NOV 5 1996

MEMORANDUM TO: Carl J. Paperiello, Ph.D, Director
Office of Nuclear Material Safety and Safeguards

FROM: Charles W. Hehl, Director
Division of Nuclear Materials Safety

Original Signed By:
Charles W. Hehl

SUBJECT: WORKSHOP ON SECURITY AND CONTROL OF LICENSED MATERIALS: WRITTEN COMMENTS RECEIVED

On August 21, 1996, Region I and Harvard University hosted a Workshop with Region I Materials Licensees responsible for large research and development programs on the Security and Control of Licensed Material. A memorandum dated October 1, 1996 from Hubert J. Miller, Regional Administrator, Region I to Hugh L. Thompson, Jr., provided a synopsis of the Workshop and summaries of each of the Participants' Small Group Discussions.

In addition to the information provided during discussions, Participants and Observers provided written comments throughout the day of the Workshop. These comments were collected and are in Attachment 1. Comments received in writing, before and after the Workshop, are shown in Attachments 2 through 7. We are forwarding these comments to you for consideration and use by your staff.

Attachments:
1. Written comments received from Participants and Observers at the August 21, 1996 Workshop on Security and Control of Licensed Materials, King of Prussia, Pennsylvania
2. Letter dated July 16, 1996 from John Pratt, Associate Director and Paul Matsudaira, Radiation Protection Officer, Whitehead Institute for Biomedical Research
3. Letter dated July 22, 1996 from Victor Evdokimoff, Radiation Protection Officer, Boston University Medical Center
4. Letter dated August 23, 1996 from Rodger W. Granlund, University Health Physicist, Pennsylvania State University
5. Letter dated September 9, 1996 from Rita Aldrich, Principal Radiophysicist, Radiological Health Unit, State of New York
6. Electronic mail letter dated August 7, 1996 from Mark Rotman, Chief, Radiolabelling Unit, Monoclonal Antibody Section, National Institutes of Health
7. ACURI Position Statement on Radioactive Materials Security received by facsimile August 16, 1996

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RETURN ORIGINAL TO
REGION I

040007

cc w/attachments:
D. Cool, NMSS
J. Lieberman, OE
B. Morris, RES
L. Camper, NMSS
J. Piccone, NMSS
C. Jones, NMSS
A. Tse, RES
J. DelMedico, OE

cc w/o attachments:
H. Miller, RI
W. Kane, RI

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SECURITY AND CONTROL WORKSHOP

WRITTEN COMMENTS

1. Understanding that this workshop focused primarily on research type uses of radionuclides, there are also issues applicable to industrial broadscope licensees. Any decisions made as a result of this workshop should also consider affects to other licensees; particularly where interpretation of regulatory wording is performed. I am a military licensee whose broadscope license covers commodity items handled/accounted in similar ways as research rad. materials (except for human/animal/traces use).

   I find it interesting that some of the programs I've been introduced to spend considerable amounts of money to secure relatively small quantities of radioactive materials. This is especially interesting since some of the carcinogenic and biohazards have less constraints than the radioactive materials.

   Perhaps a risk vs benefit hazard analysis scheme should be implemented by each licensee using a hazard analysis criteria generally recommended by the NRC in a reg guide.

2. Cultural diversity also refers to persons of certain nationalities not being able to "challenge" visitors to the lab in a way that they might interpret as very rude.

   Tracking every atom is not just not practical - there is an MDA - for survey instruments.

3. Laboratories where radioactive materials are present must always be locked or attended by a responsible authorized user.

   Radioactive waste containers must always be clearly marked and available in laboratories where radioactive waste is generated.

   Use of protective clothing must be strictly enforced.

   Survey instruments used for area and personnel surveys must be calibrated annually and checked periodically commensurate with the use of the meter.

   Personnel surveys must be performed before leaving the laboratory and the last survey of the day should be documented.

   Area surveys, as well as, wipe tests are to be performed in areas where contamination is possible. If the area survey is performed prior to the wipe test, it can help locate the contamination.

