



**DEPARTMENT OF DEFENSE
DEFENSE MEDICAL MATERIEL PROGRAM OFFICE
693 NEIMAN STREET, 2ND FLOOR
FORT DETRICK, MARYLAND 21702**

May 2, 2010

MEMORANDUM FOR Tourniquet Working Group Members

SUBJECT: Minutes of the March 23, 2010 Tourniquet Working Group

1. References: Tourniquet Working Group PowerPoint Slide Deck
2. The Tourniquet Working Group meeting was convened at 0730 at 50 Tech Parkway Stafford, VA on March 23, 2010.

3. Members in attendance were:

- a. Due to the number of attendees, please see enclosed attendee list.
- b. Defense Medical Materiel Program Office (DMMPO) members in attendance were:

Col Laura Torres-Reyes – Director, DMMPO

Lt Col Douglas Hodge – DMMPO

LTC Lisa Ingulli – DMMPO

Maj Brandi Ritter – DMMPO

MAJ James Fulton - DMMPO

Mr. Steve Burrows - DMMPO

Mr. Byron Owens – DMMPO

Ms. Kelby Conley – DMMPO

Ms. Kaitlin Armstrong – DMMPO

Ms. Christine Wasner – DMMPO

4. Summary of decisions and recommended actions from this meeting:

a. **DECISION:** All Tourniquet Working Group members will receive a copy of the agreed-upon future clinical requirements and testing parameters, and the minutes from this meeting.

b. **RECOMMENDED ACTION:** All members were encouraged to contact the DMMPO's Joint Medical Test and Evaluation (JMT&E) Department with any questions, updates or requests for information.

5. Colonel (Col) Torres-Reyes opened the meeting by welcoming the Tourniquet Working Group to the Marine Corps Systems Command (MARCORSYSCOM) facility in Stafford, VA. Col Torres-Reyes introduced Lieutenant Colonel (Lt Col) Douglas Hodge and Major (Maj)

Brandi Ritter as the facilitators of the meeting and thanked the presenting combat medics and the organizers of the meeting for their efforts.

6. Maj Brandi Ritter requested that everyone assembled complete and submit their non-disclosure agreements before the break for lunch. Maj Ritter then introduced the five combat medics, whose expertise and experiences with tourniquets in the operational setting gave a firsthand look at the importance of tourniquet use. Due to the sensitivity of the information presented, notes on the presentations have been omitted.

a. There were significant discussions among the group's participants stimulated by the combat medic presentations. One of the medics' presentations sparked a discussion regarding the locations of Combat Action Tourniquet (CAT™) breakages (mechanical failures), as well as IFAK (Improved First Aid Kit) supply issues (not enough tourniquets in the area of operations). Mr Lee from the US Army Medical Materiel Agency (USAMMA) stated that he needed accurate documentation of the reported breakages. Colonel (COL) Kragh stated that tourniquets are a one-time use item. After another medic's presentation, a discussion was held on the issue of exsanguinations due to traumatic injury. According to COL Kragh, this seems to happen only once in every one to two hundred tourniquet applications. The last presenter, a non-medic Marine Corps Corporal (CPL), stated that only one tourniquet was issued to each Marine in his group. He felt a second tourniquet issued to the troops would be invaluable. This statement prompted further discussion by the entire group. Everyone in attendance agreed this was a valid recommendation. COL Kragh stated that improved training could potentially correct the problem of tourniquets being incorrectly placed, and therefore found to be ineffective. When a tourniquet is ineffective because of improper placement, it should be removed and reapplied. A second tourniquet should be applied if the first (properly placed) tourniquet is ineffective.

7. Lt Col Douglas Hodge then set the stage for the working group and explained the goal of the meeting was to come to a consensus on tourniquet requirements and testing protocols. He then introduced the Food and Drug Administration (FDA) attendees, Ms Nada Hanafi and Ms Melissa Eakle. Lt Col Hodge showed the various Service IFAKs issued to deploying members of the Marine Corps, Army, and Air Force. He then reported that the tourniquet market will continue to grow as manufacturers produce new tourniquets, not all of which are equal. Of late, there has been a disconnect on the "ground truth" of tourniquet fielding, supply and what devices are actually in theater. Similar issues occurred with hemostatic agents regarding supply and actual fielding. Leadership listened when the hemostatic agent working group convened in June of 2009 to put Joint requirements and test parameters together for future work. Preventable deaths are still a problem, exacerbated by medical device breakage, life cycle, supply, and training variations. These are areas that may contribute to the problem. Procurement of devices has also been an issue. In previous years, all devices and technologies were "military standard" (MILSTD) driven in design and fielding. But now with commercial off-the-shelf (COTS) as the primary selection criteria, tracking an item becomes disjointed with the many different and independent databases having various sources.

