

August 14, 2007.

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Subject: Lethal Execution Protocol Review and Quality Assessment, Mark Schwab

Dear Mr. Cannon,

As requested, I have conducted an independent quality assessment of the records and documents provided by your office in the above referenced case. Although all the documents that were requested for an independent quality assessment in the subject case have not been received at this time, this letter provides a summary of the quality issues that have been identified based on review of the available records.

As referenced in the Department of Corrections Secretary's letter to the Governor certifying the Department's readiness for administration of an execution (dated July 31, 2007), the determination of readiness was based on having the necessary procedures, equipment, facilities, and personnel in place, as described in the revised lethal injection procedure (the version identified as effective for executions after August 1, 2007). Based on my review of the subject procedure and related documents, there are a number of areas in which the available records do not demonstrate that an efficacious system for meeting procedural objectives has been established.

Procedural Requirements (reference *Execution by Lethal Injection Procedures Effective for executions after August 1, 2007*, signed by James McDonough on July 31, 2007)

In the Definitions section of the procedure, the team warden is identified as a person designated by the Secretary whose qualifications have been demonstrated through experience and training. However, all the subsequent procedural references to training and qualification refer solely to training of the execution team members and the executioner; in fact, the team warden is the individual who selects and verifies the training of team members. Because the team warden's responsibilities and authority are distinctly different than those of team members, and because training and qualification should be commensurate with responsibilities, the means through which the team warden demonstrates sufficient training and qualification, and the standards for that training, are not apparent.

Throughout the procedure, references are made to "designated" individuals as being responsible for specific activities or roles, but the process through which an individual is

designated as the responsible party is not defined. In order to hold individuals accountable for their responsibilities, and to ensure that all functional assignments are made to appropriately qualified parties, designation of each responsible party should be documented in the permanent record. It is noted that this requirement should not be obviated by the necessity to protect the individual identities of execution team members.

In the procedure, the term "secure" is used without definition, and with contradictory intent. For example, 'secure' is used in reference to securing the restraining straps on the inmate, ensuring that the lethal chemicals remain 'secure,' and in reference to securing official witnesses in the witness room.

In the last sentence of Definitions section (4), it states that only the team warden can approve deviations from the procedure. It is appropriate to assign responsibility for approval of procedural deviations, but deviations should not be approved after the fact. Procedural deviations should be approved in advance, and all such approvals should be documented by the team warden.

On page 3, section (3) (f), the procedure states that team members are responsible for bringing concerns to the attention of the team warden. Given the objective of preventing unnecessary lingering, this requirement should explicitly require that concerns be immediately reported to the team warden.

On page 4, section (4) requires that there be a written record of any training activities. Such a requirement should explicitly require that the written record provide documentation of the scope and content of training. In order for the warden to verify that team members have received necessary training (including training in the approved version of the procedure), training records must provide sufficient detail. A record of attendance is insufficient for this purpose.

Page 4, section (5) requires that procedural compliance be documented through use of checklists. However, the procedure does not provide or reference the specific checklists in question, and multiple versions of checklists, with different steps in different sequences have been used in training. In addition, the checklists used in training are ineffective and were poorly designed from a quality tool perspective, as indicated by the fact that the trainees completed the checklists in an incomplete and inconsistent manner.

Page 4, section (6) requires that a designated team member ensure a sufficient supply of necessary chemicals, but it neither describes nor provides reference to a systematic means of ensuring acceptable procurement, receipt, verification, storage, maintenance, control, and disposal of the chemicals in question.

Page 4, section (6) does not address or reference a systematic means of ensuring that the chemicals that are used are of appropriate quality and have been appropriately maintained. In effect, this section delegates such responsibility for quality control of the lethal chemicals to the FDLE agent in charge of monitoring chemical preparation.

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Despite this fact, there is no evidence that the FDLE agent in question is qualified to make such an assessment, or that the necessary records documenting the procurement, receipt and storage of the chemicals would be available for the agent's review.

Page 5, section (7) (b) states that an FDLE agent is responsible for observing the preparation of the lethal chemicals, yet there is no indication that the agent in question has the technical skills and experience necessary to monitor the preparation of chemicals in a technical capacity. It is unlikely that an independent monitor without relevant technical experience would provide significant quality oversight value as a monitor of the chemical preparation process.

Page 5, section (7) (b) and (c) requires that the FDLE agents prepare detailed logs of activities. No member of the execution team is required to prepare a detailed activity log, yet this responsibility is effectively delegated to the FDLE monitors, who are not subject to the same training requirements as team members, and should not be expected to provide the sole documentary evidence of the sequence of events. In addition, the requirement for preparation of a detailed activity log should explicitly require that the log be prepared as a contemporaneous record, rather than being documented after the fact.

Page 5, section (8) (a) requires that results of a physical examination be documented in the inmate's file, and that the findings of the physical examination be reported verbally to the team warden. In order to prevent any misinterpretation or misunderstanding of the verbal report, and to ensure that the verbal message is entirely consistent with the written record, the report to the warden should include the verbal and a written report.