   The Institutions Administration should realize the importance of supporting their Radiation Safety Staff, without Administrations support it is an uphill battle for their

Radiation Safety Staff to ensure a safe working environment and maintain compliance with the regulations.
Perhaps if top loading electronic balances with accuracies +0.1% were available, the mass of the stock solutions and their containers could be measured periodically (i.e., before and after extractions, or weekly) to ensure that the appropriate balance is remaining.

Licensees should include surveys of unrestricted areas adjacent to the laboratories such as restrooms and lounges that are frequented by students and researchers.

4. **SESSION-1:** With respect to engineering techniques and access, a minor problem is admission of service staff to locked or unlocked controlled areas. How does cleaning and maintenance get carried out? How can equipment be serviced/repaired in locked areas or while sources are being used?

5. Credibility is a real issue. We have laboratories using highly toxic or carcinogenic materials, with very few restrictions other than a safety and awareness program. But, people working with small quantities of relatively less harmful 12C and 3H are heavily regulated (lock it up! constantly monitor!). It is hard to be taken seriously when you have these two disparate levels of regulation for opposite order levels of hazard.

6. Locked cabinets in unrestricted labs will never work 100%. Scientists' daily compliance is very difficult to predict or ensure and the benefits gained will not affect the trouble and cost.

   Regs are supposed to compare costs/benefits and in this case I don't think they would balance.

   Can't protect against theft and sabotage any better for RAM than can for laptop computers and gram scale balances.

7. Due to the human factors, one cannot achieve 100% compliance on security. Some error rate that is acceptable must be established-perhaps 10%.

   On deliberate malicious acts, the licensee should not be held responsible provided that the licensee was conducting its program in accordance with license conditions.

   Much less weight should be placed on "potential" security violations identified by NRC inspectors than on <u>actual</u> incidents of theft or loss of RAM due to breaches of security.

8. Integral parts of any security/control program are training, inventory disposal accountability, designation of RAM areas via posting & labeling, audits.

   NRC should re-define "restricted area" as posted area, e.g., "Caution Radioactive Material," "Caution Radiation Area," etc/

No security/control measures are needed for less than Appendix C quantities (per container) since they don't even need to be labeled.

Between Appendix C and 100x Appendix C, posting and labeling provide sufficient security/control.

Source (stock) vials need to be secured from unauthorized access.

For other than source vials, a threshold level of 100x Appendix C is reasonable for requiring security measures such as locking.

Inspectors should assess potential for accidental or inadvertent exposure when evaluating security/control measures.

Enforcement should be based on:

1. promptness/thoroughness/effectiveness of corrective action
2. type and quantity of RAM involved
3. potential hazard to general public
4. self-identified or not
5. frequency of security violations and frequency of lost/stolen RAM
6. percentile of total # labs and researchers

9.
1. Reasonable security measures cannot (and should not) be expected to prevent deliberate malicious acts.
2. Security/control measures should be implemented to prevent accidental or inadvertent exposures.
3. Security/control measures should be commensurate with the risk associated with the particular type and quantity of RAM.
4. For some types and quantities (< 100 x Appendix C) provides adequate security/control.
5. Certain forms of RAM (dry waste, dilute liquid waste, LS vials, columns, gels) should be exempted from security requirements.

10. A threshold for security must be provided by NRC. It is impossible to lock up every radioactive atom!

11. The NRC regulations are so restrictive that the create a long term problem. This problem is that radiation and radioactive materials are so restricted that it is almost impossible to find a high school or undergraduate program which provides the necessary educational foundations for a reasonable understanding of radiation by the general public. This general ignorance contributes to the public seemingly inordinate fear of radiation and political pressures on the NRC to further restrict radioactive materials use. This fundamental ignorance continues to cause problems when undergraduates continue to higher education. Most medical schools and graduate programs do not provide fundamental educational course work primarily because the regulatory issues of "exposing" untrained individuals to use radioactive materials. Eventually, these individuals become MD's or Ph.D.'s who need to use these materials. At that point, RSO's are tasked with providing a huge amount of

fundamental, operational and regulatory information in an exceeding compressed format and then allow the newly authorized users loose to learn on the job. This problem appears to be a fundamental "root cause" leading to a lot of problems we face today.