a. Lt Col Hodge repeated the expected outcomes of this meeting; A Joint, consensus-driven capability requirements list and corresponding testing parameters are needed for the next generation of tourniquets. Ultimately, a Department of Defense (DoD) Policy, utilizing both test

parameters and requirements for tourniquets, is the primary outcome of the meeting. Lt Col Hodge explained the concepts of efficacy versus suitability and effectiveness in testing, and emphasized once again that all of this data is for future use. The requirements and test parameters from this meeting will be for future tourniquets, not necessarily the currently fielded models.

b. Discussion and questions followed this portion of Lt Col Hodge's presentation, specifically regarding the counterfeit CAT model versus the regular CAT™, distributed by North American Rescue Products (NARP). Problems have arisen because both the counterfeit and the real devices have the same National Stock Number (NSN), and are outwardly extremely similar, despite significant differences in material composition. Mr Lee stated that his organization can run an All Army Activities (ALARACT) message, which does get out to people, to alert them of the situation. COL Kragh responded that his organization tried that nine months ago, and decided that an ALARACT was not necessary, because the problem was fixed. Ms Eakle of the FDA stated that their organization wishes to aggressively pursue and halt counterfeits, but other participants informed her that these counterfeit devices are already in the supply chains, and with the same NSN. It was stated that ridding the supply of the counterfeit devices will prove difficult.

c. Lt Col Hodge then turned the discussion to the relationship that the JMT&E division is building with the Armed Forces Medical Examiner System (AFMES). The JMT&E division went to Dover Air Force Base and found failures (breakages) in several of the tourniquets removed from casualties. Discussion followed this statement, with Senior Chief (HMCS) Casey requesting the number of breakages found within the 17 examined tourniquets. Lt Col Hodge replied that one or two tourniquets were broken, although buckling of parts was significantly more prevalent. Mr Mott asked if the users were double wrapping (running the tourniquet through twice, as they are instructed). Lt Col Hodge replied that at this time, they do not know the answer to that, but will look into checking that aspect in the future.

d. Lt Col Hodge then presented information on the Life Saving Initiatives (LSI) Study, which is currently at nine sites in Afghanistan and Iraq. The study fields surveys to medics on several medical devices. These surveys gather information on several facets of those devices, including outcomes, placement, and other issues. The LSI study is not examining the actual names of devices, but merely notes generic nomenclature. The study is tracking ten areas of equipment and care, including a) Oral or nasal airway, b) Endotracheal intubation, c) Cricothyroidotomy, d) Chest needle thoracostomy, e) Chest tube thoracostomy, f) Chest seal, g) Wound packing with non-hemostatic dressing, h) Wound packing with hemostatic dressing, i) Tourniquet placement, and j) Hypotensive resuscitation.

8. Maj Ritter introduced Master Sergeant (MSG) Christopher Kosiorek from the Directorate of Combat and Doctrine Development (DCDD). MSG Kosiorek presented a briefing on the importance of general capability requirements for equipment and specifically tourniquet requirements. He presented the background of tourniquet modernization going back to Somalia in 2003-2005, which showed that tourniquets were needed for combat-inflicted arterial bleeds. Tourniquets are now a part of basic medical training in the Army, and are integrated into the Soldier as a System (SaaS) program. The SaaS comprises everything worn, carried or consumed

by the soldier. Specific requirements for Army tourniquets are that the device must be adequate for both upper and lower extremity application, it must have a windlass, and the Army recommends adding one-handed use as a threshold value to the capabilities required.

