lifetime, why can't they be three years to be in line with other NRC requirements?

IC 5 has been revised to read: The licensee shall retain documentation required by these Increased controls for three years after they are no longer effective.

128. Can the records be kept in Human Resources or do they have to be kept in Radiation Safety?

The review and/or record storage can be delegated to Human Resources or any other appropriate department depending on your organization. Additionally, the process used and the information previously obtained through the hiring process or another background check process may be used to support a trustworthy and reliable finding without having to re-verify the information. However, the individual responsible for the background checks must document the basis for concluding that individuals are trustworthy and reliable. The documentation may reference pre-existing records.

F. IC 6: Information Protection

129. Will we be handling Safeguards Information?

No the Increased controls are not Safeguards Information

130. Does the Commission understand that making certain documents Safeguards (SGI) or Safeguard Information - Modified Handling (SGI-M) would cause difficulties for the well-logging industry, particularly at remote temporary job sites.

Yes, the Commission and the NRC staff took this into consideration when they designed the Increased controls. The Increased controls are not SGI or SGI-M. Measures to protect

information are to be taken by the licensee for all information generated by the licensee in response to the Increased controls including licensee's plans and procedures for the physical protection of the radioactive material covered under these Increased controls. Such handling procedures are similar to measures used in managing company proprietary, confidential commercial, or financial information, personal identification information, and individual financial information.

131. How does a licensee determine what material is Safeguards Information (SGI) or Safeguard Information - Modified Handling (SGI-M)? Overall, the Security Classification system seems burdensome.

There are no SGI or SGI-M documents associated with these Increased controls. Information generated by licensees in response to the Increased controls will not be considered SGI or SGI-M. However, the plans and procedures related to a licensees physical protection, of these radioactive materials, is sensitive information and must be protected from unauthorized disclosure.

132. Are we going to be required to provide workers with copies of sensitive information such as that contained in security procedures, etc? Do Licensees have to provide employees with copies of the Increased controls?

Copies of the Increased controls will be publically available, and can be provided to employees. In accordance with the Increased controls, sensitive information generated by the licensee, about its physical protection of the radioactive material (including policies, plans and procedures for these increased controls), must be limited to employees who have a "need-to-know" such information to perform their duties and who are considered trustworthy and reliable.

133. Do the restrictions on disclosure apply to DHS, Federal Bureau of Investigation (FBI), Central Intelligence Agency (CIA), etc.? Can we share Increased controls and associated information with other entities such as a LLEA and feel safe that it's protected?

The Increased controls will be made available to the public-at-large. Licensees will need to share some of its sensitive information with some of these agencies and LLEA as part of the coordination required for your response plan. As government employees and law enforcement officers, they have been determined to be "trustworthy and reliable." The licensee will need to determine if they have an official need to know.

134. Will the Increased controls and/or its recipients be made public?

The Increased controls will be made publicly available, however, the lists of licensees receiving the Increased controls is sensitive information and will not be disclosed to the public.

135. Can we share Increased controls with governmental agencies who inspect us and with contractors who will support us in our efforts?

Yes. The Increased controls will be made publicly available and may be shared with these entities.

136. Will the NRC provide guidance for licensees on how to share Order information to their clients, carriers and others?

Yes. Guidance is provided to licensees for the handling of sensitive information that pertains to your physical protection of the radioactive material (including policies, plans and procedures related to these increased controls). Sharing sensitive information with clients, carriers and others is on a need to know basis. The information needs to be protected the same way a licensee protects its own security, confidential, commercial, or financial information and revealed only to those persons who must have the information to conduct business.

137. What potential liability lies with the licensee in regard to safeguarding this information? Are there significant costs involved?

The licensee's physical protection information does not need to be treated as safeguards information, but it is sensitive physical protection information that needs to be protected. Violation of information protection requirements would subject licensees to traditional enforcement action, which could include civil and/or criminal penalties. Costs involved in protecting this information are expected to be minimal in that protecting the material when not in use requires it be kept in a locked cabinet or desk.