1. The General Public's Ignorance on Radiation Issues
2. Many who become authorized users have not had a significantly rigorous academic exposure to radioactive materials and their regulatory requirements.
3. RSO's cannot provide in a few hours' course the rigorous fundamental info that lab workers and authorized users need.

The NRC should investigate changes in its regulatory licensing to create an educational license category that limits the isotopes and quantities to levels low enough that high school and undergraduate science classes can include radioactivity as a regular and expected part of the hands on curriculum.

On the question of "real" risks. I would suggest that the NRC contact the REACTS group @ ORAU regarding their experience with radiation accidents. it would be interesting to note if they can point to any incident involving universities or biomedical based research sources being involved in a significant radiological "incident" which caused "real" radiation effects. To my knowledge most incidents involve industrial thickness gauges or radiography sources at multicurie levels. I don't suggest that research quantities should be totally ignored, but from a security standpoint, these quantities do not pose significant hazards to the public.

12. Comment: Risk and Security

    1. What about chemical FORM or size/volume concentration? Hard to walk off with 55-gallon drum of LLW or 5-gallon container of liquid waste. Also materials in gels or other scientific apparatus.
    2. Appendix C in aggregate or total, or per vial, container?? The same with 100x App. C.
    3. All sources not in use - security should also be commensurate with quantity.
    4. We can lock cold rooms and have installed new lock which are safe on cold rooms which are very old.
    5. Waste, etcetera, from Nuclear Medicine Procedures should also be exempt because of low risk. Particularly dry waste.

13. If there is a consensus for locking labs, what is considered locked? Key access accountability? i.e., Irradiators require all types of bells and whistles for the operation and interlocks.

14. With regard to reporting malicious "acts" the NRC already has the Misconduct of Employees rule.

15. Over the years I have come to the conclusion that locks are only for honest people. For people who want to create mischief, a lock is no barrier, especially if they are

an insider. There has be room for "reasonable security".

16. The first opinion expressed, and volubly seemed to be NIH seeking relief from everything.

17. 1. Regulation on security is adequate as written because it allows flexibility. Also a change in regs brings public scrutiny.

2. Focus instead on guidance for inspectors - e.g., various security levels based on ALI/Appendix C values. Guidance should include the failure rate that determines a violation.

18. Some generic thoughts:

1. What is the objective of requiring radioactive materials to be controlled and secured?

Is it exposure? to whom
Is it internal dose? to whom

2. Is loss of control or security the same as release to general public.

19. You can't legislate or regulate nuts & sickos!

The 2 incidents that seem to have generated a knee-jerk reaction were perpetrated by sick or immoral people. There is no way you can guard against this by locks, especially if they are an employee or researcher.

How many incidents really occur where a higher level of security would have prevented it?

There is no way to get a no-risk situation.

What is the cost benefit? Is it justified to spend hundred of thousands of dollars for low levels of low risk radionuclides (14C, 3H)?

20. I am concerned that there does not seem to be levels of regulation depending on levels and relative hazard of radiomaterials. We have many laboratories that use uCi quantities of 12C, 3H and maybe 32P. Yet, we have to be regulated as if we were a high level facility. Regulations tend to say "all" radioactive material (without regard to relative or probably hazard.

How many serious incidents occur at such facilities.

21. Two concerns regarding security of research labs. While our buildings are locked (access via card-keys), there are no doors on any of the labs. We can't lock labs and we wouldn't want to! (safety reasons-networking).

All companies are cost cutting by out-sourcing. Our janitorial staff is an outside contractor. Each individual is given a RAD indoctrination, but there is high turn-over and we have no control over who gets hired. These people clean the labs, empty trash and make deliveries-all at night. They have to have access to the labs. This is basically a corporate decision and we have no control over the situation.

22. 1. Will security and control of radioactive materials in areas other than in labs be addressed? i.e.:

    a. Receipt, handling and storage of sealed and unsealed sources in a hospital.

    b. Loss of radioactive material from patients on site and in their homes.

    2. Will NRC be reviewing regs to streamline and clarify regs on security, control and reporting requirements? If Part 35 over-rides 10 CFR 20 for Medical, when does Part 30 apply?