a. An animated discussion by the group followed MSG Kosiorek's presentation. One of the initial questions was if the companies were making tourniquets just for the military, or if there was significant demand in the civilian community. COL Kragh responded that the civilian world is expanding its tourniquet use, but not as significantly as the military. He went on to explain that there are now many more contractors in theater, in addition to active duty troops. It is speculated that the current length of tourniquets is insufficient as there are many instances reported where the tourniquet was not long enough to go around a leg and be secured properly. COL Kragh has studied the pediatric side of length, but has not yet challenged the tourniquets to the larger side of the spectrum. Demand drives industry, and we must consider that in formulating capabilities and requirements. COL Kragh suggested that as far as length is determined, the group should go to the 99th percentile of the Army's most recent anthropometric study, to accommodate the increased size of the average patient. Width of the tourniquet is an ever-present issue; the torque required for pressure applied changes directly in relation to the width of the tourniquet. (The wider the tourniquet, the less pressure is required to occlude the artery, but it will also require significantly more torque applied to the device to achieve that pressure.) Research shows the best median point at this time is 1.5 inches for the width of a tourniquet. COL Kragh also pointed out that training must be device-specific to overcome differences with design and application of the various devices. Design and use are interlinked - narrow devices have breakage and inefficacy issues, while wider ones, if used improperly, can exacerbate nerve injury. One inch is a good minimum width, two inches is a good objective width, according to the science available at this time. MSG Kosiorek asked if two CATTMs in the IFAKs would be a good idea. The majority of those in attendance agreed that two tourniquets in the IFAKs would be ideal. Mr Lee stated that the multiple injuries (bi-laterally) to patients that are now prevalent can allow him to move toward issuing two tourniquets in the IFAKs without delay. COL Harcke stated that in his experience multiple extremity injuries are common, while among those, lower extremity injuries are most common. He also stated that two tourniquets on one extremity have been presented on more than one occasion. One case had six or seven tourniquets on one patient; while this was "a rare occurrence, it was entirely feasible." COL Kragh then stated that according to "...the numbers have been published, there are approximately one and a half [tourniquets] per casualty, with a max of five." HMCS Casey stated that the Marine Corps has recently changed their Statement of Need to include two tourniquets in the IFAK.

9. Lt Col Hodge then opened the round-table discussion to agree on tourniquet requirements for the next generation of operational tourniquets. He passed around the counterfeit and real CATTM tourniquets for side-by-side visual inspection and examination by the attendees.

a. Tourniquet width was established based on previous discussion at: one and a half inch minimum width versus the torque required to generate sufficient pressure to occlude the artery. COL Kragh reiterated that the width of the device as it is used, is important; the past one inch wide device was effective, the past one and a half inch wide device was more effective, ergo, with increased width, one has a greater margin of safety. One and a half inch was agreed upon to

be the minimum accepted width for future use. A question was raised, “Does the two inch width cause application error?” COL Kragh replied that, “Yes, with respect to applied force.” Regardless of current essential characteristics (EC), COL Kragh stated that the Institute for Surgical Research (ISR) will continue to evaluate emerging new techniques and breakthrough technologies in this arena.

b. Weight was the next factor discussed. MSG Steinbaugh asked if there is an ideal weight a tourniquet should meet. He then went on to state that compactness was of greater value than weight, per se. Captain (CPT) Baker, via telecon, concurred with MSG Steinbaugh’s assertion, stating that cube is more important than weight for aviators. HMCS Casey asserted that the Marine Corps has a requirement of less than two pounds for the entire IFAK. The representative from the FDA asked that if the military is buying extra, why there was a weight concern. The responses from various participants were that the items the military requires them to carry, and what they actually do carry, are often different; for example, many have additional items in their packs. Each time an additional item is added, it adds to the weight the soldier must carry. Considering the impact of this on mission performance, the less weight added the better.

c. Size was then discussed; Captain (CAPT) Rineer stated that lower-profile bags are in development, there is however, a need for a protective tourniquet casing for carrying tourniquets outside of the IFAKs. The question was raised if a bigger IFAK bag was needed. Lt Col Lucas stated that the IFAK should be a smaller bag, and the tourniquets themselves put into a rugged enough casing to supersede the IFAK bag.

d. Length was decided based on the 99th percentile of thigh circumference, measured at 28.1 inches. Added to that is draw space and enough length to accommodate the chassis apparatus. The consideration of exploded limbs with increased space/circumference, as well as excessively large individuals, was discussed. It was decided that 37.5 inches is sufficient for the population.