138. Will Agreement State radiation control programs have to change their procedures regarding information collection and document availability for Part 35 and other licensees of concern to ensure this information is not made readily available to interested parties without a need-to-know?

Agreement States generally have processes and procedures for withholding sensitive information from the public. The NRC is working with the Agreement States to ensure that all sensitive information relating to materials licensees (including licensees' information about the physical protection of radioactive materials) be withheld from public disclosure.

139. The preface to the NRC transmission of draft documents which contains the text: "The U.S. Nuclear Regulatory Commission (NRC) considers that any information that could be useful, or could reasonably be expected to be useful, to a terrorist in a potential attack should be withheld from public disclosure" is overly broad. Can you be more specific?

The intent and objectives of the Increased controls are to enhance existing security requirements to reduce the risk for the malevolent use of radioactive material in quantities greater than or equal to Table 1 values. Reducing the access to and release of sensitive information supports this goal by adding an additional level of protection. The NRC and Agreement States determined that a "defense in depth" strategy providing multiple layers of security is the best approach to protecting radioactive material quantities of concern.

140. All of the regulatory agencies should reach consensus on what information should be protected, reduce the number of classifications, and develop a single set of document security protection standards.

The NRC has worked collaboratively with other federal and States agencies on information protection issues. While consensus has been reached on many issues, consensus on protection standards for sensitive information has not been reached. When submitting sensitive information to your regulatory agencies, the NRC expects that NRC licensees follow the recommended procedures for protecting material as described in 10 CFR 2.390 and Agreement State licensees should follow applicable State regulations. All licensees must follow the requirement in the increase controls to develop, maintain, and implement policies and procedures for the proper handling and protection of licensee generated information related to physical protection of radioactive material to avoid unauthorized disclosure.

141. If security requirements move to rulemaking and are published, how will you control sensitive information?

The NRC anticipates that rulemaking will provide the performance based security requirements and not include sensitive information that must not be publicly available. Specific licensees' measures for the physical protection of radioactive material will be protected information. (e.g., see 10 CFR Part 73 as an example).

III. Inspections: Inspection Process and Agreement State Involvement

A. Inspection Process and Agreement State Involvement

142. How will the NRC ensure consistency in the inspection process?

The NRC and Agreement State inspectors are aware of the intent of the Increased controls and are receiving training to ascertain whether licensees meet the objectives of the Increased controls. The inspections are guided by inspection procedures. There will be a process established to help ensure consistency in the inspection processes.

143. Will the inspection criteria and other guidance be available to the licensees?

Yes. Licensees will be provided informational copies of the Temporary Instruction (TI) for inspection when it is complete. TIs provide inspection guidance to NRC and Agreement State inspectors.

144. Are inspections announced?

The Initial Inspections for implementation conducted for these Increased controls will be announced.

145. Are civilian contractors going to perform inspections?

At this time, there are no plans to contract out inspections.

146. Can the security inspections be performed at the same time as routine inspections?

Yes, initial inspections may be done when inspectors are onsite for a safety inspection.

147. Does early compliance subject you to an early inspection? And if inspected before the 180 days is up, are you subject to penalties if found to be in noncompliance or do you have the full 180 days to fix the problems?

No to both questions. Initial inspections will not begin until after the 180-day implementation period. Early compliance is an advantage to licensees allowing them to self-evaluate their new procedures prior to inspection.

148. Is there more inspector training coming? Can licensees attend the inspector training or will NRC provide some other type of equivalent training?

NRC will provide training for both NRC and Agreement State inspectors. The training course is designed for inspectors. Licensees will be provided with a copy of the Temporary Instruction.

B. Agreement State Inspections

149. Agreement states are different, in that one has different "added" requirements in their respective states. Are the inspections going to be different as in the differences between states or will they be uniform?

The NRC is implementing measures to facilitate uniform inspection and enforcement for all licensees. NRC and State Inspectors will receive the same training. Inspectors are required to follow a Temporary Instruction developed for inspecting the requirements of the Increased controls. Bi-monthly teleconferences with NRC and State officials are anticipated to provide an avenue to discuss findings and issues to help ensure consistency in the nationwide implementation.