Page 6, section (f) provides fairly detailed instructions for preparation of the chemical solutions, yet the instructions are based on unstated assumptions, and in practice, the instructions can not be followed precisely as written. Section (1) calls for injection of 10 ml of sterile water to a vial containing 500 mg of sodium pentothal. Because the materials used in the procedure are not explicitly described, it is left to individual discretion whether to use purchased vials prefilled with precisely 500 mg of sodium pentothal, or whether to prepare the necessary vials by accurately measuring 500 mg of sodium pentothal on a calibrated analytical balance. In my experience as a laboratory auditor, this type of imprecise procedural instruction leads to unexpected and undesired variability, and can contribute to operational problems. In a similarly imprecise description of chemical preparation, section (2) calls for use of a volumetric syringe to draw 50 mg of pancuronium bromide. Syringes are used to measure volumes of liquids; they can not be used to directly measure the mass of a solid. Implicit in this instruction is the assumption that the pancuronium bromide is procured and available as a solution of known and appropriate concentration. It also assumes that the individual responsible for preparing the chemicals is able to accurately compute the volume of solution necessary to contain 50 mg of pancuronium bromide. This lack of specificity is inconsistent with an otherwise detailed procedure, and it requires that a second qualified party be present to carefully review and observe the preparation of the chemical solution. Finally, the same lack of specificity compromises the instructions for preparation of potassium chloride in section

(f) (3). The instructions call for use of a 60 cc syringe to withdraw 120 meq of KCl, yet the concentration of the stock or prepared KCl solution is not specified. Given the importance of the chemical solutions to the procedural objectives, it is important that these steps be accurately and completely documented in the procedure.

On page 7, section (g) implies that the lethal chemicals are prepared in a separate, but unspecified location, then they are transported, in the presence of at least one additional member of the execution team, to the executioner's room. This is inconsistent with section (7) (b) which requires that the FDLE agent responsible for monitoring preparation of the chemicals be located in the executioner's room.

On page 8, section (k) indicates that the team warden is responsible for administering a presumptive drug test and a presumptive alcohol test to each team member. At the time this testing is performed, the team warden needs to be qualified to administer such tests, yet the training and qualification section does not address this requirement. In addition, approved procedures for performance of these presumptive tests should be available for review.

Page 9 section (j) requires that a specific team member be responsible for continuously monitoring the viability of the IV lines prior to and during the administration of the execution. It is not clear how a single individual would be capable of performing this function from a single location (either in the execution chamber or in the executioner's room). In addition, it is not clear which team member would be responsible for performing this extremely important function given the limitations on people present in each room (as specified in section (11) (d) and (e)).

Page 12 section (d) provides instructions in the event that the primary venous access is compromised during the administration of lethal chemicals. This provision should be broadened to address the situation in which it is recognized that access has been compromised prior to the administration of lethal chemicals.

Page 12 section (d) refers to opening of drapes, yet all other such references have been changed to more accurately address the facility's use of a window covering.

### Training

Specific Procedures sections (2) and (3) describe requirements for training and qualification of execution team members. Given the distinctly different responsibilities of security team members and technical team members, the team members should receive training that is commensurate with their responsibilities. The training records from the period May 8 - August 1, 2007 document training in the subject "Execution by Lethal Injection Procedures." There is no indication that team members (presumably identified as STM-#) received training designed specifically to address learning objectives that were developed in consideration of their responsibilities.

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Specific Procedures section (4) requires that training be sufficient to ensure that all personnel are prepared to carry out their roles. In order for any party to make a determination that delivery of a given training curriculum has been effective in this manner, the training should include objective evidence of which individuals achieved which learning objectives. This requirement is typically satisfied through a written examination or practical demonstration of skills. The available records provided no indication that the training in question was either designed to meet specific learning objectives (cognitive, affective, or psychomotor), or that individuals demonstrated satisfactory achievement through anything other than attendance.

Multiple training attendance reports were provided which document the delivery of eight hours of training to three separate groups of employees on the same day (STMs, EXs, and MPs). The training records indicate that a single presenter was responsible for delivery of the training in each instance. Although these records might seem to indicate that three different courses were delivered, consistent with the differing responsibilities of the three groups, a full day of such training could clearly not have been delivered to all three groups by the same presenter. (See, for example, training attendance records for 7/11/07).

#### Functional Readiness

On page 2, section (2) (a) and (b), the procedure states that the team warden will select two (2) executioners to carry out the execution, and will designate one of the executioners as primary and the other as secondary. During the execution, the secondary executioner must be available to assume the role as primary at any time. Implicit in this requirement is the assumption that the team warden will have more than two qualified executioners to choose from. Review of the available training records indicates that since May 2007, only two individuals may have received training to fulfill the role of executioner (individuals identified on Training Attendance Reports as "EX-1" and "EX-2"), and neither of these parties has been trained in the provisions of the revised procedure that was approved on July 31, 2007. First, every party who may be designated as an executioner must have been trained on the approved version of the procedure. Second, certification of readiness should include qualification of sufficient backup personnel to fulfill procedural requirements in the event that a single key individual is unable to perform on the day in question.

According to training records provided, none of the medical team members have received training in the recently revised and approved procedure since it was released on July 31, 2007. Such training would be a necessary prerequisite to certifying the department's capability.

The number and nature of quality deficiencies and inconsistencies identified in the reviewed materials lead me to conclude that the department has not demonstrated that they have put in place the systems and controls necessary to ensure that they can predictably and reliably perform executions by lethal injection in accordance with their own objectives.

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Should you need any additional information, or have any questions regarding my review, please do not hesitate to contact me. Upon receipt and review of any of the requested documents that have been heretofore unavailable, I will provide additional or amended review comments, as appropriate.

Very truly yours,



Janine Arvizu