e. FDA approval was discussed next, as it is a standard Key Performance Parameter for medical devices. Commander (CDR) Bleau stated that the requirement must be specific; if the device must be FDA approved, it will need testing as well. Nada Hanafi of the FDA explained that tourniquets are Class I devices and do not require clearance from FDA. This raised the question of tourniquets being re-classified to Class II devices. Ms Hanafi said that the FDA can reconsider this, but Class II devices require additional controls. Class II devices require pre-clinical testing to ensure safety and efficacy for the intended use and population. The onus would be on manufacturers to do appropriate testing, not the FDA. CDR Bleau responded that, because of additional costs associated with testing prior to marketing the devices, this would weed out a chunk of the potential vendors. Lt Col Hodge stated that at the end of the day, the FDA will do whatever they deem necessary regardless of the military opinion. COL Kragh responded that potential tourniquet vendors tend to “evaporate” when confronted with the reality of efficacy controls (even when they are merely implied). The FDA stated that post-market analysis of failures reported (for any device, not just tourniquets and their like) is required in instances when failure rates reach a certain level. The FDA tracks these failures and does analyses on them to determine guidance and action accordingly.

f. One-handed application was discussed next by the group. CPT Baker, via telecon, stated that air soldiers have a requirement for an embedded, uniform-integrated tourniquet. The primary argument for aviators is that pilots have different spatial and application needs. For pilots, if injured in a cockpit, a one-handed application solution is optimal. Lt Col Hodge responded that while aviation may have a unique requirement, Dr Butler of the TCCC has said that the one-handed requirement will likely be phased out from the TCCC Guidelines. COL Kragh asserted that there has been a decreased percentage of self-application (close to 1%) of tourniquets. MSG Kosiorek responded, stating that the Army disagrees with the use of embedded tourniquets: the Army does not have a requirement for this and the Army does not want them, although he conceded that pilots and co-pilots may present an exception. CPT Baker, via telecon, stated that pilots unequivocally need them. Lt Col Hodge said that the embedded tourniquets have not been independently tested, and various problems arise with the embedded nature and structure of the devices. A question was raised if the group should then attempt to test the embedded tourniquets if the 1% of self-applied tourniquets holds true. The conversation then moved to the generalized issue of one-handed use standing as a requirement. COL Kragh stated that the exsanguination speed issue has been examined, and those that would have benefitted from such increased application speed were trapped-limb scenarios, which comprise a tiny proportion of the injured population. Requiring one-handed use would change a product's development, but not necessarily for the better: for example, the Emergency Medical Tourniquet (EMT), which is a "great device," although it cannot be applied with one hand. The initial requirement for one-handed use came from special operations. HMCS Casey recommended assigning a threshold value to self-application, with a corresponding objective value to one-handed application. Lt Col Hodge raised the testing issue implicit in verifying one-handed use. The group decided to keep one-handed use as an objective, and perhaps re-word to "self-application," or add "application with either hand."

g. The group decided that the manufacturer date and lot number should appear on the tourniquet to aid in life cycle determination when stored for long term.

h. Shelf Life was discussed next, specifically the issue of glue delamination and if the problem of degradation was due to environmental factors. COL Kragh responded that this was probably a temperature issue in first generations, but not in the newer ones. Lt Col Hodge stated that the temperature extremes are realistic: -60 to +150F for storage, and -60 to +130 for operational use. CDR Bleau asserted that the group should add temperate, arctic, etc. nomenclature to the requirement to accommodate different climates in addition to temperature. Lieutenant (LT) Shafer stated that the Marine Corps has an unfeasible rule to discard tourniquets after 30 days when their packaging has been opened. CDR Bleau responded that it falls on medical leadership to ensure that Line leaders understand the importance and ramifications of the medical gear issued to the warfighter.

i. The FDA then asked if a tourniquet is truly a single-use item. COL Kragh responded that they are ostensibly single-use items, but are being re-used, as they may have some multi-use applicability in the operating room. Maj Ritter stated that this multi-use functionality in surgical application needs to be spelled out in the DoD policy as an exception. Jeff Mott stated that the group would do well to be very careful on terminology, because trainers will follow this terminology precisely (for example, calling a tourniquet a "single-use item" does not mean the

same thing if one means that the re-placement or continued use on a single patient [that same patient] is valid). He emphasized that it is vital that the training be kept simple (KISS principle).