150. Is the enforcement process any different from what we are used to under the Agreement State?

No. Agreement States will use their existing enforcement processes. The NRC enforcement policy is available for your review on the NRC public website at www.nrc.gov/what-we-do/regulatory/enforcement. Bi-monthly teleconferences with NRC and State officials are anticipated to provide an avenue to discuss findings and issues to help ensure consistency in the nationwide implementation. The IMPEP procedures will be revised to assess program implementation

151. Can an Agreement State cross state lines and inspect in another state?

Agreement State inspectors perform the security inspections for the licensees in their state. One situation that may arise would be if a State inspector needed to inspect records of its licensee that are kept at a corporate office located in another state. In the case where a corporate office maintained records for licenses is several states, NRC would try to coordinate a consolidated inspection.

152. Are there going to be inspection fees for the Increased controls inspections?

NRC will not charge its Licensees a fee for the initial inspection for compliance with the Increased controls. It will be up to each Agreement State to determine whether to charge a fee

for the initial inspections. It is anticipated that the majority of inspections could be accomplished during routine health and safety inspections, minimizing the need for special inspections.

153. Are states going to be involved in the Security Findings Review Panel (SFRP) process?

No. As an alternative to the SFRP process, bi-monthly teleconferences with NRC and State officials are anticipated to provide an avenue to discuss findings and issues to help ensure consistency in the nationwide implementation.

IV. Definitions

154. What is meant by "access" and "physical control"?

A person has access and physical control when they are able to touch the radioactive material in quantities greater than or equal to Table 1 values or any device which contains such material. The licensee is expected to maintain control of such radioactive material at all times by appropriate means that fit their operations. This includes utilizing escorts for those individuals who may be in the area but do not have a need to use the radioactive material or the devices it is contained in.

155. What is meant by "immediately"?

Immediately means to initiate response without delay. It is recognized that time may be required to make an assessment of the scope of the problem and to respond to the unauthorized access to radioactive material quantities of concern.

156. What is meant by "sabotage" of radioactive material in quantities greater than or equal to Table 1 values?

The NRC and Agreement States are highly concerned with those activities that could lead to any malevolent use of radioactive material, including sabotage, which would include manipulation or rigging of the device or of the radioactive material quantities of concern, in place, with the intended outcome of causing harm. Accordingly, the Increased controls have been designed to mitigate both the potential for theft and the intentional misuse of radioactive material, resulting in detrimental consequences to public health and safety.

157. What is meant by "constant surveillance" and how must it be maintained?

A licensee can achieve constant surveillance by continuously monitoring the radioactive material quantities of concern or the device it is housed in. This can be carried out through the use of personnel and/or mechanical means. Physical detection and monitoring requirements can be met through the use of personnel who have been approved for unescorted access. Personnel would have to be trained in the security procedures, have reliable communications, and meet the immediate detection requirements.

158. Combining the definitions of mobile equipment, portable equipment and stationary equipment makes no sense and is confusing. In addition the word

device may have a different meaning to the NRC than it does to the licensees. For example, does a lead "pig" or a transport container fall into the category of a device?

IC 4 has been revised to make a clearer distinction between the requirements for portable and mobile devices.

"Device" can have different meanings to the various types of licensees that possess sources containing radioactive material quantities of concern. In the context of the Increased controls it is used in a generic sense to mean an approved device to safely contain radioactivity under the conditions of their possession and use. Devices may include but are not limited to the following examples: Self-shielded irradiators, blood irradiators, remote afterloaders, teletherapy units, gamma stereotactic radiosurgery units, radiography cameras, source changers, well logging equipment, radioisotope thermoelectric generators, gauges or controllers, storage containers, and lead "pigs" or transportation packages.

159. If a piece of equipment can be hand-carried by two or three individuals is it considered a portable device?

Definitions from the American National Standard for Gamma Radiography - Specifications for Design and Testing Apparatus, ANSI N43.9-1991, provides some guidance:

Portable: "A portable ... device, designed to be carried by one person alone. The mass of a ... device should not exceed 35 kg (77 lb)."