23. Limiting access to working hours (EG, 8-4) ONLY, is very effective - prevents secret action-but is very unpopular with researchers - damages credibility of the Safety Program.

    Strict card-reader access could work very well (especially if they invent a reader than can discriminate a bar code from a yard away) but must be backed up by a quality security force, because people forget cards or lose them.

    An engineered system that only works with perfect human beings is a system that doesn't work.

24. You can't have a regulation that says "all". This is like the Delaney clause "zero". I'm an analytical chemist and we constantly can detect lower and lower levels, from ppm to parts per trillion. It turns out that there is no longer such a thing as zero! Almost everything is present at ppt levels. What is zero for rad materials? 100 cpm of C14 in a counting vial is included in "all". We need to be reasonable and set some reasonably safe levels that are below regulatory concern The inspectors have to be reasonable.

    We also have to be consistent in our hazard requirements. A 50 or 100 uCi 14C sample doesn't have to be labeled, but it must be locked up?

25. The focus of this Workshop is research labs, but increased security requirements/recommendations will also impact on packages as well as patient wastes under 10 CFR 35.10[illegible] & 200. Will transport of hospital wastes in push carts in unrestricted corridors require "monitored" escort to present unauthorized diversion? before reaching a hospital detector before unrestricted release.

26. I concur with the recommendation not to change the regulations, but to give better interpretive guidelines for enforcement. Any specified levels or thresholds must be scientifically determined risk based standards. It is impossible to get consensus on "how much is too much".

27. Administrative technique that works for us is to have "All or none" rules in the labs, but to temper with reality of the given lab situation e.g., ethanol is a characteristic hazardous waste and under the RCRA regs may not be disposed of down the drain since dilution to eliminate the flammability characteristic is not permitted. If dilution is incidental, then it's ok.

    Another technique that has been effective is providing research staff with data to benchmark performance from other similar institutions.

28. Through the discussion, no one from the group has mentioned anything about how the Rx community has solved the exit and access requirements such as real emergency exit permitted at all times.

29. "Radiation Safety" needs to set a goal of protecting the use of radioactive materials for the future.

30. Security effort will become more difficult if door locking and keying is mandated, if keys are either lost or missing with people leaving.

    Regarding the determination of quantities of RAM to secure: Should be based upon BOTH

    1. specific activity (based upon App. C)
    2. total activity (based upon multiple of ALI) per container/source

    This would/should result in the "locking" up of stock solutions, etc. yet allow greater flexibility for waste, LSC cocktail, gels, etc.

    Concept of security and control seems to have been confused.

    If sources not secure they are not uncontrolled, still inventoried and accounted for just does not trigger violations for unlocked labs.

    - Security is to prevent illegal act. Maybe not "inside job" but same types.
    - Control's (inventory, etc.) prevent human error, mistakes, etc.???

31. Is the locking of the main entrance(s) or egress-ways considered sufficient "security" of a user lab or does every cabinet, freezer & refrigerator & fume-hood need to be locked?

32. I support keeping the current regulations on security as is. However, each licensee can submit an amendment to their license indicating how they plan to address security at their facility. It would include their program, training and how they would address (consequences) a security violation. Also include the consequences of an employee who commits a malicious act.

I support this idea because security cannot be addressed the same way at a pharmaceutical company, in academics or universities as in a hospital vs at nuclear power plants.

33. Session 3 Questions

1. Guidance - locking doors, locking source vials-general guidance.
The NRC should not prescribe locking devices and methods.

2. Quantities that must be locked and forms - give RSO's ability to address individual forms and also consider the form of the material.

Include cost vs benefit analysis. Lockup up these materials at the moment has had no demonstrable benefit and is all cost.

3. Be honest, not sneaky

34. Session 3

Standards should define performance outcomes and types of evidence that would be ok.

Inspectors should be requested to identify themselves first to RSO. In facilities such as hospitals, can observe in public areas, but should not be authorized to enter a working lab unescorted.

35. Session 3

NRC must define a level of risk below which no security is required, outside of the normal laboratory procedures and controls (e.g., inventory, surveys, posting, etc.) used by the institution and the radiation protection office.