j. Cost as a requirement was brought up, but Mr Lee responded that requirements should be capability-driven, and cost is a contracting issue.

k. Application time of a tourniquet was discussed next. Application in less than 60 seconds has been the standard measure in the past. COL Kragh stated that the application time should be rational and reasonable. HMCS Casey brought up the point that users must be fully trained in tourniquet application prior to assessing application time. CDR Bleau said that this facet can be written into the Statement of Work during test planning.

l. Lt Col Hodge stated next that instructions should be included on the packaging. Lt Col Lucas pointed out that any instructions need to be simple, because trainers will and do editorialize.

m. Ease of use in following the instruction was brought up, but Lt Col Hodge stated that this factor is not testable, so it was excluded from the requirements listing.

n. Packaging was addressed next by the group. Clear packaging was stated as the ideal, so that the user can see what is in the package. The representative from the FDA cautioned that ultraviolet light is known to degrade a variety of materials, so packaging and component materials should be considered accordingly.

o. Training devices were discussed next, with the prevailing question of whether the training model should be a different color. There was discussion about visual and muscle memory in terms of personnel looking for - reaching for - a specific-colored device (from training) and not finding it because the operational device has a different appearance. MSG Steinbaugh responded that his group uses the old tourniquets from prior deployments to train with. Mr Lee stated that there should be a different colored trainer device. COL Kragh responded that special training devices are okay.

p. Discussion regarding the conditions of the test followed. Mr Murphy asked if the test would be conducted in BDUs, or full "battle rattle," as that needs to be outlined in the requirements. Mr Joyner responded, saying that the group diverted into the actual protocol for testing, whereas this particular list should be the ECs of a tourniquet. Maj Ritter recapped the capabilities and requirements determined by the group, and there was further discussion of the training model (separate device identified for training), environmental temperatures, and the inclusion of instructions. Mr Kennedy, via telecon, asked the group to consider testing the tensile strength of component pieces/materials. Lt Col Hodge stated that the group should also consider stitch length, thread material, and welds. COL Kragh responded that this testing was not necessary, because nerve palsy does not occur until 500 mmHg is applied - a pressure which is extremely difficult to achieve with these devices. Maj Ritter stated that past reported nerve palsy from tourniquet use is transient, and resolves eventually. MSG Steinbaugh questioned why the group would concern themselves overmuch with nerve palsy, when the alternative is limb loss or death. Discussion then went back to weight and color, and Mr Nguyen reasserted that weight is

always an issue. CDR Bleau stated that a subdued color would be best. The group agreed that device breakage at 500mmHg would be acceptable, and should be integrated into design elements, with significant deformation, if not outright breakage, occurring at that pressure.

10. Maj Ritter then introduced Mr Steven Burrows from DMMPO, to discuss the market survey that he conducted. Mr Burrows presented the background of tourniquet technology, as well as a tourniquet familiarization/market survey. Mr Burrows reported that sales of tourniquets indicate 17 different models have been purchased by the DoD. Many of these purchases have been accomplished in theater via credit cards or “impact” cards. A selection of various tourniquets was presented in the room. MSG Kosiorek inquired if any tourniquets are for sale in AAFES/clothing sales. Mr Burrows and Major (MAJ) Fulton responded that this was always a possibility, but that they are not certain. Mr Burrows went on to discuss the various Service assemblages. The Navy has a different need for the time and placement of tourniquets aboard ship, which indicates an exception to their capability requirements. COL Kragh asked if there is friction between training personnel on the TK models versus the CAT™. Chief (HMC) Raniowski of Fleet Forces Command stated that there was no real friction at this time.

11. Maj Ritter then introduced Ms Christine Wasner of the DMMPO, who presented the results of an extensive literature review of tourniquet studies and efficacy experimentation over a wide period of time. Several methods of determining blood vessel occlusion were reported and compared within the literature, including pulse palpation, Doppler ultrasonography, and occlusion plethysmography. The specific tourniquets that appeared in the studies were reported, as well as the type of occlusion measurement technique used to test them. In response to the discussion of the remaining blood flow that persists when Doppler ultrasonography no longer registers movement, COL Kragh stated that when blood flow decreases to 20%, flow becomes laminar, although it is not well understood at this time what that means. COL Kragh went on to state that impedance plethysmography is an estimate of volume based on limb girth, and can lead to skewed data.