Mobile: "A mobile, but not portable, ...device, designed to be moved easily by a suitable means provided for the purpose."

In general, however, to address IC 4, the licensee shall utilize two independent physical controls forming tangible barriers to limit ease of theft by an adversary or adversaries, of a device containing radioactive material quantities of concern and considered removable.

V. General

A. Service Providers and Manufacturers and Distributors (M&Ds)

160. Should the NRC focus its security efforts on vendors who supply and replace sources?

The NRC has focused on these groups, the Manufacturing and Distribution (M&D) Licensees, as they have already been issued Orders which focus on a higher level of security than these Increased controls.

161. It is our opinion that engineering controls are much more reliable than trying to predict an individual's current or future "trustworthiness or reliability." Should the Increased controls result in maximizing licensee reliance on engineering controls?

The Increased controls provide a defense in depth strategy. The Increased controls do not prohibit the use of engineering controls to meet the intent of some of the Increased controls. However, the degree to which engineering controls are implemented is a licensee's business decision. Note: if licensees consider instituting engineering controls, those controls should not modify the actual device as described in the sealed source/device registration sheet.

162. Should the NRC require manufacturing and distribution licensees to make design changes that make the radioactive sources less accessible or retrofit an anti-theft device or engineering controls into each device to prevent quick removal?

No, not at this time. The Increased controls require the licensee to limit access to radioactive material quantities of concern. It is up to the licensee to determine how to make this limitation; either by way of engineering controls around the source itself or by limiting access to the area/room where the radioactive material is stored/used. However, an approach to make design changes to devices in lieu of Increased controls would require licensees to either purchase new equipment or retrofit existing devices. Engineering controls such as an anti-theft device are options for the M&Ds of such devices to consider, but the NRC has not mandated this requirement. The NRC's Office of Nuclear Regulatory Research is pursuing design enhancements to make sources less dispersible.

163. Please provide information gathered during security assessments so that M&Ds can make necessary modifications. Some devices require the removal of a significant amount of shielding/housing in order to gain access to the radioactive material. Does this type of configuration constitute a source containing radioactive material quantities of concern?

The specific results of security/vulnerability studies are not being released. However, those studies indicate that these device source combinations may be vulnerable under certain scenarios. The Increased controls provide the additional security deemed necessary. A number of factors were considered when creating the Increased controls including the International Atomic Energy Agency's Code of Conduct which specifically lists the activity and isotopes which constitute a source containing radioactive material quantities of concern.

164. There are differences in the requirements for the determination of trustworthiness and reliability in the Manufacturing and Distribution Licensee Order and the Increased controls for other licensed users. Is there or will there be a move towards standardization in the requirements?

The NRC and Agreement States have taken a risk informed approach in determining appropriate Increased controls for the various types of licensees.

165. Should the NRC have the three radiography source suppliers develop trustworthiness and reliability information on delivery personnel and provide it to the licensees?

The Manufacturing and Distribution (M&D) Licensees are implementing the NRC's Order for ASMs dated January 12, 2004. This Order has a trustworthiness and reliability component. If a

Licensee wants to grant unescorted access to M&D licensee's delivery or service personnel, then documentation may be requested from the M&D licensee attesting the trustworthiness and reliability of an individual has been determined in accordance with the January 12, 2004, M&D Licensee Order.

B. Medical Facilities

166. How will the thresholds identified in the quantities of concern affect High Dose Afterloaders (HDR), especially mobile units?

Most single HDRs do not exceed the thresholds and therefore Increased controls are not required if the devices are not collocated. However, for source change outs or in other cases where there are two or more collocated sources the Increased controls need to be implemented.

167. Many of the devices such as a gamma knife or blood irradiator are inherently hard to steal because the sources are hard to get at and the devices are very heavy. Why do we have to consider additional Increased controls for these devices?

Studies by national laboratories indicate that the sources in those devices are vulnerable under certain scenarios. As such, the Increased controls developed were determined to be reasonable and provide the additional security deemed necessary.