36. Enforcement Issues/Policy

1. Do not wait for a rulemaking process.
Issue enforcement policy/guidance immediately to stop current policy of zero level.

2. No person is error free. There must be some acceptable error level.

3. Give credit for self-identification and corrective actions of license's in considering violations and severity levels. Consider actual impact or consequence of violation, not only the potential.

4. Also consider error rates in proportion to total labs/personnel.

5. You cannot change some human nature, so attempting to look for "programmatic" failure for something that has no consequences, and is based on human behavior is unfair.

6. Do not treat licensee's like criminals for violations like these. This is the tendency of inspectors and the NRC.

7. Inspectors can look at security by inspection of laboratory door locks, locking on source materials (vials) etc. Materials that are in forms which do not lend themselves to diversion (electrophoresis apparatus, etc.) dry waste, etc. Make sure that the licensees do not know who you are, because if they know that you are inspectors, then they assume de facto that you are authorized and will not challenge you.

37. Each licensee is somewhat unique. Keep the regulation and policy written in a general basic fashion. Allow the licensee to determine what level of security and control is necessary. Each inspector (NRC or State) needs to then use the same criteria to rate the security levels, and other program components. The NRC can offer recommendations/guidelines, as necessary.

What the NRC should spend more time on is ensuring that each licensee has experienced, knowledgeable, and educated RSOs w/appropriate staffing and resources to make these decisions, be able to justify them and police their own institution. It is terribly unfair to cite a licensee for finding a problem and correcting it themselves. This has happened to us and many others in this audience.

38. For Guidance to Users
- what security and control procedures are effective? (what works)
- clarify/define "Lab in use" or radioisotope "in use"

39. Security requirements should not be set on specific thresholds. To do so would require a compliance-based approach which may (would not) be a "best fit" for all licensees. The NRC policy statement should mandate security for all licensed materials. The NRC Enforcement Policy should set Severity Levels on the reporting requirements in Part 20. For example, if material could reasonably result in a dose to an individual in excess of 5rem TEDE, a failure to secure would be considered to be SLIII. If in excess of 25rem TEDE, then SLII. If potentially lethal dose or substantial organ impairment, then SLI. Also, some degree of decision must be exercised. The NRC should consider the form of the material (waste vs stock), ease of access (sitting in public hallway vs in a remote lab), and other factors.

40. Materials use license applications becomes the regulation under which the licensee must operate. It appears to me, that unless amended, no alternative practices can be implemented. This might be too rigid in some instances.

    For example: We submitted, with an application, a map of our facility (small one-15 users maximum). We indicated on the map which room radioactivity will be stored. We realized that there would be a better room for storage. Therefore, we moved our storage area. As it stands now, we would be in violation of our license, even though we maintained the integrity of our security.

    I hope that the NRC is flexible enough to recognize that and not cite us for storing RAM in a different place than where we originally indicated in our license.

41. Good to have the NRC and its licensees interact on important issues. I recommend the NRC do this regularly. Perhaps a topic of the year approach.

42. DON'T LIKE OBSERVER FORMAT!

    Who was picked as participant vs observer?

    Where was your corporate perspective? I didn't see much representation from broad scope license companies.

43. Thank you for the opportunity to provide input!!

44. 1. Include to each observe a roster of the participants in each group.

    2. Have speakers identify themselves when they speak for the first time.

    3. Shorter lunch - more discussion time.

45. There should be a high representation of investigators at future meetings. While the views of RSOs are very important, the views of the people they regulate are equally important.

46. Suggestion for Future Workshops

    This sort of Topical Workshop is valuable and essential in order to resolve the obvious inconsistencies in regulations. The meeting of the licensee and regulatory minds must continue in the early stages of planning for change. However, please allow more participation by all attendees. I was very frustrated in my pre-designated status of "Dumb" observer.

47. Consideration has to be made for experiments such as tagged plants or animals, in a field study, where security by lock and key is not possible. Some research, especially with plants, has to be carried out in natural conditions because a greenhouse, for example, cannot duplicate natural conditions for some studies. It would seem a shame to have to preclude such studies in cases where quantities of radioactive materials used are in the microcurie range (or less), and calculated doses to real individuals by reasonable pathways are far less than the public dose limits.