12. Maj Ritter introduced COL John Kragh of the ISR to present his briefing on tourniquets in pre-hospital use. COL Kragh reported on his studies of tourniquet use, including consideration factors such as looseness, placement on the limb, and one versus two tourniquets applied to a single limb. His prospective studies consisted of data received in the Baghdad emergency room. COL Kragh explained that limb occlusion pressure varies based on both limb circumference and tourniquet width. An applied pressure level of 300-500 mmHg was shown as an excellent zone of safety for the tourniquets used in his studies. COL Kragh compared his testing techniques between lab, field, and user testing. He asserted that care, teaching, doctrine, research and development, and logistics have to work together, as the tourniquet issue is not just an equipment problem. The use of tourniquets used to be binary – should we use tourniquets or not – but the current issue is no longer so simple. Despite more underlying bone, the lower portions of limbs have been shown recently to be paradoxically easier to occlude than the upper portions, and reflect the extent to which tourniquet knowledge has evolved. Lt Col Lucas asked if training is a problem on the instructor’s part, to which COL Kragh responded in the affirmative. He stated trainers generate their own scripts, and invent their own doctrine. Maj Ritter stated that a significant issue is getting the information out there; not everyone reads the journals, and thus

information trickles down, instead of being widely disseminated. COL Kragh agreed, stating that every avenue to broadcast the information is taken, but it is still not always effective.

13. Lt Col Hodge then facilitated the discussion of testing parameters for future tourniquet research and testing. Several agencies have completed various tourniquet efficacy test events with wildly disparate results. A consensus from this group was stated as necessary to eliminate duplication and inefficiency in test events. COL Kragh inquired what the real issue with testing is. Maj Ritter explained that hemostatic agents are an example of the problem: too many items, too many test events, and no correlation of data across the spectrum of research. Ms Wasner further stated that while it is important not to limit the research's scope, it remains vital to maintain the scientific integrity of the study. COL Kragh responded that new knowledge will be acted upon as it becomes available. The group decided to use the ISR test model as a basis for the group's recommendations that will be forthcoming.

14. Maj Ritter introduced MSG John Steinbaugh from the Army Special Operations Command (USASOC), who presented on future tourniquet technologies his organization is exploring. Due to the sensitivity of this information, notes have been omitted.

15. Maj Ritter introduced Mr Kevin Joyner, who discussed the tourniquet integrated product team (IPT). Mr Joyner explained that in order to facilitate verification of the protocol established by the group, MARCORSYSCOM will run and fund an upcoming study, in collaboration with the other Services. Mr Joyner emphasized the concept of "cross-pollination" of testing so that the next generation of tourniquets can be "born Joint," as well as to ensure the comparability of test data. Concerns at this time include the timeline for use of the money available for this testing. Mr Joyner stated that all results will be sent to DMMPO for validation and dissemination.

16. Maj Brandi Ritter of the DMMPO then gave a presentation on policy and standards, explaining that while rigid protocols exist for various aspects of military and medical testing, no such protocols exist for medical equipment. Maj Ritter used hemostatic agents as an example of the policy process, outlining its many component parts and lengthy duration. She stated that the DMMPO, as the medical equipment Joint representative should be the program office to develop medical equipment policy. Maj Ritter emphasized that although the timeline for staffing a policy can be extensive, one does not always have the time to go through this process if lives literally hang in the balance. DMMPO's current focus in terms of policy is to finalize the hemostatic agent policy, as well as the AFIP policy for leaving medical equipment on the deceased. The tourniquet policy, integrating the results from this meeting, will be next, and surgical airways will be on deck after that. The FDA representative affirmed that there are no standards for tourniquets at this time.

17. Lt Col Hodge summarized the meeting's accomplishments. The meeting concluded with a consensus of Joint tourniquet requirements and a foundation for Joint tourniquet test parameters. These items will be vetted through the group prior to their release for public dissemination. Lt Col Hodge thanked all who attended and participated, as this meeting's results will have far-reaching ramifications in future tourniquet research, testing, and validation.

18. Meeting adjourned at 1700 hours.


Laura Torres-Reyes
Col, USAF, MC, FS
Staff Director

Attachment
As stated

Created by:

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23 March, 2010
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