C. Agreement State Licensee Concerns

168. Are the Agreement States allowed to impose stricter requirements?

The NRC and Agreement States worked cooperatively in developing these Increased controls. The Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc. were represented on the Materials Security Working Group and Steering Committee. The requirement for implementing these Increased controls is being issued by both NRC and the Agreement States to protect the public health and safety. To affect nationwide implementation, these measures have been determined by the Commission to be an matter of compatibility Category "B" for Agreement States. In parallel with the Commission issuing Orders to its Licensees, each Agreement State is issuing legally binding requirements to put similar measures in place for licensees under their regulatory jurisdiction.

169. Will a licensee who only holds a State license only correspond with the State or will they correspond with the NRC also?

Licensees' responses go directly to the NRC or Agreement State licensing agency issuing the requirement to implement the Increase Controls.

170. Is there any chance that the NRC will take back the Agreements from the Agreement States because of all the security measures being implemented? Is this the first step towards everyone having an NRC license?

No, the NRC is not considering “taking back” Agreements as a result of requirements to implement these Increase controls.

D. Miscellaneous

171. How are the NRC and Agreement States ensuring that the appropriate licensees receive the Increased controls?

The NRC and Agreement States use their licensing databases to determine which licensees should receive these Increased controls. If States or other licensees are aware of licensees that should receive these Increased controls but have not, they should contact their Agreement State licensing authority or the NRC’s Office of Nuclear Material Safety and Safeguards.

172. If one licensee who owns material and transfers it to another licensed individual, with the intent that the original transferor gets it back, is the transferee responsible for security while they have it in their possession?

Yes. NRC or Agreement State licensees must provide security for licensed radioactive material they possess under their license (see 10 CFR §20.1801 and §20.1802) whether or not they own the radioactive material (e.g., many licensee possess Department of Energy owned material).

173. Who is responsible for security if an “off-site” licensee brings its own radioactive materials to use at another licensee’s facility?

With respect to radioactive material in quantities greater than or equal to Table 1 values brought to a licensee’s facility by an "off-site licensee," the responsibility for security will depend on the purpose and status of the material being brought on-site. If the material, such as a radiography source, is brought onsite by another licensee for the purpose of that off-site licensee performing its licensed functions (in this example, industrial radiography) at a "temporary job-site," the security of the material is the responsibility of the off-site licensee. If the material is being brought on-site for the purpose of being transferred to the licensee, then the responsibility for security belongs to the transferee (i.e., the licensee), upon delivery of the material.

174. On remote sites, sources stored in lead “pigs” are typically left unattended for periods of time. Will this practice still be acceptable under the Increased controls?

No. Under current regulations this practice is not acceptable. The regulations, 10 CFR §20.1801 Security of stored material, requires: “The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas,” and § 20.1802 Control of material not in storage requires: “The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.”

175. Is there any possibility that NRC is going to modify 10 CFR Part 34 to require two qualified individuals to transport radiography cameras?

At this time the NRC does not have any plans for such a proposed rulemaking.

176. At what point does a service provider, who takes temporary possession of radioactive material for service or installing it into a device, transfer responsibility for security of the radioactive material back to the facility licensee?

Licensees under requirements to implement the Increased controls are responsible for security at its facility whether or not a service provider takes temporary possession while working with the licensee's radioactive material. A service provider, when taking temporary possession of its customer's radioactive material, takes responsibility for implementing radiation safety requirements while working with the customer's radioactive material or device containing the radioactive material. A service provider, when in temporary possession of radioactive material for radiation safety purposes, is not responsible for implementing the requirements of the Increased controls related to its customer's radioactive material.

177. Can the NRC sensitive information be communicated to a single, centralized location for licensees that conduct business in multiple states?

If requested in writing, the NRC can communicate sensitive information to a single, appropriately identified, licensee-designated contact.

178. How does the NRC determine to whom the Increased controls and related materials are sent for, at a licensed facility?

The NRC and Agreement States send the information to the licensee's designated "contact person" (as provided in the licensee's application). The licensee has a responsibility, based on a "need-to-know," to make a determination as to which individuals in their organization should be provided copies of the Increased controls.

179. Can the Increased controls be sent via overnight delivery, with conspicuous markings to indicate their importance and the requirement for a response?

NRC will send the Increased controls to licensees via overnight delivery; however, the NRC will not include conspicuous markings regarding licensee response requirements. During the last few years, the NRC has received responses to Orders and other regulatory actions, and to date, has not observed difficulties by its licensees in responding to these special transmittals. Agreements States will each determine the best method to send the requirements to implement the Increased controls to its licensees.

180. Can the delivery of the Increased controls be timed so they do not arrive during major professional meetings?

The NRC and Agreement States will consider the timing of the Increased Control issuance in light of special events, such as national holidays and major professional meetings, affecting the regulated community.

181. Is the DHS aware of the NRC activities concerning radioactive materials?

The NRC maintains an ongoing relationship with several governmental agencies (e.g., DOT, Department of Defense, DHS, Department of Energy) to ensure coordination and consistency in overlapping areas of responsibility and enforcement.

182. Has the NRC coordinated with other federal agencies to promote consistency of security measures?

Yes. The NRC is working collaboratively on security issues, including enhancement to nuclear materials security, in efforts to assure security measures are effective and reasonably consistent with other State and Federal agency actions. The NRC continues to work with the U.S. DHS and other Federal agencies to integrate Federal Response Plans into a unified National Response Plan and National Incident Management System, and to refine the National Preparedness Policy.

In addition, the NRC has ongoing discussions with Federal agencies, including U.S. DOT and DHS, in developing an integrated federal approach for radioactive materials security measures. The NRC is also working in conjunction with the State Department and the international communities to harmonize all regulations associated with the safety and security of radioactive sources.

183. What is the overall intent and objective of the Increased controls?

The intent and objective of the Increased controls is to enhance existing security and control requirements to reduce the risk of malevolent use of radioactive material quantities of concern. The Increased controls cannot prevent 100% of all attempts at theft, sabotage or diversion; however, in total, the Increased controls provide multiple layers of control, or a “defense in depth,” that are designed to provide enhancements to mitigate the risk of malevolent uses.

184. Are you more concerned with theft or sabotage-in-place of radioactive material quantities of concern?

The NRC and Agreement States are concerned with those activities that could lead to any malevolent use of radioactive material. Accordingly, the Increased controls have been primarily designed to mitigate against theft, but also provide appropriate protection against sabotage-in-place of radioactive material, resulting in detrimental consequences to public health and safety .

185. What is the basis for the Table 1 quantities of concern identified in the Increased controls?

The NRC and Agreement States adopted the International Atomic Energy Agency (IAEA) Code of Conduct Category 2 threshold quantities as the basis for the Increased controls to allow consistency between domestic and international efforts for security of radioactive materials that are deemed to be attractive targets for malevolent use. The IAEA process uses the international units of Terabequerels (TBq) and as such, the NRC is using the TBq values as the regulatory standard. The decision to adopt these quantities was supported by earlier NRC and DOE analyses.

186. The expression of Curie (Ci) values to one significant digit might be considered insufficiently precise. Also, the regulated community, that still works largely in Ci units, might not readily identify the distinction in Footnote 2 to Table 1, that "TBq values are the regulatory standard and Curie values are rounded to one significant figure and are provided for informational purposes only." Can Table 1 be revised to provide Ci values to two or more significant figures so that it would not be so easily misinterpreted, misapplied, or the cause of potential violations?

Curie values are provided for informational purposes only, since the values have been rounded after conversion. Any conversion to the curie must still meet the TBq limit.
From a scientific perspective, the radionuclide thresholds in the International Atomic Energy Agency (IAEA) Code of Conduct are quoted to one significant figures in recognition of the limitations on the accuracy of the modeling. However, Table 1 has been revised to provide curie values with two significant figures, for licensee's convenience and to facilitate consistency in the enforcement area and in other aspects of NRC's and Agreement States' regulatory programs.

187. The Table 1 Quantity of Concern for Am-241 and Am-241:Be is 0.6 TBq (20 Ci). That is a problem for the oil and gas industry. In addition, there seems to be a discrepancy between Table 1 and page 15 of the Code of Conduct which lists well logging as a category 3 source/activity. Is there any way that the threshold for Am-241 and Am-241:Be can be raised? Or can alternative criteria for meeting the goal of the increased controls be determined for remote temporary job sites (i.e., offshore rigs, and the north slope).

There is no discrepancy between Table 1: Radionuclides of Concern and page 15 of the International Atomic Energy Agency (IAEA) Code of Conduct. Although the Code of Conduct describes Category 3 sources as "typically used in practices such as.... well logging," IAEA TECDOC-1344, "Categorization of Radioactive Sources," which was the basis for the Code of Conduct, lists Am-241 well logging sources as having a range of activity from 0.019 TBq (Category 4) to 0.85 TBq (Category 2). The IAEA Category 2 threshold quantity for Am-241 is 0.6 Tbq (16 Ci). The IAEA threshold quantities for Category 2 sources are the bases for Table 1 radionuclides and values. The U.S. Government is committed to implementing the IAEA Code of Conduct. Any changes in the threshold quantities will have to be accomplished through the IAEA process. The NRC and Agreement States will consider suggestions from industry on alternative methods for achieving the objectives of the Increased controls.

188. Was the potential financial impact of the Increased controls considered?

The cost of implementing Increased controls was considered during the drafting process. The NRC and Agreement States considered effectiveness, the potential burden on licensees, and costs required of licensees to comply with the Increased controls. The Increased controls allow for substantial flexibility in meeting the objectives so that licensees can tailor measures to their own specific programs and operations. With appropriate enhancements, existing security, safety, and business practices can adequately address the requirements of the Increased controls. Also, the bases for the Increased controls are very similar to the requirements of other agencies (e.g., select agent, hazardous material, or explosive material security requirements), which many licensees are already implementing.

189. Is there financial aid or funding available to assist in the implementation of the Increased controls? Will the licensees be compensated in any way? Perhaps forgoing fees for a year?

The NRC and Agreement States can not compensate licensees or forgo fees to alleviate potential costs. However, there will be no fees for the initial compliance inspections related to the Increased controls. There are no specific funds or financial resources available, at this time, to defray the costs to licensees for enhancing security of these radioactive materials. This is considered a new cost for doing business that many other industries with hazardous materials are facing. The objectives of the Increased controls can be met through procedural changes to existing safety and security programs and through the use of detection, alarm, and communications technologies that are widely available on the commercial market.

190. Were the Increased controls derived from a vulnerability or design basis threat analysis?

There is no design basis threat analysis. However security/vulnerability assessments were used to inform the selection of the Increased controls. The NRC and Agreement States are concerned with those activities that could lead to any malevolent use of radioactive material. Accordingly, the Increased controls have been designed to mitigate both the potential for theft and sabotage-in-place of radioactive material as well as potential detrimental consequences to public health and safety.

191. What steps is the Commission taking to educate the public, in terms of its response to an event?

The NRC and the Agreement States are working with DHS and other government and private organizations to assist in educating the public in this regard. DHS has programs to assist in training for first responders.

192. One commenter recommended that more prescriptive security measures be developed, such as requirements for a written security program and performance of facility specific risk assessments.

The Increased controls are purposely not prescriptive in order to allow licensees to tailor programs to their specific facility and operations. Various approaches are available to licensees to meet the objectives of the Increased controls, and that there exists no one solution for all licensees.

193. Some licensees would only possess quantities that meet or exceed the thresholds for very short periods such as during source change outs. Will these licensees be required to implement the Increased controls?

Licensees that possess quantities that meet or exceed the thresholds will have to implement the Increased controls for those periods they possess those quantities. However, there will provide an opportunity for licensees to request exceptions to some or all of the Increased controls and the staff will consider those requests. If adequate justification is provided by the licensee, exceptions may be granted.

194. Should “high-risk radioactive material” be replaced with “quantities of concern of radioactive material”?

The term “high-risk radioactive material” will no longer be used throughout the Increased controls, and Implementing Guidance. The term "high-risk" used to define the subset of radioactive material covered by the Increased controls is deleted. It is not used internationally or found in the International Atomic Energy Agency (IAEA) Code of Conduct or its Guidance, which refer to sources "...that may pose a significant risk to individual, society and the environment, if handled improperly." The Increased Control defines this subset of material as that listed in Table 1.

195. Does the database include all old radiography cameras (and sources) prior to 1996 when new cameras were required to be purchased by licensees? (i.e. cobalt-60 cameras)

The interim database contains information about sources containing radioactive material that exceed the quantities listed in Table 1, Radionuclides of Concern. The database does not contain information about devices or old cameras.

196. Why is NRC regulating Ra-226 listed in Table 1?

Ra-226 was originally included in Table 1 for informational purposes and for consistency with the IAEA Code of Conduct. Table 1 has since been changed to align with NRC’s authority. The Atomic Energy Act of 1954, as amended, does not authorize NRC to regulate naturally occurring radioactive material like Ra-226. However, Agreement Sates, have the authority and may choose to apply the Increased controls to Ra-226.

197. If a terrorist does blow up a source, how does the licensee know how large an area to evacuate? Has the NRC or one of the National Laboratories taken sources and tested them to see what level of explosives it would take to disperse the radioactive material?

National Laboratories have done explosives tests to better determine the dispersibility and consequences of various radioactive sources of concern for use in a Radiological Dispersal Device (RDD). The extent of local contamination would depend on a number of factors, including the size of the explosive, the amount and type of radioactive material used, the means of dispersal, and weather conditions. Those closest to the RDD would be the most likely to sustain injuries due to the explosion. As radioactive material spreads, it becomes less concentrated and less harmful. Prompt detection of the type of radioactive material used will greatly assist local authorities in advising the community on protective actions, such as sheltering in place, or quickly leaving the immediate area. While the explosive blast will be immediately obvious the initial evacuation would be based on the size of the explosion. The presence of radiation will not be known until trained first responders with specialized equipment are on the scene and can determine the radiation dose rates for recommended protective actions based on the Environmental Protection Agency’s Protective Action Guidelines. Licensees can best advise the LLEA on safe distances for radiation protection if a source is used as an exposure device.

198. Was any media invited to attend or allowed to attend any of the Stakeholder meetings on the draft Measures?

No. Attendance at all the Stakeholder meetings to discuss Increased controls was by invitation and confirmed reservation only.

199. If a facility has multiple sources that when added together would exceed the quantity of concern, but they are spread out over a large facility (i.e., cesium flow meters on process piping), would they still be covered under the aggregate activity even though they are not collocated?

Footnote 3 on Table 1 indicates: "Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material." There is a process by which a licensee may request relief from the Increased Control if compliance with any of the requirements is unnecessary in specific circumstances. The process is communicated in the language of the Increased Control.

200. Could certain licensees be categorically excluded or exempted from some or all of the Increased controls based on inherently low specific activity?

NRC and Agreement States agree that low specific activity radioactive material inventories pose a lower risk. Increased controls are being issued to certain types of licensee's based on their authorized possession limits. Specific activity thresholds were not established for categorical exclusion. Rather, implementation of the Increased controls is based on possession of quantities of radioactive material that are greater than or equal to Table 1. There is a process by which a licensee may request relief from the Increased controls if compliance with any of the requirements is unnecessary in specific circumstances.

201. Are the Increased controls proportional to the uses of the radioactive materials and do they allow licensees to take into account the circumstances, location and security measures that may already be in place for other things?

Yes, the NRC and Agreement States have developed various Compensatory Measures, ASMs and Increased controls for different types of licensees that are in proportion to today's regulatory environment and potential consequences of malevolent acts. The NRC and Agreement States recognize that various approaches are available to licensees to meet the objectives of the Increased controls, and that there exists no one solution to any safety or security challenge facing licensees. If programs exist for other activities at a licensees site, that accomplish the same objectives as the Increased controls, licensees do not have to create a separate program for their radioactive material.